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Research on Medical Practices: Why Patients Consider Participating and the Investigational Misconception

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Tables

All the tables for this article are available via the *IRB: Ethics & Human Research* web page, part of the Hastings Center website.

It is important to understand why patients are or are not willing to participate in clinical research. By understanding these reasons, researchers can alter protocols to take account of patients' concerns, better educate prospective participants about studies, and anticipate and address common misconceptions. Such steps can also help increase recruitment rates and attract a more diverse range of participants.[1]

A number of studies have looked at willingness to participate in clinical trials among patients[2] and the general public;[3] others have studied why current[4] or prospective[5] biobank participants are willing or unwilling to contribute their biospecimens. The perception of benefit to others or oneself[6] and reliance on a recommendation from one's physician[7] are among the most commonly cited reasons for participating in research. Reasons for not participating include concerns about safety or side effects[8] and dislike of being part of an experiment or feeling like a "guinea pig."[9] A meta-analysis of barriers to participation in oncology trials similarly identified concerns about safety, being randomized to receive the investigational drug, and a negative effect on the physician-patient relationship.[10]

It is not clear, however, how these reasons apply in the context of research on medical practices (ROMP), which is embedded within the clinical setting and combines elements of traditional clinical trials and usual clinical care. As defined in this study, ROMP refers to comparative effectiveness research on medications that have already been demonstrated to be effective, are approved by the U.S. Food and Drug Administration (FDA), and are commonly prescribed in clinical practice. Prior studies have shown that many prospective participants would consider enrolling in ROMP,[11] but these studies have not yet systematically assessed the reasons that prospective participants are or are not willing to participate in ROMP.

This exploratory study describes prospective participants' reasons for being willing or unwilling to consider participating in ROMP. Because little is known about this topic, we presented research scenarios to a general public sample and asked open-ended questions to elicit respondents' reasoning. All scenarios presented a ROMP study, but they varied in terms of the research method (medical record review versus randomizing patients to different interventions), the condition being studied (hypertension versus a "more serious condition"), and the prospective participant (oneself versus a family member).

Study Methods

Survey design and embedded videos

We conducted a cross-sectional, web-based survey of 1095 adults in the United States in August 2014. Research Now[12] provided the sample from a combination of online research panel members (n = 805) and a convenience river sample of Internet users (individuals who were invited to participate when they visited general, social media, and loyalty websites) (n = 290). The survey included brief embedded animated videos, developed by the study team along with Booster Shot Media,[13] to explain basic concepts about ROMP. The animated videos posed an example of doctors wanting to compare three effective and commonly prescribed antihypertensive medications to discover which is best. The first video conveyed that different doctors might treat the same patient with different medications. The second

video described two research methods—randomization and medical record review—that could be used to compare the medications. After viewing the videos, respondents answered survey questions about their attitudes about ROMP. The videos were iteratively refined by the study team, with input from patient focus groups. We designed the survey questions based on a series of focus groups in which we qualitatively assessed patients' views about ROMP,[14] and we refined the survey using a series of cognitive interviews with members of the public to ensure that the questions were clearly written. The videos and survey instrument are available on the ROMP Ethics Study website.[15] Further details about survey development and administration are described elsewhere.[16] The University of Washington and Stanford University institutional review boards approved this study.

Measures

After respondents had viewed the videos, the survey presented three hypothetical examples of ROMP: a medical record review study of antihypertensive medications, a randomized study of antihypertensive medications, and a randomized study of medications for a "more serious condition" described as causing an increased risk of stroke. Each scenario was followed by a question asking respondents whether they would be willing to consider participating in the study described. For the first and second scenarios, we also asked respondents to imagine that they were the medical decision-maker for a family member and to state whether they would be willing to consider giving permission for their family member to participate in the study. For the questions about randomized studies of hypertension when the patient is oneself, hypertension when the patient is a family member, and a more serious condition when the patient is oneself, we offered respondents the opportunity to write an open-ended response about why they would or would not consider participating. Table 1 shows the wording of each scenario and the subsequent questions (all tables for this article are available through the *IRB: Ethics & Human Research* web page). We limited open-ended responses to these three scenarios to minimize the burden on survey respondents. We also asked a series of standard demographic questions at the end of the survey.

Data analysis

One author (DMK) preliminarily reviewed and cleaned all the open-ended responses, removing nonresponsive or nonsensical responses. A total of 113 such responses were deleted from the hypertension-self scenario, 135 from the hypertension–family member scenario, and 154 from the more-serious-condition–self scenario. A subgroup of the authors (KMP, DMK, MC, and CJ) used a conventional content analysis approach[17] to inductively develop a codebook based on initial review of respondents' open-ended answers, which the entire study team iteratively reviewed and revised. Two coders (SAK and KMP) subsequently underwent a training process wherein they applied the codebook to a subset of respondent answers, stratified by question and by response of willing or unwilling, and made additional revisions to finalize the codebook (see the Appendix, available through the *IRB: Ethics & Human Research* web page). The two coders then each independently coded half of the respondent answers, stratified proportionally based on question and response. Inter-rater reliability was calculated on 20% of all respondent answers, resulting in a Cohen's kappa of

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0.84. Coding, inter-rater reliability testing, and calculation of kappa were done using Dedoose qualitative software.[18] Basic descriptive statistics were calculated using Microsoft Excel.

Study Results

Characteristics for all survey respondents (n = 1095) and for each of the three open-ended questions are presented in Table 2. There were no statistically significant differences in key demographics between respondents who answered at least one of the three open-ended questions (n = 834) and all respondents in the study sample (chi-square, $p < .05$).

A majority of respondents were willing to consider participating in all scenarios, ranging from 80.6% for enrolling oneself in a medical record review study of hypertension to 63.1% for enrolling a family member in a randomized study of a more serious condition (Table 3). About two-thirds of all 1095 survey respondents completed each of the three open-ended questions (n1 = 742, n2 = 720, n3 = 701). For all three questions combined, there were a total of 1658 open-ended responses from respondents who were willing to consider participating and 505 responses from those who were unwilling to consider participating. Table 4 shows the most commonly cited reasons for being willing or unwilling to consider participating. Reasons cited in less than 1% of the total responses for each category are not reported.

Perceived benefits

Respondents willing to consider participating identified the benefits of the research, either for themselves or others, as their primary reason for considering participating. A majority of these respondents (56.3%) pointed to the benefit to others, which includes benefit to society in general. Many identified altruistic motives, saying they wanted to "help other patients" or "benefit the greater good." Others focused on the benefits to science, research, or the overall health system. As one respondent put it, "We have to find some way to improve the system, why not me as a guinea pig?"

Some respondents willing to consider participating (19.1%) also brought up the likelihood of a clinical benefit to the participant. Often this went hand in hand with benefit to others. "Maybe by participating in this research," a respondent suggested, "it could help me and other patients with the right medication." Many believed that they would gain a direct personal benefit, saying that participating would allow them to "find out what is the best medication for me" or "be one medicine closer to my cure," to quote two of the respondents. Similarly, when asked about giving permission on behalf of a family member, many respondents identified clinical benefits to that family member. One stated, "I would want to find the best medication for their individual needs." In addition, a few of the respondents

(1.0%) identified curiosity as a reason for considering participating, making statements like, “It would be interesting to participate.”

Perceived risks

Respondents’ perceptions of the level of risk involved in ROMP were also relevant to their decision about whether to consider participating. Both those willing to consider participating (9.6%) and those unwilling to consider participating (35.2%) cited the issue of whether ROMP is safe or unsafe. Respondents who were willing to consider participating often noted that “it seems safe” or there is “little added risk,” while a few discussed safety as a condition of participation. As one explained, “I have no objections to using this type of research as long as it doesn’t affect my health.” Respondents who were unwilling to consider participating felt the level of risk and potential side effects were too much, saying, for example, “It’s too risky,” or, “I wouldn’t want to gamble with serious side effects.” Safety was particularly concerning to respondents in the scenario about the more serious condition, with many distinguishing between the severity of the two studies. “It is one thing to play the randomization research game for [blood pressure],” a respondent wrote, “but strokes are nothing to mess with.”

Respondents raised three additional ROMP-specific concerns related to risk, sometimes specifically citing the information presented in the videos: drug similarity, the ability to switch medications, and the understanding that there is no added risk beyond usual care. First, some of the respondents who were willing to consider participating (9.4%) noted that, in ROMP, all medications are FDA-approved, with one respondent concluding that “there doesn’t seem to be a huge difference in the drugs.” However, a few of the respondents who were not willing to consider participating (1.6%) expressed doubt in drug similarity, especially when taking their individual characteristics into account. “People may react differently to each medication,” a respondent observed. Second, some respondents who were willing to consider participating highlighted the ability to change medications if the one initially prescribed for them didn’t work (6.8%). This option was often framed as a condition of participating secondary to another primary reason, as this response conveys: “[I would participate] for the good of all other patients who had a condition like mine—as long as I was able to switch medications if I experienced major side effects.” Third, a few pointed to the comparability of risks between participating in ROMP and receiving usual clinical care (1.7%); as one respondent put it, ROMP was “not really any different than my doctor guessing at which medication is best for me.”

Trust

Trust, whether in an individual physician or in health institutions in general, appeared as a theme in the responses both of those who were willing (7.8%) and unwilling (11.9%) to consider participating in ROMP. Both groups of respondents highlighted the physician-patient relationship as an important factor in their decision. Respondents willing to consider participating highlighted trust in a specific physician or institution. Some said they would rely on their physician to make a recommendation about participation. For example, one explained, “If they felt it wasn’t safe then I don’t think they would have me do it. I trust my doctor.” Others wanted to discuss the study with their physician before enrolling or know

that their physician was aware of which medication was prescribed and able to monitor their progress. Respondents who were unwilling to consider participating similarly valued the physician-patient relationship but said their desire for physician control over treatment decisions made them unwilling to be randomized to a medication; for example, one respondent asserted that randomization is "great in theory, but I want to know my doctor looked at all the options, and picked the medication that is best for ME."

A few of the respondents willing to consider participating (1.3%) and respondents unwilling to consider participating (4.2%) also discussed general or institutional trust or mistrust. Some respondents willing to consider participating expressed general trust in the medical system. One stated, "I trust the healthcare community enough to participate in research using randomization so long as I am given information about the process." Others were willing to consider participating in spite of their mistrust of pharmaceutical or insurance companies, with one saying that he or she would participate "only after discussion with my physician, not a representative of a health system or insurance company." Among respondents unwilling to consider participating, some simply did not trust the research process. "I don't trust randomization," one wrote. Others lacked trust in the health care system in general. "You would have to put your trust in more people," one explained, "and I simply no longer trust our health care system."

Randomization and experimentation

Some respondents specifically discussed the use of randomization, either as a research methodology per se or because they equated it with experimentation. Some of the respondents willing to consider participating (7.7%) had a favorable view of randomization; several described it as "the gold standard," and it was also called "more objective." By contrast, some of the respondents unwilling to consider participating (7.3%) had an unfavorable view of randomization. "It creates more variables, red tape, and is not patient centered in my opinion," one assessed.

Twenty-seven percent of respondents unwilling to consider participating expressed a generally unfavorable view of experimentation. Some respondents did not want to feel like a "lab rat" or "guinea pig" or simply felt that this kind of research was inappropriate. "I don't believe humans should be experimented on!" one exclaimed. For others, this centered on a desire for personalized medicine. For example, a respondent insisted, "I want the right medicine the first time using my doctor's experience with my condition. I don't want to experiment." In addition, some respondents who spoke negatively about experimentation seemed to be conflating randomization with arbitrariness. For example, several expressed a desire to avoid taking "random drugs." Others were more skeptical about the overall process: "Are you kidding," one remarked, "randomness in treating me for perhaps a grave medical condition, or creating side conditions as a result of using a random approach to treatment … ludicrous!!!"

Informed consent

Some respondents pointed to the importance of an adequate informed-consent process, including the ability to obtain adequate information and to make a choice. Both respondents

willing to consider participating (4.1%) and those unwilling to consider participating (6.7%) said their participation was conditional on transparency and information about the medications and the research more generally. Respondents willing to consider participating offered qualifications like, “so long as I am given information about the process,” and, “if my doctor was to explain everything and tell me the risks.” Respondents unwilling to consider participating similarly suggested that, if their conditions were fulfilled, they might consider participating. “I would need to know further information and at this time I don’t know enough to say yes,” one explained.

A few of the respondents willing to consider participating (2.0%) and those unwilling to consider participating (6.7%) also said their participation was conditional on a patient’s ability to make an active choice. Respondents willing to consider participating often had other primary motivations but felt that it was important to have the opportunity to give consent. For example, one said, “As long as I receive informed consent, I would do so in the name of science.” Respondents unwilling to consider participating likewise identified individual written consent as a necessary condition. “I would only participate if I have signed a document,” one asserted. Individual choice was also important for many respondents when asked about making decisions for a family member; some felt that it was not their role to give permission on behalf of another. As one respondent said, “I can take the risk for myself, but I wouldn’t decide that for another person.”

Privacy and confidentiality

For some respondents unwilling to consider participating (4.8%), the decision not to participate was based on privacy or confidentiality concerns. Several simply wrote “privacy,” while others were more explicit about their concerns, as in this example: “I do not like the idea of my medical records or conditions being shared.”

Misconceptions about ROMP

A few of the respondents willing to consider participating (1.8%) and those unwilling to consider participating (6.0%) indicated clear misconceptions about ROMP in their answers. Despite the explanations given in the videos and survey instrument, some in both groups explicitly expressed the misconception that the proposed study would be testing a new medication. This led some respondents willing to consider participating to identify inaccurate research benefits. One respondent wrote, for instance, that “if no one tests the new drugs, no one will know if they are effective.” Others believed that they would have access to medication only by participating in the study. “If it is the only way to get medication for said condition, it’s worth it,” one person declared. Some respondents unwilling to consider participating similarly believed that the study was about new medications, but they saw this as a reason not to take a chance. “I would just prefer to be given a medication that has already been proven to work,” one explained. In addition, some thought that there was nothing left to research after a medication had been approved. Along these lines, one respondent asserted that “randomization should be completed long before medications hit the market.”

Discussion

While this study shows that a majority of respondents were willing to consider participating in all of our ROMP scenarios, this study's aim was not to estimate participation rates for specific types of studies but, rather, to identify common motivations for being willing or unwilling to consider participating in ROMP. The most commonly cited reason for being willing to consider participating was to help others. Prior work has similarly shown that altruism is a key motivator for some research participants,[19] even if is not necessarily the primary reason for participation.[20] In addition, a number of respondents believed that participating in the research would benefit them personally, although it was not clear whether respondents who had this belief misunderstood the purpose of ROMP, were referring to the benefit to their subsequent care from the knowledge gained, or were thinking about the benefits of receiving usual clinical care as a part of ROMP. Further study could help elucidate this issue and help investigators develop educational materials to ensure that they are clearly conveying study goals to prospective participants.

Safety was another common consideration for respondents, especially in the more-serious-condition scenario. Both those willing and those unwilling to consider participating made judgments about how the perceived level of risk in the study compared to their personal threshold for risk. This, as well as some respondents' clear statements that they desire transparency and choice, highlights the need to be specific about risks and benefits of the medications in each study arm during the informed-consent process for a ROMP study. Notably, some respondents willing to consider participating also cited ROMP-specific issues from the videos: drug similarity, the ability to change medications or leave the study, and the lack of added risk beyond usual care. Respondents who cited these characteristics of ROMP seemed more willing to consider participating, which underlines the importance of clearly and specifically pointing out these elements during the informed-consent process.

Additionally, some respondents—both willing and unwilling to consider participating—viewed their physician's opinion as critical, although this view was not as prevalent in our study as has been reported in other studies that asked specifically about trust. The physician-patient relationship has been identified as a key issue in the existing literature on patient and public attitudes toward ROMP[21] and clinical research participation.[22] Our results suggest that physicians should be involved in the informed-consent process or at least available to give patients an opinion about whether to proceed. However, this process must be balanced carefully to avoid any undue influence on the patient arising from the physician-patient relationship.[23]

Despite respondents' overall willingness to consider participating, this study supports prior findings about patient and public misconceptions about ROMP.[24] We found that there were persistent ROMP-specific misconceptions among both groups of respondents. For example, some respondents confused the methodology of randomization with arbitrariness. Others believed that doctors always know the best medication for a particular patient, which indicates that many patients are confused about the certainty of medical decisions and hence unaware of the need for research on "accepted" medical practices.

The most pervasive misunderstanding we found, which we term the "investigational misconception," was that all research involves testing a new, nonvalidated intervention, whereas the actual goal of ROMP is to compare existing, approved interventions and fill gaps in medical knowledge about their relative effects with different groups of patients. The investigational misconception, which has not been previously described, manifested in different ways: some respondents said they would participate because they believed it was their only chance to get a new and beneficial medication, while others declined because they did not want to risk receiving a placebo or an untested medication. As ROMP becomes increasingly common, the investigational misconception is ethically problematic because it could result in both over- and underenrollment. Some patients might consider enrolling in ROMP because they believe it is the only way to receive a standard treatment. Other patients might not consider enrolling because of an unfounded fear of receiving a placebo or an investigational intervention, in spite of the fact that ROMP includes neither. To avoid these unwanted outcomes, efforts to improve informed consent for ROMP—such as pragmatic clinical trials of multimedia consent tools, which have begun to show promise for overcoming this misconception[25]—are needed. In addition, alternative study designs and approaches to notification should be considered and assessed to see if they may also help minimize misconceptions.

However, it is important to acknowledge that even significant efforts to improve prospective participants' understanding of ROMP may fail to address all possible misunderstandings.[26] Notably, the misconceptions we highlighted in this study were among the issues that our animated videos were designed to explain. It is clear that more work is needed to improve the efficacy of future educational tools, at least to the extent that these issues are necessary for prospective participants to understand. In addition, we also conducted follow-up interviews with a limited number of survey respondents for the purpose of improving future surveys; while we did not systematically analyze the interview data, those interviews suggested that at least some respondents continued to have misconceptions even after lengthy discussion. Thus, providing thorough education about all aspects of ROMP will likely be an ongoing challenge. Further research is needed to better understand the prevalence and persistence of the investigational misconception and other misunderstandings about ROMP, as well as what steps investigators can take to minimize their effects on enrollment decisions.

This study has two main limitations. First, the open-ended questions were designed to allow survey respondents to submit brief comments and thus did not allow for expanded discussion or clarification. Subsequent qualitative work could continue to explore the themes identified in this study. Second, our survey presented hypothetical scenarios rather than actual enrollment decisions. Because this was an exploratory study and not embedded in an actual trial, the scenarios lacked some contextual information that would likely inform enrollment decisions. The specificity of the scenarios also limits our findings' applicability to other types of research that could fall within a broader definition of ROMP or comparative effectiveness research. Therefore, we offer our findings as an overview of the range of factors patients consider, not as a definitive accounting of their decision-making process for a particular study. Further study is needed in the context of ongoing pragmatic clinical trials to assess participants' actual, rather than hypothetical, reasons for participating.

Despite these limitations, this exploratory study is strengthened by the large number of respondents and the use of open-ended questions, which allowed us to identify respondents' top priorities related to participation in ROMP in their own words and to describe the range of ROMP-specific reasons, concerns, and misconceptions related to study participation. This study provides insight into the important question of why people are or are not willing to consider participating in ROMP and offers a starting point for future research. Moreover, the investigational misconception may present an obstacle to recruitment and informed decision-making by patients invited to participate in ROMP; overcoming this fundamental misunderstanding of the nature of ROMP is a critical issue for future research.

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Appendix

Appendix

Reasons for Being Willing or Unwilling to Participate—Codebook

Code	Description
	1. Benefit
1.1 Clinical benefit	Direct clinical benefit to self or other research participant or motivation to receive benefit on own behalf. Must include use of "my" or "me" or "I" or, for family member questions, be specifically about benefit to family member.
1.2 Curiosity	Self-knowledge, understanding, curiosity, knowledge, information, discovery, etc.
1.3 Others, society, general support for research	Altruism or general support for research (e.g., "I support research") or results of research (e.g., "I want to help find the best treatment"). May reference helping family members, patients, the disease group, society, the future; improving treatments; finding the best drug; the word "help"; or help or benefit for "all."
	2. Risk
2.1 Safety	Safety, including both high risk and low or no risk (e.g., "doesn't seem too risky"). Includes mention of or concerns about side effects.
2.2 Ability to switch medications, leave study	Ability, or perceived lack of ability, of self or doctor to switch or control medications or to leave the study.
2.3 No added risk beyond usual care	Additional risk from the study as compared to the general risk of clinical care.
2.4 Drug similarity	Similar or dissimilar effectiveness of all of the drugs in the study.
	3. Trust or relationships
3.1 Physician or specific institution	Trust or mistrust in personal doctor or specific health care institution, belief that physician will manage or filter risk, or other reference to a clinical relationship. Includes wanting doctor to choose treatments for you.
3.2 General or institutional	Trust or mistrust (including extreme mistrust of system) in medical system, pharmaceuticals, researchers, research and development, drugs, results, method, etc.
	4. Privacy or confidentiality
4.1 Privacy, confidentiality	Concerns about release or sharing of medical records, protected health information, data sharing, etc.
	5. Informed consent

Code	Description
5.1 Active patient choice	Importance of patient's having the choice to participate or not participate; personal control in consent process.
5.2 Transparency, information	Needs more information before deciding, wants to know that research is happening, wants to talk to someone else before deciding, etc.
	6. Research
6.1 Randomization	Specific mention of positive or negative aspects of randomization as a methodological approach. May include sound or unsound research method, sample size, reduced bias, dangers of randomization, concerns about study design (must clearly address randomization, either by name or proxy [i.e., "gold standard"]).
6.2 Experimentation	Dislike of being "experimented" on, including mention of being a "guinea pig" or wanting control over health care or medications. Includes desire for personalized medicine as a reason not to participate.
6.3 Misunderstandings	Misunderstandings or confusions about research design or approach, specifically about placebos, testing new treatments, or other clear misunderstandings of ROMP or randomization.
	7. Specific surrogate issues
7.1 Specific family-member issues	Explicit comments about differences when making decisions for a family member.
	8. Specific "more serious" issues
8.1 Specific "more serious" issues	Explicit comments about differences in the context of a more serious condition.
	9. Vague, irrelevant, other
9.1 Vague, irrelevant, other	Answers that are too vague to interpret, are irrelevant, or do not fit in any of the above categories. Apply only if nothing else fits.

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25. See ref. 24, Kraft et alet al. 2016.
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Table 1.

ROMP Scenarios and Questions

Scenario	Willingness to participate (Y/N)	Open-ended response
Scenario 1: Medical record review, hypertension, self		
Now we would like you to think about the videos and imagine your health system using medical record review to compare 3 high blood pressure medications in newly diagnosed patients. Doctors don't know which of these medications is better at preventing heart disease. Each doctor decides which medication to use based on his or her judgment and on patient preferences. Please assume the following when you are answering the following questions: •These are commonly used, FDA-approved medications. •Each medication causes occasional mild side effects. •The out-of-pocket costs to the patient are the same.	Would you be willing to consider having your medical records reviewed for this research on high blood pressure medications?	n/a
Scenario 2a: Randomization, hypertension, self		
Still thinking about the videos, now imagine that your health system is using randomization to compare the 3 blood pressure medications in newly diagnosed patients. Each patient and their doctor will know which medication the patient is getting. Their doctor will provide usual medical follow-up and will not change the medication unless the patient or doctor has concerns.	Would you be willing to consider participating in this research using randomization?	Please tell us more about why you would [not] be willing to consider participating in this research using randomization.
Scenario 2b: Randomization, hypertension, family member		
Imagine that you are the medical decision-maker for one of your close family members (such as a child, spouse, or parent) and they are eligible to participate in this research using randomization.	Would you consider giving permission for them to participate?	Please tell us more about the reasons why you would [not] consider giving permission for them to participate.
Scenario 3a: Randomization, more serious condition, self		
Finally, consider a more serious health condition that increases your risk for stroke. There are 3 commonly used medications that can reduce your risk, but they all have serious side effects. Imagine your health system using randomization to compare these 3 medications in newly diagnosed patients. These are FDA-approved medications, but doctors don't know which of these medications is better.	Would you be willing to consider participating in this research using randomization?	Please tell us more about why you would [not] be willing to consider participating in this research using randomization.
Scenario 3b: Randomization, more serious condition, family member		
Imagine that you are the medical decision-maker for one of your close family members (such as a child, spouse, or parent) and they are eligible to participate in this research using randomization for this more serious condition.	Would you consider giving permission for them to participate?	n/a

Table 2.

Respondent Characteristics

Characteristic	All survey respondents (n = 1095)	Respondents who answered at least one open-ended question (n = 834)
Sex (% male)	49.0	46.3
Age		
21–26 years	7.9	6.1
27–44 years	37.4	34.0
45–64 years	37.2	39.7
≥ 65 years	17.6	19.3
Race		
white	74.0	75.3
Asian	2.8	2.8
African American	13.1	12.4
other or multiracial	10.1	9.6
Hispanic ethnicity	16.1	14.3
Education		
high school or less	13.9	11.7
some college or associate's degree	30.5	31.6
college graduate	34.4	34.3
graduate or professional school	21.2	22.5
Household income		
≤ $30,000	16.5	14.8
> $30,000–$55,000	23.2	23.4
> $55,000–$95,000	29.5	29.6
> $95,000	30.8	32.2
Self-reported health status		
excellent	18.3	18.0
very good	40.7	42.1
good	29.0	28.1
fair	10.8	10.7
poor	1.3	1.2
Prior clinical research participant	9.2	8.5
Has children	63.2	64.0

Table 3.

Willingness to Consider Participating in ROMP (n = 1095)

Method	Condition	Prospective participant	% willing to consider participating
Medical record review	Hypertension	Self	80.6
Randomization	Hypertension	Self	72.9
Randomization	Hypertension	Family member	74.2
Randomization	More serious condition	Self	67.4
Randomization	More serious condition	Family member	63.1

Table 4.

Reasons for Being Willing or Unwilling to Consider Participating

Respondents who were willing (all questions combined) (n = 1658)	
Reason	*n (%)*[*]
Benefit to others	934 (56.3)
Clinical benefit to the participant	317 (19.1)
Safe	159 (9.6)
Drug similarity	156 (9.4)
Trust in a specific physician or institution	130 (7.8)
Favorable view of randomization	127 (7.7)
Ability to switch medications	112 (6.8)
Conditional on transparency and information	68 (4.1)
Conditional on a patient's ability to make an active choice	33 (2.0)
Misconceptions about ROMP	30 (1.8)
No added risk beyond usual care	28 (1.7)
General or institutional trust or mistrust	21 (1.3)
Curiosity	17 (1.0)
Respondents who were unwilling (all questions combined) (n = 505)	
Reason	*n (%)*[*]
Unsafe	178 (35.2)
Unfavorable view of experimentation	136 (27.0)
Desire for physician control over treatment decisions	60 (11.9)
Unfavorable view of randomization	37 (7.3)
Conditional on a patient's ability to make an active choice	34 (6.7)
Conditional on transparency and information	34 (6.7)
Misconceptions about ROMP	30 (6.0)
Privacy or confidentiality	24 (4.8)
General or institutional trust or mistrust	21 (4.2)
Doubt in drug similarity	8 (1.6)

[*]All relevant codes were applied to each response, so percentages do not sum to 100%.