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First do no harm: ethical concerns of health researchers that discourage the sharing of results with research participants.

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Introduction

Health research participants report a desire to obtain results from studies that they have participated in (Dixon-Woods et al. 2006; Partridge et al. 2005; Fernandez et al. 2009; Baylor et al. 2013; Trinidad et al. 2015; Purvis et al. 2017). Some Institutional review boards (IRBs) require that researchers inform participants of plans for disseminating results during the consent process (Fernandez et al. 2003; Markman 2006; Curran, Kekewich, and Foreman 2018) and health research funding agencies such as the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI) emphasize the importance of sharing study results with study participants and other lay audiences

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(Carpenter et al. 2005; Patient-Centered Outcomes Research Institute 2018). Health researchers also report that aggregate results should be returned to participants (Partridge and Winer 2002; Chen et al. 2010; Fernandez et al. 2003; Partridge et al. 2004; Wilson et al. 2010). However, researchers acknowledge they often do not disseminate study results to study participants (Chen et al. 2010; Partridge et al. 2004; Long et al. 2016). Even community-based participatory research (CBPR) studies, which hold dissemination as a key component of ethical research, struggle to share results widely (Chen et al. 2010; Shalowitz and Miller 2008b; Long et al. 2016). A 2010 systematic review of 101 journal articles describing CBPR studies found that dissemination of results beyond publication in peer-reviewed journals was reported in less than half (48%) of the articles (Chen et al. 2010).

While participants express their interest in obtaining study results, and researchers generally report their support for the practice of sharing results, little is known about researchers' ethical considerations regarding sharing results with participants. Research on such ethical considerations focuses on debates of what types of results to share, how to share, and when to share, demonstrating a lack of consensus on these topics (Miller et al. 2008). For example, there is debate about the definition of research results and whether or not researchers should share clinical trial results, individual-level results, or a combination of both with study participants (Miller et al. 2008; Fernandez, Skedgel, and Weijer 2004; Rigby and Fernandez 2005; Shalowitz and Miller 2005; Shalowitz and Miller 2008b; Shalowitz and Miller 2008a; Knoppers et al. 2006) Some argue the principle of respect for persons signifies that researchers have an ethical obligation to communicate aggregate and individual-level results to research participants (Shalowitz and Miller 2008a; Fernandez, Skedgel, and Weijer 2004). Others have investigated researchers' ethical concerns regarding returning results to participants. Those studies have focused on researchers who conduct studies on specific health conditions, such as cancer (Cox et al. 2011) and genetics (Knoppers et al. 2006), and found that clinicians and patients support returning results but have different opinions on how and when results should be shared.

The study presented in this article examines researchers' ethical concerns when returning research results to participants. We explore researchers' ethical considerations related to returning aggregate results to research participants, such as de-identified, aggregate information about study findings or study progress updates.

Methods

We utilized an explanatory analysis to explore the ethical concerns researchers had with returning aggregate results to research participants (Creswell and Piano Clark 2010; Creswell 2013). This project was determined to be exempt from human protections oversight (#205983) on October 12, 2016.

Inclusion Criteria and Recruitment

Participants were age 18 or older and self-reported as a faculty or post-doctoral health researcher at an academic medical institution. Research responsibilities of these participants included eliciting informed consent from human subjects. Participants for the study were primarily recruited from universities with a Clinical and Translational Science Award

(CTSA) program. The CTSA program is funded by the National Institutes of Health's (NIH) National Center for Advancing Translational Sciences (NCATS) and consists of a national network of medical research centers working to improve the process of translating research in order to increase patient access to innovative treatments (National Institutes of Health National Center for Advancing Translational Sciences). Additional researchers were recruited from universities with a Prevention Research Center (PRC). PRCs study how communities and people can reduce or offset risks for chronic illnesses (Centers for Disease Control and Prevention).

Email notifications were sent to the Principal Investigators (PIs) at CTSAs and PRCs. The notification gave a brief overview of the study and requested the PIs' assistance in recruiting health researchers at their institutions who were eligible to participate in an online survey about returning aggregate research results to participants. A survey invitation template was provided to the PIs. The template described the study objective to collect quantitative and qualitative responses regarding researchers' perceptions and experiences with returning results to study participants. The template invitation contained a link to the online survey where researchers were given the opportunity to provide electronic consent, and to confirm that they met the study's inclusion criteria. No compensation was provided to researchers participating in the survey. Two weeks after the initial email to CTSA PIs, they were sent a second email requesting that they send a reminder invitation to their investigator network. All researchers who met the inclusion criteria and provided consent were included in the study. Participant identification numbers were generated by Research Electronic Data Capture (REDCap). Participants' email addresses were also captured and compared to remove multiple responses from the same e-mail address, and to ensure that there were no participant duplications. A full description of the study protocol is published elsewhere (McElfish, Purvis, and Long 2018).

Survey

Research Electronic Data Capture (REDCap) was utilized to administer the online survey (Harris et al. 2009). After the survey was drafted, the research team reviewed and discussed all questions. The research team refined and revised the survey four times before a final version was approved by consensus (McElfish, Purvis, and Long 2018). The survey took approximately ten minutes for researchers to complete. Closed-ended questions, as well as percentage slider questions, were used to document perceptions and experiences researchers had with returning research results to participants. Open-ended questions were used to encourage researchers to provide more in-depth explanations of their responses to the closed-ended questions. The present study focuses on detailed analyses of researchers' ethical considerations; a broad overview of researchers' general opinions, experiences, and barriers related to results sharing is published elsewhere (Long et al. 2019).

Analytic Strategy

Item-level descriptive analyses were conducted for demographic and closed-ended survey items. In order to analyze the large number of open-ended responses collected, a coding template was identified as the appropriate strategy (King, Cassell, and Symon 2004; Nadin and Cassell 2004). A preliminary coding template was designed by the research team. Two

members of the research team, experienced in qualitative methods coded the data, identified emergent themes that were then incorporated into the coding template. Initial coding began by naming each data segment with short summaries of emergent themes. Illustrative excerpts were extracted from the open-ended responses and incorporated into a codebook that organized the responses under each domain or theme they best represented. The analysis product was then critically reviewed by four (two female and two male) additional members of the research team to confirm that the data and illustrative excerpts were correctly extracted to each domain and to ensure reliability and analytic rigor. Any discrepancies in data interpretation were discussed and resolved via consensus of the research team.

Results

Participant characteristics

Participants included 414 researchers who provided electronic consent and responded to at least one survey item. Of these, 355 researchers completed the entire survey. Researchers were 57.5% female, with a mean age of 50.6 years (SD = 11.3), and with PI, Co-PI, or Co-I qualifications for a mean of 14.0 studies (SD = 22.6). Other participant characteristics are reported in Table 1.

Barriers to results sharing

Researchers were asked to indicate the percentage of their health research studies in which a specific factor served as a barrier to the returning of aggregate results to participants. The response scale ranged from *0%- not a barrier at all* to *100%- always a barrier*. Across researchers, the mean percentage of studies for which ethical concerns were reported as a barrier was 38.5% (SD = 30.7). Eighty-three researchers (23.4%) reported that ethical concerns were a barrier to returning results in 0.0%−5.0% of their studies, and 10 researchers (2.8%) reported that ethical concerns were a barrier to returning results in 95.0% −100.0% of their studies.

An overarching desire to prevent harm to participants was researchers' primary ethical concern with returning aggregate research results to participants as articulated in survey data. Three broad ethical concerns emerged as harm caused by: 1) distress; 2) understanding; and 3) privacy. Sub-themes emerged within each thematic domain. See Table 2. A description of the emergent themes along with quotes that best represent each theme are presented.

Distress

Researchers reported that their motives for not sharing results were to prevent harm that could potentially be caused by emotional distress and to prevent the disclosure of results that might be stigmatizing to participants. Furthermore, researchers reported a lack of time, resources, and processes available for participants who might experience distress and stigma due to receiving research results.

Emotional Distress.—Generally, researchers expressed deep concerns about "creating angst in participants" (ID #432) if they returned results to them. When discussing their

decision to withhold findings, a researcher explained “study findings could be upsetting” (ID #601) and another stated sharing results would “create anxiety” (ID #233). Other researchers reported “participants may be distressed if outcome found is not a good one” (ID #147). In addition to the general distress that research results might cause, researchers reported that “patients might be upset that they didn’t get the better arm of treatment” (ID #648). Other researchers explained participants “might feel frustrated in a study that had negative results” (ID #528).

Stigma.—Researchers also expressed ethical concerns about sharing results that could potentially stigmatize participants or the broader community that participants belonged to. Researchers explained their concern with “disseminating information that, if misinterpreted, could lead to incorrect stereotyping of a certain group” (ID #136). Other researchers stated, “Communities I work with may not want to hear results in a way that reflects their community in a poor light” (ID #693) and “not all research is considered ‘good’ research by the community … it may be seen as a method to cast a negative shadow” (ID #290). Other researchers had concern that the topic of research could be stigmatizing. A mental health researcher explained their concern with sharing results: “I have researched connection between mental health factors and cancer outcomes and do not want there to be perceived blame on those with mental illness until the data can be better understood beyond correlations” (ID #358).

Lack of time, resources, and processes to prevent distress and stigma.—Researchers voiced their concerns about the lack of time, resources, and processes to support their efforts to return results to research participants while also preventing harm that might be caused by emotional distress or stigma. Several researchers reported their concerns about sharing results without being able to provide additional support or context to research participants. For example, one researcher explained that “disseminating results without discussion and context can result in more questions…without a process to address these issues participants may be left with serious concerns without any way to address them” (ID #406). Another researcher stated, “some of the results may increase anxiety in participants without having someone to fully explain the implications” (ID #374). A genomics researcher said, “in genomic analyses studies if there are mutations associated with potential disease risk, there may be implications to communicating this to patients who have no access to genetic counselors or who are able to take preventative measures” (ID #339). Another researcher stated, “if I share with participants about their level of psychological distress (outcome measured in my study), I am fearful that I won’t have sufficient resources to provide to them if/when they need it” (ID #497).

Understanding

Another theme researchers cited often and at length was their concern that sharing results with participants would cause harm due to poor understanding of the results, therapeutic misconception (Henderson et al. 2007) about the role of research, and concerns that participants would take action based upon misunderstood results. While researchers acknowledged the need to ensure participants had sufficient understanding, they also expressed a lack of time and resources to do so.

Lack of sufficient understanding.—Researchers reported ethical concerns that participants might not understand the complex research process or the context of the research results. A researcher stated “most of my research involved very difficult to understand concepts and many of the participants would have difficulty interpreting the results and what they mean” (ID #616). Another researcher explained “research often revolves around methods and measures which are beyond current medical practice. Thus, conveying or even accurately interpreting results may not be appropriate and at worst can be misleading” (ID #10). Other researchers expressed concern that complex “data does not lend itself to translation to lay populations” (ID #34). Additionally, researchers also explained that their “biggest concern is that subjects will take the findings out of context,” and that the results would not be interpreted within the larger context of the overall study (ID #478).

Therapeutic Misconception.—Researchers also stated that they held ethical concerns about returning results to participants because participants might experience therapeutic misconception. That is, participants might not understand that the primary purpose of research is to produce generalizable knowledge, not to provide an individual health care intervention (Henderson et al. 2007). Participating in health research may benefit the participant, but benefiting participants is not the direct purpose of research. Researchers articulated their fear of patients having “therapeutic misconception” in terms of a concern that sharing results with participants could lead to a misunderstanding about the applicability of results to a participant’s health. Therefore researchers had “concerns that participants will have therapeutic misconception” and this “may discourage a PI from disseminating results to research participants” (ID #551). Furthermore, researchers stated “participants may not understand the short term information contributes to a larger body of knowledge” (ID #363). Researchers discussed their fear that therapeutic misconception might “give a false impression of a ‘cure’ for the problem under study,” (ID #365) and “individual participants may expect the research results to apply to individual cases” (ID #147).

Action based on misunderstanding.—Researchers expressed concerns that if participants did not understand results it could negatively affect participant’s health behavior and health care choices. Researchers stated that for participants not trained in research “it may be difficult to understand the study results, which may lead to confusion and poor health care decision making” (ID #450). Researchers discussed their concern that “study findings may not be actionable at the patient level” (ID #628) and were “concerned about people making health decisions based on a single study, and often based on preliminary data from that study” (ID #617). Other researchers stated concern that sharing results might alter how the participant made treatment decisions: “In participants who are already having difficulty with treatment adherence, certain study results might tip them over into non-adherence,” (ID #192) or “sometimes the intervention - drug - may have abuse liability, which, if participants believe it was ‘helpful,’ could lead to unauthorized use that could then lead to subsequent abuse. Also, a belief that the intervention would be helpful may bias subjects against other forms of treatment already available” (ID #92). Other researchers explained their concern that participants’ lack of understanding would lead to poor health care choices: “the risk that participants may misunderstand/misinterpret the results is a huge concern, especially if it has health care decision-making implications (i.e. surgery)” (ID

#526) or that “despite explaining to participants, there have been times when they think we use [preliminary] research information to make clinical decisions” (ID #671). A genetics researcher explained “we are collecting genetic information, which in aggregate may not tell specific enough information to the individual participants, therefore the participants could misconstrue the results to be universally applicable to them when this is not the case” (ID #582).

Lack of time and resources to ensure sufficient understanding.—Researchers acknowledged the need to explain results, stating “if the results are presented in a way that is not at the appropriate level of literacy and health literacy, there are ethical concerns” (ID #83). Furthermore, researchers consistently discussed their belief “that if we widely disseminate findings to patients, we have an ethical obligation to help them understand them” (ID #680). A researcher concerned about misinterpretation of results said they “would need to spend time writing [a] very careful summary to try to explain results in layman’s terms” because they “have been concerned about misinterpretation of results” (ID #589). The main issue, a researcher stated, was working “to explain the findings clearly in lay terms” (ID #199). However, researchers also explained that returning results in a way that ensured an appropriate level of understanding was difficult without additional time and resources. Researchers reported “some results are nuanced and may be difficult for participants to understand unless time and effort are invested to make sure they do understand” (ID #659). Other researchers stated they lacked the necessary time to translate published results into results summaries for lay audiences. “Study results as we create them for peer-reviewed manuscripts would need to be further translated for our study populations to find useful” (ID #521). As another researcher explained peer-reviewed publications are “typically written for the academic community who has a basic understanding of the research” and “writing for the general public takes extra time” (ID #296). This extra time is often not covered by grant funds. As one researcher said, “preparing study results for a lay audience should be done with care, but grants have not traditionally included time/funding for this step” (ID #686).

Privacy

The potential to violate a participant’s privacy was voiced as an ethical concern that discouraged researchers from sharing results. Researchers discussed two concerns regarding participants’ privacy. First, researchers discussed concerns that they might violate privacy policies governing research. Secondly, researchers were concerned that returning results would increase the likelihood that participants’ confidentiality would be breached.

Violating privacy policies.—Researchers discussed apprehension about returning results because they believed it would violate the Health Insurance Portability and Accountability Act (HIPAA) or institution review board (IRB) polices. One researcher explained “contacting former participants…could be considered a violation of HIPAA” (ID #240). Another researcher explained they thought there was always an ethical concern of sharing results “for large retrospective studies that have received an IRB exemption status” (ID #32). Researchers also stated concerns for participants’ “privacy, confidentiality” (ID #422) and

were not sure “if patients can be contacted again by the study investigators after the study is complete” (ID #191).

Loss of confidentiality.—Researchers expressed concerns that contacting participants to share study results increased the risk for a loss of participant confidentially. A researcher whose study participants were anonymous explained that returning results “require[s] researchers to collect participants’ personal data which increases the risk” of a loss of confidentiality (ID #597). Additionally, researchers stated their ethical concern with attempts to contact participants with results would be one “more way that participant privacy is at risk” (ID #532) and that “mail coming from an institution would identify the participant as being involved in a study” (ID #301). A researcher that studies adolescents said, “research on sensitive issues…without parent consent, [means] additional contacts are potential breaches [of] confidentiality” (ID #611).

Discussion

The present study used an exploratory design to understand researchers’ ethical concerns related to returning aggregate research results to participants. When asked to report the percentage of their studies in which ethical concerns served as a barrier to sharing results with participants, researchers’ mean response was 38.5%. In the open-ended responses, researchers overwhelmingly reported that their main ethical concern with sharing results stemmed from a desire to prevent harm to study participants. Three overarching ethical concerns related to the way harm could result emerged: 1) distress; 2) understanding; and 3) privacy.

Within the theme of distress, researchers explained they had ethical concerns with returning results because participants might become upset, anxious, or angry about the results of a study in which they had participated. Furthermore, researchers stated that they also wanted to prevent stigmatization of participants or communities. It is interesting to note that the vast majority of ethical concerns expressed by researchers related to the harm that could be caused by disclosing results, rather than the injury that could come from not disclosing them. Researchers did not express their consideration of what happens to a participant’s view of research if the participant later learns that findings were withheld. Researchers’ concern about preventing harm to participants is a consistent theme found in literature documenting the lack of dissemination of study results to participants (Cox et al. 2011; Partridge et al. 2004; Miller et al. 2008; Shalowitz and Miller 2008b). However, it is not clear if this fear comes from actual participant feedback or concern about researchers’ liability. Data suggests participants feel they should be part of the process of deciding which results are returned (Clift et al. 2015), and that health professionals, particularly those working in genetics, tend to be more conservative about which results should be shared relative to participants and the general public (Middleton et al. 2016). Additionally, it is not clear why upsetting participants is such an important harm to be avoided. If participants are going to learn negative results of a study, should they not be allowed to react with a range of emotions? Why are their customary, human responses seen as an ethical problem to be avoided?

Researchers also explained their ethical concerns about sharing potentially distressing or stigmatizing results because they did not have the time, staff, or support services necessary to share results. The lack of time and resources to share results is consistent with many other studies (Chen et al. 2010; Rigby and Fernandez 2005) reporting the barriers researchers encounter with returning results.

Researchers expressed concerns about what at least one of them called the “therapeutic misconception” when framing their ethical concerns with returning results. For this study, the research team used the National Institutes of Health’s definition of therapeutic misconception that “participants do not understand that the purpose of research is to produce generalizable knowledge, regardless of whether the participants enrolled in the [study] may potentially benefit from the intervention or other aspects of the [study]” (Henderson et al. 2007). Researchers explained their concern that participants do not understand the research process and its goal of producing generalizable knowledge. This is a notable finding because it shows how some researchers may misapply the term “therapeutic misconception” as they frame their ethical concerns with sharing results. In Henderson et al., therapeutic misconception is understood as occurring when a participant agrees to join a research study because they mistakenly believe it will personally benefit them. Researchers we surveyed reported that they were discouraged from sharing results because they were concerned participants would use incomplete data or misinterpreted information to make individual health care choices that might negatively impact their health. Researchers connected this concern to the concept of therapeutic misconception and discussed their concern that participants would not understand that research is intended to produce generalizable knowledge and not inform personal treatment decisions of participants. However, therapeutic misconception as defined by Henderson et al. occurs at the time of consent to participate in the trial and does not refer to former study participants who are making treatment decisions based on their interpretation of research findings once they have been made public. From an ethical perspective, understanding potential research results is a necessary component of informed consent. The time taken to explain this information is somewhat immaterial; participants who do not understand the purpose of research or the utility of preliminary results are not fully informed and not ready to be enrolled in a study. Informed consent is a centerpiece of ethical research. Similarly, a researcher who is not able to explain his or her study in lay terms is not ready to enroll participants in a study. This finding indicates that researchers may be mistakenly conceptualizing such key concepts in research ethics as the appropriate structure of truly informed consent and the possibility of subjects consenting to research because they seek apparent benefits of treatment rather than seeking to benefit humanity by contributing to the growth of generalizable knowledge, or in other words, the therapeutic misconception (Christopher et al. 2017; Atz, Sade, and Williams 2014; Lidz et al. 2015).

Researchers again explained that they lacked time and resources to ensure participants fully understood results. For example, researchers’ statements implied that results should only be shared with other experts since the results typically would not be easily understood by participants. However, only sharing results with other researchers does not meet the definition that research intends to contribute to “generalizable knowledge.” Other studies have reported researchers’ concerns about sharing understandable results (Shalowitz and

Miller 2008b); however, this study extends the current literature by providing researchers' explanations of their ethical concerns that participants' lack of understanding of results and therapeutic misconception may impact participants' personal health care decisions.

Finally, researchers explained they were discouraged from sharing results because they did not wish to breach participant privacy. In particular, researchers expressed concern that returning aggregate results to study participants could be considered a violation of HIPAA or IRB regulations. It is not clear how researchers developed these concerns, which represent an inaccurate interpretation of HIPAA and IRB regulations. Concerns for participants' privacy are appropriate; however, most of the concerns cited by researchers in this study demonstrated their misunderstandings about privacy regulations. HIPAA is meant to protect patients' private health information, but does not bar researchers from activities such as contacting participants or sharing research results with them. IRBs often require data safety and monitoring plans that explain how researchers will protect participant data, in order to mitigate loss of confidentiality. However, IRBs still allow and, in some cases, encourage the sharing of study results with participants.

Limitations and strengths.

This study is limited by the lack of a random sample. PIs from participating CTSAs recruited participants from their investigator networks instead of being recruited directly by the study team. There may be unknown biases as the research team does not know who the PIs did, or did not, send the survey link to. Recruitment methods did not allow the research team to calculate a response rate since it is unknown how many eligible researchers received the invitation but chose not to participate. The limitations of a non-random sample and a lack of recruitment response rate are somewhat mitigated by the broad sample of participants from universities across the US. Despite the limitations, the study is the first of its kind to explore the ethical concerns of a broad sample of health researchers regarding the return of results to participants.

Implication for policy and practice.

These findings can inform policy and practice in several ways. First, researchers voiced concern with not having the time or resources to adequately share sensitive and difficult to understand results that might cause emotional distress. Research institutions and funding agencies could require detailed plans and budgets for returning results to research participants in grant proposals. Likewise, contracts could ensure researchers will have funded time and resources needed to return research results to participants. Researchers shared deep concerns that participants would not understand the results and that their lack of understanding would cause harm if research results were shared. To address this, researchers could work with health literacy experts at their institutions to create lay summaries of aggregate study results for participants. The lay summaries could include both the context of the research and the results of the research conducted. This could minimize harm to participants. Researchers' concerns about therapeutic misconception is reminiscent of clinicians' concerns about disclosing cancer diagnoses to their patients and the effect on those patients' future health outcomes, which we now know was unfounded (Novack et al. 1979). There is a need for empirical studies to investigate the impact of sharing research

results with participants and its effect on future treatment decisions and adherence. In addition, research compliance staff or medical ethicists should offer training on therapeutic misconception to researchers. Researchers also discussed concerns about breaching participants' privacy. To address this concern, researchers could ask participants to choose whether or not to receive results at the time of consent. Researchers could offer several scenarios about the types of results participants might receive (i.e., results are incomplete or inconclusive, results are negative, or results are preliminary and require further testing). Finally, compliance offices could offer additional guidelines and training on how to minimize the loss of confidentiality while also sharing study results with participants. Further, researchers may benefit from additional HIPAA training that clearly explains how HIPAA protects participant privacy but does not prohibit researchers from contacting or sharing results with participants.

Conclusion

While research participants overwhelmingly state that they want to receive results from the studies in which they participate, and researchers acknowledge that returning results to participants is important, research results are rarely shared with participants. This is the first study to broadly explore researchers' ethical concerns with sharing aggregate research results with their participants. Results and analysis reveal that researchers' ethical concerns are closely tied to the ethical obligation to do no harm. In order to increase dissemination of results to participants, steps must be taken to help researchers minimize potential harm when sharing results. Research universities and health research funding agencies can help encourage the sharing of results with participants through improved policies, resource allocation, and training.

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Table 1.

Characteristics of online survey respondents.

	Number (% of survey respondents) or Mean ± SD
Gender (n = 350)	
Female	202 (57.7%)
Male	147 (42.0%)
Other	1 (0.3%)
Age (n = 311)	50.6 ± 11.3
Degrees held (n = 353)[a]	
PhD	199 (56.4%)
MD	158 (44.8%)
MPH	38 (10.8%)
Other	28 (7.9%)
Primary academic appointment (n = 359)	
Medicine	234 (65.2%)
Public Health	30 (8.4%)
Allied Health Professions	24 (6.7%)
Nursing	21 (5.8%)
Other	50 (13.9%)
Number of completed health research studies as PI, Co-PI, or Co-I (n = 358)[a]	14.0 ± 22.6

Note. Percentages are based on the number of valid responses for each item.

[a]Respondents could select more than one response.

Table 2:

Emergent themes and sub-themes of ethical concerns reported by researchers

Thematic Domain	Sub-themes	
Distress	**1**	Emotional distress
	2	Stigma
	3	Lack of time, resources, and processes to prevent distress and stigma
Understanding	**1**	Lack of sufficient understanding
	2	Therapeutic misconception
	3	Action based on misunderstanding
	4	Lack of time and resources to ensure sufficient understanding
Privacy	**1**	Violating privacy policies
	2	Loss of confidentiality