Supplement 1

1. Funder (PCORI)-approved Research Strategy, including complete statistical analysis plan

2. Full study protocol submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (November 2017)

3. Summary of a formal modification to the PCORI contract (September 2018), and the full revised study protocol (1st revision) submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (March 2018)

4. Summary of a formal modification to the PCORI contract (January 2018); no revision to the study protocol

Funder (PCORI)-approved Research Strategy, including complete statistical analysis plan

PCORI RESEARCH PLAN TEMPLATE
RESEARCH STRATEGY

A. Background

Mental illness is the leading cause of combined death and disability for all women and for men ages 15-44 years; it is the 2nd highest cause of combined death and disability for all men[1, 2, 3]. Mental illnesses frequently co-occur with general medical problems[4, 5], and negatively influence the course and treatment of these medical conditions. Mental illnesses are the 5th most expensive health problem in the United States[6]; however, when taking into account lost productivity, depression alone is *the* most expensive[7]. Mark et al.[8] demonstrated that mental health care (MHC) accounts for 6.2% of the nation's *direct* health expenditures. Indirect costs are even more staggering; individuals with untreated mental illness have more emergency room costs and early mortality than individuals with treated mental illness[9, 10]. Adults with, versus without, mental illness are less likely to be employed[11]. When employed, there is more frequent absenteeism, reduced productivity, more days of disability, and more job-related accidents[12, 13, 7]. Annually, more than 33 million Americans seek care for mental health problems[1], and many millions who need help do not seek or receive it[14]. When untreated, most mental health issues worsen or wax and wane; some become chronic[15]. *The evidence is overwhelming: mental illness is an extraordinary public health problem and highly burdensome to individuals, families, employers, communities, and the health care system.*

Disturbingly, even when people receive MHC, it is often substandard[1, 16]. Research has consistently demonstrated that approximately 10-15% of patients will deteriorate or experience harm during treatment[17, 18, 19, 20]. Further, when deterioration rates are combined with no-change rates (i.e., ineffective treatment), the number is strikingly higher (over 60%)[17]. These estimates are largely derived from naturalistic, patient-focused research studies where routine outcome data have been collected on numerous patients and providers. Importantly, research has consistently identified significant variability in skill and outcomes between therapists[21, 22, 23], *even when therapists utilize an empirically supported treatment (EST)*. In fact, differences between treatment providers account for a greater portion of treatment outcome variance than the specific interventions delivered in controlled trials[24, 25]. Thus, *improvements in MHC can occur by identifying effective providers in addition to promoting ESTs*[24]. In the largest study to date on this topic, our team investigated therapists' naturalistic treatment outcomes over many different problem domains (e.g., depression, anxiety, substance use, mania, sleep) in a sample of 6,960 patients and nearly 700 providers[17]. The majority of therapists demonstrated a differential pattern of effectiveness depending on the problem domain, and therapist domain-specific effectiveness correlated poorly across domains suggesting that therapist competencies may be domain-specific, rather than reflecting a core attribute or general underlying therapeutic skill. Importantly, although some therapists demonstrated effectiveness over multiple problem domains, *no therapists demonstrated reliable effectiveness across all domains*. Further, a small, but notable 4% of the therapists did not demonstrate effective outcomes on any domain. These data suggest that in any population of therapists (payer network, hospital, or community mental health system), there is an opportunity for behavioral health to do what medicine did decades ago—encourage provider specialization. Virtually every clinician has an area where they are above average (82-96%)[17, 26], and our research suggests that if they specialize to their unique skills, population-level outcomes (i.e., symptom reduction, behavior change, increased functionality) will improve dramatically. This would reflect a major, and likely highly impactful shift to current MHC systems.

However, patients and referrers are typically unaware of the unique track record ("Report Cards") of local-area providers, which represents a critical gap in knowledge transfer within the MHC system. Sadly, the choice of a MHC provider is often random (e.g., the first one to return a call), or based on convenience or insurance restrictions. Simply stated, the MHC provider influences treatment outcomes and stakeholders *lack systematic access to valid and actionable information to optimize effective patient-provider matches*. Without systematically collecting and disseminating performance Report Cards, stakeholders (e.g., patients, therapists, administrators responsible for case assignment, primary care physicians) *lack vital information on which to base MHC choices and referral decisions, and that can inform personalized treatment*[27]. Conversely, there is potentially immense advantage to matching patients to providers based on scientific outcome data[28]. Consistent with this notion, the Institute of Medicine (IOM)[1] has made recommendations to: (a) customize care based on the patient's needs, (b) share knowledge, (c) engage in data-driven decision-making, (d) promote transparency (*including information on performance and patient satisfaction*[29]), and (e) use valid and reliable assessment instruments to assess progress and to aid decision-making. The IOM has also recommended that MHC systems and patients be informed of the demonstrated effectiveness of different treatment options, and that *patients be provided with information on the quality of*

practitioner care and use this information when making treatment decisions. In essence, the IOM strongly recommends routine assessment and the dissemination of provider Report Cards. Importantly, we have survey data that point to MHC patients, therapists, and administrators endorsing such applied knowledge transfer as a high priority[27]. Provider track record Report Cards are meaningful data to the MHC patient population, as are the mental health benefits that could stem from being well matched to provider.

We have developed over the past 20 years an innovative, technology-based mechanism/intervention[17] to deliver Report Cards and drive this match concept within a patient-centered MHC model. Our longitudinal data suggest that our match algorithm, based on our multidimensional outcome tool (the Treatment Outcome Package[30] [TOP] described below), is efficacious for MHC outcomes. In addition to our study highlighted above[17], a more recent prospective study of 59 therapists and 3,540 patients resulted in a between-treatment controlled Cohen's *d* effect size of .80[26]. Each therapist's first 30 patients were used to classify a therapist's skills in twelve domains of symptoms and functioning as either statistically above average, average, or below average. The best matching algorithm functioned as follows: for each new, successive patient, he or she was classified as well-matched if the risk of harm was eliminated (i.e., the therapist was not below average when treating any elevated domain) and the therapist was above average in treating the patient's three most out-of-the-norm domains (e.g., depression, suicidality, and panic). *Poorly matched patients had below average outcomes, with small effect sizes (d = .30). Well-matched patients, by contrast, achieved very large pre- vs. post-treatment effect sizes of d = 1.19*. These data lend strong support that the proposed comparative effective research (CER) will yield similar results (i.e., increased efficacy and reduced harm) in re-aligning the skills of a large population of therapists at our partner site (Psychological and Behavioral Health Consultants; PBC) when matching empirically-derived therapist skills with patient need. The technology/intervention is well established, it has demonstrated efficacy, and awaits investigation in a well-powered randomized controlled trial (RCT).

CER designs in this area are lacking[31]. For example, in a recent Cochrane Review of studies investigating the effects of publicly disseminating surgeons' performance data on patients' treatment decisions and service utilization[32], no studies were deemed to be of sufficient quality to meet inclusion criteria (i.e., RCTs, quasi-RCTs, or controlled pre-post studies). The authors concluded that *future research on the provision of provider performance data should include CER designs involving multiple stakeholders*. In a second Cochrane Review of studies involving the public release of provider outcomes[31], only 4 were deemed methodologically suitable (i.e., RCT, quasi-RCT, interrupted time series, or controlled pre-post design). Public dissemination of provider performance data was linked to small improvements in acute myocardial infarction mortality rates[33], and increased organization quality improvement activity[34]. *None of the identified studies (or any of the studies cited but excluded) involved MHC treatment*. Furthermore, these studies involved passive dissemination of provider outcome information to large numbers of patients in selected health plans. Theoretically, access to such provider Report Cards can encourage patients to compare individual providers and preferentially choose the best performing treatment provider. However, passive dissemination ignores the complexity of performance data and the necessary involvement of multiple key stakeholders *across the MHC system* (e.g., providers, administrators, PCPs, and other referrers[35]). Passive dissemination of Report Cards (in the absence of an identified patient's needs or communication with providers or administrators who manage referrals and case assignments) is likely to be confusing and overwhelming to patients[36 37]. *What is needed is a coordinated system of using provider outcomes data to optimize patient-provider matches in the service of rendering patient-centered outcomes more effective, efficient, and safe in an easy-to-use, when-I-need-it data access model.*

To address the limitations of existing research, including the glaring lack of attention to MHC and patient-centeredness, we are engaging in a collaborative research project with the stakeholder groups referenced above. For this CER, we have been working in close partnership with PBC. Dr. Kraus, Co-PI on this project, has a well-established and long-standing partnership with PBC, which has contracted with Outcome Referrals, Inc. [ORI] to process outcome data on all patients as part of routine care (Donald K. Sykes, Jr., Managing Director at PBC, is also a Co-PI on this project). In preparation for the proposed research, we collected preliminary data to explore stakeholders' (patients, psychotherapists, and MHC administrators) attitudes toward patient-focused, data-driven MHC decision-making[27]. Specifically, in collaboration with several partnering community mental health centers in Massachusetts (MA), we surveyed adult outpatients (age 18-65 years; *N*=17), psychotherapists (*N*=20), and administrators (*N*=8) to assess perceived need for change in treatment decision-making determinants and overall interest in using a scientific match algorithm. All participants were recruited voluntarily and completed parallel versions of a web-based survey over an 8-week period. Patient survey items were primarily aimed at assessing attitudes and beliefs about differential therapist effectiveness and the role of Report Cards in provider selection. Therapist survey items were primarily aimed at assessing attitudes and beliefs about differential therapist effectiveness, performance measurement, and the role of Report Cards in provider selection. Administrator survey

items were primarily aimed at assessing attitudes and beliefs related to differential therapist effectiveness, Report Cards, and the use of Report Cards to inform treatment decisions, such as case assignments. The Internal Review Board (IRB) at the University of Massachusetts (UMass) approved this study.

Results for patient stakeholders (*M* age = 40.7 years; majority female [76.9%], White [69.2%], income below $25K [61.5%]) showed that each had seen an average of 7 different therapists in their lifetime; 83% reported having trouble figuring out which therapist could best help them; 67% reported that they would use information about therapists' track records in helping people with issues similar to their own if they could access it; 75% would want to be assured that a referring clinician (e.g., a PCP) was informed of therapists' track records and used this information to make a referral determination; *100% indicated that it would be important for them to be assigned to a therapist based on that therapist's track record of helping people like them (suggesting that even if patients do not directly access Report Cards themselves, they ultimately want to be assured that they are being well matched to their therapist)*. For participating therapists (*M* age = 37.8 years; *M* experience = 6.10 years; majority female [86.4%], White [90.9%]), 53% agreed that therapists should specialize in areas where they achieve good outcomes, rather than acting as generalists; 89% would participate in a service that referred them patients who have problems that they have been successful in treating; *100% indicated that it would be important for them to be referred or assigned cases that were particularly well matched to their strengths*. For participating administrators (*M* age = 43.0 years; majority female [87.5%], White [87.5%]), 100% reported that if they had access to data on their therapists' track records, they would use it to determine case assignment; *100% indicated that it would be important for them to refer or assign cases that were well-matched to a therapist's strengths*; 100% agreed that it is their ethical responsibility to collect and use information that could substantially reduce the chances of a patient being harmed by treatment.

These results are consistent with the literature (above) and support this stakeholder-centered proposal. Variability in provider-level outcomes is indisputable. Prominent health care systems have placed performance measurement at the center of core initiatives. Despite this rhetoric, results from multiple Cochrane Reviews highlight crucial knowledge gaps in this area. Based on its own analysis of important evidence gaps, PCORI has called for an increase in "precision" or "personalized" treatment, with a focus on tailoring[38]. Previous research, including our own, has empirically demonstrated substantial differences in projected treatment effect sizes depending on to which therapist a patient is referred. Heeding the call from the Cochrane Reviews and IOM, we will test in a RCT, the comparative effectiveness of an innovative, scientifically based patient-therapist match algorithm with proven efficacy and compare it to the commonplace pragmatic referral matching (based on provider availability, convenience, or self-reported specialty). Psychosocial treatment itself, across both conditions, will remain naturalistically administered by varied providers (e.g., psychologists, social workers) to patients with complex mental health concerns within another of our partner clinical networks, PBC – one of the largest providers of outpatient mental healthcare services in Ohio. Given the general efficacy of psychosocial treatment[39], both treatment groups are grounded not only in evidence-based practice, but also a realistic MHC treatment choice that patients face. The comparators are the defined strategy of match-algorithm referral/case assignment vs. pragmatic referral/case assignment. The results of this trial will provide practical information that can assist patients and other stakeholders to make evidence-informed decisions about their MHC and health outcomes.

B. Significance

Patients rarely have access to information that would help them select the personally best available provider (i.e., Report Cards). Although routine patient-reported outcomes data are the lynchpin of so-called "patient-focused research," the utilization of these data to inform treatment decision-making has been unsystematic and non-patient-centered. *This trial will be the first of its kind – in any area of healthcare – to use performance data to match specific patients with a short list of empirically well-matched providers*. The goal is to provide choice while minimizing or eliminating the risk of harm. MHC has been virtually absent in discussions regarding the communication and dissemination of performance data to guide optimal patient-provider matching. Given its nature and history (e.g., stigma, misinformation, lack of parity with other health problems), perhaps more so than any other health care category, quality MHC decision-making is complex[1]. To account for this complexity, patients and other key stakeholders (primary care, administrators, and therapists) need to contribute to the development and testing of novel strategies. This includes research design, which is why we have engaged an Advisory Board that includes all of the relevant stakeholders in the implementation of our preliminary studies and development of the current proposal to test the comparative effectiveness of our scientific-match algorithm. In doing so, we hope to avoid the pitfalls of previous research that has failed to engage relevant stakeholders and has, instead, assumed passive dissemination was an adequate method for making Report Cards accessible and useful. Stakeholder involvement

increases the odds of identifying mutually beneficial, feasible, replicable, and sustainable strategies for making provider performance Report Cards relevant and useful.

Information and having options are critical to improving MHC. Providers vary significantly in their effectiveness. Even when patients are in the rare position of having complete control over selecting their provider, the choice represents a "roll of the dice" when it comes to the likelihood of benefit. Convincing evidence demonstrating the differential effectiveness among MHC providers[40] indicates that matching patients to providers with actuarially derived strengths in the individual patient's problem area(s) will lead to better outcomes[24]. Because the proposed matching is specifically geared toward a *patient's identified difficulties*, the matching process and subsequent outcomes will be of direct relevance to each individual patient. Results from systematic reviews and the recommendations of the IOM[1] highlight (a) the importance of providing patients with comparative information on the quality of care provided by practitioners and the use of this information when making treatment decisions and (b) the inadequacy of previous research designs and early approaches to achieving (a). Stakeholders have highlighted the importance of improving communication, dissemination, and resources for decision-making (see our preliminary study results, as well as[36,37]). What has been lacking, however, is an effort to bring together relevant stakeholder groups to examine systematically how to achieve these improvements in MHC. The proposed research is thus novel in its aim to bring together these stakeholders, and in its level of directiveness and patient-centeredness. Previous research involving the dissemination of Report Cards (none of which has been conducted in MHC) has involved the passive dissemination of performance data to large groups of patients, regardless of whether or not these data were relevant to an individual patient's needs at the time. The proposed research will use information that is specifically relevant to each individual patient to inform the assignment/referral of *this patient to one of a short list of scientifically well-matched psychotherapists at a crucial juncture in the care decision-making process*.

In addition, the application of an empirically derived match system to inform case assignment and patient decision-making would yield substantial health benefits with limited burden. Complementary approaches to improving MHC have largely focused on the dissemination and implementation of lab-tested multicomponent psychological treatments. This EST approach on its own is limited because: (a) this research uses aggregated data that masks response variability between patients, and (b) training therapists to apply a complicated intervention to a criterion level of adherence and competence is extremely costly, time consuming, and often continues to disregard variability between patients[22]. Furthermore, differences between individual treatment providers consistently explain more outcome variance than the specific interventions employed. *The evidence, therefore, suggests that we will have a greater likelihood of improving outcomes if patients and stakeholders have information that can help match patients to the most personally appropriate treatment provider* than if we randomly select a provider who employs a complex, lab-vetted treatment protocol[24]. Currently, with rather random therapist assignment, the chances of being harmed are not trivial. Our study[17] demonstrated that for any given problem area (e.g., depression, psychosis), about 50% of therapists are highly competent in treating the problem, 36% are ineffective, and 14% are harmful. With the average patient having more than 3 problem areas needing treatment[40], and assuming random case assignment, 52% of therapies are ineffective, 34% harmful, and 14% effective. The problem is that a provider need only be harmful in 1 domain to cause harm, yet needs to be effective in all patient-relevant domains to deliver maximum treatment benefit. Our prospective study has demonstrated that we can triple the effect size of standard, real-world outcomes with a patient-centered matching algorithm. Thus, the logical next step, which is the crux of this proposal, is to test our match algorithm in a fully powered RCT.

A significant part of the match benefit is eliminating the risk of harm. Treatment failures result in significant direct and indirect costs to patients, families, and society. Research indicates that had these deteriorating patients been referred to or been given the option of selecting a therapist who has demonstrated consistent effectiveness in the relevant problem domain(s), their increased likelihood of experiencing a benefit would represent a large effect size. This is a sizable benefit that, practically speaking, mainly involves the collection and dissemination of routine outcomes data. Although routine assessment has become more common[41], the implications of this information for higher quality MHC have yet to be fully examined or realized. Research has shown that outcome data from as few as 5 different patients are needed to reliably estimate the effectiveness of a given treatment provider[42]. Our recent study demonstrates that predicting future success of therapists becomes remarkably stable after 20 cases. *Thus, the potential scalability of this patient-centered decision-making strategy is extremely high*.

This research is patient-centered at every stage. Because the proposed scientific-matching system identifies providers who have demonstrated effectiveness (by *patient-reported outcomes*) in the specific problem domain(s) of concern *to the identified patient*, the focus of the intervention is optimally patient-centered. Furthermore, the multidimensional outcome measure of interest (TOP) has been developed and refined based on "real world" patient-feedback over the past 25 years. It is a measure that has been jointly created by patients. It is also important to note that rather than prescribing a single "best-match," the matching output will generate a short list of well-matched

therapists participating at PBC. This will allow support staff to make case assignments to this short list with typical operating procedures (i.e., still allowing for pragmatics like availability). This not only limits burden on the staff, therapists, and patients, but it also maintains methodological rigor (via the double-blind) and underscores how the match algorithm, if found effective in this trial, can be readily incorporated into MHC systems in a way that maximizes impact, but minimizes disruption of patient flow and systemic operations.

The spirit of routine outcome assessment is to improve treatment quality for individual patients[43]. The extant literature and our own research has shown that patients and their caregivers are frustrated with their current level of involvement and access to information that could lead to better informed MHC decisions[44]. We have assembled an Advisory Board consisting of the following members who represent the voices of key stakeholder groups: three patient partners who have experience receiving mental health services, two practicing psychotherapists (one a PhD psychologist in Cleveland, and one a LICSW in Boston), the Executive Director for the National Alliance on Mental Illness Greater Cleveland, and a psychiatrist and researcher at the VA's Center for Healthcare Organization and Implementation Research in Boston. As detailed in the Engagement Plan below, our Advisory Board stakeholders have been centrally involved in the development and modification of this research proposal.

C. Study Design or Approach

Specific Aims

The proposed study will compare the effectiveness of naturalistic individual MHC either with or without the scientific match algorithm with an *individual level RCT*. The details of the design are provided below, though finalization of the study protocol will occur in tandem with the Advisory Board and will be presented to PCORI as a year-one deliverable. Consenting adults referred for MHC presenting to our partner PBC clinics will be randomly assigned, by an intake specialist, to naturalistic treatment (in accordance with the PBC care model) with either a scientifically matched provider (experimental group) or to a pragmatically matched provider (control group) (*this randomized CER design meets PCORI's standards for causal inference methods*). To inform the match condition, we will first conduct a naturalistic baseline assessment of PBC therapists' performance (across a minimum of 15 cases) to determine their strengths in treating 12 behavioral health domains measured by the primary outcome measure on which the match algorithm is based: the TOP[30]. (The TOP is already administered routinely in our partner network; thus, we can leverage existing resources within this practice-based research network to support this study with little to no extra burden on administrators, providers, and patients.) Wampold and Brown[43] determined that therapists' skills can be reliably determined with as few as 5 cases, and our previous study demonstrated the predictive validity of therapists' strengths is maximized with 20[26]. Being assigned at least 15 new cases in a naturalistic baseline period is readily achievable for most full-time therapists. Thus, the empirical foundation of the match algorithm can be readily adoptable in systems of various sizes.

Following the naturalistic baseline period, new patients will be randomly assigned to the match versus no match condition, remaining unaware of their assignment. Patients in the match condition will be assigned to therapists who have a demonstrated strength (derived from the baseline period) in treating, at a minimum, the patient's highest self-reported distress domain on the TOP. Therapists will also be unaware of their patient's treatment condition (double blind), and they will treat both matched and non-matched patients (i.e., they will be crossed over the two conditions to minimize administrative disruptions). Patients will be assessed at baseline and at regular intervals during treatment. For the sake of the trial, treatment outcome will be considered the actual point at which treatment terminates if under 16 weeks, or at week 16 for those being treated longer term.

Based on initial feedback from Advisory Board members (responding to the query of what outcomes are of most importance to stakeholders), trial assessment will include risk-adjusted TOP scores throughout treatment, self-rated global symptomatology and functioning, therapeutic alliance quality, patient outcome expectations, treatment dropout, and patient satisfaction. *We predict that the scientific match group will outperform the no match group to a clinically significant degree on TOP outcomes and global symptomatology. We also expect that the match group will be more effective in promoting alliance quality and facilitating positive patient outcome expectations, both of which are established correlates (and candidate mechanisms) of positive treatment outcomes*[45 46]*. Finally, we expect there to be less unilateral patient dropout in the match condition, and higher patient satisfaction* (*these questions meet PCORI's standards for formulating research questions*).

Secondarily, we will examine 4 potential moderators of the expected between-group treatment effects on the primary TOP outcomes (i.e., heterogeneity of treatment effect; *HTE, as per PCORI standards*): (a) patient race (as it may be that the match algorithm is particularly potent, and an important responsiveness tool, for historically understudied or underrepresented patients), (b) degree of match of therapist strengths to patient problems (rated dimensionally as a ratio given that therapists can be matched on more than just the minimum 1 domain, and the elimination of harmful matches for any distressed domain reported by the patient), (c) patient distress severity, and

(d) complexity of patient presenting problem. Thus, we will test if matching is only, or particularly, effective under the conditions of a central patient characteristic, a multiple domain match, and/or for patients with the most severe or complex pathology. Also, the TOP collects medication information, including type and dose. Thus, we will be able to assess and monitor medication use, which is also integrated into the risk-adjusted TOP scoring. Moreover, in assessing for medication use, we can also explore it as a correlate of outcomes and, if significant, include it as a covariate in our primary statistical models. The TOP also tracks whether the referral and treatment is voluntary, and we can explore the impact of this variable as a possible moderator of the treatment condition-outcome association if there is enough variability (i.e., enough people who self-report as being an involuntary participant for one reason or another).

We will also assess therapists' self-perceived strengths on the TOP domains. We expect to replicate previous literature showing that therapists are poor judges of their own efficacy, tending to underestimate negative effects and overestimate positive effects with their patients[47], which would further underscore the importance of a data-driven match process. Finally, we will conduct exit interviews, and corresponding qualitative analyses, with a subsample of participating stakeholders to gather input on how to be maximally responsive to the study findings in terms of dissemination, implementation, and policy-making. Our Advisory Board members will play a central role in collecting these data and incorporating them into post-trial action plans (*as our Advisory Board includes MHC patients, this element of our design addresses PCORI's standards associated with patient-centeredness, as does the very nature of our experimental manipulation*).

Research Method

Patients. Participants will be adult men and women (age 18-70) in PBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation) at baseline, at regular intervals during treatment, and at the trial's definition of posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, suicidality, and poor quality of life. The only study-related, patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*[48]) diagnoses (including high severity, chronicity, and comorbidity rates typical at PBC). The composition of our sample will roughly match the average utilization data for age, gender, and race/ethnicity at PBC (see Section E, "Patient Population," for additional detailed information on the patient sample, including the targeted/planned enrollment table based on our PBC utilization projections and our power analysis below). With this composition, we can analyze HTE on race as one of our patient-level moderators.

Statistical power analysis and attrition. For the primary 3-level hierarchical model assessing treatment condition effects at the patient level on linear change rates within patients, we used Raudenbush and Liu's[49] formula as incorporated in the Optimal Design program to determine the minimum numbers of therapists and patients needed to detect a moderate effect of condition (standardized difference between change rates = .50). With repeated measurements spaced over the maximum 16 treatment weeks and assuming 5 patients per therapist, an intra-class correlation of .15, and an alpha of .05, we will need a total of 44 therapists and 211 patients to achieve a power of .80 to detect moderate condition effects on linear change rates. Factoring a conservative 25% dropout rate at the patient level, running our experiment on a minimum of 281 patients (6-7 per therapist) should provide sufficient statistical power to detect group differences on our primary outcome variables.

We will also analyze the secondary outcome of domain-specific TOP scores; that is, TOP change as a function of condition on the most elevated presenting domain (which for patients in the match condition would be the domain on which they were matched to their provider). To maintain power, and to maintain the appropriate multilevel data structure, we will run the same hierarchical linear models as above (powered to the same degree) with the outcome being each person's standardized score on their most elevated TOP domain.

Patient recruitment and informed consent. Patients will flow into PBC via primary care referrals, hospital discharge referrals, internal office (PBC) referrals, or self-referrals. To increase potential patients' awareness of our study, which may in turn increase their willingness to enroll vs. view it as an unexpected inconvenience, PBS will liaise with community physicians and hospital discharge staff. Specifically, these referrers will be asked to mention the study to their referees according to the following script that we will provide:

"Are you struggling with mental health concerns and looking for a therapist?

Contact Psychological and Behavioral Consultants (PsychBC) to speak with one of our specialists about setting up an appointment, and consider participating in a research study aimed at matching patients to good-fitting therapists.

To participate, you need to be 18 years of age or older, and seeking therapy at a participating PsychBC location: Avon, Beachwood, Brecksville, North Olmstead, or Willoughby.

Far too many patients struggle to find the right therapist. Information from this study will help us make better decisions about who is the best fitting therapist for your needs. Participation simply involves completing some online questionnaires before the start of your therapy and on a few occasions during your therapy. That's it!

Participants will receive up to $150 for their participation.

To hear more about the study and/or to set up an appointment with a study therapist, please contact Felicia Romano at 844-468-5050.

Take care,
PsychBC and Collaborators"

As an additional measure to increase patient recruitment, PBC will announce the study on its website's banner in close proximity to the intake telephone number. It will simply read: *"If you are interested in participating in a research project with compensation, ask about the **Match Project.**"*

In whatever way they are referred, patients first call the PBC intake line. At this initial contact, PBC intake specialists (for which there are typically five working at any given time), screen the patient for basic study eligibility – i.e., is an adult (age 18 to 70) who (a) will make their own treatment decisions, (b) will receive outpatient therapy from a PBC provider, and (c) can access their email immediately. If the caller is not eligible, the intake specialist completes the intake call as usual, with no mention of the study script. If the caller meets basic eligibility criteria, the intake specialist presents the following study script:

"Here at PsychBC, we prioritize a personalized care experience for our new clients. We do this by having you complete a few brief forms online, starting with today's intake. These standard forms ask questions about you and your well-being. Answering a few questions today can help us assign you to a personally best-matched therapist for your needs. During treatment, your responses provide you and your therapist valuable feedback on your progress. Many clients do this and find it very useful.

Also, because this is part of an ongoing project here at PsychBC, I can pay you $15 for your time to review the materials. If you opt into completing the forms regularly, you can earn more money. Do you have any questions?

[after addressing any questions] Okay, so I can email you the link to the materials now. We can also schedule an immediate call back so that I can assign you to a therapist today. Again, who that is can be personalized to you based on your responses to the form."

The intake specialist will then ask patients for permission to send, via email, a study consent form and baseline measures packet if they are interested in learning more about participation. If given verbal authorization to do so, the PBC intake specialist will push the study link immediately. As part of the online consent document, patients are informed that their participation in the trial will largely mimic the same treatment that they would receive if they were not participating. However, to be enrolled, the patient must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), and accept assignment to an eligible treatment format as per below. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment. If a patient does not consent via the online form, their second call with the intake specialist will proceed as usual. If a patient consents to be enrolled, they have signed the consent form and completed a baseline survey of measures (including the TOP) through the online platform. Patients will then be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match) on their second call with the intake specialist. From there, treatment proceeds as usual, with the project coordinator sending

weekly measures to study patients via email for the duration of their treatment, or the 16-week outer limit for those in longer-term treatment. All patients who consent are sent a hand-written "thank you" note from the research team within 1 week of enrolling. Regardless of consent status, the project coordinator sends (within 1 week) a $15 Amazon eGift card to all patients who view the consent form. This compensation incentivizes patients' willingness to leave the initial intake call to review the study consent form.

We do not anticipate problems meeting our recruitment numbers in the project time frame. As one of the largest Ohio providers of outpatient behavioral health care, PBC employs over 80 therapists. Moreover, their care model already uses the TOP for routine outcome monitoring, and they are willing to use a patient-level-best-matched clinician list that is generated in real time (based on the predictive validity of our match algorithm). Including this randomization control into the treatment delivery model will not create any systemic barriers. PBC schedules approximately 950 new patients per month. Recruitment will be coordinated among our project coordinator, PBC intake staff and dedicated research assistant, and PBC administrators, and will involve presenting information about the study as per the protocol outlined above. Moreover, PBC will offer periodic incentives (in the form of a payment bonus or tickets to local events) to the intake specialist who successfully directs the most patients to our online study consent form in a given period of time (e.g., a 1-week or 1-month competition). Note that this bonus is completely unrelated to PBC's project budget; this is simply a motivational strategy within their own payroll system.

Again, patients will be ensured that their participation in the trial will largely mimic the same treatment at the PBC site that they would receive if they were not participating. All patients will be told that the study is examining various referral processes that will not influence their treatment. They will be kept unaware of the *specific* nature of the referral manipulation, but will be told that it may help connect them with a well-match provider. Patients will also be informed that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Patients will be asked to remain with the same therapist through the end of their treatment or at least 16 weeks of treatment (our maximum end point for the trial); however, if they request a transfer earlier, this will be treated as the termination point for that course of treatment with the study provider (to avoid a multi-provider confound, with the latter provider not having been part of the match process). Patients will also be informed that they will complete all assessments that are part of their standard clinical care within PBC, as well as several study-specific measures. For completing the additional measures, each patient will be compensated $50 total.

Therapist recruitment, informed consent, and characteristics. Therapists will be employed at PBC, and will include psychologists, clinical counselors, and social workers. At the trial's outset, *a total of 58 adult therapists will be eligible to participate and be screened. The goal N is 44 providers to ensure sufficient power.* We anticipate that at least 90% (52 therapists) will agree to participate in this research, as the procedures largely mimic their typical practice, as well as the culture of routine outcome measurement at PBC. Recruitment will be coordinated among our project coordinator, PBC site staff members, and PBC administrators, and will involve presenting information about the study to providers through telephone or email. Interested participants will meet or speak via teleconference with the project coordinator to learn about the study details/procedures and to provide consent through an online baseline survey to which they will be directed. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be blind to the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Interested providers will need to agree to keep sufficient openings on their case roster until they meet their required case numbers (this will not be an issue for PBC providers). They will also be informed that their study patients will complete a few study-specific measures throughout and after treatment. Consenting therapists will complete a brief, one-time survey that will assess demographic information, clinical experience, practice information, and perceptions of typical therapeutic actions and outcomes. This single-administration survey will take no longer than 25 minutes to complete, and therapists will be compensated with $20. Therapists will also need to agree to complete a few study-specific, during-treatment measures (with their study-enrolled patients) for which they will be compensated $50 per patient for this additional, but minimal, time burden. Non-consenting therapists will receive case assignments as per usual protocol and will simply not be included in the trial (we will analyze consenting and non-consenting therapists on demographic differences to see if any systematic sample bias exists). Reflecting PBC psychotherapist demographics, we anticipate that our sample will roughly breakdown as follows: clinicians will be social workers, psychologists, and licensed clinical counselors. Approximately 70% of therapists will be female; 88% will be white/non-Hispanic; 3% Black; 2% Hispanic; 2% "Other/mixed"; and 5% Asian. age *range* = 30-65 years Based on these projections and our power analysis, we have included a targeted/planned therapist enrollment Table in Appendix A.

It should also be noted that as the study proceeds, additional therapists at PBC will become eligible for the study by virtue of having 15 completed cases for which TOP data can be used to generate Report Cards. As of 8/22/18, there are 28 of these clinicians. We will engage a second wave of therapist recruit if it helps (a) mitigate any

therapist attrition from wave 1, and/or (2) facilitate patient recruitment. Regarding the latter, it is possible that participating therapists from wave 1 will have a full caseload at a time when their name comes up in a match. In this case, having more therapists in the match pool could allow an intake specialist to assign the patient to the next therapist in the well-matched list who *does* have an opening. As another example, it is possible that patients will be willing to be in the study, but only if they can see a therapist at a particular location. Again, if we increase our pool of therapists, we might increase our ability to match at a particular study site with a clinician who has an opening. Or, if enough wave 2 clinicians enroll in a given area, we *might* be able to add a site to our current list of six active PBC sites.

Randomization protocol. *Individual treatment referral is the point of entry into the present study (i.e., the randomization occasion)*. Consecutive consenting patients will be randomly assigned to condition. The project coordinator, unaware of therapist baseline performance, will generate the randomization sequences using an online random generator. Therapists will be crossed—that is, some of their cases will be matched, while others will be non-matched. Within condition, patients will be assigned sequentially to therapists until therapists reach their study quota. In the low probability event that there is no therapist meeting minimal match criteria for a patient in the match condition, that patient will be removed from the study protocol (though will, of course, still receive treatment) and replaced with the next patient where a match does exist (this will also be carefully tracked).

Treatment. For the sake of standardizing outcome assessment in the trial, patients' data will be tracked for 16 weeks following the start of therapy. Treatment outcome will be considered the point of mutual termination or 16 weeks, whichever comes later. With this naturalistic design, mutual termination for some patients will occur in response to outcome data-informed clinically significant improvement. Some treatments will be longer-term, and we will consider week 16 the endpoint for assessing acute response in the present trial. Thus, our primary outcome variable will be rate of improvement over a maximum of 16 weeks. We selected 16 weeks for several reasons. First, 16 weeks, or roughly 16 weekly sessions, is a common treatment dose in clinical trials. Second, the psychotherapy dose-response literature has shown that treatment response is best modeled by a negatively accelerating relation to number of sessions[43] where each subsequent therapy session evidences, on average, less change than the previous session[51]. Third, of those patients who evidenced improvement in a large naturalistic sample, 80% met criteria for reliable change by session 15[52]. Thus, given the relatively short-term nature of treatment in managed care, as well as the empirical evidence that most psychotherapy change takes place in the early sessions, we will set our trial treatment outcome to a maximum of 16 weeks (*yet will also track a random subset of patients through 1 year*).

Patient demographic characteristic assessment. Patient demographics will be assessed with the *TOP-Consumer Registration Form* (TOP-CR; see Appendix B), which is part of the TOP suite of self-report measures used routinely in our partner PBC system. On this form, patients indicate their age, gender, ethnicity, marital status, income level, employment status, religious identification, education level, general health status, and medical and mental health treatment history.

Therapist characteristic and self-efficacy assessment. PBC providers will complete a study-specific *Provider Characteristics Form* (PCF) to assess demographic information, clinical experience, degree type, percent time seeing various patient types/diagnoses, any specialty training they have received, and dimensional ratings of the influence of various theoretical orientations on their treatment approach. Providers will also complete a study-specific *Therapist-Perceived Strengths* (TPS) measure to assess their beliefs about their effectiveness in treating the various TOP domains when uninformed of their data-driven TOP track record.

Treatment outcome evaluation and the match algorithm. The TOP suite of measures will provide our primary outcome measures[30], which are administered routinely at PBC. The TOP, which was developed and revised over the past 25 years with extensive input and feedback from consumers, is a behavioral health assessment and outcome battery designed for clinical and research purposes in naturalistic settings. The TOP evaluates behavioral health symptoms, functioning, and case mix variables (e.g., divorce, job loss, comorbidity). The *TOP Clinical Scales* (TOP-CS; see Appendix B) consist of 58 items assessing 12 symptom and functional (including strengths) domains (risk-adjusted based on the case mix assessment; see Appendix C): work functioning, sexual functioning, social conflict, depression, panic (somatic anxiety), psychosis, suicidal ideation, violence, mania, sleep, substance abuse, and quality of life. Global symptom severity can also be assessed by summing all items or by averaging the z-scores (i.e., standard deviation units relative to the general population mean; see Appendix D for a sample report) across each of the 12 clinical scales. Domain-specific symptom severity is quantified as the risk-adjusted individual z-scores for each clinical scale. For our primary analyses, we will assess change rates on global distress/symptom severity for the entire sample, and change rates on the most salient distress domains (i.e., the most elevated scales on which patients in the matched condition were matched to therapist strength) for patient subsamples. The TOP has been shown to have excellent factorial structure, as well as good 1-week test-retest reliability across the 12 scales. It is sensitive to change while possessing limited floor and ceiling effects[30]. The TOP also has demonstrated good

convergent validity[58] with scales like the Beck Depression Inventory[58] and the Brief Symptom Inventory[59].

The prototype for our scientific match protocol was established in our prior work on ascertaining "effective," "neutral," or "ineffective" therapists within a TOP outcome domain[17, 26]. These classifications are based on the Reliable Change Index (RCI), an established procedure in clinical research that determines whether patient change exceeds the measurement error of the scale[60]. Following this strategy, we will first conduct a naturalistic baseline assessment of therapists' performance across 15 past cases for which baseline and follow-up TOP data exist to determine their strengths and weaknesses in treating the 12 TOP domains. TOP change assessed through the follow-up period will inform the matching in the trial. If a patient's score on a given TOP scale exceeds the RCI for that scale, change will be considered to exceed the TOP's measurement error and the patient will be considered reliably changed. The direction of reliable change determines improvement (decreased TOP scores) or deterioration (increased TOP scores). An "effective" therapist on a given domain (e.g., depression, work functioning) will be one whose average patient (across his or her 15 baseline cases) reliably improves. An "ineffective" therapist will be one whose average patient reliably deteriorates. A "neutral" therapist will be one whose average patient neither reliably improves nor deteriorates (i.e., maintains initial level of severity). These classifications will be made for all 12 TOP scales; thus, therapists can demonstrate multiple strengths, multiple weaknesses, and multiple domains for which they affect little to no change. It is these varying Report Card *profiles* that will allow us to match therapists to subsequent patients based on their baseline track record.

Following this naturalistic baseline period, new, successive patients presenting to PBC and consenting to participate in the RCT will be randomized to condition (and remain blind to it), with patients in the match condition being assigned to therapists from a short-list of those who would be an empirically good fit to that patient. The algorithm generates the short list based on 5 levels of match, ranging from highest to lowest:

1. The therapist is effective in treating the patient's 3 most elevated TOP domains, and is not ineffective on any TOP domain
2. The therapist is effective in treating the patient's single most elevated TOP domain, and is not ineffective on any TOP domain
3. The therapist is effective in treating the patient's 3 most elevated TOP domains, though may be ineffective on others
4. The therapist is effective in treating the patient's single most elevated TOP domain, though may be ineffective on others
5. The therapist is not considered effective on any elevated domain, but is also not ineffective on any domain

(Note that patients randomly assigned to the non-match condition will be assigned as per usual procedure within PBC; thus, as the logical, ecologically valid comparator, patients in this condition may or may not have matched domains due to the natural odds.) To determine elevation, all TOP domains for each patient will be ranked ordered for distance away from the general population (i.e., standard deviations beyond the non-clinical reference group). Variability in the match level within the match condition, and naturally occurring match variability in the control condition *will allow us to measure degree of match dimensionally as a moderator variable of our main treatment effect* (an HTE question). We will treat match degree as a ratio variable (i.e., number of matched domains to number of elevated domains >2 SDs away from the general population). Further, because we are not controlling for severity of elevation on a given domain beyond the minimum of a patient being 2 SDs more severe than the general population, *we will also have random variability on patient severity of presenting problems that also can be tested as a moderator treatment effects* (an HTE question). For example, one patient's most elevated scale could be 2.5 SDs from the mean of the general population, while another patient's might be 6 SDs from the general population. *We will also examine complexity as a potential moderator (i.e., the number of elevated domains; another HTE question).*

To evaluate outcome with an index separate from the TOP (to test convergence and enhance the validity of any condition effects), we will also assess global distress with the *Symptom Checklist-10* (SCL-10[61]), a 10-item, well validated and widely used self-report inventory that assesses psychological wellbeing.

Treatment process evaluations. We will assess multiple patient-level process variables repeatedly over time (i.e., every other session). To assess the quality of the patient-therapist relationship, both patients and therapists will complete respective versions of the short form of the *Working Alliance Inventory* (WAI[62]). The WAI is the most widely used alliance measure, and the short form has demonstrated sound psychometric properties. To assess patient and therapist outcome expectations, each will complete respective versions of the *Credibility/Expectancy Questionnaire* (CEQ[63]), a widely used and psychometrically sound measure of perceived logicalness of a given

treatment and expectations for the personal efficacy of that treatment. Patient dropout will be assessed with a study-specific *Nature of Termination Form*. Patient satisfaction will be assessed with the *TOP Satisfaction Scale*.

Data collection schedule. For the sake of the trial, and to maximize ecological validity, "treatment outcome" will be considered the point at which the patient and therapist mutually terminate or 16 weeks, whichever comes *later*. For a subsample of stakeholders, we will conduct post-trial exit interviews (*N*s = 5 patients, 5 therapists, 5 administrators) to gather invaluable input on how to be responsive to the study findings in terms of dissemination, implementation, and policymaking, including the potential importance of integrating diagnosis, provider age, race, or gender into subsequent matching approaches. We will recruit stakeholders in order of completion until we reach our target *N*s (therapists can only be involved once they have treated all 6 of their study patients). Fully reflecting stakeholder engagement, and to eliminate any biases or power dynamics introduced by the PIs or their research staff, Advisory Board members will conduct the individual interviews. The PIs (Constantino & Boswell) will train 3 Advisory Board members on qualitative interviewing, and each will administer 1-2 pilot interviews as part of the training, plus 5 study interviews. The interviews will be conducted and audio-recorded via a webconferencing service and will last approximately 60 min. Participants will be compensated $100 for their time. RAs will transcribe the interviews, removing any identifying patient information.

Data management. TOP assessment is coordinated and processed through PBC and ORI's well-established business agreement. All supplemental, study-specific measures will be completed via a secure web-based platform managed by the research team.

Data analysis. The primary efficacy/outcome measure will be the TOP-CS total score. To take full advantage of its longitudinal assessment, hierarchical linear modeling (HLM[64]) will be used to examine rates and patterns of change, as well as levels of treatment outcome at specific time points (e.g., beginning, middle, and end of therapy). A 3-level HLM model will be used to estimate within-patient differences (level 1), between-patient differences (level 2), and between-therapist differences (level 3). At level 1, a change trajectory will be fit to each individual's TOP scores across treatment. We will fit a series of models to determine whether a linear, quadratic, or cubic model best fits the data. If there is significant variability in individual trajectories and outcome levels, a level 2 model will be estimated with patient-specific covariates. Our primary interest is examining change trajectories and outcome levels as a function of treatment condition, which will be analyzed at level 2. Estimates of effect size (r^2 & pseudo-r^2) will be calculated by standardizing the coefficients from the HLM model. Multilevel modeling is currently the most suitable method for analyzing longitudinal data, as it accounts for the dependent data in repeated measures designs, provides more accurate estimates of standard errors, and addresses missing data in outcome variables[64].

In addition to the primary TOP total score, we will assess secondary outcomes, including SCL-10, alliance quality, patient outcome expectations, patient satisfaction, dropout, and domain-specific TOP scores. SCL-10, alliance quality, outcome expectations, and satisfaction are continuous variables that will be measured repeatedly across the 16 weeks of treatment, and we will assess these with 3-level growth models as described for the TOP total score. Dropout will be a binary yes/no variable, which we will assess with a 2-level logistic model with patients nested within therapists. We will analyze the secondary outcome of domain-specific TOP scores; that is, TOP change as a function of condition on the most elevated presenting domain (which for patients in the match condition would, in most cases, be the domain on which they were matched to their provider). To maintain power, and to maintain the appropriate multilevel structure, we will run the same model as above (powered to the same degree) with the outcome being each person's standardized score on their most elevated TOP domain.

Secondary analyses will include assessment of potential moderators, the modeling of variability in patient outcomes, and the exploration of site effects. First, we will include 4 moderator variables in the multilevel framework outlined previously to determine whether race, the degree of match, distress severity, or distress complexity (all modeled at level 2) moderate the relation between treatment and outcome change rates or scores at specific time points. Second, we expect more variability in outcomes among patients in the non-match group relative to the match group, which would support the scientific match promoting more consistently good outcomes among patients. We will assess this hypothesis by modeling the heterogeneity of level-1 variances as a function of treatment status in a 2-level HLM model with patients nested within therapists. Third, we will examine medication as a correlate of outcome and, if significant, we will include this as a covariate in our primary statistical models. The analyses outlined *meet PCORIs' standards on data integrity and rigorous analyses*.

In longitudinal studies, there may be missing values due to missed occasions and/or attrition. We will employ state-of-the-art techniques for missing data. When missingness is deemed to be completely at random (MCAR) or at random (MAR)[65], we will employ inference by multiple imputation. Using routines developed by Schafer and Yucel[66] and Yucel[67], we will incorporate the longitudinal design in the imputation phase. We will conduct sensitivity analyses to gauge the impact of departures from MCAR/MAR, and employ pattern-mixture models[68; 69], which lead

to valid inferences under missing not at random, and compare inferential quantities with those that assume MCAR/MAR. Our handling of missing data *meets PCORI's standards for handling missing data*.

For the exit interviews, Co-PIs Constantino and Boswell will train a team of 4 RAs (2 at UMass, 2 at SUNY Albany) to serve as primary judges of the interview data. Drs. Constantino and Boswell will serve as data auditors. Data will be analyzed according to a blend of grounded theory (GTA[70]) and consensual qualitative research (CQR[71]), an inductive method that allows investigators to gain a rich understanding of participants' perceptions of the target phenomena. The 4 judges will first independently identify broad content domains from several transcripts until domain saturation has been achieved. Any discrepancies in domain formation will be settled via discussion and consensus among the coding team. After the content domains are established, the judges will then independently open code the material to identify meaning units that represent participants' complete thoughts about the focal domains. Open coding involves the primary exploration of the data, through a process of discussion and constant comparison to participant responses to identify categories, concepts, and properties[72,73]. Discrepancies in the open coding will be settled via discussion and consensus. As part of the open coding, meaning units are successively sorted into their representative categories that represent commonalities both within and between transcripts. This process continues across transcripts, with modifications being made to the data structure as needed. As another layer of consensual coding to reduce bias and increase reliability, data auditors will provide feedback at both the domain generation and open coding phases. Back and forth between coders and auditors continues until consensus is achieved. Data saturation is achieved when additional data would not add to the understanding of the phenomenon; we expect that 15 interviews will be sufficient to demonstrate saturation.

Alternative Design Considerations

We considered various design options before finalizing this plan. First, we considered using a more homogeneous sample; that is, patients with a primary elevation on 1 prevalent TOP domain. Although this would have simplified the match and increased internal validity, we felt that it would have sacrificed ecological validity and the ability to deliver our match protocol to PBC which sees patients with various and complex problems. Further, ruling out patients would render our study less *patient-centered* (this concern was also specifically identified by Advisory Board members), and it would likely create more disruption for our partner PBC clinic (limiting immediate dissemination and implementation plans if we find an effect…such deliverables are central to PCORI). Finally, the mental health field as a whole is moving away from focused RCTs on discrete diagnostic categories[74, 75].

Second, we considered a third comparison group, involving matching patients to therapists' self-perceived strengths. However, the literature suggests therapists have limited variability in their self-proclaimed strengths; they tend to believe they are strong at treating most problems[76]. Thus, it would have been difficult to create this condition. Moreover, adding a third condition causes problems such as increasing the required sample size (and project costs) and creating more differences between the conditions, thus compromising our ability to isolate causation. Given these concerns, we chose our two-group comparison, and decided instead to measure therapist accuracy of self-perceived strengths in ancillary analyses.

Third, we considered making sure that patients in the non-match group were intentionally assigned to a non-matched therapist. This would address the problem that any assignment-as-usual is going to occasionally, and randomly, lead to a good match. If this is a common occurrence, it might attenuate a between group match effect. However, making these non-matched assignments would not reflect customary case assignment in these clinics. Administrators would never intentionally make scientifically informed ill-matched assignments, as that could be considered unethical. Thus, we felt it was vital to retain usual case assignment as the control condition, and to track how often (and how well) patients in the control group were matched. We do not expect the number of instances to be so high as to wash out an effect; we should be sufficiently powered to be robust to this problem. However, the possibility of any attenuation is the rationale for modeling patient outcome variability by condition as another means to determine the influence of the match protocol.

D. Project Milestones and Timeline

The overarching goal of this project is to demonstrate the comparative effectiveness of a scientifically derived patient-provider matching intervention that can be integrated into MHC systems to aid in treatment decision-making, as well as increase personalization. Toward this end, our goals will be to maximize stakeholder engagement throughout the process, demonstrate the feasibility and scalability of the intervention, and disseminate our results in scientific and professional outlets, as well as direct-to-consumer outlets (e.g., study website, newsletters, brochures, local conferences, visiting chapter meetings). Progress reports will be submitted every 6 months. Throughout the study period, we will convene regular Advisory Board and DSMB meetings. Minutes will be recorded at each meeting, and brief reports will be disseminated describing the meeting content and outcomes. Major outcomes at the

end of the first year will be (a) demonstration of the scalability of the match intervention that will be implemented in the RCT beginning in year two, and (b) registration of the trial with clinicaltrials.gov. By the end of the second year, we plan to submit a brief report that includes preliminary analyses after 50% of the patient RCT sample has been recruited. By the end of the third year, we will complete the active RCT and primary data analyses. In addition, we will submit a final manuscript reporting the primary study outcomes to a high quality, high visibility journal, as well as submit final data sets and codebooks to PCORI. We will also submit a study journal that cohesively catalogues "lessons learned" and the efforts of the Advisory Board over the course the study. Finally, we will engage in all dissemination efforts, including adding a plain language summary of results to a website that can be accessed by participants (as they will be informed at the time of debriefing). Please see the most recent Timeline/Milestone document for more specific information.

E. Patient Population

The patient population will be adult men and women (age 18-70) referred to PBC for MHC. Recall that the baseline phase (to determine therapist report cards) does not require active patient recruitment, but rather draws on historical data from 15 cases previously treated by eligible PBC clinicians. Given PBC's large referral stream (950 new scheduled patients each month), we anticipate no insurmountable difficulties when we actively recruit patients to enroll in the RCT. Moreover, we expect a high participation rate given the low burden and minimal change from treatment-as-usual. For the RCT, based on our power calculations, the *goal patient participant is N = 281* (accounts for a conservative estimate of potential attrition). As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, suicidality, and poor quality of life. The only study-related patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*[48]) diagnoses (including high severity, chronicity, and comorbidity rates typical at PBC).

The composition of our study sample will roughly match the average PBC utilization data for age, gender, race, and ethnicity. These projections are based on administrative data from the broad PBC system. Percentages are likely to vary slightly between specific service settings. That being said, it is reasonable to expect the average age to be 40 years, and that ~62% of patients will be female (~38% male). For race, based on recent PBC outpatient data, we expect the following: ~77% White, ~12% Black/African American, ~2% Asian, ~2% multiracial, ~6% Hispanic, and less than 1% Native American and Hawaiian/Pacific Islander. With this composition, we can analyze HTE on gender, race, and ethnicity as patient-level moderators.

Recruitment will be coordinated among our project coordinator, PBC intake and research staff members, and PBC administrators. Patients will be ensured that their participation in the trial will largely mimic the same treatment at the PBC site that they would receive if they were not participating. All patients will be told that the study is examining various referral processes that will not affect the nature their treatment (though *may* help connecting them to a well-matched therapist). Patients will also be informed that they will complete all assessments that are part of their standard clinical care within PBC, as well as several study-specific measures. For completing the additional measures, each patient will be compensated $50 total. The research Advisory Board will closely monitor recruitment numbers and work with PBC site administrators to address potential systemic barriers, should the need arise.

Recruitment Plan

Total number of study participants expected to be screened:	~11,000
Total number of study participants expected to be eligible of those screened:	~7,000
Target sample size (use same number stated in milestones):	211 usable cases in our data analysis (will require enrolling 281 patients when a taking a conservative 25% attrition estimate into account)

Estimated Final Racial/Ethnic and Gender Enrollment Table

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	1	0	1
Asian	2	4	6
Black/African American	14	23	37
Hawaiian/Pacific Islander	0	1	1
White	87	143	230
Multirace	2	4	6
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	6	11	17
Non-Hispanic	100	164	264

F. Research Team and Environment

Our research team has been collaborating for years and is well qualified to undertake this research.

Dr. Constantino (PI) is an expert on psychotherapy process and outcome research. In his 18 years of experience, he has conducted process research that has underscored complex and clinically important interactions between participant (i.e., patient & therapist), relationship, and both theoretically specific and pantheoretical intervention variables[77, 78]. Informed by this work, Dr. Constantino has also conducted multiple RCTs aimed at enhancing the efficacy of evidence-based psychotherapies for depression[79] and generalized anxiety disorder (CIHR-funded RCT in progress). Dr. Constantino also has extensive experience examining interpersonal processes as predictors, moderators, mediators, and/or outcomes of psychotherapy using self-report, other report, independent coder, and qualitative methodologies[80, 81]. He has also produced a number of empirical and clinical-conceptual papers on psychotherapy change theory[82], psychotherapy training[83], harmful therapy effects[84], and routine outcomes monitoring in mental health care settings[85, 27]. Finally, Dr. Constantino has experience with multilevel modeling in psychotherapy research[86], as well as grounded theory and consensual qualitative research approaches[87]. Dr. Constantino's expertise is underscored in the numerous awards that he as received, as well as his election to his current office as President of the North American Society for Psychotherapy Research. Dr. Constantino's research environment and resources are described below in the Consortium Contractual Arrangements section.

Dr. Boswell (Co-PI) is an expert on psychotherapy process-outcome research, community-based research methods, and measurement-based care. He has conducted process research on the complex interactions between participant (i.e., patient & therapist), relationship, and intervention variables[88, 89, 22, 90]. This research has included the identification of patient factors that moderate relationships with treatment outcome (e.g., readiness to change, hostility), and the use of multilevel modeling to examine therapist effects[88,22]. Dr. Boswell's research has utilized both quantitative (e.g., HLM, SEM) and qualitative methods (e.g., CQR). He has produced a number of empirical and clinical-conceptual papers and chapters on participatory research[88, 91], outcome measure development[57, 92], and the implementation of measurement and feedback in routine mental health care settings[42, 27]. Dr. Boswell's expertise in the area of performance measurement and feedback was underscored in his being invited to serve as a technical expert panelist on the U.S. Department of Health and Human Services sponsored white paper on *Strategies for Measuring the Quality of Psychotherapy*. Dr. Boswell's research environment and resources are described below in the Consortium Contractual Arrangements section.

Dr. Kraus (Co-PI) is the developer of the TOP[30] and inventor of the unique software that drives services for hospitals and behavioral health providers (US. Patent No. 7,415,663). Dr. Kraus also invented the scientific matching protocol to be tested in the RCT (U.S. Patent No. 7,873,525), and he is successful in turning scientific knowledge into consumer- and provider-based services[93, 94]. Stakeholder engagement in the modification of ORI products and services, like the TOP, has been key to ORI's success. PBC is an ORI customer and has helped them integrate TOP into all aspects of their intake and outcome monitoring protocols. ORI centrally processes all TOP data as a public service and has amassed the world's largest de-identified database of behavioral health outcomes that has been mined to advance the understanding of therapist effectiveness and provider quality improvement initiatives[17, 95]. Kraus's team includes world-renowned experts in consumer-driven market research, who have developed consumer-driven products for companies like FedEx, Volvo, BNY Mellon, and UPS. Dr. Kraus also leads an experienced R&D and engineering staff that are collaborating with the Annie E. Casey Foundation in the formation of a non-profit Institute for Child Outcomes (ICO) that is bringing scientific measurement and refining

scientific matching for abused and neglected children in child welfare system. Dr. Kraus's research environment and resources are described below in the Consortium Contractual Arrangements section.

Mr. Sykes (Co-PI) is the Managing Director of Psychological and Behavioral Health Consultants, where he is chiefly responsible for the design and implementation of the routine collection of quality metrics. His experience includes clinical positions at the Cleveland Clinic and Glenbeigh Hospital, and senior executive positions at Willow Creek Hospital, Windsor Hospital and Laurelwood Hospital. Mr. Sykes's specialization is in the treatment of adolescents and young adults. He has authored more than a dozen professional publications, presented more than 100 times throughout the country, and has been recognized in *Who's Who Among Human Service Professionals and Who's Who in the World.*

The designated consultants will each serve a specific and clearly defined role. Each has been consulted on the present application, with further consultation to take place through project implementation.

Mark Bauer, Neil Fontecchio, Kevin Kennedy, Sean Roohan, Michael Baskin, Abe Wolf, & Megan Moran: Board members will be heavily engaged in this project through monthly-to-bi-monthly meetings. Feedback on all aspects of the trial will be elicited from not only the Advisory Board members, but also outside contributors whom they represent (participating patients, other advocates at NAMI, etc.). Board members will be instrumental in conducting the exit interviews, and they will play a central role in disseminating study information and results to both scientific and stakeholder communities.

Todd Farchione, Ph.D.; Liz Rekowski, nurse practitioner; Heather Wightman, social worker (Data Safety and Monitoring Board [DSMB] members): The DSMB is external to the project and at arms-length from the PIs, vetting issues of conduct, safety, and integrity of the trial. All have experience with mental health care and/or psychotherapy research, and will review procedures prior to initiating the study and will meet with the Co-PIs every 6 months of the trial (6 times total).

Center for Research on Families' (CRF) Methodological Program at the University of Massachusetts' Amherst (statistical consultation services): Dr. Aline Sayer, Director, is an expert in research design and statistical methodology.

The Co-PIs and identified Advisory Board members to-date have been meeting and communicating regularly via teleconference and email for the development and preparation of the proposed project. Contributors exchange information freely on all aspects of project design and execution. The Co-PIs have a history of successful collaborations and work extremely well together. PBC and ORI have a well-established partnership, as does ORI, Albany, and UMass. The leadership team will continue to meet regularly through the entire project to discuss activities and issues germane to its successful execution. All decisions are made jointly upon thorough discussion and achievement of consensus. As noted in the support letters, people/places templates, and the Consortium Contractual Arrangements section, the multiple environments involved in this project are appropriate and well equipped to meet the project goals.

G. Engagement Plan

1. PLANNING THE STUDY: Patient and stakeholder partners have played and will continue to play critical roles in this collaborative research. In recent years, we have developed collaborative relationships with partners representing patient, clinician, and administrator perspectives. This has taken place through face-to-face meetings, conference calls, manuscript writing, and conference presentations. These interactions began with shared interests and motivations to improve mental health care decision-making and increase personalization through the use of routinely collected outcome information. As a group, we were surprised by the clear absence of patient-centeredness and engagement in this area. There was also a high degree of shared enthusiasm for PCORI's mission and goals. Patient partners shared their frustration with finding "the right provider," and administrator and system partners expressed a need for easily integrated data-driven processes (e.g., internal referrals) that improve outcomes, efficiency, and reduce risk of harm. Providers acknowledged that they have not been helpful to all of their patients, and that they would be interested in any strategy that could help them make better decisions and predict who is more or less likely to benefit from work with them. In these meetings, patient partners highlighted the importance of utilizing a diverse set of outcomes. In particular, they helped guide the decision to consider multiple domains of functioning, including quality of life, rather than general symptom severity. They also advocated for broad inclusion criteria, so that individuals with more severe and complex illnesses would be represented. Some of these partners have formally joined the research team as **Advisory Board** members. All members of the Advisory Board helped refine the study design and write this proposal. Stakeholder partners within PBC helped us to operationalize their pragmatic case assignment as usual, the comparator in this study. Additional feedback from administrator partners outside of the PBC setting increased our confidence that we had captured the standard, widely accepted, referral and

case assignment process in routine settings. In short, patient and stakeholder partners have been integral in developing the "soul" of this work, as well as relatively concrete elements of the design.

2. CONDUCTING THE STUDY: Patient and stakeholder partners will play important roles in the conduct of this study. Most prominently, we have assembled the core of a project Advisory Board that includes diverse representatives: three patient partners who have experience receiving mental health services, two practicing psychotherapists (one a PhD psychologist in Cleveland, and one a LICSW in Boston), the Executive Director for the National Alliance on Mental Illness Greater Cleveland, and a psychiatrist and researcher at the VA's Center for Healthcare Organization and Implementation Research in Boston. This Advisory Board will function as part of the core research team, and these board members have already contributed to the development of materials and protocols. Through continued discussion with current Advisory Board members and feedback from stakeholder partners, we will identify additional areas of importance that should be represented (e.g., recruit a board member who can best represent the primary care perspective). The Advisory Board will meet on a regular basis throughout the study, both face-to-face and via teleconference (see Timeline in Section D). Responsibilities will include: reviewing and finalizing assessment items and protocols (including consent forms), monitoring recruitment, monitoring responsible research conduct, monitoring methodology standards, reviewing the budget, discussing interim analyses, preparing presentations and content for dissemination, and communication of progress and outcomes to stakeholder groups. The process and outcomes of these Advisory Board meetings will be recorded and summarized in a written report that will include action items. These reports will also be sent to PCORI. The frequency and structure of these meetings will allow the Advisory Board to closely monitor study procedures and progress, as well as facilitate responsiveness to any issue that may arise (e.g., need to bolster recruitment activities; unforeseen study disruptions to PBC workflow). One key activity/goal of the Advisory Board will be to assist PBC in the development of its online patient portal where consumers will access key health related information, including outcome monitoring and feedback mechanisms. In addition, Advisory Board members will share the responsibility of conducting exit interviews with randomly selected study participants. We have also begun to assemble a data safety and monitoring board (DSMB) that represents multiple stakeholder perspectives. This DSMB will help ensure that our procedures are implemented in a manner that maximizes protection of participants at each stage and level. We will round out DSMB membership early in our milestone timeline.

3. DISSEMINATING THE STUDY RESULTS: Advisory Board members will play a significant role in the planning and implementation of communication and dissemination efforts. Each identified Advisory Board member has made a commitment beyond the 3-year study period, including the post-study dissemination efforts in their respective communities. A particular strength of our Advisory Board is that not only will diverse patient and stakeholder partners be represented, but members have pre-existing relationships with key communication and dissemination targets, including advocacy groups that often serve important dissemination functions for patients and other key stakeholders (e.g., Institute of Medicine, Robert Wood Johnson Foundation, Veterans Administration). For example, we have established collaborative relationships with several National Alliance on Mental Illness (NAMI) chapters. Members of our Advisory Board have functioned as representatives for this organization, and are committed to disseminating progress and outcome information (e.g., presenting findings at meetings and through listserves and newsletters). We have been invited by the editor of the Schenectady NAMI E-Newsletter to submit articles related to PCORI and this project; the drafting of such articles and letters will be a collaborative process. We have also established a connection with the Berkshire Coalition for Suicide Prevention and Empowerment Exchanges that serve a number of vital functions for mental health care consumers. We will pursue these outlets at various stages during the project, as well as following its completion. The Advisory Board will work directly with ORI and PBC to develop and execute mechanisms of dissemination to their wide customer and stakeholder bases. As we have done in previous practice-research network publications, Advisory Board members will serve as co-authors on empirical and conceptual manuscripts and presentations (professional conferences, as well as local patient advocacy conferences, such as those sponsored by the New York State Office of Mental Health). We have budgeted $1,000 for each of two Advisory Board member representatives to attend 1-2 professional conferences.

4. PRINCIPLES FOR ENGAGEMENT

- **Reciprocal Relationships:** In all elements of this research we will strive to maintain a non-hierarchical, collaborative process and structure. Nevertheless, members of the research team have been assembled to represent diverse perspectives and areas of expertise that complement one another and will create a synergy to optimize this work. We have included patient and stakeholder partners as key personnel, and have included biosketches for each individual that highlight the specific and diverse skills and experiences that will help

maximize this study's potential. For example, the PIs will be primarily responsible for the application of sound scientific methods (that meet PCORI's standards), budget oversight, and direct communication with institutional IRB (e.g., initial approval and renewals), PCORI (e.g., progress reports), and professional journals (e.g., communicating directly with journal action editors regarding manuscripts). Whenever possible, Advisory Board members (patient and stakeholder partners) will also be involved in such decision-making. For example, Advisory Board members will co-author manuscripts and assist with revisions. Patient partners will not be involved in patient recruitment, but will be directly involved in the development of recruitment and consent materials (e.g., to ensure the language is clear and understandable), the final assessment protocols, and assuring that the methods and deliverables maintain a high degree of patient-centeredness. Advisory Board members with expertise in implementation and policy will be more directly involved in steering communication and dissemination activities.

- **Co-learning:** Several strategies will be employed to ensure that patient and stakeholder partners understand the research process. For example, all thus far identified Advisory Board members have already reviewed PCORI's Methodology Standards, as well as read and contributed to this proposal. Given their prominent role in the research, all patient and stakeholder partners (if not already completed) will need to complete ethical conduct of research training. Specifically, each member will either complete or update CITI research ethics training (e.g., human subjects research and HIPAA modules). We will also review key Methodology Standards and Protection of Human Subjects information as part of our regular Advisory Board meetings. Advisory Board members coming from more traditional academic backgrounds (e.g., the PIs) will engage in activities to better understand patient and stakeholder engagement and patient-centeredness. Specifically, these Advisory Board members will attend local NAMI and Empowerment Exchange meetings to gain additional information and perspective on patient concerns and values. In addition, the PIs will attend meetings and review articles and information disseminated through the University at Albany Faculty Committee for Community Engaged Research (FCCER), as well as attend Community Mental Health Forums that are sponsored by local communities in affiliation with university partners who are engaged in community based participatory research.
- **Partnership:** We highly value the time and effort that patient and stakeholder partners have already devoted, and are committing to devote, to this work. Our patient and stakeholder partners represent key stakeholder groups implicated in the present research, and this representativeness will broaden further upon the finalization of the Advisory Board roster. These contributions are vital to the success of this project. Consequently, we have included financial compensation for Advisory Board members in the requested budget. Patient and stakeholder partners will be compensated $100/hour for their participation in the many scheduled Advisory Board meetings. In addition, we have included reimbursement for patient and stakeholder partner travel to and from in-person Advisory Board meetings, as well as professional conferences. All in-person and teleconference meetings will be held at a time that is convenient for patient partners. Finally, as noted, patient partners will be co-authors on manuscripts and presentations.
- **Trust, Transparency, Honesty:** By necessity, day-to-day research conduct and decisions will be made by the designated research personnel. However, the Advisory Board is being constructed to maximize oversight and collaborative decision-making. The primary context for sharing ideas and decision-making will be regularly scheduled Advisory Board meetings. Research procedures, updates, and impending milestones will be collaboratively reviewed and confirmed during these meetings. The final product of each meeting will be a brief report that represents the diverse perspectives of the board. The PIs will be responsible for sending this document, but it will need to be approved by all board members (a similar process will be utilized for other reports and written materials such as conference proposals, manuscripts, newsletters, and any IRB modification). We have scheduled a total of 21 separate Advisory Board meetings over the three-year study period. A minimum of one meeting per year will be in-person. Each meeting will convene for approximately one hour. More frequent, informal communication will take place via email and on the telephone. We will utilize more streamlined communication strategies where possible (e.g., establish an email list, share documents via cloud storage). Transparency will also be enhanced by explicitly integrating the *Engagement ACTivity (ENACT) Inventory* into Advisory Board meetings to objectively assess our level of engagement to make sure that we are on track.

DISSEMINATION AND IMPLEMENTATION POTENTIAL

A. Describe the potential for disseminating and implementing the results of this research in other settings.

Given the ease of reproducibility and scalability of the proposed scientific match algorithm, we believe that the results will have enormous dissemination and implementation potential. We have devised a multicomponent, collaborative dissemination and implementation plan. Dissemination efforts will actually begin prior to the completion of the study period. We will have ongoing communication with stakeholder groups, which will be facilitated by our Advisory Board members. Our Board members are well connected in local and regional communities. We will utilize multiple media outlets, including university-driven media reports. For example, results will be disseminated in a NAMI newsletter. We will also convene a conference for stakeholders and advocates where we will discuss the research results, implications, and implementation strategies. In addition, we will present our findings at national and international scientific, professional, and advocacy conferences (e.g., American Psychological Association, Society for Psychotherapy Research, NY and MA State NAMI conventions). Multiple advisory board members will have the opportunity to collaborate on presentations. We will also pursue dissemination through publication in widely circulated peer-review journals.

If the scientific matching tool does not lead to differentially positive outcomes in the RCT, the Advisory Board will meet to discuss components of the research proposal and results that might be of interest to relevant stakeholder groups. For example, patients may still value having access to provider information, regardless of the specific impact on observed outcomes. Alternatively, PBC can still use patient-focused outcomes data to inform resource allocation and training initiatives. The Advisory Board will also discuss future research plans and patient-centered initiatives.

ORI is the largest behavioral health outcomes management system in the United States. Research results will be disseminated to ORI clients and partners across the country. Rapid implementation will also begin upon project completion, starting with our partner PBC. A key to ORI's dissemination success is delivering new scientific information ***just in time***, at the point in care when critical decisions are made. Attached to a TOP client report (which is scored and delivered in real-time) are new and relevant research citations that can inform therapy responsiveness to patients who may not be responding to treatment, or even deteriorating. ORI has built such systems for individual patients who screen positive for likelihood of adverse outcomes, including hospitalization[88], and for entire mental health care networks based on risk-adjusted, benchmarked, aggregate data tied to libraries of evidence-based practices and principles.

Based on the results of the trial, direct-to-patient scientific matching strategies (promoted through primary care offices) will be piloted in OH, MA, and NY. The identified scientific matching algorithm and feedback system will no doubt continue to be refined with the accumulation of new data and implementation in new, diverse settings. Additional test-sites are currently under negotiation with Medicaid in North Carolina, Colorado, and Delaware. Due to our patient-centered research approach and rigorous methodology, we believe our scientific matching strategy will represent the optimal decision-making intervention of its kind. Showing that scientific matching feedback significantly improves valued outcomes and patient and stakeholder decision-making capabilities will revolutionize the provider referral and case assignment process in mental health care. Because reliable estimates can be obtained on a small sample of patients per therapist, matching algorithms can be employed quite rapidly. In addition, such a system is likely to be of tremendous value to various stakeholders—patients, administrators, insurance companies, providers, trainers/supervisors; this widespread relevance will also facilitate rapid adoption and use.

B. Describe possible barriers to disseminating and implementing the results of this research in other settings.

We do not anticipate significant barriers to disseminating and implementing the results of this research in other settings. This is for several reasons. First, as part of this research, the matching system will be further developed and refined based on the interests and values of actual patients, therapists, and administrators. Second, our sample and the research context will be representative of other settings, including treatment settings that are typically under-resourced and serve complex populations. Third, a reliable matching algorithm can be established in relatively little time and with minimal burden.

Although highly unlikely, potential barriers may exist. For example, some treatment settings may simply refuse to collect outcomes data. Data must be collected to "teach" the algorithm. In reality, due to a variety of pressures, it will be difficult to find such a setting in the near future. Furthermore, patients consistently demonstrate highly favorable attitudes toward outcomes monitoring and feedback[103] Another possible barrier is that different settings use alternative measurement systems; however, we have every reason to believe that the matching strategy being tested in the proposed research could be replicated with other outcome tools, which ultimately represents a strength.

C. Describe how you will make study results available to study participants after you complete your analyses.

All participating patients and therapists will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Participants will also be informed at the time of debriefing that the final study results will be made available to them in form of a brief, plain language summary. Participants can choose to have the summary sent as a PDF in an email, or they can access a study-specific website. The website will be updated throughout the trial, and will include the results summary once available. The website URL will be provided at the time of debriefing, which will allow patients to opt out of providing an email address.

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING

A. Describe the ability to reproduce potentially important findings from this research in other data sets and populations.

Findings will have a high degree of reproducibility and scalability, and the implications reach beyond mental health care (MHC). First, our sample and the research context will be highly representative of MHC consumer populations and routine community treatment settings, including treatment settings that serve more severe and complex patients. Arguably the most critical factor is the ability to replicate and reproduce the empirical matching intervention (algorithm). The present research will actually represent the third time that this particular outcome monitoring system (TOP) has been used to develop a predictive algorithm on a new sample of providers. The match technology is dependent on gathering data from multiple providers treating multiple patients; however, our own work and other research has demonstrated that relatively few cases are needed per provider to obtain estimates that will result in a match that will outperform pragmatic or random case assignment. We expect to demonstrate that once routine outcome monitoring is integrated into a health care system, it does not take long to gather sufficient data to employ such a scientific matching system. The replicability and reproducibility potential of this work extends beyond this specific outcome monitoring system. Theoretically, any reliable and valid multidimensional measure of symptom and functioning domains of concern to patients and stakeholders could be used to develop empirically derived matching algorithms. The particular domains of interest will only depend on the context and area of healthcare, yet the care model will be easily reproducible and improved upon as more data of importance to key stakeholders are integrated. The primary requirement for reproducibility, reliability and validity will be the accumulation of sufficient data on a diverse sample of patients and providers in identified settings. Once an outcome monitoring system is in place, healthcare systems can conduct similar CER in an attempt to replicate and examine generalizability of findings within and outside of MHC. It is also critical to note that the complexity of mental healthcare creates barriers for dissemination, implementation, and reproducibility. For example, it takes a single clinician many months of intensive training, supervision, and feedback to begin to deliver a complex multi-component psychosocial treatment with a sufficient fidelity. In the absence of continued training and feedback, evidence demonstrates that this clinician will eventually resort to previous practice patterns. Alternatively, a match algorithm can be integrated into a *system* at low cost, produce measureable improvements in outcomes (and reductions in risk of harm) within a short period of time, and be self-sustaining/enhancing. Our proposed research methods will also maximize the ability to reproduce and replicate our findings. Specifically, our limited patient exclusion criteria will increase the generalizability of our results to routine, naturalistic treatment settings. In addition, we will create a detailed data codebook and dictionary, as well as a study journal that documents the research process, key decision points, methods, and "lessons learned." We will also register this trial with ClinicalTrials.gov.

B. Describe how you will make available, within 9 months of the end of the final year of funding, a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses, or your data-sharing plan, including the method by which you will make this data set available, if requested.

The research team will work diligently to develop and maintain a comprehensive, clean, and easily interpretable data set with a clear codebook and dictionary. This will begin early in the conduct of the research with a sound data management and checking plan. Most of the data collected in the proposed research will be in an electronic or web based platform, so information will be downloaded into a database without the usual risk of human error that coincides with data entry. In addition, ORI has been making such data sets available for analysis by academic research teams (including Drs. Constantino and Boswell) for more than 10 years. Outcome Referrals has pre-programmed computer routines that de-identify data and build the relevant data dictionaries. In addition, our conduct of interim analyses will allow us to establish an intuitive data structure, variable list, and codebook well in advance of the final analysis and delivery of the final, cleaned data set. A cleaned, de-identified copy of the final data set used in conducting the primary analyses will be available upon request to the PIs. Data will be made available in Microsoft Excel or SPSS file format. We will also donate the dataset to the Society for Psychotherapy Research (SPR) Data Archive initiative.

C. Propose a budget to cover costs of your data-sharing plan, if requested.

The primary cost for data sharing will be software renewal. Database storage, management, and codes (e.g.,

syntax for analysis) will rely on a continuation of software licenses. There may also be additional time costs for the PIs and Advisory Board members (e.g., correspondences, review of request, material preparation, and potential negotiation with SPR Executive Committee). Consequently, we propose a budget that includes funds for statistical software license renewal fees ($600) and the personnel time/effort cost of two additional Advisory Board meetings (~8 members, $100/hour, 2 hours = $1600). The proposed total budget for covering data-sharing costs is $2200.

PROTECTION OF HUMAN SUBJECTS

Describe the protection of human subjects who will be involved in your research.

4.1.1 Risks to Human Subjects

a. Human Subjects Involvement and Characteristics, and Design

We will conduct a RCT involving PBC therapists and patients. Both categories of participant will be adult men and women (age 18-70) recruited from the PBC outpatient clinic. Virtually all patients who would be considered clinically appropriate outpatients at PBC will be eligible. The only exclusion criteria will be patients who are not the primary, informed decision-maker for their care and adults over age 70 years. The latter is because older adults (a) represent a small portion of patients at PBC, and (b) their mental health treatment is complicated by aging issues for which specialized care may be required. With no additional attempt to limit the variability of patients by diagnosis or other characteristics, patients will present with a multitude of presenting problems. Eligible, consenting patients will be randomly assigned to receive either naturalistic treatment with a scientifically matched provider or naturalistic treatment with a non-scientifically matched provider through pragmatic assignment as usual. No particularly vulnerable populations (e.g., prisoners, institutionalized) will be involved in the proposed research.

We anticipate that our therapist sample will resemble the existing PBC demographic statistics (see section C and the targeted/planned therapist enrollment Table in Appendix A for details). We also expect the composition of our patient sample to roughly match the average utilization data for gender, race, and ethnicity for PBC (see the "Estimated Final Racial/Ethnic and Gender Enrollment Table" that we included in section C).

Collaborating Sites and Personnel. Study recruitment and primary data collection will take place within PBC. All treatments will be conducted at PBC. The Co-PIs, project coordinator, PBC site staff members, PBC administrators, Advisory Board, and the DSMB will oversee recruitment, data collection, management, and protection. PBC routinely handles private health information and is in compliance with HIPAA regulations. Any "hard" materials that are collected will be stored in a locked cabinet in a locked office at the PBC site or PI's institution. PBC site staff, PBC administrators, and Advisory Board members will ensure protection of data until the project coordinator or Co-PIs formally collect them. However, most of the data collection will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms.

b. *Sources of Materials*

In the RCT, each patient will complete a battery of demographic, symptom, and functioning self-report measures. For the therapist baseline, participating PBC therapists will complete self-report measures assessing demographic information, clinical experience, license type, and dimensional ratings of the influence of various theoretical orientations on their treatment approach. Providers will also complete a study-specific measure to assess their beliefs about their effectiveness in treating the various TOP domains when uninformed about their prior data-driven TOP track record. Subsequent to the baseline assessment, each patient will complete self-report assessments of symptoms, functioning, and treatment process during the course of treatment and at post-treatment. A subset of patients will have the option of participating in a semi-structured exit interview conducted by an Advisory Board member.

The research will involve routine treatment conducted at PBC. Therefore, treating clinicians and administrators will have access to treatment-relevant private health information, as they would in routine practice. PBC routinely handles private health information and is HIPAA-compliant. Only designated study personnel will have access to identifiable, study specific, private information about human subjects. When registering on the TOP system, both patients and therapists are assigned a random number code that links all subsequent assessments and is separated from identifiable information. This random number code will function as each participant's study code and will be used to link participants' data. As noted, most of the data will be collected through a web-based platform. The assigned participant code will be used to link/aggregate information, so private information will not be requested after the baseline assessment/consent process. Only the PI and project coordinator will have access to the signed consent forms and the list that links identifiable information with the participant's study code. This information will be temporarily stored in a locked cabinet in a locked office at PBC. At regular intervals, this information will be collected by the project coordinator or PI and taken to UMass for long-term secure storage. At this point, only the PI will have access to this identifiable information. Any audio recordings from exit interview will be immediately uploaded to a secure website. All data will be encrypted and password protected. Only the Co-PIs will know this password and have the capacity to access the recordings. When it is time to analyze the recordings, designated, trained coders will also have access to the recordings; however, they will not have access to additional identifiable information (only the information required to complete the analysis).

c. *Potential Risks*

Regardless of condition, all participating therapists will employ their usual treatments and patients will be receiving their usual treatments. Consequently, there are no risks over and above what would normally be expected in routine psychotherapy. The major research question is whether or not scientific-matching significantly outperforms routine pragmatic case assignment. For those participants randomized to "pragmatic case assignment as usual", they will be assigned to a therapist in a manner consistent with routine practice. Further, the primary outcome monitoring system (TOP) is already being used at PBC without incident.

As is typical in psychological research, some of the assessment questions may be experienced as intrusive and/or may cause anxiety. The risk from such increased anxiety, however, is minimized by the use of skilled and extensively trained assessors who are aware that such reactions may be related to a person's presenting problems, or simply a function of the intimate and emotionally intense nature of psychological services. In addition, the PIs, project coordinator, and PBC site staff and administrators will be available to meet with any participant who may be unduly disturbed. In treatment, some individuals may experience emotional upset during sessions. Additionally, some participants may experience disappointment with their rate of progress or setbacks. The risk associated with such reactions will be minimized by the use of therapists who are sensitive to these issues and who have peer and administrative support. PBC has well-established procedures in place for managing treatment-related disturbances (although these are a natural part of treatment, rather than a unique risk of this research).

4.1.2 Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

Therapist participants will be providers within PBC. Recruitment will be coordinated among our project coordinator, PBC site staff members, and PBC administrators, and will involve presenting information about the study to providers through flyers, verbal script, telephone, or email. Interested participants will meet or speak via teleconference with the project coordinator to learn about the study through the consent process. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be blind to the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Interested providers will need to agree to keep sufficient openings on their case roster until they meet their required case numbers (this will not be an issue for PBC providers). They will also be informed that their study patients will first undergo an in-person baseline assessment with a RA, as well as complete a few study-specific measures throughout treatment. Therapists will also need to consent to completing a few study specific therapist-report measures, and will be informed that they will be compensated $50 per patient for this additional, but minimal, time burden.

Patient participants will flow into PBC via primary care referrals, hospital discharge referrals, internal office (PBC) referrals, or self-referrals. These referrals get logged into the electronic medical record. The intake specialist will then ask patients for permission to send, via email, a study consent form and baseline measures packet if they are interested in learning more about participation. If given verbal authorization to do so, the PBC intake specialist will the study link immediately. As part of the online consent document, patients are informed that their participation in the trial will largely mimic the same treatment that they would receive if they were not participating. However, to be enrolled, the patient must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), and accept assignment to an eligible treatment format as per below. For completing the additional measures, each patient will be compensated $50 total. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment. If a patient does not consent via the online form, their second call with the intake specialist will proceed as usual. If a patient consents to be enrolled, they have signed the consent form and completed a baseline survey of measures (including the TOP) through the online platform. Patients will then be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match) on their second call with the intake specialist. From there, treatment proceeds as usual, with the project coordinator sending weekly measures to study patients via email for the duration of their treatment, or the 16-week outer limit for those in longer-term treatment. All patients who consent are sent a hand-written thank you note from the research team within 1 week of enrolling. Regardless of consent status, the project coordinator sends (within 1 week) a $15 Amazon eGift card to all patients who view the consent form.

b. *Protection Against Risks*

Consent forms and self-report data (therapist and patient) will be completed and stored via secure, password-protected web-based platforms. All participants will be informed about the nature of their involvement prior to

participating. After participating, they will also be fully debriefed on the purpose of the study. Only the relevant members of the research team will have access to the participants' data and only the PI will have long-term access to identifiable information. As noted, all assessments will be linked with a de-identified participant code. Any records linking the code to the participants name or voice recording will be kept in a separate locked file cabinet in the PI's office. All hard copy data will be destroyed (via shredder) 5 years after publication of the primary findings.

As noted above, this will be a low risk RCT. The Co-PIs, project coordinator, PBC site staff members, PBC administrators, and Advisory Board will monitor the treatments and data collection; thus, they can assist in regularly monitoring any adverse events. Such negative occurrences are unlikely to be trial-related, as all patients will be receiving treatment-as-usual. Therefore, any adverse event will be addressed with PBC's well-established procedures for monitoring services and managing treatment-related disturbances. Nevertheless, any adverse event will be recorded and immediately reported to the IRB, PCORI, and the DSMB.

The potential risks associated with the assessment procedures and treatments will be minimized by the use of skilled assessors and therapists. Therapists will be meeting regularly with patients as part of routine treatment, and this will include monitoring changes in mood, behavior, and/or general mental status as they would in their typical practice. Should, during the course of the study, a patient show evidence of psychological or physical deterioration, the patient will be assessed comprehensively in the domains of concern (except in the case of a life-threatening physical emergency such as the emergence of acute chest pain, in which case 911 will be called immediately). If the therapist deems that the patient meets criteria for a psychiatric hold (e.g., patient is an imminent danger to self or others), the therapist will arrange for the patient to be brought to the emergency department and will contact his/her PBC administrator and the PI to debrief. If a patient is not meeting criteria for a psychiatric hold, but is showing clear signs of decreased mental status, the therapist will continue to meet with the patient, as well as - in consultation with the PBC administrator - make arrangements for the most appropriate level of care (e.g., day treatment).

To ensure the safety and confidentiality of participants, any non-web based assessment material will be kept in a locked cabinet and office, and labeled with a study code only. The list of identifiable information that corresponds to the study codes will be kept separate from the other assessment materials in 2 forms: (1) a hard copy that will be stored in a locked filing cabinet in the PI's office, and (2) an electronic version that will be stored on the PI's password-protected office computer that is separate from where other materials and the main electronic database will be stored. Moreover, the signed consent forms will be maintained in the separate hard copy file just discussed, as this will also help to prevent participant names from being associated with study codes. The main electronic database will be maintained on a password-protected computer in a research office. All files and documents related to this study - whether stored at PBC or the PI's office - will be kept in either locked file cabinets and/or on password-protected computers. Only designated personnel involved in the study will have access to participant data, as needed. For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others

The most direct benefit a participant in this study may receive is the reduction of symptom-related distress and improved functioning. In addition, patients will receive more personalized mental healthcare. Psychotherapists may experience a greater level of positive impact across their caseloads. Given that the actual treatments being provided will not be manipulated, the benefits of participation are judged to far outweigh the potential study-specific risks.

4.1.4 Importance of the Knowledge to be Gained

The results of this patient-centered RCT will tell us whether or not (and to what degree) scientific matching outperforms routine pragmatic case assignment. If scientific matching demonstrates superior outcomes in this highly generalizable community mental health context (as we anticipate), then mental health systems will have a low-cost, scalable, data-driven approach to improving patient outcomes and increasing the personalization of care. Scientific matching can be easily transferred and adapted to other settings and health conditions. The importance of the knowledge to be gained far outweighs the low level of risk in this phase.

4.1.5 Data and Safety Monitoring Plan

Our data and safety monitoring plan is designed to meet the anticipated risks of this specific research. A comprehensive data safety and monitoring plan has been developed, involving (a) Co-PIs, (b) Advisory Board members, (c) IRB, (d) project coordinator, (e) and a formal DSMB. Adverse events will be immediately

reported to the IRB, PCORI, and the DSMB. Although the research will be conducted in outpatient treatment settings, patients will be receiving naturalistic treatment as usual. Consequently, potential treatment-related adverse events are not directly within the purview of this research. Patient data (e.g., outcomes) will be collected via self-report measures. All participants must review a written *informed consent* and will have numerous opportunities to ask study personnel questions or share concerns regarding study participation and procedures. The individuals listed above will oversee the following monitoring and risk management plan:

Data safety and monitoring will be a routine agenda item at month Advisory Board meetings. In addition to immediate report to the PIs, any *adverse event* will be reviewed at this meeting. An adverse event is defined as both an expected side effect that is of a serious nature, or an unexpected side effect/event regardless of severity. All events will be graded as to their attribution (unrelated to protocol, or possibly, probably, or definitely related to protocol and level of severity). Any event that is reported to the PI by a participant or study personnel and which meets these criteria will be documented as such. Reports of adverse events will include a description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event or the reporting of the event. All adverse events will also be summarized annually and submitted to the UMass IRB. Adverse event reports and annual summaries will not include participant-identifiable material. The PIs will include a summary of safety review results (including adverse events) in the progress reports submitted to the UMass IRB and PCORI. PCORI will receive more frequent progress reports, yet the *annual IRB reports will address*: (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely.

Patients will have regular contact with their therapists. In cases where there is an acute deterioration or imminent risk of suicide, therapists (with assistance from the PBC administrators) will take the necessary course of clinical action and the study protocol will become secondary. Based on the assessment of the therapist and/or PBC administrator, if the patient is deemed to require a higher level of care, this will be arranged. Given that the treatments will not be manipulated, existing PBC procedures will be followed. Study related responsibilities (e.g., self-report assessments) would, of course, cease for the patient. PBC has medical professionals on staff who manage patient safety locally. PBC has extensive safety precautions in place for patient safety in general as well as risks to confidentiality.

There is a chance that some participants might find the psychological assessments to be distressing, yet this risk is considered to be minimal. Patients will be asked questions related to their symptoms, functioning, and perceptions of the treatment, yet this content is not different from what would be shared in treatment and their information will also remain confidential. Therapists will regularly review crisis procedures with patients. That is, the patient will be informed to go directly to the emergency room or call 911 in the event of needing emergent psychiatric or medical care. Less serious study related issues (e.g., difficulty completing self-reports) will be reported to the project coordinator who will address these issues as appropriate and report them to the Co-PIs. If any issues cannot be readily addressed, they will be brought to the Advisory Board for consensual resolution.

Most self-report data (therapist and patient) will be collected via a secure, password-protected web-based platform. All self-report responses will be linked by this password. Identifiable information will not be collected during web-based assessments. Only dedicated study personnel (e.g., the PIs) will have password-protected access to the online database, which includes only study code to link data. No identifiable information will be used in publications are presentations. *Audio recordings*. Exit interviews will be digitally recorded and archived for subsequent analysis. Such recordings are considered identifiable information even when linked by study code alone. Recording equipment and software will be handled by dedicated study personnel. Upon completion of a recording, these data will be transferred to a digital storage system. The system will be user study code and password protected, with state-of-the-art web security. Research personnel who are responsible for coding of recorded data will have mandatory ethics training in human subjects' research, data management, and HIPAA. These coders will be essentially independent evaluators who will not have access to other therapist or patient data. As noted, the recordings themselves will not be labeled with any identifiable information. The PIs will routinely monitor the collection and analysis of recorded data. *Database protection*. As noted, the web-based data storage system is password protected and information is linked by study code. When data are ultimately exported to a statistical software package for analysis, only the study code will link the data. The data files used for statistical analysis will be password protected any physical storage (e.g., a flash drive) will be kept in a locked office.

The DSMB will meet a minimum of 6 times (every 6 months) to review the data collected thus far completeness and accuracy, as well as protocol compliance. The DSMB will also review (a) risk management protocols, as well as any modifications to the protocols; (b) procedures for maintaining confidentiality, data

collection, and analyses, (c) progress toward meeting recruitment and enrollment goals, (d) if applicable, deciding whether or not individual patients should be removed from the study protocol, (e) recommending continuation, discontinuation, modification, or termination of the study based on evaluation of risk/benefit ratio. DSMB reviews (e.g., assessment results, recommendations) will be summarized in written reports that will be sent to PCORI.

CONSORTIUM CONTRACTUAL ARRANGEMENTS

Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project.

Dr. Constantino (PI; prime contract) has extensive experience and expertise in the research methods that will be employed in the proposed research. He is an expert on psychotherapy process-outcome research, community-based participatory research methods, and measurement-based care in routine treatment settings. Specifically, he has expertise in overseeing RCTs, engaging in multi-site research, statistical methods, diagnostic assessment, qualitative methods, community-based research, collaborating with a DSMB, and providing direct clinical care as a licensed clinical psychologist in MA. As the PI and prime organization, respectively, Dr. Constantino and UMass will play the most integral and substantive roles in the proposed research. Dr. Constantino will oversee the entire study and is co-responsible for the scientific design. More specifically, he will lead the entire research team and organize its deliberations, write and manage the IRB and research protocols, directly supervise the project coordinator and all UMass graduate (paid) and undergraduate (volunteer or credit-based) research assistants, co-develop the patient and stakeholder exit interview, co-train the qualitative analysis team, oversee participant/patient recruitment, co-create the algorithm for the randomization procedure, oversee data management, engage in appropriate consultations (including assisting with statistical analyses), manage the prime (UMass) budget and co-manage the subcontracts (to ensure that all activities conform to PCORI policies and standards), convene and participate in Advisory Board meetings and keep meeting minutes, write regular progress reports to PCORI (and participate in conference calls with contract officers); liaise with community groups who are invested in the project and its results (e.g., ongoing connections and dissemination with patient advocate groups), and assist in the dissemination of project findings through publications in peer-reviewed journals, presentations at scientific conferences, presentations to patient advocate group meetings, and publications in advocate newsletters/blogs. Dr. Constantino's organization/institution, the **University of Massachusetts Amherst (UMass)**, is well resourced and situated to perform the proposed research. **LABORATORY:** Dr. Constantino has at his disposal a dedicated Psychotherapy Research Laboratory in the Department of Psychological and Brain Sciences (PBS) at UMass. PBS is housed in Tobin Hall at 135 Hicks Way, Amherst, MA. The lab includes 3 rooms, the main one of which is located in the Psychological Services Center (PSC). This room is an ideal operations center for conducting psychotherapy research given its proximity to the adjacent PSC therapy rooms where participants receive their services. The room is equipped with a dedicated phone line, a digital voicemail service, locking file cabinets for secure storage of paper files and digital media, and multiple work stations for a project coordinator and research assistants. The other 2 lab rooms, which are located outside of the PSC, but in Tobin Hall, provide additional workstations for research assistants for data entry, coding, transcription, and other lab tasks. The PSC also has two conference rooms that can be reserved for regular lab meetings, web conferencing, etc. **COMPUTERS:** The main lab room is equipped with 3 Windows-based desktop PCs, digital transcription equipment, and a laser printer. One of the other lab rooms is equipped with 2 Mac-based computers, two workstations, and a scanner/copier/printer inkjet. The third lab room is equipped with 1 Mac-based computer, 1 workstation, and copious files cabinets for storage. All computers are networked together, connected to the Internet via Ethernet, and set up with necessary software (e.g., Microsoft Office, Adobe Acrobat, SPSS, etc.). Electronic data are backed up on a dedicated secure cloud server (Box) through the University Server. **OFFICE:** The PI's office is also located in Tobin Hall, which makes it convenient to supervise the research staff. The office is equipped with a phone line, a digital voicemail service, locking file cabinets for secure storage of paper files and digital media, and a MacBook Air laptop computer with an external second monitor. The computer is networked with a high-speed laser printer, and electronic are data are backed up on a secure cloud server. **OTHER:** Full-time technical support is provided both by the UMass Office of Information Technology, as well as the PBS's electronics shop. Faculty members are supported for their research through the Office of Grants and Contracts and for their teaching through the Center for Teaching and Faculty Development. PBS is equipped with a large number of software and hardware resources and the building provides ample space for the PI's research operations. Administrative support is provided by the PBS in the form of two full-time bookkeepers, a building manager, a shop staff, a Human Subjects manager, etc. Necessary books and journals are available at UMass's W. E. B. Dubois Library. UMass faculty members also have full access to a library consortium through the Five College Network (UMass, Amherst College, Mt. Holyoke College, Hampshire College, & Smith College). The PI and his research staff also have full-text access to PsychINFO, PubMed, and other relevant databases.

Dr. Boswell (Co-PI; subcontract) has experience and expertise in the research methods that will be employed in the proposed research. He is an expert on psychotherapy process-outcome research, community-based research, and measurement-based care in routine treatment settings. Specifically, he has expertise in statistical methods,

diagnostic assessment and outcome monitoring, and qualitative methods. Dr. Boswell is considered an expert on performance measurement in psychotherapy; he has significant experience in the development and sustainability of PRNs, and he has conducted rigorous clinical research using experimental designs in routine mental health settings. Dr. Boswell's organization/institution, the **University at Albany, SUNY**, is well resourced and situated to perform the proposed research. SUNY's Research Foundation is committed to the successful conduct and completion of sponsored programs. It is well resourced and staffed, with dedicated support for Dr. Boswell and his academic department. Dr. Boswell has a private office and multiple rooms of dedicated lab space in the department of psychology. In addition, he has research and office space in the SUNY Psychological Services Center (PSC), a CMHC/training site located in downtown Albany, NY. In both settings, Dr. Boswell has access to computers, word processing and computer software, and administrative support. He also has access to departmental and center fax machines, copiers, and voicemail. In addition to conducting mental health treatment research, Dr. Boswell is a licensed clinical psychologist in Massachusetts and New York who sees patients and supervises doctoral students. Dr. Boswell currently directs a research lab at SUNY Albany. He works closely with graduate students and undergraduate research assistants in the development and implementation of his research. The Psychology Department and SUNY Albany are committed to Dr. Boswell's research program and his conduct of collaborative research. They have provided him with institutional start up funds, as well as allow for course reductions and summer salary for sponsored research activities. Dr. Boswell and SUNY Albany are well-situated and partnered with patient and stakeholder advocate groups. The Capital District is home to several large, well-connected advocacy groups (e.g., NAMI, Mental Health Empowerment Exchange) that frequently collaborate with the department of psychology and the schools of public health and social welfare, as well as similar groups in Western Massachusetts. All of these partners will figure prominently in this project's dissemination and implementation plan. Given these strengths and resources, Dr. Boswell and SUNY will play an important role in the proposed research. Specifically, Dr. Boswell will **(a)** oversee study implementation (e.g., IRB, recruitment, etc.); **(b)** assist in the management of the primary study database; **(c)** co-train and supervise research assistants; **(d)** co-supervise qualitative coding (including auditing); **(e)** oversee this subcontract budget and activities to ensure that all activities conform to PCORI policies and standards; **(f)** participate in Advisory Board meetings and assist in the writing of meeting reports, as well as regular progress reports to PCORI (and participate in conference calls with contract officers); **(g)** liaison community groups who are invested in the project and its results (e.g., ongoing connections and dissemination with patient advocate groups); **(h)** assist in the conduct of the primary and secondary statistical analyses; **(i)** assist in the dissemination of project findings through publications in peer-reviewed journals, presentations at scientific conferences, and activities noted in (g) above.

Dr. Kraus (Co-PI; subcontract) and **Outcome Referrals, Inc. (ORI)** will develop and manage the TOP data collection and scoring systems (and for other measurement tools as needed), as well as create, deploy, and refine the computerized matching algorithms and interfaces that PBC will utilize in the RCT. Dr. Kraus has more than 20 years experience developing and operating similar systems for small- and large-scale projects (e.g., entire Medicaid departments, state-wide provider networks, and commercial health plans). Dr. Kraus will lead the direct-to-consumer (and direct-to-provider) dissemination of the project findings, and will assist in the publication and presentations of the findings at conferences and peer-reviewed journals. **COMPUTERS:** ORI has dual networks of 24/7 data collection servers co-located at Tier 1 internet facilities running Oracle databases and Java-driven proprietary code. ORI also has two high-speed scanners, and more than 30 desktop computers with Windows Office and several with SPSS and other statistical software. **OFFICES:** ORI offices (6,000 square feet) will host the in-person Advisory Board meetings in one of our three conferences rooms, one of which has a large display screen and video conferencing capabilities.

Mr. Sykes (Co-PI; Subcontract) and **Psychological and Behavioral Health Consultants (PBC)** will (a) develop standard work to incorporate study protocols (e.g., recruitment and assessment) into routine care at PBC; (b) oversee all PBC employees (therapists, front office staff, research support personnel) involved in the randomization of patients into experimental condition; (c) oversee training of triage clinicians to the standards required as part of the study; (d) act as liaison with appropriate PBC personnel as necessary to facilitate the study; (e) provide clinical oversight to ensure that patients' rights and needs are protected; and (f) assist in the dissemination of project findings through publications in peer-reviewed journals, presentations at scientific conferences, and through professional and political venues. Mr. Sykes has been providing clinical services to children, adolescents, adults and families for more than 30 years. His experience includes clinical positions at the Cleveland Clinic and Glenbeigh Hospital, and senior executive positions at Willow Creek Hospital, Windsor Hospital and Laurelwood Hospital. Currently, he is the Managing Director of Psychological and Behavioral Health Consultants. PBC is a team of 12

psychiatrists, 10 advanced practice nurses, and 100 psychologists, clinical counselors and social workers serving children, adolescents, adults and families in locations throughout Ohio and northern Kentucky. PBC's experienced specialists provide therapy and treatment for a wide range of mental health issues. Their mission is to inspire and empower the patients, staff and clinicians of PBC and the communities they serve. PBC strives to be the community leader in behavioral outcomes, patient and staff experience, and education. Mr. Syke's specialization is in the treatment of adolescents and young adults. He has authored more than a dozen professional publications, presented more than 100 times throughout the country, and has been recognized in *Who's Who Among Human Service Professionals and Who's Who in the World.*

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APPENDIX (optional)

Appendix A

Targeted/Planned Enrollment Table (Therapists)

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	0	0	0
Asian	0	1	1
Black/African American	1	3	4
Hawaiian/Pacific Islander	0	0	0
White	13	27	40
Multirace	0	0	0
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	1	1	2
Non-Hispanic	16	26	42

Full study protocol submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (November 2017)

PROTOCOL
APPLICATION FORM
SOCIAL, BEHAVIORAL, AND EDUCATIONAL FULL BOARD
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH

University of Massachusetts Amherst (UMass)
Institutional Review Board (IRB)

Protocol ID: 2016-3401
Title: Enhancing Mental Health Care

Revision Form

1. Summarize the proposed changes to the protocol in lay terms (including details of ALL changes proposed AND modify all relevant protocol sections and attachments accordingly).

As recently and extensively discussed with Margaret Burggren and Gaurav Dhawan, we submit here a revised protocol based on a contract modification for our PCORI-funded research project. The revisions are included in all relevant sections of this protocol; however, for ease of review, we have also attached a Word document that tracks all changes (in the "Other" section of the attachments page). The title of the document is: "PCORI IRB Proposal_R1_for PsychBC_FINAL submitted.docx"

PsychBC is our new clinical subcontractor (replacing Atrius Health). All revisions in the protocol itself, and in all attachment attachments, reflect this new partnership.

In the aforementioned Word document, we also note with comment bubbles when an attachment to this protocol has been revised, has stayed the same, or has been deleted because it is no longer relevant. Again, we hope that such use of tracked changes/comments is helpful to the review team. Of course, we can also answer any remaining questions.

Thank you for your time and efforts in reviewing this protocol revision.

2. Indicate Level of Risk involved with the changes proposed.

No change.

3. Describe any Other Changes.

None

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Title: Professor
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Human Subjects Training Completed? yes

Subject Populations(s) Checklist	Yes/No
Minors (under 18)	N
Pregnant Women	N
Cognitively Impaired or Decisionally Challenged	N
Older individuals (75 and over)	N
Healthy Volunteers	N

Students/Employees	N
International Populations	N
Prisoners	N
Other (i.e., any population that is not specified above)	Y

Other: Subjects will include two mental health care stakeholder groups: (1) therapists affiliated with PsychBC who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy for varied mental health complaints from the participating therapists. PsychBC, a formal subcontract to UMass on this project, is an innovative health care organization and one of the largest providers of outpatient mental healthcare services in Ohio. PsychBC's role on this project is restricted to providing the research team access to these two subject populations, and assisting the team in recruitment. Thus, PsychBC is not engaged in human subjects' research.

Study Location(s) Checklist	**Yes/No**
University of Massachusetts Amherst	Y
Baystate Medical	N
University Health Services	N
Hartford Hospital	N
Other (Specify other Study Locations)	Y

Other: All study operations will be coordinated through Dr. Michael Constantino's (PI) Psychotherapy Research Lab at UMass Amherst. Subject data will be collected through our clinical partner, PsychBC, which employs a large team of psychiatrists, advanced practice nurses, psychologists, clinical counselors, and social workers serving children, adolescents, adults, and families in locations throughout Ohio and northern Kentucky. PsychBC's experienced specialists provide therapy for a wide range of mental health issues. PsychBC includes multiple treatment sites in Ohio that will contribute to data collection.

General Checklist	**Yes/No**
Training Grant?	N
Funded Study (or proposal submitted to sponsor)?	Y
Cooperating Institution(s)?	Y
Federally Sponsored Project?	Y
Human blood, cells, tissues, or body fluids (tissues)?	N
Subjects will be paid for participations?	Y

Cooperating Institution(s): (1) University at Albany, SUNY (Dr. James Boswell; Co-PI and subcontract); (2) Outcome Referrals Institute, Inc. (ORI; Dr. David Kraus; Co-PI and subcontract); and (3) PsychBC (Dr. Tom Swales; subcontract director). Note: At the time of this revision, an IAA has already been established for the approved original protocol with SUNY Albany and ORI. After consulting with UMass IRB staff, it is now clear that our new subcontract, PsychBC, is not engaged in human subjects' research; thus, no IAA is required/requested.

Funding Checklist
Grants/Contracts:

Funding Administered By: UNIVERSITY
PGCA#: 1503-28753
GAID#:
Funded By: Patient-Centered Outcomes Research Institute
1828 L Street, NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700 | Fax: (202) 355-9558
info@pcori.org
Principle Investigator: Michael J. Constantino
Grant/Contract Title: Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths

Are the contents of this protocol the same as described in grant/contract proposal? Y
Is this a training grant? N
Are any subcontracts issues under this grant? Y

Fellowships – None
Gift Funding – None
Dept. Funding – None
Other Funding – None

1. Purpose of the study

a. Provide a brief lay summary of the purpose of the study.

Research has shown that mental health care (MHC) providers differ significantly in their ability to help patients. In addition, providers demonstrate different patterns of effectiveness across symptom and functioning domains. For example, some providers are reliably effective in treating numerous patients and problem domains, others are reliably effective in some domains (e.g., depression, substance abuse) yet appear to struggle in others (e.g., anxiety, social functioning), and some are reliably ineffective, or even harmful, across patients and domains. Knowledge of these provider differences is based largely on patient-reported outcomes collected in routine MHC settings.

Unfortunately, provider performance information is not systematically used to refer or assign a particular patient to a scientifically based best-matched provider. MHC systems continue to rely on random or purely pragmatic case assignment and referral, which significantly "waters down" the odds of a patient being assigned/referred to a high performing provider in the patient's area(s) of need, and increases the risk of being assigned/referred to a provider who may have a track record of ineffectiveness. This research aims to solve the existing non-patient-centered provider-matching problem.

Specifically, we aim to demonstrate the comparative effectiveness of a scientifically-based patient-provider match system compared to status quo pragmatic case assignment. We expect in the scientific match group significantly better treatment outcomes (e.g., symptoms, quality of life) and higher patient satisfaction with treatment. We also expect to demonstrate feasibility of implementing a scientific match process in a community MHC system and broad dissemination of the easily replicated scientific match technology in diverse health care settings. The importance of this work for patients cannot be understated. Far too many patients struggle to find the right provider, which unnecessarily prolongs suffering and promotes health care system inefficiency. A scientific match system based on routine outcome data uses patient-generated information to direct this patient to this provider in this setting. In addition, when based on multidimensional assessment, it allows a wide variety of patient-centered outcomes to be represented (e.g., symptom domains, functioning domains, quality of life).

b. What does the Investigator(s) hope to learn from the study?

The goal of this project is to test the effectiveness of an innovative, scientifically-informed patient-therapist referral match algorithm based on MHC provider outcome data. We will employ a randomized controlled trial (RCT) to compare the match algorithm with commonplace pragmatic referral matching (based on provider availability, convenience, or self-reported specialty). Psychosocial treatment will remain naturalistically administered by varied providers (e.g., psychologists, social workers) to patients with mental health concerns. We hypothesize that the scientific match group will outperform the pragmatic match group in decreasing patient symptoms and treatment dropout, and in promoting patient functional outcomes, perceived treatment credibility, outcome expectation, and care satisfaction, as well as therapeutic alliance quality. Doing so will establish the match algorithm as a mechanism of effective patient-centered MHC, and will suggest that this scientifically derived patient-provider matching intervention can be integrated into MHC systems to aid in treatment decision making, as well as increase personalization.

2. Study Procedures

a. Describe all study procedures.

We will compare the efficacy of naturalistic treatment either with or without the aid of scientific matching to a provider with a double-blind RCT. The project will involve two main phases. First, we will access a naturalistic baseline assessment of consenting PsychBC therapists' performance to determine their relative strengths and weaknesses in treating the problem domains measured by a multidimensional outcome tool. This period will establish our therapist sample pool and inform the RCT match manipulation (a match will represent a patient being assigned to a therapist who has empirically demonstrated during the baseline phase that he or she is stably effective at treating patients with the same type of presenting complaint).

Second, and after the baseline period, new consenting outpatients will be randomly assigned to the match (experimental) or no match (control) condition. The PsychBC administrators and their project-specific coordinator will collaborate with the research team to apply the randomization protocol. Treatment outcome will be assessed through the patient's actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after the point of termination on a randomly selected subsample). Outside of being matched to a therapist from a short-list of providers who have demonstrated (during the phase 1 baseline) reliable success in treating the patient's primary problem area, and completing study-specific measures for which participants will receive monetary compensation, treatment will be delivered as usual (the short list still allows for pragmatic considerations like availability and administrator assignment options).

Additional methodological details by study phase follow.

<u>Phase 1:</u> The most significant revision to the research protocol is that we no longer need to recruit/enroll patients for phase 1. Rather, phase 1 now focuses solely on PsychBC clinicians as our research participants. To inform the match condition, we will first establish the baseline track record of participating therapists' performance (across a minimum of 15 adult psychotherapy cases each) to determine their strengths in treating behavioral health domains measured by the primary outcome measure on which the match algorithm is based – the Treatment Outcome Package (TOP; Kraus, Seligman, & Jordan, 2005), which is described below in the listing of relevant phase 1 attachments to this protocol. Developed and processed by our Co- PI (Dr. Kraus) and his subcontractor company, Outcome Referrals, Inc. (ORI), the TOP is administered routinely as a core element of the PsychBC care model. That is, PsychBC already has an executed business agreement with ORI to have their patients complete the TOP as part of their standard clinical routine. Thus, we can leverage the existing PsychBC infrastructure to support the present study with little to no extra burden on administrators, providers, and patients. Moreover, although patient data are part of this baseline phase, they are protected within the business agreement between ORI and PsychBC, and the agreement allows for these coded data to be used to establish therapists' performance "report cards." So, to reiterate, patient TOP data are collected as part of standard operating procedure for PsychBC. At this stage, we are not collecting these patient data as a research protocol; rather, these coded patient data points (i.e., clinical care data points) inform our match intervention (by establishing therapist performance report cards across at least 15 cases) that is at the heart of phase 2 (described below). In phase 1, we are only actively recruiting provider participants; thus, no patient protected health information (PHI) is transmitted to the research team.

Importantly, at the time of this proposed IRB revision, most PsychBC clinicians who will choose to participate in the study will already have baseline data on the minimum 15 adult cases (through the patient's actual termination point or 16 weeks, whichever comes sooner) to establish their track record. In these cases, we simply need to enroll the therapist in the study (as discussed next). For therapists who wish to participate, but have yet to accumulate baseline performance data on the minimum 15 cases, we will track their performance (as per the TOP) on new, consecutive referrals until 15 total cases have been established for which the patient has either terminated or has been seen for at least 16 weeks. Few therapists will fall in this second category, and even if they do, they will generally only need a few cases to reach 15. Thus, we expect no issues completing the phase 1 performance baseline and finalizing the match algorithm for the phase 2 RCT by the established contractual milestone of 10/1/17.

Our minimum target therapist sample is 44 PsychBC providers (all of whom will be over the age of 18 themselves, and treating patients within the age range of 18-65). Therapists will be psychologists, clinical counselors, and social workers. Recruitment will be coordinated among our UMass-employed project coordinator (PC), the PsychBC-employed PC, clinic staff members, and the Co-PIs. Specifically, the PsychBC team will verbally present information about the study (both phases 1 and 2) to their providers during staff meetings. Alternatively, this information can be presented through email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. (The verbal script for staff meetings and the email text are included as phase 1 attachments to this protocol.) The PsychBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study.

The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT (the baseline survey and the phase 2 attachments are described in the relevant sections below and are included as phase 1 and 2 attachments, respectively, to this protocol). Relevant to phase 1, therapists will be compensated with a $20 Amazon gift card for the one-time completion of the online baseline survey, which will take no longer than 25 minutes to complete. Non-consenting therapists will receive case assignments as per standard care protocol and will simply not be included in the study (though we will analyze consenting and non-consenting therapists on demographic differences to see if any systematic sample bias exists).

Once therapists are enrolled in the study, the research team will access their naturalistically collected TOP data to establish their performance across the minimum 15 cases to determine their personal strengths in treating patients across the risk-adjusted mental health problem domains measured by the TOP (recall that nothing changes in the therapist's service operation during this phase and, in fact, most of these TOP data points will have already been processed through ORI for cases seen by the providers in the past). Specifically, to establish therapists' performance track records, we will draw on each relevant patient's coded TOP data from baseline, week 8, and their termination point or week 16, whichever comes sooner (to mimic the definition of treatment outcome in the RCT phase discussed below). To reiterate, the research team is not formally enrolling patients into phase 1 of the study; rather, their coded data are simply processed by ORI, through its business agreement with PsychBC and its subcontractor role in the current project, to inform participating therapist report cards and the match algorithm).

Note that enrolled therapists will have an already-established TOP ID. This will allow the research team to link therapists' baseline survey data to their RCT data (i.e., responses to their own measures and their participating patients' measures) without use of any identifying information. As per customary precautions described below, a key that links therapist names and contract information with their data code will be kept in a separate, secure file that only trained research personnel can access.

Relevant phase 1 attachments to this protocol:

(1) Therapist recruitment materials: verbal script; email
(2) Therapist consent form and baseline phase 1 survey measures:

Provider Characteristics Form (PCF). This measure was developed by the research team to assess therapist demographic information, clinical experience, degree type, percent time seeing various patient types/diagnoses, any specialty training they have received, and dimensional ratings of the influence of various theoretical orientations on their treatment approach.

Therapist Perceived Strengths (TPS). This measure was developed by the research team to assess therapists' beliefs about their effectiveness in treating the various TOP domains when uninformed of their data-driven TOP track record. This measure will allow us to examine how accurate therapists are in perceiving their own strengths and weaknesses.

Phase 2: At this phase, the RCT will commence. The therapists will have already consented prior to phase 1 to be involved in the entire study, and they will know that patient data from their naturalistic baseline cases will have been used to create a personalized performance report card that will inform a prospective match with new patients they will treat in the trial. The therapists themselves will not see their report cards (as they will have been informed at the time of consent); rather, this information will be used by the research team with regard to the match manipulation.

Phase 2 marks the beginning of *patient* recruitment into the RCT. The patient population will be adult men and women (age 18-65) in PsychBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition based on TOP-derived presenting problem and to complete supplemental assessments (for monetary compensation, as per below) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsychBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*[48]) diagnoses. Our minimum study target sample size is 264 patients (6 per therapist).

We do not anticipate problems meeting our recruitment numbers in the project time frame, as PsychBC schedules approximately 950 new patients per month. Moreover, their care model already uses the TOP to screen patients for appropriate level of care, and, as a formal subcontract on the project, they are willing to use a patient-level-best-matched clinician list that is generated in real time (based on the predictive validity of our match algorithm). Including the randomization protocol into the treatment delivery model will not create any systemic barriers.

Patients will flow into PsychBC via electronic or self-referrals. At initial contact, the PsychBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation (this verbal script remains included as a phase 2 attachment to this protocol). If they are, they will be asked by the PsychBC PC to sign an authorization agreement (included in the phase 2 consent form) to allow their contact information (name, email address, and phone number) to be shared with the research team. The PsychBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsychBC personnel will be engaged in human subjects' research.

The PsychBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they

would receive if they were not participating, they must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial.

If a patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems, all described below in the listing of relevant phase 2 attachments to this protocol) through a secure online platform linked to their typical TOP administration. Next, the trained research assistant (RA) will administer (on the same individual teleconference) the *M.I.N.I. 7.0.2 International Neuropsychiatric Interview* (described below in the listing of relevant phase 2 attachments to this protocol). Following PsychBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match). For their involvement in the additional diagnostic assessments and the additional measures that they will complete during the active treatment phase, patients will be compensated with a $50 Amazon gift card (on a prorated schedule for any missed assessments).

After the full baseline assessment, patients will be randomly assigned to condition (scientifically informed matched vs. pragmatic match) with a participating PsychBC provider. The UMass PC will generate the randomization sequences using an online random generator. Within condition, patients will be assigned sequentially to the therapists until they reach their study quota of 6 patients. Patients in the match condition will be assigned to therapists who have a demonstrated strength (derived from the baseline period) in treating, at a minimum, the patient's highest self-reported distress domain on the TOP-CS. Beyond the minimal match on the most elevated TOP-CS domain, our match algorithm will attempt to match patients to therapists on as many TOP-CS dimensions as possible, ultimately providing PsychBC with at least several well-matched choices for assignment within the match condition. In order to preserve this level of choice, there will be natural variability in the number of well-matched domains (some patients matched only on the minimum 1 TOP-CS domain, others matched on 2 or more domains). The match variability across both conditions will allow us to measure degree of match dimensionally as a moderator variable of our main treatment effect. Therapists will also be unaware of their patient's treatment condition (double blind), and they will treat both matched and non-matched patients (i.e., they will be crossed over the two conditions to minimize administrative disruptions). In the low probability event that there is no therapist meeting minimal match criteria for a patient in the match condition, that patient will be removed from the primary study analyses (though will, of course, still be offered treatment-as-usual at the clinic) and replaced with the next patient where a match does exist. As described in our power analysis below, we are oversampling in order to account for these "dropouts," or removed data points.

In addition to the baseline assessments already described, patients will be assessed via online surveys at regular intervals during treatment (the secure ORI platform will email hyperlinks to these surveys with reminders to complete them at the appropriate time intervals; the UMass PC can also follow-up with phone calls if needed). These during-treatment assessments will include the TOP-CS and measures of existential isolation and interpersonal problems at every odd-numbered week after the start of treatment, as well as global distress, therapeutic alliance quality, perceived treatment credibility, and outcome expectation after every even-numbered session (all measures of these constructs are described below in the listing of relevant phase 2 attachments to this protocol). During treatment, participating therapists will also be asked to complete their respective versions of the alliance and credibility/expectation measures (also at even-numbered weeks; the UMass PC will email hyperlinks to these online surveys with reminders to complete them at the appropriate time intervals; the PC will also follow-up with phone calls if needed). For completing these measures, therapists will be compensated $50 per patient (again in the form of Amazon gift cards). All data collection will be coordinated through ORI, for which patients and therapists are assigned unique codes. Through their

business agreement, ORI has direct access to PBC medical records; thus, it can push the relevant measures and track patient/therapist progress throughout the study.

As reminder, in both conditions, the providers will deliver treatment naturalistically (i.e., with no manipulation or influence from the research team). For the sake of the RCT, "treatment outcome" will be considered the point at which treatment terminates, or 16 weeks, whichever comes sooner. After the 16th week, or the termination session if it comes sooner, patients will complete posttreatment measures: the TOP-CS and TOP-CM, a measure of treatment satisfaction, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems (all described below in the listing of relevant phase 2 attachments to this protocol). Therapists will also document the nature of termination (measure described below in the listing of relevant phase 2 attachments to this protocol). Also at posttreatment, as defined by the trial, patients will undergo a repeat diagnostic telephone assessment (i.e., an RA-administered M.I.N.I., as described above).

We will also conduct a follow-up outcome assessment at 1 year after the patient's own termination on a randomly-selected subsample of 40 patients. Patients can easily be tracked in coordination with ORI and PsychBC; further, patients will have provided consent for this follow-up contact (should they be randomly chosen for it). At this assessment point, patients will again complete online the TOP-CS and TOP-CM, the brief measure of global distress, the measure of existential isolation, and the measure of interpersonal problems.

Note that all self-report measures (for both patients and therapists) at all time-points will be completed on Wi-Fi-connected tablets, or on home computers, through ORI's secure web-based platform. The TOP has its own dedicated website and HIPAA-compliant, secure server, and all other study-specific measures will be integrated into the TOP administration process.

We predict that the scientific match group will outperform the no match group to a clinically significant degree on TOP outcomes, global symptomatology, and interpersonal problems. We also expect that the match group will be more effective in promoting alliance quality and fostering more positive patient perceptions of treatment credibility and outcome expectation, all of which are established correlates (and candidate mechanisms) of positive treatment outcomes. Finally, we expect there to be less patient dropout in the match condition, and higher patient treatment satisfaction. Secondarily, we will examine 4 potential moderators of the expected between-group treatment effects on the primary TOP outcomes: (a) patient race (as it may be that the match algorithm is particularly potent, and an important responsiveness tool, for historically understudied or underrepresented patients), (b) degree of match of therapist strengths to patient problems (rated dimensionally as a ratio given that therapists can be matched on more than just the minimum 1 domain, and the elimination of harmful matches for any distressed domain reported by the patient), (c) patient distress severity, and (d) complexity of patient presenting problem. Thus, we will test if matching is only, or particularly, effective under the conditions of a central patient characteristic, a multiple domain match, and/or for patients with the most severe or complex pathology. As noted, we will also assess therapists' self-perceived strengths on the TOP domains. We expect to replicate previous literature showing that therapists are poor judges of their own efficacy, tending to underestimate negative effects and overestimate positive effects with their patients (Lambert, 2011), which would further underscore the importance of a data-driven match process.

Finally, for a subsample of stakeholders, we will conduct post-trial exit interviews (*N*s = 5 patients, 5 therapists) to gather invaluable input on how to be responsive to the study findings in terms of dissemination, implementation, and policymaking, including the potential importance of integrating diagnosis, provider age, race, or gender into subsequent matching approaches. We will recruit stakeholders in order of completion until we reach our target *N*s (therapists can only be involved once they have treated all 6 of their study patients). There are no other inclusion/exclusion criteria for the exit interviews; we will simply stop asking if participants are interested once we have reached our target Ns. This is consistent with the study consent forms, which clearly state that interested participants may be selected to engage in the interview.

Fully reflecting stakeholder engagement, and to eliminate any biases or power dynamics introduced by the PIs or their research staff, Advisory Board members (with appropriate credentialing for working with human subjects) will conduct the individual interviews. The PIs (Constantino & Boswell) will train 3 Advisory Board members on qualitative interviewing, and each will administer 1-2 pilot interviews as part of the training, plus 5 study interviews. The interviews will be conducted and audiorecorded via a secure webconferencing service and will last approximately 45-60 minutes. Participants will be compensated with a $100 Amazon gift card for their time. RAs will transcribe the interviews, removing any identifying patient information. These RAs will also conduct a qualitative analysis of these text-based data.

Relevant phase 2 attachments to this protocol:

(1) Patient phase 2 recruitment verbal script
(2) Patient phase 2 consent form and phase 2 baseline measures packet:

TOP-Consumer Registration Form (TOP-CR; Kraus et al., 2005). The TOP-CR will be used routinely during the phase 1 baseline (and the phase 2 RCT) to assess patient demographics. On this form, patients indicate their age, gender, ethnicity, marital status, income level, employment status, religious identification, education level, general health status, and medical and mental health treatment history.

TOP-Clinical Scales and Case Mix (TOP-CS & TOP-CM; Kraus et al., 2005). This is the primary measure in our study; it will be used to establish the therapist report cards during the baseline phase to inform the match manipulation in phase 2. It also tracks patient outcomes. The TOP-CS consists of 58 items assessing 12 symptom and functional (including strengths) domains (risk-adjusted for case mix variables assessed via 37 items on the companion TOP-CM, such as divorce, job loss, comorbidity): work functioning, sexual functioning, social conflict, depression, panic (somatic anxiety), psychosis, suicidal ideation, violence, mania, sleep, substance abuse, and quality of life. Global symptom severity is assessed by summing all items or by averaging the z-scores (i.e., standard deviation units relative to the general population mean) across each of the 12 clinical scales. Domain-specific symptom severity is quantified as the individual z-scores for each clinical scale using general population means and standard deviations for the conversion. The TOP-CS has been shown to have excellent factorial structure, as well as good test-retest reliability across all scales. It is sensitive to change while possessing limited floor and ceiling effects (Kraus et al., 2005). The TOP also has demonstrated good convergent validity with scales like the Beck Depression Inventory (Beck, Steer, & Brown, 1996) and the Brief Symptom Inventory (Derogatis, 1975).

Symptom Checklist-10 (SCL-10; Rosen, Drescher, Moos, & Gusman, 1999). To evaluate outcome with an index separate from the TOP (to test convergence and enhance the validity of any between condition effects), we will also assess global distress with the SCL-10, a 10-item, well-validated and widely used self-report inventory that assesses psychological wellbeing.

Existential Isolation Scale (EIS; Pinel et al., 2014). To assess this isolation subtype, participants will complete the EIS, a six-item scale that requires participants to rate the extent to which they agree with items such as “I often have the same reactions to things as other people around me do” (reverse-coded) and “Other people usually do not understand my experiences” and “People often have the same ‘take’ or perspective on things that I do” (reverse-coded). Participants respond using a 7-point scale. The EIS has high internal consistency, and has been validated extensively (Pinel et al., 2014).

Inventory of Interpersonal Problems-32 (IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000). To assess interpersonal problems, participants will complete the 32-item circumplex version of the IIP. This widely used instrument reflects interpersonal inhibitions and excesses, with each item rated on a 5-point scale. Higher total scores indicate more interpersonal problems. The IIP-32 also has 8 subscales (Domineering, Vindictive, Intrusive, Cold, Socially Inhibited, Nonassertive, Overly Accommodating, and Self-Sacrificing) that comprise a circumplex of problematic interpersonal behavior around the main interpersonal dimensions of affiliation and control. Like the original measure

(Horowitz, Rosenberg, Baer, Ureno, & Villansenor, 1988), the IIP-32 has evidenced good psychometric properties.

(3) RA administered diagnostic assessment (baseline and posttreatment):

M.I.N.I. 7.0.2 International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 2016). The M.I.N.I. is a brief, structured diagnostic interview for DSM-5 and International Classification of Diseases (ICD; World Health Organization, 2008) psychiatric disorder classification. With its administration time of approximately 15 minutes, the M.I.N.I. is the psychiatric interview of choice in clinical trials and epidemiological studies. Despite its brevity, its psychometric properties compare favorably to longer instruments like the *Structured Clinical Interview for DSM* (SCID; First, Spitzer, Gibbon, & Williams, 1996). As part of the diagnostic evaluation, the RAs will complete the *Clinical Global Impression* (CGI), a widely used observer-rated scale that includes a 0-7 judgment of illness severity for which higher scores indicate more extreme illness.

(4) Patient phase 2 during-treatment measures:

TOP-CS, SCL-10, EIS, IIP-32. All described previously.

Working Alliance Inventory-Short Form, patient version (WAI-SF-P; Tracey, & Kokotovic, 1989). The WAI is the most widely used alliance measure, assessing patient-therapist agreement on the goals and tasks of treatment, and the quality of their relational bond. This 12-item short form, assessing these dimensions from the patient's perspective, has demonstrated sound psychometric properties.

Credibility/Expectancy Scale, patient version (CEQ; Devilly & Borkovec, 2000). The CEQ is the most widely used and psychometrically sound measure of the patient's perceived logicalness of a given treatment and expectation for the personal efficacy of that treatment.

(5) Therapist phase 2 during-treatment measures:

Working Alliance Inventory-Short Form, therapist version (WAI-SF-T; Tracey & Kokotovic, 1989). This is the parallel version of the WAI-SF described above, though now as rated from the therapist's perspective.

Credibility/Expectancy Scale, therapist version (CEQ; Devilly & Borkovec, 2000). This is the parallel version of the CEQ described above, though now as rated from the therapist's perspective (i.e., the therapist's sense of how logical the patient sees the treatment and how optimistic the patient is about receiving benefit from it).

(6) Patient phase 2 posttreatment measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

TOP-Satisfaction with the Treatment Process (TOP-STP; Kraus et al., 2005). This 32-item measure assesses patient's satisfaction with their provider, the treatment they received, and the treatment milieu (e.g., staff, other patients, etc.).

(7) Therapist phase 2 posttreatment measure:

Nature of Termination Form (NTF). This measure was developed by the research team to assess the nature of patients' termination from the provider's open-ended perspective, as well as through a choice format of unilateral/patient-generated, unilateral/therapist-generated, or mutual. Therapists can also describe in an open-ended format any unusual or noteworthy circumstances that may have led to the termination of therapy with this client (e.g., transfer of client to another therapist).

(8) Patient phase 2 subsample follow-up measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

(9) Stakeholder exit interview protocols (patient and therapist versions)

b. State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

For the baseline and posttreatment patient assessments during phase 2, RAs will administer via teleconference the semi-structured diagnostic interview (M.I.N.I.), which will be audiorecorded. This will allow a different RA to review the recording and to make independent diagnostic and symptom severity determinations. With these two sets of ratings, we can then calculate interrater reliability on baseline and posttreatment diagnosis.

Audio recordings from the baseline diagnostic assessments will be digitally stored through the secure web-conferencing service. All data will be encrypted and password protected. Only the necessary research team members will know the login and password information and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings. The RAs, of course, will have completed the mandatory ethics training in human subjects' research, data management, and HIPAA compliance. These RAs will be independent evaluators who will not have access to other therapist or patient data. The recordings themselves will not be labeled with any identifiable information. The PI will routinely monitor the collection and analysis of recorded data.

After the recordings have been assessed for diagnostic reliability, the files will be securely deleted by the sponsored project contract term date of 6/16/20. No audio data or identifiable text data stemming from the recordings will be presented at meetings or in published articles. Only the reliability coefficients will be disseminated with the results of the full trial.

c. State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).

Although the protocol does not involve deception, it does involve incomplete disclosure in Phase 2 given that participants are not given all of the information about the study until debriefing. Thus, in the debriefing form, we provide participants the opportunity to withdraw their data upon learning the full scope of the research.

3. Background

a. Describe past findings leading to the formulation of the study.

Research has consistently identified significant variability in skill and outcomes between therapists (Baldwin & Imel, 2013; Boswell et al., 2013; Westra, Constantino, Arkowitz, & Dozois, 2011), even when therapists utilize an empirically supported treatment (EST). In fact, differences between treatment providers account for a greater portion of treatment outcome variance than the specific interventions delivered in controlled trials (Krause, Lutz, & Saunders, 2007; Wampold & Imel, 2015). Thus, improvements in MHC can occur by identifying effective providers in addition to promoting ESTs (Kraus et al., 2007).

In the largest study to date on this topic, our team investigated therapists' naturalistic treatment outcomes over many different problem domains (e.g., depression, anxiety, substance use, mania, sleep) in a sample of 6,960 patients and nearly 700 providers (Kraus, Castonguay, Boswell, Nordberg, & Hayes, 2011). The majority of therapists demonstrated a differential pattern of effectiveness depending on the problem domain, and therapist domain-specific effectiveness correlated poorly across domains suggesting that therapist competencies may be domain-specific, rather than reflecting a core attribute or general underlying therapeutic skill. Importantly, although some therapists demonstrated effectiveness over multiple problem domains, no therapists demonstrated reliable effectiveness across

all domains. Further, a small, but notable 4% of the therapists did not demonstrate effective outcomes on any domain. These data suggest that in any population of therapists (payer network, hospital, or community mental health
system), there is an opportunity for behavioral health to do what medicine did decades ago – encourage provider specialization. Virtually every clinician has an area where they are above average (82-96%; Kraus et al., 2011, 2016), and our research suggests that if they specialize to their unique skills, population-level outcomes (i.e., symptom reduction, behavior change, increased functionality) will improve dramatically. This would reflect a major, and likely highly impactful shift to current MHC systems.

However, patients and referrers are typically unaware of the unique track record ("report cards") of local-area providers, which represents a critical gap in knowledge transfer within the MHC system. Without systematically collecting and disseminating performance report cards, stakeholders (e.g., patients, therapists, administrators responsible for case assignment, primary care physicians) lack vital information on which to base MHC choices and referral decisions, and that can inform personalized treatment (Boswell, Constantino, Kraus, Bugatti, & Oswald, 2015). Conversely, there is potentially immense advantage to matching patients to providers based on scientific outcome data (Constantino, Boswell, Bernecker, & Castonguay, 2013).

Consistent with this notion, the Institute of Medicine (IOM) has made recommendations to: (a) customize care based on the patient's needs, (b) share knowledge, (c) engage in data-driven decision-making, (d) promote transparency (including information on performance and patient satisfaction; Kohn, Saxena, Levav, & Saraceno, 2004), and (e) use valid and reliable assessment instruments to assess progress and to aid decision-making. The IOM has also recommended that MHC patients be provided with information on the quality of practitioner care (e.g., provider report cards) and use this information when making treatment decisions. Importantly, we have survey data that point to MHC patients, therapists, and administrators endorsing such applied knowledge transfer as a high priority (Boswell et al., 2015). Provider track record report cards are meaningful data to the MHC patient population, as are the mental health benefits that could stem from being well matched to provider.

We have developed over the past 20 years an innovative, technology-based mechanism/intervention to deliver report cards and drive this match concept within a patient-centered MHC model (Kraus et al., 2011). Our longitudinal data suggest that our match algorithm, based on our multidimensional outcome tool (the TOP) is efficacious for MHC outcomes. In addition to our study highlighted above (Kraus et al., 2011), a more recent prospective study of 59 therapists and 3,540 patients resulted in a between-treatment controlled Cohen's d effect size of .80 (Kraus et
al., 2016). Each therapist's first 30 patients were used to classify a therapist's skills in the 12 domains of symptoms and functioning as either statistically above average, average, or below average. The best matching algorithm functioned as follows: for each new, successive patient, he or she was classified as well-matched if the risk of harm was eliminated (i.e., the therapist was not below average when treating any elevated domain) and the therapist was above average in treating the patient's three most out-of-the-norm domains (e.g., depression, suicidality, and panic). Poorly matched patients had below average outcomes, with small effect sizes (d = .30) Well-matched patients, by contrast, achieved very large pre- vs. posttreatment effect sizes of d = 1.19. These data lend strong support that the proposed comparative effectiveness research (CER) will yield similar results (i.e., increased efficacy and reduced harm) in realigning the skills of a large population of therapists in one of the forerunner Accountable Care Organizations (our partner PsychBC) when matching empirically derived therapist skills with patient need. The technology/intervention is well established, it has demonstrated efficacy, and awaits investigation in a well-powered RCT.

4. Subject Population

a. State how many subjects you propose to use and state the rationale for the proposed number.
For the primary 3-level hierarchical model assessing treatment condition effects at the patient level on linear change rates within patients, we used Raudenbush and Liu's (2001) formula as incorporated in the Optimal Design program to determine the minimum numbers of therapists and patients needed to

detect a moderate effect of condition (standardized difference between change rates = .50). With a minimum of 6 measurements spaced over the maximum 16 treatment weeks and assuming 5 patients per therapist, an intra-class correlation of .15, and an alpha of .05, we will need a total of 44 therapists and 220 patients to achieve a power of .80 to detect moderate condition effects on linear change rates. Factoring a 20% dropout rate at the patient level, running our experiment on 264 patients (6 per therapist) should provide sufficient statistical power to detect group differences on our primary outcome variables.

To summarize, based on this power analysis, we will for phase 1 access a naturalistic baseline assessment of a minimum of 44 consenting therapists' performance across a minimum of 15 cases to determine their strengths in treating the risk-adjusted domains measured by the TOP. We will then recruit a minimum of 264 patients for the phase 2 trial, assigning patients to the same 44 therapists who participated in phase 1 (they will see 6 cases each during the trial).

b. Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).

Therapist participants: As noted, our target sample is 44 therapist participants (age *range* = 30-65 years) who will be social workers, psychologists, and licensed clinical counselors. Reflecting PsychBC's therapist pool demographics, we anticipate that our provider sample will break down as follows: approximately 70% will be female; 88% will be white/non-Hispanic, 3% Black, 2% Hispanic, 2% "Other/mixed," and 5% Asian. Based on these projections and our power analysis, our targeted/planned therapist enrollment is indicated in an attached Targeted/Planned Enrollment Table (Therapists).

Patient participants: Patient participants will be 264 adult men and women (age 18-65) in PsychBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsychBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related, patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*) diagnoses. The composition of our sample will roughly match the average utilization data for age, gender, and race/ethnicity at PsychBC. Based on these projections and our power analysis, our targeted/planned patient enrollment is attached in an Estimated Final Racial/Ethnic and Gender Enrollment Table (Patients).

c. State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

We are not specifically targeting these specific vulnerable populations, and our research design and/or the PsychBC care system will specifically exclude minors and prisoners. However, given the effectiveness design focused on maximizing ecological validity, some of our patients are sure to have economic and educational vulnerabilities, which are risk factors for mental health issues. Some women might also be pregnant.

d. If women, minorities, or minors are not included, a clear compelling rationale must be provided.

Minors will be excluded because they are typically not solely responsible for their own treatment decisions, and the outcome measure used in this study, and on which the match manipulation is based, focuses on adults.

e. State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.
N/A

f. State the number, if any, of subjects who are involved in research conducted abroad and describe any unique cultural, economic or political conditions.
N/A

g. Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach advertisements, flyers, etc. in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.
Therapist participants:

Recruitment will be coordinated among our UMass-employed PC, the PsychBC-employed PC, clinic staff members, and the Co-PIs, and will involve presenting information about the study (both phases 1 and 2) to providers through verbal script at staff meetings or by email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. The PsychBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study. The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT.

Patient participants:

Phase 2 marks the beginning of *patient* recruitment into the RCT. Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation). Patients will flow into PsychBC via electronic or self-referrals. At initial contact, the PsychBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation. If they are, they will be asked by the PsychBC PC to sign an authorization agreement (included in the consent form) to allow their contact information to be shared with the research team. The PsychBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsychBC personnel will be engaged in human subjects' research.

The PsychBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they would receive if they were not participating, they must consent to be randomized, complete extra

study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial. If the patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems) through a secure online platform linked to their typical TOP administration. Next, the trained RA will administer (on the same individual teleconference) the M.I.N.I. Following PsychBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match).

h. Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.

Therapist participants:

Therapists will complete, in no longer than 25 minutes, a few study-specific measures as part of a phase 1 baseline survey for which they will be compensated $20 in total (in the form of an Amazon gift card).

During Phase 2, therapists will also complete a few study-specific measures throughout treatment with each of the 6 participating patients treated during the phase 2 RCT; they will be compensated $50 per patient for this additional, but minimal, time burden. The compensation will again be in the form of an Amazon gift card.

If therapists complete their measurement schedule through all possible contact points for a given participating patient (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination for a participating patient that occurs prior to week 16 of treatment, they will receive full compensation (i.e., a $50 gift card for that patient).

However, if a therapist withdraws from the study, they will have the option to be compensated on a prorated basis for the measures that they have already completed regarding each of their participating patients. This proration works out to approximately $3 per week for a participating patient, which will be deducted for the number of weeks "missing" from therapists' assessment schedule (i.e., based on the point at which the therapist withdrew from the study). For example, if a therapist completes the measurement schedule for a given patient through week 8 (9 weeks, including baseline) and then withdraws from the study, they will have "missed" 8 weeks of data collection for that participating patient. Their compensation for this participating patient will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26. This adjustment will be completed for any and all relevant participating patients. To summarize, therapists who withdraw from the study will have the option either to (a) receive their relevant prorated compensation, or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the therapist participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Patient participants:

Patients in Phase 2 will undergo a semi-structured diagnostic interview at both baseline and posttreatment, as well as complete several study specific measures throughout treatment (and, if randomly selected, at a follow up); they will be compensated $50 total for these non-routine aspects of their care. The compensation will be in the form of an Amazon gift card. If patients complete their measurement schedule through all possible contact points (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination that occurs prior to

week 16 of treatment, they will receive full compensation. However, if they drop out of treatment prior to week 16, and their end point was not a planned termination that can be considered posttreatment for the purpose of the study, compensation will occur on prorated schedule. This works out to approximately $3 per week, which will be deducted for the number of weeks "missing" from the schedule. For example, if a patient completes the measurement schedule through week 8 (9 weeks, including baseline), and they did not engage in a planned termination, they will have "missed" 8 weeks of data collection. Their compensation will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26.

Patients who withdraw from the study (which is distinct from simply dropping out of treatment) will be given the option to (a) receive prorated compensation for the completion of measures up until the point of withdrawal (following the proration schedule outline above), or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the patient participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Finally, note that in the event that a participant (either a patient or therapist) withdraws from the study during phase 2, the other dyad member (either the patients seen by a withdrawing therapist or the therapist treating a withdrawing patient) will not be penalized; that is, as long as they have already consented to the study, they will receive the full amount of reimbursement (i.e., a $50 gift card) regardless of the point at which their patient/therapist withdraws. However, note that consistent with the wishes of the participant, we will, of course, stop collecting data at the point of withdrawal (i.e., if therapists withdraw, we will stop collecting data from their patients who will be compensated fully; if patients withdraw, we will stop collecting data from their therapist regarding that patient and the therapist will be compensated fully for that patient).

i. Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).

A) The project is funded in the form a cost-reimbursement contract for which a specific milestone schedule exists. The contract start date is 9/15/16 and the contract term date is 6/15/20. All analyses will be completed by the term date. Details are available in the attached updated milestone schedule.

B) Therapist subjects will be involved for 2 months in phase 1, as well as through the phase 2 trial (approximately 2 years, though with variability depending on when they have been assigned and have treated their 6 study cases). Patients in phase 2 only will be involved in the study protocol through their actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after termination on a randomly-selected subsample of 40 patients).

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a. Describe the risks related to:

Physical well-being

None anticipated.

Psychological well-being

Regardless of condition, PsychBC will employ its usual triage assessments, therapists will employ their usual treatments, and patients will be receiving their usual care. Consequently, there are no risks from our research protocol over and above what would normally be expected in routine assessment and

psychotherapy, and PsychBC has its usual clinical and safety protocols in place (and the clinical personnel to execute them).

In treatment, some individuals may experience emotional upset during sessions. Additionally, some participants may experience disappointment with their rate of progress or setbacks. The risk associated with such reactions will be addressed clinically by the therapists who are treating these issues and who have peer and administrative support. To reiterate, these treatment risks would occur in the course of treatment-as-usual. These are not additional risks stemming from the research protocol. Further, the TOP outcome monitoring system, which is at the center of our research project, is already being used by PsychBC providers without incident.

As is typical in psychological research, some of the assessment questions from the research measures may be experienced as intrusive and/or may cause anxiety. The risk from such increased anxiety, however, is mitigated by the use of skilled and extensively trained assessors who are aware that such reactions may be related to a person's presenting problems, or simply a function of the intimate and emotionally intense nature of psychological services. In addition, the PIs, PCs, and/or PsychBC staff and administrators will be available to meet with any participant who may be unduly disturbed due to the few research tasks. Because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

Economic well-being

Given that therapist performance data are being collected, it is reasonable to be concerned about possible employment implications were an employer (i.e., clinic administrator) to attempt to interpret study information incompletely (i.e., infer lack of therapist effectiveness to the point of questioning employability). This risk, however, is extremely minimal for the following reasons:

(1) As a condition of being involved in the study, clinic administrators will be required to agree that therapists' participation or non-participation in this research will in no way affect their standing/employment at their community mental health clinic.

(2) The research team will not reveal therapist performance data to clinic administrators or staff members; that is, the study could be considered "triple-blind." Neither patients nor therapists will know when they are in an experimentally-matched vs. typically-matched dyad, and administrators/staff members will not have access to the therapists' report cards.

(3) However, administrators and staff members are required to be in the know about well-matched therapist "short-lists," as this is essential to the research design; that is, when patients are randomized to a well-matched therapist, those potential therapists need to be identifiable. It is possible that administrators or staff members might misinterpret these data to suggest that a given therapist is ineffective (if he or she is never or rarely showing up on a shortlist). However, we will guard against this misinterpretation by educating administrators and staff members that the shortlist only represents, in a small cross-section of time, therapists that have been shown to be effective on at least 1 of 12 domains, which represents a given patient's most severe problem at that time (the match criterion). We will stress that this does not mean that a therapist is globally ineffective. It may just be that patients randomly assigned to the match group are tending not to have the types of problems for which a given therapist is relatively effective. That therapist, though, could be highly effective at treating one or even many other domains.

(4) Finally, administrators and staff members will not be told which therapists are or are not participating in the study. Thus, lack of being on a shortlist, for all that they will know (unless a

therapist openly reveals that he or she is participating in the study), could simply connote a choice to not participate in the project.

Social well-being
None anticipated.

Breach of confidentiality (including audio/video taping)
A breach of confidentiality represents a risk, but every step will be taken to minimize this risk. PsychBC and ORI routinely handle PHI and are in compliance with HIPAA regulations. Any "hard" materials (e.g., diagnostic assessment summaries) that are collected for research purposes only will be stored in a locked cabinet in the PI's Psychotherapy Research Lab. There will be no hard copy data collected at the PsychBC clinic sites. Most of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Finally, digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted

b. For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)
N/A

c. Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.
The Co-PIs, project coordinator, PsychBC staff members, and PsychBC administrators will monitor the treatments and data collection; thus, they can assist in regularly monitoring any adverse events. Such negative occurrences are unlikely to be trial-related, as all patients will be receiving treatment-as-usual. Therefore, any adverse event will be addressed with PsychBC's well-established procedures for monitoring services and managing treatment-related disturbances. Nevertheless, any adverse event will be recorded and immediately reported to the IRB (UMass), PCORI (funder), and the project's Data Safety and Monitoring Board (DSMB).

Should, during the course of the study, a patient show evidence of psychological or physical deterioration, the patient will be assessed comprehensively in the domains of concern (except in the case of a life-threatening physical emergency, such as the emergence of acute chest pain, in which case 9-1-1 will be called immediately). If the therapist deems that the patient meets criteria for a psychiatric hold (e.g., patient is an imminent danger to self or others), the therapist will arrange for the patient to be brought to the emergency department and will contact his/her PsychBC administrator and the PI to debrief. If a patient is not meeting criteria for a psychiatric hold, but is showing clear signs of decreased mental status, the therapist will continue to meet with the patient, as well as - in consultation with the PsychBC administrator - make arrangements for the most appropriate level of care.

As noted, because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

6. Benefits

a. Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

The most direct benefit a participant in this study may receive is the reduction of symptom-related distress and improved functioning. In addition, patients (especially those in the match condition) will receive more personalized MHC. Psychotherapists (especially those in the match condition) may experience a greater level of positive impact across their caseloads. Given that the actual treatments being provided will not be manipulated, the benefits of participation are judged to far outweigh the potential study-specific risks.

There is immense potential for future therapists and patients to benefit from the results of this study; if the hypotheses are supported, there will be cause for substantial revamping of MHC systems to capitalize on matching patients to therapists who have an empirically demonstrable track record of strength in treating patients with similar presenting problems.

7. Procedures to Maintain Confidentiality

a. Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

Multiple steps will be taken to protect confidentiality. As mentioned, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy data collected at the PsychBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted.

Only designated study personnel will have access to identifiable, study specific, private information about human subjects. When registering on the TOP system, as required by PsychBC's standard operating procedures, both patients and therapists are assigned a random number code that links all subsequent assessments and is separated from identifiable information. This random number code will function as each participant's study code and will be used to link participants' data. As noted, all therapist and patient data (outside of diagnostic assessment summaries and the TOP administrations) will be collected through a web-based platform. The assigned participant code will be used to link/aggregate information, so private information will not be requested after the baseline assessment/consent process. Only the PI and essential research staff will have access to the list that links identifiable information with the participant's study code. Any audio recordings will be encrypted and password protected. Only the Co-PIs will know this password and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings; however, they will not have access to additional identifiable information (only the information required to complete the analysis). For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

b. If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

The PI is required to submit information (i.e., contractual "deliverables") on a regular basis to PCORI (the study sponsor), including IRB protocols, interim progress reports, advisory board meeting minutes, engagement plan updates, evidence of diagnostic criterion reliability from training cases, interim data reports, presentation abstracts and documentation of acceptance, manuscript copies, letters of endorsement from scientific and consumer groups, final data analysis summary, and final research report. Details on deliverables are available in the aforementioned (and attached and updated) milestone schedule. No PHI will be transmitted to PCORI.

c. Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

As noted, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy research-only data collected at

the PsychBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. Digital recordings of diagnostic assessments will be stored in a password protected website, and securely deleted by the project contract's term date. Only the relevant members of the research team will have access to the participants' data and only the PI will have long-term access to identifiable information. As noted, all assessments will be linked with a participant code. Any records linking the code to the participant's name or voice recording will be kept in a separate locked file cabinet in the PI's office. These records will be destroyed 5 years after the contract term date.

8. Potential Conflict of Interest

a. Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? Y

b. Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? N

c. Is any Investigator(s) a member of an advisory board with the Sponsoring company? N

d. Do any investigators receive gift funds from the Sponsoring company? N

e. Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol? Y

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner. If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1. Consent Form – therapist consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
Therapists will meet or speak via teleconference with the UMass PC or an RA to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
The PI and his collaborators will provide close oversight of the entire protocol, including regular consultations with a study Advisory Board and the DSMB.

9.2. Consent Form – therapist exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a therapist agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the therapist will be directed. Coercion will be minimized by clearly stating that participation is voluntary.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
If the interviewer interacts with a therapist who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediately bring this concern to the PI or a Co-PI before enrolling them. The team will then make an informed decision as to whether to include that person in the interview protocol.

9.3. Consent Form – patient consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RAs will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will be an inclusion criterion for the study. Moreover, if a clinic staff member, the PC, or an RA interacts with a patient who appears to have competency issues in the decision-making process for engaging in the study, they will immediately bring this concern to the PI or a Co-PI before enrolling them. The team will then make an informed decision as to whether to include that person in the study. The DSMB will be consulted if appropriate.

9.4. Consent Form – patient exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a patient agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will have been an inclusion criterion for the main study. Moreover, if the interviewer interacts with a patient who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediately bring this concern to the

PI or a Co-PI before enrolling them. The team will then make an informed decision as to whether to include that person in the interview protocol. The DSMB will be consulted if appropriate.

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

11. Attachments

Document Type	Document Name	Attached Date
Questionnaires	Patient Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	Therapist Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	TOP-STP	10/04/2016
Questionnaires	Stakeholder Exit Interview Protocols	10/04/2016
Federal Grant/Sub-contract	PCORI IHS-1503-28573_Constantino_executed contract	10/04/2016
Federal Grant/Sub-contract	PCORI Original Contract Proposal_all sections	10/04/2016
Other	Constantino Lab Personnel Link- Google Docs	10/04/2016
Other	PCORI_Phase 2_Patient Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Patient Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Reminder Call Script	11/13/2016
Questionnaires	MINI 7.0.2 Standard	11/13/2016
Advertisements	PCORI_Clinician Recruitment_Verbal Script_REVISED_clean	08/13/2017
Advertisements	PCORI_Clinician Recruitment_Email_REVISED_clean	08/13/2017
Advertisements	PCORI_Patient Recruitment_Verbal Script_REVISED_clean	08/13/2017
Questionnaires	PCORI_Clinician Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Posttreatment Measures Packet_REVISED	08/13/2017

	w. debriefing form	
Questionnaires	PCORI_Clinician Posttreatment Measures Packet_REVISED w. debriefing form	08/13/2017
Questionnaires	TOP-CS & TOP-CM	08/13/2017
Other	PCORI_Targeted Enrollment Tables_REVISED_clean	08/13/2017
Other	PCORI Milestone Schedule_REVISED	08/13/2017
Other	Participant Flow_REVISED	08/13/2017
Other	Data Collection Schedule Revised	08/13/2017
Federal Grant/Sub-contract	Constantino_IHS1503-28573_Mod 001 SUB_FE 20170808_FINAL EXECUTED MOD	08/13/2017
Other	PCORI IRB Proposal_R1_for PsychBC_FINAL submitted	08/13/2017
Other	ORI-PBC_Business Associate Agreement	08/13/2017

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days; Continuing Review – IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.” Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five (5) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.”

The Principal Investigator has read and agrees to abide by the above obligations. Y

Summary of a formal modification to the PCORI contract (September 2018), and the full revised study protocol (1st revision) submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (March 2018)

CONTRACT MODIFICATION SUMMARY

On September 14, 2018, PCORI approved a contract modification to IHS-1503-28573, which included the following changes – all in the service of boosting patient recruitment and retention:

- We increased the number of PsychBC telephone intake specialists who were trained to recruit and assign study patients. This increased the number of potential patients who could be recruited to the study on any given day.

- We revised the language of the study script/pitch that the PsychBC telephone intake specialists used to recruit patients. This revision better emphasized how completing a routine outcome measure was already standard practice at PsychBC, and how completing such a measure at intake could improve a patient's quality of care through personalized matching to providers. This immediately normalized the measurement process as part of usual care, and it highlighted personalized care over participant burden. In fact, the entire first part of the recruitment pitch had to do with clinical care; the introduction of the study came after, and it was billed as an opportunity to be part of an ongoing project on this personalized care notion and to earn financial compensation for doing so.

- PsychBC began offering periodic incentives (in the form of a payment bonus or tickets to local events) to the intake specialist who successfully directed the most patients to our online study consent form in a given period of time (e.g., a 1-week competition). This bonus was completely unrelated to the project budget; it was a motivational strategy within their own payroll system.

- We started offering a $15 recruitment incentive. This compensation incentivized patients' willingness to leave the initial intake call to review the study consent form. We felt that this would be useful given that a high percentage of people were enrolling *if* they reviewed the materials. However, getting potential participants to agree to review the form was an early challenge.

- We eliminated the diagnostic interview calls (using the M.I.N.I.), as these assessments were providing little yield and may have been perceived as off-putting and burdensome. In practice, many early patients who enrolled in the study were failing to keep their baseline telephone assessment appointment with our research assistants. Although we regularly followed up to reschedule, we feared that these potentially burdensome assessments were posing a risk to retention. Moreover, even if it was not leading to a patient dropping out of the study, many enrolled patients were completing all assessments *other than* the M.I.N.I., which was resulting in missing data regardless. We also wondered whether when people read the consent form and saw that we were asking them to engage in two 30-minute phone calls in addition to completing measures, this may have deterred them from enrolling. Thus, given the limited yield (at best) and overt disruption (at worst) of the diagnostic interview, we dropped it from our protocol. Fortunately, the data were never intended to be primary, and we could still characterize our sample with the TOP data (our primary match and outcome measure). Further, the diagnostic assessments were not included in PsychBC's standard intake process (as they were with our former clinical partner). Thus, using them actually rendered our study less naturalistic vis-à-vis the system that we were trying to affect/improve with our intervention.

- PsychBC hired a full-time employee whose sole job description was to recruit patients to the trial.

- Our PsychBC collaborator, Tom Swales, who holds a significant amount of regional credibility, agreed to liaise with community physicians to market the study, which they could then mention to their patients prior to them contacting PsychBC. We suspected that the more patients were in the know about the project prior to calling or arriving for care, the more likely they would agree to take part vs. view it as an unexpected inconvenience.

- We posted a special announcement about the study on PsychBC's website, with the idea that it might predispose patients to participate if they read about the potential personal benefits before the intake call.

- We raised the upper age limit of study-eligible patients to 70 instead of 65. The literature does not demarcate older adulthood at 65, so we felt that raising the age would have no untoward effect on response to treatment.

- We continued to monitor PsychBC therapists who were not enrolled in the study, but now had the requisite number of baseline cases with TOP data for which we could establish a baseline report card. This would allow us to recruit from this pool if there was employment turnover from study-enrolled clinicians, or if other strategic needs arose (e.g., if having more therapists at a particular site could also positively affect patient recruitment and retention).

- The project's milestone schedule was unrevised for this contract modification.

For this modification, the only *major* changes to the protocol included the recruitment incentive and increase in the upper patient age limit, which our funder, PCORI, had already suggested and verbally approved in March 2018. Thus, at that time, we submitted the following 2nd (and minor) revision of our study protocol to the UMass IRB, which was approved in March 2018. This was the final protocol in place for the remainder, and majority, of the study. (Note that the protocol still references the diagnostic interviewing component, as that study element was not jettisoned until September 2018, as per the contract modification details noted above.)

PROTOCOL
APPLICATION FORM
SOCIAL, BEHAVIORAL, AND EDUCATIONAL FULL BOARD
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH

University of Massachusetts Amherst (UMass)
Institutional Review Board (IRB)

Protocol ID: 2016-3401
Title: Enhancing Mental Health Care

Revision Form
1. Summarize the proposed changes to the protocol in lay terms (including details of ALL changes proposed AND modify all relevant protocol sections and attachments accordingly).
By way of a brief reminder, subjects in the current study include two mental health care stakeholder groups: (1) therapists affiliated with Psychological and Behavioral Health Consultants (PsychBC) who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy (for varied mental health complaints) from the participating PsychBC therapists. PsychBC is a formal subcontract to UMass on this project, and their role on this project is restricted to providing the research team access to these two subject populations, and assisting the team in recruitment. Thus, PsychBC is not engaged in human subjects' research. The amendment proposed here deals solely with patient recruitment procedures. There are no changes to the research protocol itself.

Specifically, we are behind in our recruitment milestones, and our funder, PCORI, has asked us to consider strategies for increasing recruitment. In response, and internal to their business, PsychBC has provided additional resources to help boost recruitment. For example, they have devoted more intake staff to accept calls and to pitch the study via our verbal recruitment scripts. We initially rolled out the recruitment via just one of several intake call lines in order to work closely with just one PsychBC staff member. This, however, limited the number of potential patients to be recruited during a given day; opening up multiple lines for recruitment should help increase our numbers. PsychBC has also implemented a financial bonus for the intake worker who successfully recruits the most patients. We appreciate PsychBC's active role in attempting to bump recruitment; however, our PCORI Program Officer is concerned that these internal resources changes might not be sufficient on their own. Hence the present proposed amendment.

For context, at present, more PsychBC patients than we anticipated simply decline to learn more about the study during their initial intake call, presumably because they are eager to be assigned to a clinician immediately on that initial call vs. going to a website to read about the study, to consent, to complete baseline measures, and then to return to a second intake call to be assigned to their clinician. Although we have successfully recruited 40 patients at present, with data to support that people are generally willing to participate if they agree to access the study information/consent form, we need to increase the number of people agreeing to access our online study consent form in order to catch up to our recruitment milestone projections (currently set at 66 patients recruited by March 1, and 112 by April 15).

The proposed strategy, which was recommended by our Program Officer, is to provide a monetary incentive for patients to agree to review our study materials online vs. declining outright on the initial intake call. PCORI has worked with research teams in the past who have used this strategy to successful effect, and they are willing to help us re-work our budget if the IRB approves this recruitment incentive. Our rationale is that a small monetary incentive may have a big impact in getting people to agree to pause momentarily their intake process to learn about, and consent to, our study (as noted, once patients get to the consent form, they often agree to participate). Given that reading the consent form takes several minutes, and that the person has to be willing to have their intake process span two different calls (which can delay by minutes to hours their assignment to a PsychBC therapist), we think that it is reasonable to compensate potential participants $15 for this time added to the intake process. As noted, because this money is tied to recruitment only, not participation, it is squarely a recruitment incentive, not a participant compensation/payment (for which a compensation schedule already exists in the current protocol). Although PCORI originally suggested offering $25, as did our DSMB and Advisory Board when consulting them about our recruitment issue, we feel that this might end up being a disincentive to actually participate (i.e., a person may be content with earning $25 simply to read a consent form, but then say “no thanks” to participating). Instead, we think that offering enough to be an incentive, but an amount that is more proportional to the time ask and to the compensation being offered for engaging in the full study protocol (i.e., $50), is likely to be more effective.

In sum, we are asking for approval to offer a $15 recruitment incentive to access our study consent form. We are also increasing the upper age limit of patients from 65-70. As the literature does not demarcate older adulthood at 65, this change is very minor, but *might* allow us to recruit a few extra patients who are interested in participating. There are no new attachments or other revisions to the study protocol language for this proposed amendment, and this recruitment incentive incurs no additional risk to potential participants.

2. Indicate Level of Risk involved with the changes proposed.
No change.

3. Describe any Other Changes.
As our funder is eager to learn if we can implement this recruitment incentive, I can be available to talk during your meeting on 3/7 if questions arise. My cell phone is 413-320-5752. Thank you!

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Title: Professor
Department Name: Psychological & Brain Sciences
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E-mail: mconstantino@psych.umass.edu
Human Subjects Training Completed? yes

Subject Populations(s) Checklist	Yes/No
Minors (under 18)	N
Pregnant Women	N
Cognitively Impaired or Decisionally Challenged	N
Older individuals (75 and over)	N
Healthy Volunteers	N
Students/Employees	N

International Populations	N
Prisoners	N
Other (i.e., any population that is not specified above)	Y

Other: Subjects will include two mental health care stakeholder groups: (1) therapists affiliated with PsychBC who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy for varied mental health complaints from the participating therapists. PsychBC, a formal subcontract to UMass on this project, is an innovative health care organization and one of the largest providers of outpatient mental healthcare services in Ohio. PsychBC's role on this project is restricted to providing the research team access to these two subject populations, and assisting the team in recruitment. Thus, PsychBC is not engaged in human subjects' research.

Study Location(s) Checklist	**Yes/No**
University of Massachusetts Amherst	Y
Baystate Medical	N
University Health Services	N
Hartford Hospital	N
Other (Specify other Study Locations)	Y

Other: All study operations will be coordinated through Dr. Michael Constantino's (PI) Psychotherapy Research Lab at UMass Amherst. Subject data will be collected through our clinical partner, PsychBC, which employs a large team of psychiatrists, advanced practice nurses, psychologists, clinical counselors, and social workers serving children, adolescents, adults, and families in locations throughout Ohio and northern Kentucky. PsychBC's experienced specialists provide therapy for a wide range of mental health issues. PsychBC includes multiple treatment sites in Ohio that will contribute to data collection.

General Checklist	**Yes/No**
Training Grant?	N
Funded Study (or proposal submitted to sponsor)?	Y
Cooperating Institution(s)?	Y
Federally Sponsored Project?	Y
Human blood, cells, tissues, or body fluids (tissues)?	N
Subjects will be paid for participations?	Y

Cooperating Institution(s): (1) University at Albany, SUNY (Dr. James Boswell; Co-PI and subcontract); (2) Outcome Referrals Institute, Inc. (ORI; Dr. David Kraus; Co-PI and subcontract); and (3) PsychBC (Dr. Tom Swales; subcontract director). Note: At the time of this revision, an IAA has already been established for the approved original protocol with SUNY Albany and ORI. After consulting with UMass IRB staff, it is now clear that our new subcontract, PsychBC, is not engaged in human subjects' research; thus, no IAA is required/requested.

Funding Checklist
Grants/Contracts:

Funding Administered By: UNIVERSITY
PGCA#: 1503-28753
GAID#:
Funded By: Patient-Centered Outcomes Research Institute
1828 L Street, NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700 | Fax: (202) 355-9558
info@pcori.org
Principle Investigator: Michael J. Constantino
Grant/Contract Title: Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths

Are the contents of this protocol the same as described in grant/contract proposal? Y

Is this a training grant? N
Are any subcontracts issues under this grant? Y

Fellowships – None
Gift Funding – None
Dept. Funding – None
Other Funding – None

1. Purpose of the study

a. Provide a brief lay summary of the purpose of the study.

Research has shown that mental health care (MHC) providers differ significantly in their ability to help patients. In addition, providers demonstrate different patterns of effectiveness across symptom and functioning domains. For example, some providers are reliably effective in treating numerous patients and problem domains, others are reliably effective in some domains (e.g., depression, substance abuse) yet appear to struggle in others (e.g., anxiety, social functioning), and some are reliably ineffective, or even harmful, across patients and domains. Knowledge of these provider differences is based largely on patient-reported outcomes collected in routine MHC settings.

Unfortunately, provider performance information is not systematically used to refer or assign a particular patient to a scientifically based best-matched provider. MHC systems continue to rely on random or purely pragmatic case assignment and referral, which significantly "waters down" the odds of a patient being assigned/referred to a high performing provider in the patient's area(s) of need, and increases the risk of being assigned/referred to a provider who may have a track record of ineffectiveness. This research aims to solve the existing non-patient-centered provider-matching problem.

Specifically, we aim to demonstrate the comparative effectiveness of a scientifically-based patient-provider match system compared to status quo pragmatic case assignment. We expect in the scientific match group significantly better treatment outcomes (e.g., symptoms, quality of life) and higher patient satisfaction with treatment. We also expect to demonstrate feasibility of implementing a scientific match process in a community MHC system and broad dissemination of the easily replicated scientific match technology in diverse health care settings. The importance of this work for patients cannot be understated. Far too many patients struggle to find the right provider, which unnecessarily prolongs suffering and promotes health care system inefficiency. A scientific match system based on routine outcome data uses patient-generated information to direct this patient to this provider in this setting. In addition, when based on multidimensional assessment, it allows a wide variety of patient-centered outcomes to be represented (e.g., symptom domains, functioning domains, quality of life).

b. What does the Investigator(s) hope to learn from the study?

The goal of this project is to test the effectiveness of an innovative, scientifically-informed patient-therapist referral match algorithm based on MHC provider outcome data. We will employ a randomized controlled trial (RCT) to compare the match algorithm with commonplace pragmatic referral matching (based on provider availability, convenience, or self-reported specialty). Psychosocial treatment will remain naturalistically administered by varied providers (e.g., psychologists, social workers) to patients with mental health concerns. We hypothesize that the scientific match group will outperform the pragmatic match group in decreasing patient symptoms and treatment dropout, and in promoting patient functional outcomes, perceived treatment credibility, outcome expectation, and care satisfaction, as well as therapeutic alliance quality. Doing so will establish the match algorithm as a mechanism of effective patient-centered MHC, and will suggest that this scientifically derived patient-provider matching intervention can be integrated into MHC systems to aid in treatment decision making, as well as increase personalization.

2. Study Procedures

a. Describe all study procedures.

We will compare the efficacy of naturalistic treatment either with or without the aid of scientific matching to a provider with a double-blind RCT. The project will involve two main phases. First, we will access a naturalistic baseline assessment of consenting PsychBC therapists' performance to determine their relative strengths and weaknesses in treating the problem domains measured by a multidimensional outcome tool. This period will establish our therapist sample pool and inform the RCT match manipulation (a match will represent a patient being assigned to a therapist who has empirically demonstrated during the baseline phase that he or she is stably effective at treating patients with the same type of presenting complaint).

Second, and after the baseline period, new consenting outpatients will be randomly assigned to the match (experimental) or no match (control) condition. The PsychBC administrators and their project-specific coordinator will collaborate with the research team to apply the randomization protocol. Treatment outcome will be assessed through the patient's actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after the point of termination on a randomly selected subsample). Outside of being matched to a therapist from a short-list of providers who have demonstrated (during the phase 1 baseline) reliable success in treating the patient's primary problem area, and completing study-specific measures for which participants will receive monetary compensation, treatment will be delivered as usual (the short list still allows for pragmatic considerations like availability and administrator assignment options).

Additional methodological details by study phase follow.

Phase 1: The most significant revision to the research protocol is that we no longer need to recruit/enroll patients for phase 1. Rather, phase 1 now focuses solely on PsychBC clinicians as our research participants. To inform the match condition, we will first establish the baseline track record of participating therapists' performance (across a minimum of 15 adult psychotherapy cases each) to determine their strengths in treating behavioral health domains measured by the primary outcome measure on which the match algorithm is based – the Treatment Outcome Package (TOP; Kraus, Seligman, & Jordan, 2005), which is described below in the listing of relevant phase 1 attachments to this protocol. Developed and processed by our Co- PI (Dr. Kraus) and his subcontractor company, Outcome Referrals, Inc. (ORI), the TOP is administered routinely as a core element of the PsychBC care model. That is, PsychBC already has an executed business agreement with ORI to have their patients complete the TOP as part of their standard clinical routine. Thus, we can leverage the existing PsychBC infrastructure to support the present study with little to no extra burden on administrators, providers, and patients. Moreover, although patient data are part of this baseline phase, they are protected within the business agreement between ORI and PsychBC, and the agreement allows for these coded data to be used to establish therapists' performance "report cards." So, to reiterate, patient TOP data are collected as part of standard operating procedure for PsychBC. At this stage, we are not collecting these patient data as a research protocol; rather, these coded patient data points (i.e., clinical care data points) inform our match intervention (by establishing therapist performance report cards across at least 15 cases) that is at the heart of phase 2 (described below). In phase 1, we are only actively recruiting provider participants; thus, no patient protected health information (PHI) is transmitted to the research team.

Importantly, at the time of this proposed IRB revision, most PsychBC clinicians who will choose to participate in the study will already have baseline data on the minimum 15 adult cases (through the patient's actual termination point or 16 weeks, whichever comes sooner) to establish their track record. In these cases, we simply need to enroll the therapist in the study (as discussed next). For therapists who wish to participate, but have yet to accumulate baseline performance data on the minimum 15 cases, we will track their performance (as per the TOP) on new, consecutive referrals until 15 total cases have been established for which the patient has either terminated or has been seen for at least 16 weeks. Few therapists will fall in this second category, and even if they do, they will generally only need a few cases to reach 15. Thus, we expect no issues completing the phase 1 performance baseline and finalizing the match algorithm for the phase 2 RCT by the established contractual milestone of 10/1/17.

Our minimum target therapist sample is 44 PsychBC providers (all of whom will be over the age of 18 themselves, and treating patients within the age range of 18-65). Therapists will be psychologists, clinical counselors, and social workers. Recruitment will be coordinated among our UMass-employed project coordinator (PC), the PsychBC-employed PC, clinic staff members, and the Co-PIs. Specifically, the PsychBC team will verbally present information about the study (both phases 1 and 2) to their providers during staff meetings. Alternatively, this information can be presented through email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. (The verbal script for staff meetings and the email text are included as phase 1 attachments to this protocol.) The PsychBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study.

The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT (the baseline survey and the phase 2 attachments are described in the relevant sections below and are included as phase 1 and 2 attachments, respectively, to this protocol). Relevant to phase 1, therapists will be compensated with a $20 Amazon gift card for the one-time completion of the online baseline survey, which will take no longer than 25 minutes to complete. Non-consenting therapists will receive case assignments as per standard care protocol and will simply not be included in the study (though we will analyze consenting and non-consenting therapists on demographic differences to see if any systematic sample bias exists).

Once therapists are enrolled in the study, the research team will access their naturalistically collected TOP data to establish their performance across the minimum 15 cases to determine their personal strengths in treating patients across the risk-adjusted mental health problem domains measured by the TOP (recall that nothing changes in the therapist's service operation during this phase and, in fact, most of these TOP data points will have already been processed through ORI for cases seen by the providers in the past). Specifically, to establish therapists' performance track records, we will draw on each relevant patient's coded TOP data from baseline, week 8, and their termination point or week 16, whichever comes sooner (to mimic the definition of treatment outcome in the RCT phase discussed below). To reiterate, the research team is not formally enrolling patients into phase 1 of the study; rather, their coded data are simply processed by ORI, through its business agreement with PsychBC and its subcontractor role in the current project, to inform participating therapist report cards and the match algorithm).

Note that enrolled therapists will have an already-established TOP ID. This will allow the research team to link therapists' baseline survey data to their RCT data (i.e., responses to their own measures and their participating patients' measures) without use of any identifying information. As per customary precautions described below, a key that links therapist names and contract information with their data code will be kept in a separate, secure file that only trained research personnel can access.

Relevant phase 1 attachments to this protocol:

(1) Therapist recruitment materials: verbal script; email
(2) Therapist consent form and baseline phase 1 survey measures:

Provider Characteristics Form (PCF). This measure was developed by the research team to assess therapist demographic information, clinical experience, degree type, percent time seeing various patient types/diagnoses, any specialty training they have received, and dimensional ratings of the influence of various theoretical orientations on their treatment approach.

Therapist Perceived Strengths (TPS). This measure was developed by the research team to assess therapists' beliefs about their effectiveness in treating the various TOP domains when uninformed of their data-driven TOP track record. This measure will allow us to examine how accurate therapists are in perceiving their own strengths and weaknesses.

Phase 2: At this phase, the RCT will commence. The therapists will have already consented prior to phase 1 to be involved in the entire study, and they will know that patient data from their naturalistic baseline cases will have been used to create a personalized performance report card that will inform a prospective match with new patients they will treat in the trial. The therapists themselves will not see their report cards (as they will have been informed at the time of consent); rather, this information will be used by the research team with regard to the match manipulation.

Phase 2 marks the beginning of *patient* recruitment into the RCT. The patient population will be adult men and women (age 18-70) in PsychBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition based on TOP-derived presenting problem and to complete supplemental assessments (for monetary compensation, as per below) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsychBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*[48]) diagnoses. Our minimum study target sample size is 264 patients (6 per therapist).

We do not anticipate problems meeting our recruitment numbers in the project time frame, as PsychBC schedules approximately 950 new patients per month. Moreover, their care model already uses the TOP to screen patients for appropriate level of care, and, as a formal subcontract on the project, they are willing to use a patient-level-best-matched clinician list that is generated in real time (based on the predictive validity of our match algorithm). Including the randomization protocol into the treatment delivery model will not create any systemic barriers.

Patients will flow into PsychBC via electronic or self-referrals. At initial contact, the PsychBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation (this verbal script remains included as a phase 2 attachment to this protocol). If they are, they will be asked by the PsychBC PC to sign an authorization agreement (included in the phase 2 consent form) to allow their contact information (name, email address, and phone number) to be shared with the research team. The PsychBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsychBC personnel will be engaged in human subjects' research.

The PsychBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they

would receive if they were not participating, they must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial.

If a patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems, all described below in the listing of relevant phase 2 attachments to this protocol) through a secure online platform linked to their typical TOP administration. Next, the trained research assistant (RA) will administer (on the same individual teleconference) the *M.I.N.I. 7.0.2 International Neuropsychiatric Interview* (described below in the listing of relevant phase 2 attachments to this protocol). Following PsychBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match). For their involvement in the additional diagnostic assessments and the additional measures that they will complete during the active treatment phase, patients will be compensated with a $50 Amazon gift card (on a prorated schedule for any missed assessments).

After the full baseline assessment, patients will be randomly assigned to condition (scientifically informed matched vs. pragmatic match) with a participating PsychBC provider. The UMass PC will generate the randomization sequences using an online random generator. Within condition, patients will be assigned sequentially to the therapists until they reach their study quota of 6 patients. Patients in the match condition will be assigned to therapists who have a demonstrated strength (derived from the baseline period) in treating, at a minimum, the patient's highest self-reported distress domain on the TOP-CS. Beyond the minimal match on the most elevated TOP-CS domain, our match algorithm will attempt to match patients to therapists on as many TOP-CS dimensions as possible, ultimately providing PsychBC with at least several well-matched choices for assignment within the match condition. In order to preserve this level of choice, there will be natural variability in the number of well-matched domains (some patients matched only on the minimum 1 TOP-CS domain, others matched on 2 or more domains). The match variability across both conditions will allow us to measure degree of match dimensionally as a moderator variable of our main treatment effect. Therapists will also be unaware of their patient's treatment condition (double blind), and they will treat both matched and non-matched patients (i.e., they will be crossed over the two conditions to minimize administrative disruptions). In the low probability event that there is no therapist meeting minimal match criteria for a patient in the match condition, that patient will be removed from the primary study analyses (though will, of course, still be offered treatment-as-usual at the clinic) and replaced with the next patient where a match does exist. As described in our power analysis below, we are oversampling in order to account for these "dropouts," or removed data points.

In addition to the baseline assessments already described, patients will be assessed via online surveys at regular intervals during treatment (the secure ORI platform will email hyperlinks to these surveys with reminders to complete them at the appropriate time intervals; the UMass PC can also follow-up with phone calls if needed). These during-treatment assessments will include the TOP-CS and measures of existential isolation and interpersonal problems at every odd-numbered week after the start of treatment, as well as global distress, therapeutic alliance quality, perceived treatment credibility, and outcome expectation after every even-numbered session (all measures of these constructs are described below in the listing of relevant phase 2 attachments to this protocol). During treatment, participating therapists will also be asked to complete their respective versions of the alliance and credibility/expectation measures (also at even-numbered weeks; the UMass PC will email hyperlinks to these online surveys with reminders to complete them at the appropriate time intervals; the PC will also follow-up with phone calls if needed). For completing these measures, therapists will be compensated $50 per patient (again in the form of Amazon gift cards). All data collection will be coordinated through ORI, for which patients and therapists are assigned unique codes. Through their

business agreement, ORI has direct access to PBC medical records; thus, it can push the relevant measures and track patient/therapist progress throughout the study.

As reminder, in both conditions, the providers will deliver treatment naturalistically (i.e., with no manipulation or influence from the research team). For the sake of the RCT, "treatment outcome" will be considered the point at which treatment terminates, or 16 weeks, whichever comes sooner. After the 16th week, or the termination session if it comes sooner, patients will complete posttreatment measures: the TOP-CS and TOP-CM, a measure of treatment satisfaction, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems (all described below in the listing of relevant phase 2 attachments to this protocol). Therapists will also document the nature of termination (measure described below in the listing of relevant phase 2 attachments to this protocol). Also at posttreatment, as defined by the trial, patients will undergo a repeat diagnostic telephone assessment (i.e., an RA-administered M.I.N.I., as described above).

We will also conduct a follow-up outcome assessment at 1 year after the patient's own termination on a randomly-selected subsample of 40 patients. Patients can easily be tracked in coordination with ORI and PsychBC; further, patients will have provided consent for this follow-up contact (should they be randomly chosen for it). At this assessment point, patients will again complete online the TOP-CS and TOP-CM, the brief measure of global distress, the measure of existential isolation, and the measure of interpersonal problems.

Note that all self-report measures (for both patients and therapists) at all time-points will be completed on Wi-Fi-connected tablets, or on home computers, through ORI's secure web-based platform. The TOP has its own dedicated website and HIPAA-compliant, secure server, and all other study-specific measures will be integrated into the TOP administration process.

We predict that the scientific match group will outperform the no match group to a clinically significant degree on TOP outcomes, global symptomatology, and interpersonal problems. We also expect that the match group will be more effective in promoting alliance quality and fostering more positive patient perceptions of treatment credibility and outcome expectation, all of which are established correlates (and candidate mechanisms) of positive treatment outcomes. Finally, we expect there to be less patient dropout in the match condition, and higher patient treatment satisfaction. Secondarily, we will examine 4 potential moderators of the expected between-group treatment effects on the primary TOP outcomes: (a) patient race (as it may be that the match algorithm is particularly potent, and an important responsiveness tool, for historically understudied or underrepresented patients), (b) degree of match of therapist strengths to patient problems (rated dimensionally as a ratio given that therapists can be matched on more than just the minimum 1 domain, and the elimination of harmful matches for any distressed domain reported by the patient), (c) patient distress severity, and (d) complexity of patient presenting problem. Thus, we will test if matching is only, or particularly, effective under the conditions of a central patient characteristic, a multiple domain match, and/or for patients with the most severe or complex pathology. As noted, we will also assess therapists' self-perceived strengths on the TOP domains. We expect to replicate previous literature showing that therapists are poor judges of their own efficacy, tending to underestimate negative effects and overestimate positive effects with their patients (Lambert, 2011), which would further underscore the importance of a data-driven match process.

Finally, for a subsample of stakeholders, we will conduct post-trial exit interviews (*N*s = 5 patients, 5 therapists) to gather invaluable input on how to be responsive to the study findings in terms of dissemination, implementation, and policymaking, including the potential importance of integrating diagnosis, provider age, race, or gender into subsequent matching approaches. We will recruit stakeholders in order of completion until we reach our target *N*s (therapists can only be involved once they have treated all 6 of their study patients). There are no other inclusion/exclusion criteria for the exit interviews; we will simply stop asking if participants are interested once we have reached our target Ns. This is consistent with the study consent forms, which clearly state that interested participants may be selected to engage in the interview.

Fully reflecting stakeholder engagement, and to eliminate any biases or power dynamics introduced by the PIs or their research staff, Advisory Board members (with appropriate credentialing for working with human subjects) will conduct the individual interviews. The PIs (Constantino & Boswell) will train 3 Advisory Board members on qualitative interviewing, and each will administer 1-2 pilot interviews as part of the training, plus 5 study interviews. The interviews will be conducted and audiorecorded via a secure webconferencing service and will last approximately 45-60 minutes. Participants will be compensated with a $100 Amazon gift card for their time. RAs will transcribe the interviews, removing any identifying patient information. These RAs will also conduct a qualitative analysis of these text-based data.

Relevant phase 2 attachments to this protocol:

(1) Patient phase 2 recruitment verbal script
(2) Patient phase 2 consent form and phase 2 baseline measures packet:

TOP-Consumer Registration Form (TOP-CR; Kraus et al., 2005). The TOP-CR will be used routinely during the phase 1 baseline (and the phase 2 RCT) to assess patient demographics. On this form, patients indicate their age, gender, ethnicity, marital status, income level, employment status, religious identification, education level, general health status, and medical and mental health treatment history.

TOP-Clinical Scales and Case Mix (TOP-CS & TOP-CM; Kraus et al., 2005). This is the primary measure in our study; it will be used to establish the therapist report cards during the baseline phase to inform the match manipulation in phase 2. It also tracks patient outcomes. The TOP-CS consists of 58 items assessing 12 symptom and functional (including strengths) domains (risk-adjusted for case mix variables assessed via 37 items on the companion TOP-CM, such as divorce, job loss, comorbidity): work functioning, sexual functioning, social conflict, depression, panic (somatic anxiety), psychosis, suicidal ideation, violence, mania, sleep, substance abuse, and quality of life. Global symptom severity is assessed by summing all items or by averaging the z-scores (i.e., standard deviation units relative to the general population mean) across each of the 12 clinical scales. Domain-specific symptom severity is quantified as the individual z-scores for each clinical scale using general population means and standard deviations for the conversion. The TOP-CS has been shown to have excellent factorial structure, as well as good test-retest reliability across all scales. It is sensitive to change while possessing limited floor and ceiling effects (Kraus et al., 2005). The TOP also has demonstrated good convergent validity with scales like the Beck Depression Inventory (Beck, Steer, & Brown, 1996) and the Brief Symptom Inventory (Derogatis, 1975).

Symptom Checklist-10 (SCL-10; Rosen, Drescher, Moos, & Gusman, 1999). To evaluate outcome with an index separate from the TOP (to test convergence and enhance the validity of any between condition effects), we will also assess global distress with the SCL-10, a 10-item, well-validated and widely used self-report inventory that assesses psychological wellbeing.

Existential Isolation Scale (EIS; Pinel et al., 2014). To assess this isolation subtype, participants will complete the EIS, a six-item scale that requires participants to rate the extent to which they agree with items such as “I often have the same reactions to things as other people around me do” (reverse-coded) and “Other people usually do not understand my experiences” and “People often have the same ‘take’ or perspective on things that I do” (reverse-coded). Participants respond using a 7-point scale. The EIS has high internal consistency, and has been validated extensively (Pinel et al., 2014).

Inventory of Interpersonal Problems-32 (IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000). To assess interpersonal problems, participants will complete the 32-item circumplex version of the IIP. This widely used instrument reflects interpersonal inhibitions and excesses, with each item rated on a 5-point scale. Higher total scores indicate more interpersonal problems. The IIP-32 also has 8 subscales (Domineering, Vindictive, Intrusive, Cold, Socially Inhibited, Nonassertive, Overly Accommodating, and Self-Sacrificing) that comprise a circumplex of problematic interpersonal behavior around the main interpersonal dimensions of affiliation and control. Like the original measure

(Horowitz, Rosenberg, Baer, Ureno, & Villansenor, 1988), the IIP-32 has evidenced good psychometric properties.

(3) RA administered diagnostic assessment (baseline and posttreatment):

M.I.N.I. 7.0.2 International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 2016). The M.I.N.I. is a brief, structured diagnostic interview for DSM-5 and International Classification of Diseases (ICD; World Health Organization, 2008) psychiatric disorder classification. With its administration time of approximately 15 minutes, the M.I.N.I. is the psychiatric interview of choice in clinical trials and epidemiological studies. Despite its brevity, its psychometric properties compare favorably to longer instruments like the *Structured Clinical Interview for DSM* (SCID; First, Spitzer, Gibbon, & Williams, 1996). As part of the diagnostic evaluation, the RAs will complete the *Clinical Global Impression* (CGI), a widely used observer-rated scale that includes a 0-7 judgment of illness severity for which higher scores indicate more extreme illness.

(4) Patient phase 2 during-treatment measures:

TOP-CS, SCL-10, EIS, IIP-32. All described previously.

Working Alliance Inventory-Short Form, patient version (WAI-SF-P; Tracey, & Kokotovic, 1989). The WAI is the most widely used alliance measure, assessing patient-therapist agreement on the goals and tasks of treatment, and the quality of their relational bond. This 12-item short form, assessing these dimensions from the patient's perspective, has demonstrated sound psychometric properties.

Credibility/Expectancy Scale, patient version (CEQ; Devilly & Borkovec, 2000). The CEQ is the most widely used and psychometrically sound measure of the patient's perceived logicalness of a given treatment and expectation for the personal efficacy of that treatment.

(5) Therapist phase 2 during-treatment measures:

Working Alliance Inventory-Short Form, therapist version (WAI-SF-T; Tracey & Kokotovic, 1989). This is the parallel version of the WAI-SF described above, though now as rated from the therapist's perspective.

Credibility/Expectancy Scale, therapist version (CEQ; Devilly & Borkovec, 2000). This is the parallel version of the CEQ described above, though now as rated from the therapist's perspective (i.e., the therapist's sense of how logical the patient sees the treatment and how optimistic the patient is about receiving benefit from it).

(6) Patient phase 2 posttreatment measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

TOP-Satisfaction with the Treatment Process (TOP-STP; Kraus et al., 2005). This 32-item measure assesses patient's satisfaction with their provider, the treatment they received, and the treatment milieu (e.g., staff, other patients, etc.).

(7) Therapist phase 2 posttreatment measure:

Nature of Termination Form (NTF). This measure was developed by the research team to assess the nature of patients' termination from the provider's open-ended perspective, as well as through a choice format of unilateral/patient-generated, unilateral/therapist-generated, or mutual. Therapists can also describe in an open-ended format any unusual or noteworthy circumstances that may have led to the termination of therapy with this client (e.g., transfer of client to another therapist).

(8) Patient phase 2 subsample follow-up measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

(9) Stakeholder exit interview protocols (patient and therapist versions)

b. State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

For the baseline and posttreatment patient assessments during phase 2, RAs will administer via teleconference the semi-structured diagnostic interview (M.I.N.I.), which will be audiorecorded. This will allow a different RA to review the recording and to make independent diagnostic and symptom severity determinations. With these two sets of ratings, we can then calculate interrater reliability on baseline and posttreatment diagnosis.

Audio recordings from the baseline diagnostic assessments will be digitally stored through the secure web-conferencing service. All data will be encrypted and password protected. Only the necessary research team members will know the login and password information and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings. The RAs, of course, will have completed the mandatory ethics training in human subjects' research, data management, and HIPAA compliance. These RAs will be independent evaluators who will not have access to other therapist or patient data. The recordings themselves will not be labeled with any identifiable information. The PI will routinely monitor the collection and analysis of recorded data.

After the recordings have been assessed for diagnostic reliability, the files will be securely deleted by the sponsored project contract term date of 6/16/20. No audio data or identifiable text data stemming from the recordings will be presented at meetings or in published articles. Only the reliability coefficients will be disseminated with the results of the full trial.

c. State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).

Although the protocol does not involve deception, it does involve incomplete disclosure in Phase 2 given that participants are not given all of the information about the study until debriefing. Thus, in the debriefing form, we provide participants the opportunity to withdraw their data upon learning the full scope of the research.

3. Background

a. Describe past findings leading to the formulation of the study.

Research has consistently identified significant variability in skill and outcomes between therapists (Baldwin & Imel, 2013; Boswell et al., 2013; Westra, Constantino, Arkowitz, & Dozois, 2011), even when therapists utilize an empirically supported treatment (EST). In fact, differences between treatment providers account for a greater portion of treatment outcome variance than the specific interventions delivered in controlled trials (Krause, Lutz, & Saunders, 2007; Wampold & Imel, 2015). Thus, improvements in MHC can occur by identifying effective providers in addition to promoting ESTs (Kraus et al., 2007).

In the largest study to date on this topic, our team investigated therapists' naturalistic treatment outcomes over many different problem domains (e.g., depression, anxiety, substance use, mania, sleep) in a sample of 6,960 patients and nearly 700 providers (Kraus, Castonguay, Boswell, Nordberg, & Hayes, 2011). The majority of therapists demonstrated a differential pattern of effectiveness depending on the problem domain, and therapist domain-specific effectiveness correlated poorly across domains suggesting that therapist competencies may be domain-specific, rather than reflecting a core attribute or general underlying therapeutic skill. Importantly, although some therapists demonstrated effectiveness over multiple problem domains, no therapists demonstrated reliable effectiveness across

all domains. Further, a small, but notable 4% of the therapists did not demonstrate effective outcomes on any domain. These data suggest that in any population of therapists (payer network, hospital, or community mental health
system), there is an opportunity for behavioral health to do what medicine did decades ago – encourage provider specialization. Virtually every clinician has an area where they are above average (82-96%; Kraus et al., 2011, 2016), and our research suggests that if they specialize to their unique skills, population-level outcomes (i.e., symptom reduction, behavior change, increased functionality) will improve dramatically. This would reflect a major, and likely highly impactful shift to current MHC systems.

However, patients and referrers are typically unaware of the unique track record ("report cards") of local-area providers, which represents a critical gap in knowledge transfer within the MHC system. Without systematically collecting and disseminating performance report cards, stakeholders (e.g., patients, therapists, administrators responsible for case assignment, primary care physicians) lack vital information on which to base MHC choices and referral decisions, and that can inform personalized treatment (Boswell, Constantino, Kraus, Bugatti, & Oswald, 2015). Conversely, there is potentially immense advantage to matching patients to providers based on scientific outcome data (Constantino, Boswell, Bernecker, & Castonguay, 2013).

Consistent with this notion, the Institute of Medicine (IOM) has made recommendations to: (a) customize care based on the patient's needs, (b) share knowledge, (c) engage in data-driven decision-making, (d) promote transparency (including information on performance and patient satisfaction; Kohn, Saxena, Levav, & Saraceno, 2004), and (e) use valid and reliable assessment instruments to assess progress and to aid decision-making. The IOM has also recommended that MHC patients be provided with information on the quality of practitioner care (e.g., provider report cards) and use this information when making treatment decisions. Importantly, we have survey data that point to MHC patients, therapists, and administrators endorsing such applied knowledge transfer as a high priority (Boswell et al., 2015). Provider track record report cards are meaningful data to the MHC patient population, as are the mental health benefits that could stem from being well matched to provider.

We have developed over the past 20 years an innovative, technology-based mechanism/intervention to deliver report cards and drive this match concept within a patient-centered MHC model (Kraus et al., 2011). Our longitudinal data suggest that our match algorithm, based on our multidimensional outcome tool (the TOP) is efficacious for MHC outcomes. In addition to our study highlighted above (Kraus et al., 2011), a more recent prospective study of 59 therapists and 3,540 patients resulted in a between-treatment controlled Cohen's d effect size of .80 (Kraus et
al., 2016). Each therapist's first 30 patients were used to classify a therapist's skills in the 12 domains of symptoms and functioning as either statistically above average, average, or below average. The best matching algorithm functioned as follows: for each new, successive patient, he or she was classified as well-matched if the risk of harm was eliminated (i.e., the therapist was not below average when treating any elevated domain) and the therapist was above average in treating the patient's three most out-of-the-norm domains (e.g., depression, suicidality, and panic). Poorly matched patients had below average outcomes, with small effect sizes (d = .30) Well-matched patients, by contrast, achieved very large pre- vs. posttreatment effect sizes of d = 1.19. These data lend strong support that the proposed comparative effectiveness research (CER) will yield similar results (i.e., increased efficacy and reduced harm) in realigning the skills of a large population of therapists in one of the forerunner Accountable Care Organizations (our partner PsychBC) when matching empirically derived therapist skills with patient need. The technology/intervention is well established, it has demonstrated efficacy, and awaits investigation in a well-powered RCT.

4. Subject Population

a. State how many subjects you propose to use and state the rationale for the proposed number.
For the primary 3-level hierarchical model assessing treatment condition effects at the patient level on linear change rates within patients, we used Raudenbush and Liu's (2001) formula as incorporated in

the Optimal Design program to determine the minimum numbers of therapists and patients needed to detect a moderate effect of condition (standardized difference between change rates = .50). With a minimum of 6 measurements spaced over the maximum 16 treatment weeks and assuming 5 patients per therapist, an intra-class correlation of .15, and an alpha of .05, we will need a total of 44 therapists and 220 patients to achieve a power of .80 to detect moderate condition effects on linear change rates. Factoring a 20% dropout rate at the patient level, running our experiment on 264 patients (6 per therapist) should provide sufficient statistical power to detect group differences on our primary outcome variables.

To summarize, based on this power analysis, we will for phase 1 access a naturalistic baseline assessment of a minimum of 44 consenting therapists' performance across a minimum of 15 cases to determine their strengths in treating the risk-adjusted domains measured by the TOP. We will then recruit a minimum of 264 patients for the phase 2 trial, assigning patients to the same 44 therapists who participated in phase 1 (they will see 6 cases each during the trial).

b. Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).

Therapist participants: As noted, our target sample is 44 therapist participants (age *range* = 30-65 years) who will be social workers, psychologists, and licensed clinical counselors. Reflecting PsychBC's therapist pool demographics, we anticipate that our provider sample will break down as follows: approximately 70% will be female; 88% will be white/non-Hispanic, 3% Black, 2% Hispanic, 2% "Other/mixed," and 5% Asian. Based on these projections and our power analysis, our targeted/planned therapist enrollment is indicated in an attached Targeted/Planned Enrollment Table (Therapists).

Patient participants: Patient participants will be 264 adult men and women (age 18-70) in PsychBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsychBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related, patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*) diagnoses. The composition of our sample will roughly match the average utilization data for age, gender, and race/ethnicity at PsychBC. Based on these projections and our power analysis, our targeted/planned patient enrollment is attached in an Estimated Final Racial/Ethnic and Gender Enrollment Table (Patients).

c. State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

We are not specifically targeting these specific vulnerable populations, and our research design and/or the PsychBC care system will specifically exclude minors and prisoners. However, given the effectiveness design focused on maximizing ecological validity, some of our patients are sure to have economic and educational vulnerabilities, which are risk factors for mental health issues. Some women might also be pregnant.

d. If women, minorities, or minors are not included, a clear compelling rationale must be provided.

Minors will be excluded because they are typically not solely responsible for their own treatment decisions, and the outcome measure used in this study, and on which the match manipulation is based, focuses on adults.

e. State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.
N/A

f. State the number, if any, of subjects who are involved in research conducted abroad and describe any unique cultural, economic or political conditions.
N/A

g. Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach advertisements, flyers, etc. in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.
Therapist participants:

Recruitment will be coordinated among our UMass-employed PC, the PsychBC-employed PC, clinic staff members, and the Co-PIs, and will involve presenting information about the study (both phases 1 and 2) to providers through verbal script at staff meetings or by email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. The PsychBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study. The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT.

Patient participants:

Phase 2 marks the beginning of *patient* recruitment into the RCT. Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation). Patients will flow into PsychBC via electronic or self-referrals. At initial contact, the PsychBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation. If they are, they will be asked by the PsychBC PC to sign an authorization agreement (included in the consent form) to allow their contact information to be shared with the research team. The PsychBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsychBC personnel will be engaged in human subjects' research.

The PsychBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they would receive if they were not participating, they must consent to be randomized, complete extra

study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial. If the patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems) through a secure online platform linked to their typical TOP administration. Next, the trained RA will administer (on the same individual teleconference) the M.I.N.I. Following PsychBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match).

h. Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.

Therapist participants:

Therapists will complete, in no longer than 25 minutes, a few study-specific measures as part of a phase 1 baseline survey for which they will be compensated $20 in total (in the form of an Amazon gift card).

During Phase 2, therapists will also complete a few study-specific measures throughout treatment with each of the 6 participating patients treated during the phase 2 RCT; they will be compensated $50 per patient for this additional, but minimal, time burden. The compensation will again be in the form of an Amazon gift card.

If therapists complete their measurement schedule through all possible contact points for a given participating patient (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination for a participating patient that occurs prior to week 16 of treatment, they will receive full compensation (i.e., a $50 gift card for that patient).

However, if a therapist withdraws from the study, they will have the option to be compensated on a prorated basis for the measures that they have already completed regarding each of their participating patients. This proration works out to approximately $3 per week for a participating patient, which will be deducted for the number of weeks "missing" from therapists' assessment schedule (i.e., based on the point at which the therapist withdrew from the study). For example, if a therapist completes the measurement schedule for a given patient through week 8 (9 weeks, including baseline) and then withdraws from the study, they will have "missed" 8 weeks of data collection for that participating patient. Their compensation for this participating patient will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26. This adjustment will be completed for any and all relevant participating patients. To summarize, therapists who withdraw from the study will have the option either to (a) receive their relevant prorated compensation, or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the therapist participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Patient participants:

Patients in Phase 2 will undergo a semi-structured diagnostic interview at both baseline and posttreatment, as well as complete several study specific measures throughout treatment (and, if randomly selected, at a follow up); they will be compensated $50 total for these non-routine aspects of their care. The compensation will be in the form of an Amazon gift card. If patients complete their measurement schedule through all possible contact points (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination that occurs prior to

week 16 of treatment, they will receive full compensation. However, if they drop out of treatment prior to week 16, and their end point was not a planned termination that can be considered posttreatment for the purpose of the study, compensation will occur on prorated schedule. This works out to approximately $3 per week, which will be deducted for the number of weeks "missing" from the schedule. For example, if a patient completes the measurement schedule through week 8 (9 weeks, including baseline), and they did not engage in a planned termination, they will have "missed" 8 weeks of data collection. Their compensation will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26.

Patients who withdraw from the study (which is distinct from simply dropping out of treatment) will be given the option to (a) receive prorated compensation for the completion of measures up until the point of withdrawal (following the proration schedule outline above), or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the patient participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Finally, note that in the event that a participant (either a patient or therapist) withdraws from the study during phase 2, the other dyad member (either the patients seen by a withdrawing therapist or the therapist treating a withdrawing patient) will not be penalized; that is, as long as they have already consented to the study, they will receive the full amount of reimbursement (i.e., a $50 gift card) regardless of the point at which their patient/therapist withdraws. However, note that consistent with the wishes of the participant, we will, of course, stop collecting data at the point of withdrawal (i.e., if therapists withdraw, we will stop collecting data from their patients who will be compensated fully; if patients withdraw, we will stop collecting data from their therapist regarding that patient and the therapist will be compensated fully for that patient).

i. Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).

A) The project is funded in the form a cost-reimbursement contract for which a specific milestone schedule exists. The contract start date is 9/15/16 and the contract term date is 6/15/20. All analyses will be completed by the term date. Details are available in the attached updated milestone schedule.

B) Therapist subjects will be involved for 2 months in phase 1, as well as through the phase 2 trial (approximately 2 years, though with variability depending on when they have been assigned and have treated their 6 study cases). Patients in phase 2 only will be involved in the study protocol through their actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after termination on a randomly-selected subsample of 40 patients).

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a. Describe the risks related to:

Physical well-being

None anticipated.

Psychological well-being

Regardless of condition, PsychBC will employ its usual triage assessments, therapists will employ their usual treatments, and patients will be receiving their usual care. Consequently, there are no risks from our research protocol over and above what would normally be expected in routine assessment and

psychotherapy, and PsychBC has its usual clinical and safety protocols in place (and the clinical personnel to execute them).

In treatment, some individuals may experience emotional upset during sessions. Additionally, some participants may experience disappointment with their rate of progress or setbacks. The risk associated with such reactions will be addressed clinically by the therapists who are treating these issues and who have peer and administrative support. To reiterate, these treatment risks would occur in the course of treatment-as-usual. These are not additional risks stemming from the research protocol. Further, the TOP outcome monitoring system, which is at the center of our research project, is already being used by PsychBC providers without incident.

As is typical in psychological research, some of the assessment questions from the research measures may be experienced as intrusive and/or may cause anxiety. The risk from such increased anxiety, however, is mitigated by the use of skilled and extensively trained assessors who are aware that such reactions may be related to a person's presenting problems, or simply a function of the intimate and emotionally intense nature of psychological services. In addition, the PIs, PCs, and/or PsychBC staff and administrators will be available to meet with any participant who may be unduly disturbed due to the few research tasks. Because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

Economic well-being

Given that therapist performance data are being collected, it is reasonable to be concerned about possible employment implications were an employer (i.e., clinic administrator) to attempt to interpret study information incompletely (i.e., infer lack of therapist effectiveness to the point of questioning employability). This risk, however, is extremely minimal for the following reasons:

(1) As a condition of being involved in the study, clinic administrators will be required to agree that therapists' participation or non-participation in this research will in no way affect their standing/employment at their community mental health clinic.

(2) The research team will not reveal therapist performance data to clinic administrators or staff members; that is, the study could be considered "triple-blind." Neither patients nor therapists will know when they are in an experimentally-matched vs. typically-matched dyad, and administrators/staff members will not have access to the therapists' report cards.

(3) However, administrators and staff members are required to be in the know about well-matched therapist "short-lists," as this is essential to the research design; that is, when patients are randomized to a well-matched therapist, those potential therapists need to be identifiable. It is possible that administrators or staff members might misinterpret these data to suggest that a given therapist is ineffective (if he or she is never or rarely showing up on a shortlist). However, we will guard against this misinterpretation by educating administrators and staff members that the shortlist only represents, in a small cross-section of time, therapists that have been shown to be effective on at least 1 of 12 domains, which represents a given patient's most severe problem at that time (the match criterion). We will stress that this does not mean that a therapist is globally ineffective. It may just be that patients randomly assigned to the match group are tending not to have the types of problems for which a given therapist is relatively effective. That therapist, though, could be highly effective at treating one or even many other domains.

(4) Finally, administrators and staff members will not be told which therapists are or are not participating in the study. Thus, lack of being on a shortlist, for all that they will know (unless a

therapist openly reveals that he or she is participating in the study), could simply connote a choice to not participate in the project.

Social well-being
None anticipated.

Breach of confidentiality (including audio/video taping)
A breach of confidentiality represents a risk, but every step will be taken to minimize this risk. PsychBC and ORI routinely handle PHI and are in compliance with HIPAA regulations. Any "hard" materials (e.g., diagnostic assessment summaries) that are collected for research purposes only will be stored in a locked cabinet in the PI's Psychotherapy Research Lab. There will be no hard copy data collected at the PsychBC clinic sites. Most of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Finally, digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted

b. For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)
N/A

c. Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.
The Co-PIs, project coordinator, PsychBC staff members, and PsychBC administrators will monitor the treatments and data collection; thus, they can assist in regularly monitoring any adverse events. Such negative occurrences are unlikely to be trial-related, as all patients will be receiving treatment-as-usual. Therefore, any adverse event will be addressed with PsychBC's well-established procedures for monitoring services and managing treatment-related disturbances. Nevertheless, any adverse event will be recorded and immediately reported to the IRB (UMass), PCORI (funder), and the project's Data Safety and Monitoring Board (DSMB).

Should, during the course of the study, a patient show evidence of psychological or physical deterioration, the patient will be assessed comprehensively in the domains of concern (except in the case of a life-threatening physical emergency, such as the emergence of acute chest pain, in which case 9-1-1 will be called immediately). If the therapist deems that the patient meets criteria for a psychiatric hold (e.g., patient is an imminent danger to self or others), the therapist will arrange for the patient to be brought to the emergency department and will contact his/her PsychBC administrator and the PI to debrief. If a patient is not meeting criteria for a psychiatric hold, but is showing clear signs of decreased mental status, the therapist will continue to meet with the patient, as well as - in consultation with the PsychBC administrator - make arrangements for the most appropriate level of care.

As noted, because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

6. Benefits

a. Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

The most direct benefit a participant in this study may receive is the reduction of symptom-related distress and improved functioning. In addition, patients (especially those in the match condition) will receive more personalized MHC. Psychotherapists (especially those in the match condition) may experience a greater level of positive impact across their caseloads. Given that the actual treatments being provided will not be manipulated, the benefits of participation are judged to far outweigh the potential study-specific risks.

There is immense potential for future therapists and patients to benefit from the results of this study; if the hypotheses are supported, there will be cause for substantial revamping of MHC systems to capitalize on matching patients to therapists who have an empirically demonstrable track record of strength in treating patients with similar presenting problems.

7. Procedures to Maintain Confidentiality

a. Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

Multiple steps will be taken to protect confidentiality. As mentioned, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy data collected at the PsychBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted.

Only designated study personnel will have access to identifiable, study specific, private information about human subjects. When registering on the TOP system, as required by PsychBC's standard operating procedures, both patients and therapists are assigned a random number code that links all subsequent assessments and is separated from identifiable information. This random number code will function as each participant's study code and will be used to link participants' data. As noted, all therapist and patient data (outside of diagnostic assessment summaries and the TOP administrations) will be collected through a web-based platform. The assigned participant code will be used to link/aggregate information, so private information will not be requested after the baseline assessment/consent process. Only the PI and essential research staff will have access to the list that links identifiable information with the participant's study code. Any audio recordings will be encrypted and password protected. Only the Co-PIs will know this password and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings; however, they will not have access to additional identifiable information (only the information required to complete the analysis). For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

b. If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

The PI is required to submit information (i.e., contractual "deliverables") on a regular basis to PCORI (the study sponsor), including IRB protocols, interim progress reports, advisory board meeting minutes, engagement plan updates, evidence of diagnostic criterion reliability from training cases, interim data reports, presentation abstracts and documentation of acceptance, manuscript copies, letters of endorsement from scientific and consumer groups, final data analysis summary, and final research report. Details on deliverables are available in the aforementioned (and attached and updated) milestone schedule. No PHI will be transmitted to PCORI.

c. Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

As noted, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy research-only data collected at

the PsychBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. Digital recordings of diagnostic assessments will be stored in a password protected website, and securely deleted by the project contract's term date. Only the relevant members of the research team will have access to the participants' data and only the PI will have long-term access to identifiable information. As noted, all assessments will be linked with a participant code. Any records linking the code to the participant's name or voice recording will be kept in a separate locked file cabinet in the PI's office. These records will be destroyed 5 years after the contract term date.

8. Potential Conflict of Interest

a. Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? Y

b. Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? N

c. Is any Investigator(s) a member of an advisory board with the Sponsoring company? N

d. Do any investigators receive gift funds from the Sponsoring company? N

e. Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol? Y

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner. If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1. Consent Form – therapist consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
Therapists will meet or speak via teleconference with the UMass PC or an RA to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
The PI and his collaborators will provide close oversight of the entire protocol, including regular consultations with a study Advisory Board and the DSMB.

9.2. Consent Form – therapist exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a therapist agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the therapist will be directed. Coercion will be minimized by clearly stating that participation is voluntary.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
If the interviewer interacts with a therapist who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediately bring this concern to the PI or a Co-PI before enrolling them. The team will then make an informed decision as to whether to include that person in the interview protocol.

9.3. Consent Form – patient consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RAs will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will be an inclusion criterion for the study. Moreover, if a clinic staff member, the PC, or an RA interacts with a patient who appears to have competency issues in the decision-making process for engaging in the study, they will immediately bring this concern to the PI or a Co-PI before enrolling them. The team will then make an informed decision as to whether to include that person in the study. The DSMB will be consulted if appropriate.

9.4. Consent Form – patient exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a patient agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will have been an inclusion criterion for the main study. Moreover, if the interviewer interacts with a patient who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediately bring this concern to the

PI or a Co-PI before enrolling them. The team will then make an informed decision as to whether to include that person in the interview protocol. The DSMB will be consulted if appropriate.

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

11. Attachments

Document Type	Document Name	Attached Date
Questionnaires	Patient Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	Therapist Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	TOP-STP	10/04/2016
Questionnaires	Stakeholder Exit Interview Protocols	10/04/2016
Federal Grant/Sub-contract	PCORI IHS-1503-28573_Constantino_executed contract	10/04/2016
Federal Grant/Sub-contract	PCORI Original Contract Proposal_all sections	10/04/2016
Other	Constantino Lab Personnel Link- Google Docs	10/04/2016
Other	PCORI_Phase 2_Patient Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Patient Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Reminder Call Script	11/13/2016
Questionnaires	MINI 7.0.2 Standard	11/13/2016
Advertisements	PCORI_Clinician Recruitment_Verbal Script_REVISED_clean	08/13/2017
Advertisements	PCORI_Clinician Recruitment_Email_REVISED_clean	08/13/2017
Advertisements	PCORI_Patient Recruitment_Verbal Script_REVISED_clean	08/13/2017
Questionnaires	PCORI_Clinician Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Posttreatment Measures Packet_REVISED	08/13/2017

	w. debriefing form	
Questionnaires	PCORI_Clinician Posttreatment Measures Packet_REVISED w. debriefing form	08/13/2017
Questionnaires	TOP-CS & TOP-CM	08/13/2017
Other	PCORI_Targeted Enrollment Tables_REVISED_clean	08/13/2017
Other	PCORI Milestone Schedule_REVISED	08/13/2017
Other	Participant Flow_REVISED	08/13/2017
Other	Data Collection Schedule Revised	08/13/2017
Federal Grant/Sub-contract	Constantino_IHS1503-28573_Mod 001 SUB_FE 20170808_FINAL EXECUTED MOD	08/13/2017
Other	PCORI IRB Proposal_R1_for PsychBC_FINAL submitted	08/13/2017
Other	ORI-PBC_Business Associate Agreement	08/13/2017

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days; Continuing Review – IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.” Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five (5) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.”

The Principal Investigator has read and agrees to abide by the above obligations. Y

Summary of a formal modification to the PCORI contract (January 2018); no revision to the study protocol

CONTRACT MODIFICATION SUMMARY

On January 8, 2018, PCORI approved a contract modification to IHS-1503-28573, which included the following changes:

- We updated our patient enrollment target from 264 to 281 based on a more conservative attrition rate of 25% (up from our original, less conservative estimate of 20%). With this modification, enrolling 281 patients into the trial allowed us to meet our target of 211 usable case for final data analysis (281 * .75 = 211). Based on this adjustment, we also updated accordingly our *Estimated Final Racial/Ethnic and Gender Enrollment Table*.

- We updated our timeline and milestone schedule based on the PCORI-approved 6-month extension to the contract end date. This no-cost extension was precipitated by delays in patient recruitment, which we successfully addressed via our formal project remediation plan.

For this modification, there were no changes to the study protocol.