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## On Using Ethical Principles of Community-Engaged Research in Translational Science

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### Abstract

The transfer of new discoveries into both clinical practice and the wider community calls for reliance on interdisciplinary translational teams that include researchers with different areas of expertise, representatives of healthcare systems and community organizations, and patients. Engaging new stakeholders in research, however, calls for a re-consideration or expansion of the meaning of ethics in translational research. We explored expert opinion on the applicability of ethical principles commonly practiced in community-engaged research (CEnR) to translational

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research. To do so, we conducted two online, modified-Delphi panels with 63 expert stakeholders who iteratively rated and discussed nine ethical principles commonly used in CEnR in terms of their importance and feasibility for use in translational research. The RAND/UCLA Appropriateness Method was used to analyze the data and determine agreement and disagreement among participating experts. Both panels agreed that ethical translational research should be “grounded in trust.” While the academic panel endorsed “culturally appropriate” and “forthcoming with community about study risks and benefits,” the mixed academic-community panel endorsed “scientifically valid” and “ready to involve community in interpretation and dissemination” as important and feasible principles of ethical translational research. These findings suggest that in addition to protecting human subjects, contemporary translational science models need to account for the interests of, and owe ethical obligations to, members of the investigative team and the community at large.

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## INTRODUCTION

Translational research, defined by the National Institutes of Health (NIH) as a “process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease,” is seen as one of the means of successfully incorporating research findings into healthcare practice.<sup>1,2</sup> Nowadays, translational research focuses not only on implementing basic science discoveries into routine clinical practice<sup>3</sup> (bench to bedside translation), but also on ensuring that evidence-based treatments are adopted in community settings (bench to curbside translation).<sup>4,5</sup>

The transfer of new discoveries into both clinical practice and the wider community calls for reliance on interdisciplinary translational teams that include not only researchers with different areas of expertise, but also representatives of healthcare systems and community organizations, and patients.<sup>6</sup> Comparative effectiveness methods and stakeholder engagement techniques aim to increase healthcare effectiveness and reduce healthcare disparities by addressing “the gap that exists between research and practice,” which is a known roadblock in translational research.<sup>7</sup> Indeed, research suggests that engagement of a broad range of stakeholder groups, including academic and non-academic partners, can foster ownership of the research process and results; promote two-way capacity-building; improve recruitment in scientific research, especially among under-represented minority populations; increase relevance of research findings to a larger number of stakeholders; and ultimately facilitate the use of research findings in practice.<sup>1,2,8</sup>

Inclusion of non-academic partners on investigative teams and the emphasis on pragmatic use of research findings, however, call for changes in the way scientific research is conducted. For example, proponents of stakeholder- and community-engaged research (CEnR) – such as community-based participatory research and community-partnered participatory research – recommend that research decisions be made by committees that include representatives of all stakeholder groups on the project; power is shared among partners; and conflicts are addressed early on.<sup>9,10</sup>

Moreover, previous research suggests that the ethical conduct of CEnR calls for re-conceptualization, re-interpretation, and/or expansion of the meaning of the Belmont

principles of respect for persons, beneficence, and justice. CEnR practitioners argue that the Belmont principles are limited in scope and are too abstract, which limits their interpretation and application.<sup>11,12</sup> They suggest that investigators should not only consider interests of, and owe certain ethical obligations to, “human subjects” participating in research, but should also be concerned about those community stakeholders who are engaged in the actual conduct of research and take into consideration interests of communities these stakeholders represent.<sup>13</sup> Moreover, the principle of respect for persons assumes that individuals should be given an opportunity to make an autonomous decision. CEnR proponents not only apply autonomy to the research team members, but also work to redress the power differences between academic researchers and community members of research teams to be sure that community partners have equal opportunity in decision-making.<sup>14</sup> They also suggest that communities in which research takes place should have an opportunity to influence the research focus and receive benefit from it.<sup>15</sup>

Although these re-conceptualized and expanded ethical principles are important for CEnR, it is not known how relevant they might be to translational research in general. As a preliminary step in the analysis of translational research ethics, we conducted two online modified-Delphi panels to explore expert opinion on the applicability of ethical CEnR principles to translational research. Due to the exploratory nature of this project, we recruited a diverse set of expert stakeholders who work on different types of translational research projects and deliberately asked participants to think about a broad definition of translational research (as presented above). We reasoned that if diverse stakeholders can agree on a particular ethical principle, additional research should further explore the types of translational research this principle applies to. By exploring the degree to which translational researchers view the expanded ethical obligations typical of CEnR as relevant to their own research, we aim to identify shifts in contemporary approaches to research ethics as well as map areas of uncertainty in the conduct of ethical translational research.

## MATERIAL AND METHODS

### Ethical CEnR Principles

Based on the results of a recent literature review on,<sup>13</sup> and qualitative analysis of,<sup>16</sup> CEnR ethics, we selected nine ethical principles that move beyond those listed in the Belmont report. We deliberately used strong language (e.g., “must” rather than “should”) in describing some principles to make them more provocative and to encourage debate among participants. Because we assumed the principles could be generally seen favorably, we used strong language to seek to discriminate between those principles researchers viewed positively and those they saw as essential or non-negotiable to ethical research. We classified these principles into two groups based on who they apply to.

#### Ethical Principles that Apply to Community at Large:

- 1 *Action-Oriented*: All research must produce useful knowledge, help advocate for vulnerable community needs, lead to policy changes, and/or have a real world impact.<sup>17–19</sup>

- 2 *Community-Driven*: The needs and priorities of the participating community must drive the choice of the study topic and its focus.<sup>10,20</sup>
- 3 *Culturally Appropriate*: All study activities and protocols must be culturally appropriate and not stigmatizing.<sup>21,22</sup>
- 4 *Beneficial to Community*: Research activities must result in tangible benefits to the participating community; investigators should be ready to address individual participants' needs uncovered in the course of research.<sup>23</sup>
- 5 *Forthcoming with Community about Study Risks and Benefits*: Not only participants, but also community at large must be fully aware of study risks and benefits.<sup>24,25</sup>

Ethical Principles that Apply to Research Team Members:

- 6 *Ready to Involve Community in Interpretation and Dissemination*: Study findings should be analyzed, interpreted, and disseminated with the active participation of community partners and community members at large.<sup>21,26</sup>
- 7 *Based on Equal Partnership*: Academic and community investigators actively collaborate in all phases of research and equally share power, resources, and responsibility for the study and its outcomes.<sup>17,27</sup>
- 8 *Grounded in Trust*: Academic and community investigators must ensure that all study team members feel trusted and respected; their motives and decisions must also be transparent.<sup>11,28,29</sup>
- 9 *Scientifically Valid*: Academic and community partners must work collaboratively to ensure that research protocols address important scientific questions; data collection techniques are valid and rigorously applied; data are being carefully analyzed; and findings are objectively interpreted and presented in an unbiased manner.<sup>11,30</sup> Scientific validity is an ethical priority in CEnR because of the concerns related to data integrity,<sup>31,32</sup> and bioethicists discuss the centrality of scientific validity to risk-benefit deliberations.<sup>33,34</sup>

### Study Participants

To ensure that we engaged individuals from both academic and community sectors with relevant expertise and practical experience in conducting translational research, we used a purposeful sampling approach, which is typical for expert panels.<sup>35</sup> We used the NIH Reporter website and the Patient Centered Outcomes Research Institute (PCORI) website to identify principal investigators of ongoing translational research projects funded through R01 and R21 NIH grant mechanisms or PCORI's Assessment of Prevention, Diagnosis, and Treatment Options mechanism as of December 2013. We also reached out to the first authors of the 25 "hottest" and "most viewed" articles published in *Translational Research* and *Implementation Science* journals, respectively. To identify relevant non-academic stakeholders, we contacted members of two Clinical and Translational Science Institutes, Community-Campus Partnerships for Health, the Community Based Public Health Caucus

of the American Public Health Association, and the National Community-Based Organization Network.

108 stakeholders with experience in conducting different types of translational research expressed an interest in participating in our study by filling out an online study registration form, which included basic demographic questions and questions about professional background and experiences with different types of translational research and CEnR. We also asked an open-ended question about the principles and practices that make research ethical, which we used to validate the list of ethical research principles that participants rated during the panel process. Of 108 registered participants, 63 (58%) participated in our panel.

### Panel Design

We used an innovative online panel approach with a modified-Delphi structure common for expert panels.<sup>36,37</sup> Such an approach allows for engaging a large number of diverse stakeholders by providing them with an opportunity to anonymously share their perspectives and interact with other participants using their own computer at a time that is convenient to them.<sup>38</sup> Although participants were not paid for their time, five randomly selected individuals who completed all study rounds received a Kindle reading device. This study was conducted according to The Code of Ethics of the World Medical Association (Declaration of Helsinki). Informed consent was obtained from every participant. The authors' institutional review board approved the study.

Previous research on online panels suggests that a panel of approximately 40 participants is likely to create a positive and engaging environment for productive online discussion, and that participation rates in such panels vary between 50% and 60% across the rounds.<sup>39</sup> The number of registered participants (n=108) allowed us to conduct two concurrent panels using an identical research protocol. We deliberately created panels that differed significantly in their composition because the iterative Delphi process means that panel composition determines which viewpoints participants will be exposed to. We randomly assigned 54 translational researchers working at universities and non-profit research institutions to an "academic" panel. The remaining stakeholders, including translational researchers, healthcare professionals, and representatives of community agencies and healthcare services organizations, were assigned to a "mixed" panel. While the academic panel helped us explore the perspective of translational researchers, the mixed panel helped us investigate the perspectives of a group that more closely resembles a community-engaged translational research team.

### Data Collection

To collect stakeholder input, we used a RAND-developed system called ExpertLens - a previously evaluated online platform that uses a modified-Delphi structure to elicit expert opinion and engage stakeholders.<sup>39</sup> ExpertLens has been used in more than a dozen studies to engage large and diverse stakeholder groups, including researchers, providers, administrators, policy-makers, and community members, such as patients and their family members. Study topics ranged from the development of national suicide prevention research goals,<sup>40,41</sup> to the identification of definitional features of continuous quality improvement in

health care,<sup>39,42</sup> to the development of quality and performance indicators/measures for arthritis patients.<sup>43–45</sup>

Each panel completed a three-round ExpertLens process.

- In Round One, participants used 9-point Likert-type scales to rate the importance and feasibility of the nine principles as components of ethical research that all translational studies should follow. In rating importance, participants were instructed to consider the extent to which each principle is critical to the definition of ethical research. In rating feasibility, they were asked to consider how easy or difficult it would be to evaluate whether each principle had been achieved. Participants were instructed to provide rationales for their answers. Round One was open between March 31 and April 9, 2014.
- In Round Two, participants saw how their Round One responses compared to those of other panelists and reviewed the group results for each question, which were displayed as simple statements describing whether or not agreement was reached and whether the group rated each principle positively (i.e., as important or feasible), negatively (i.e., as not important or not feasible), or as uncertain (see Online Appendix A). Group results were determined automatically by ExpertLens using a two-step approach described in the RAND/UCLA Appropriateness Method User's Manual<sup>46</sup> (see Table 1). Participants also engaged in a discussion using asynchronous, anonymous, and moderated online discussion boards. Round Two was open between April 9 and April 21, 2014.
- In Round Three, panelists re-answered Round One questions in light of Round Two statistical feedback and discussion and answered questions about their experiences participating in this online panel. Round Three was open between April 21 and May 12, 2014.

### Data Analysis

The final group rating for each question was determined by applying the same RAND/UCLA Appropriateness Method techniques to the analytic sample of responses from each panel, which consisted of Round Three responses of those participants who participated in that round and Round One responses of those participants who had not provided their Round Three responses. We combined these responses because there were no statistically significant changes in panel means between the two rating rounds and because looking just at the Round Three responses yielded the same results (analyses not shown). This approach has been used in previous large-scale stakeholder engagement panels because it allows for using the input from every stakeholder who participated in the panel if there are no statistically significant round effects.<sup>40</sup>

We compared ratings across panels to identify ethical principles endorsed by both panels. Based on consensus method guidelines, the definitions of importance and feasibility were determined in advance.<sup>37</sup> We considered a particular ethical principle to be important and/or feasible for translational research if both panels agreed on its importance and feasibility and their median rating was between 7 and 9 on a 9-point scale. We also compared individual

panel ratings with those of a combined sample by way of a sensitivity test. Finally, we identified principles that were deemed both important and feasible.

To better explain why a certain principle was considered important or feasible, we thematically analyzed qualitative data we collected in Round One (rationale comments explaining participants' ratings) and in Round Two (discussion comments). We grouped all rationale comments based on the numeric rating they referred to and identified ethical principles each discussion thread was related to. An experienced qualitative researcher coded all qualitative comments inductively to identify emerging themes that could be used to explain the results of the rating process. Coding results were reviewed by two other qualitative researchers to ensure consistency; disagreements were discussed until consensus was achieved.<sup>42</sup>

## RESULTS

Our final analytic sample consisted of 63 stakeholders (58% of study registrants): 33 participants in the academic panel and 30 in the mixed panel. Both panels were similar in terms of the demographic composition (see Table 2). On average, both panels were approximately 70% female, and 80% of panelists were White. 80% of the mixed panel and all members of the academic panels reported having previous CEnR experiences. Over two-fifths of both panels' members reported conducting population health research and roughly 30% stated conducting treatment/intervention discovery and development research. While 7% of the mixed panel reported conducting pre-clinical or bench research, the academic panel did not include any such participants. Moreover, although 27% of the academic panel members reported conducting health services/implementation science research, only 17% of the mixed panel participants reported doing so. The difference in the type of translational research that panelists conduct, however, was not statistically significant.

### Quantitative Results

Table 3 shows that five out of nine ethical principles were consistently deemed important for all translational studies by both panels and the combined sample of participants. Two of these principles relate to community at large ("cultural appropriateness" and "forthcoming with community about study risks and benefits"), and three principles apply to research team members ("scientific validity," "grounded in trust," and "readiness to involve community in interpretation and dissemination of study findings"). The median values for these principles were 7 or higher on the 9-point importance scale in both panels and the combined sample. Two other principles ("community-driven" and "based on equal partnerships") were deemed to be of uncertain importance by both panels and the combined sample. Median values were equal to 6 in both panels and the combined sample. There was variation in the way two principles related to community at large ("beneficial to community" and "action-oriented") were rated: while the academic panel considered "beneficial to community" to be important (median=7) and "action oriented" to be of uncertain importance (median=6), the mixed panel had an exact opposite opinion. Combined sample results, however, suggest that both of these principles were rated as important (median values for both were equal to 7). None of the principles were rated "not important" for translational research.

Table 4 illustrates variation in panel ratings of feasibility of applying these ethical principles to translational research. Only one principle (“grounded in trust”), which describes the relationships among research team members, was deemed feasible by both panels and the combined sample. “Cultural appropriateness” and “scientific validity” were deemed feasible by one of the two panels and the combined sample. “Ready to involve community in interpretation and dissemination of findings” and “forthcoming about risks and benefits” were deemed feasible only by one panel. It is interesting to note that all principles deemed feasible in any of the three samples had median ratings of 7. Four principles were consistently considered to be of uncertain feasibility: “action-oriented,” “community-driven,” “beneficial to community,” and “based on equal partnership,” with median values ranging from 4 to 6. Finally, no principle was deemed unfeasible by the panelists.

Combining results on both rating criteria shows that “grounded in trust” was the only principle deemed important and feasible by both panels and the combined sample. “Cultural appropriateness” was considered both important and feasible by the academic panel and the combined sample, whereas “scientific validity” was deemed important and feasible by the mixed panel and the combined sample. Moreover, only the academic panel deemed “forthcoming with community about risks and benefits” as both important and feasible; at the same time, the mixed panel considered “involvement of community in interpretation and dissemination” to be important and feasible.

### Qualitative Results

Results of our thematic analyses of the qualitative data suggest that trust, which was unanimously deemed important and feasible, is crucial for ethical conduct of translational research because, as one participant put it, “scientific research is a team sport. All team members should be treated well and respected.” Another participant described the feasibility of using trust as an ethical principle of translational research by saying that “...the [assessment of] motives and decisions...is pretty feasible to implement and evaluate... Feelings of trust and respect are an individual perception that could be assessed in a survey.”

“Cultural appropriateness,” which was considered important by both panels, and feasible by the academic panel and the combined sample, was described as “ecologically valid,” meaning that it applies to all research and all interventions. Some participants commented that, regardless of the type of research, study findings should never be stigmatizing. Others, however, noted that the meaning of cultural appropriateness is open for interpretation and differs across communities. One participant stressed the need to find “a balance between not stigmatizing and at the same time not idealizing,” which may explain a degree of uncertainty that is evident in the feasibility ratings of the mixed panel.

The principle of “scientific validity” was of particular significance to the mixed panel. Although several participants noted the importance of balancing scientific rigor with community relevance, they acknowledged the challenge of adhering to scientific standards that were developed for conducting research in more controlled environments; stressed the value of educating community partners on the issues of privacy, study timelines, and threats to validity; and commented on the difficulty of ensuring “fidelity when doing research in the field, especially if non-researchers are hired to collect data and administer programs.” These



concerns may be helpful in understanding uncertain feasibility ratings of this principle in the academic panel.

Ratings of the importance and feasibility of using “action-orientation” as an ethical principle illustrate some concerns that academics had about the real world impact of every study. As one academic put it, “research protocol cannot promise the outcomes [that will have a real world impact]. Findings can be surprising, contradictory, and unexpected...” Others mentioned that studies can yield null outcomes, which may not lead to a policy change but are important from the scientific point of view. Some participants, however, had a more favorable view of this principle and stressed that all research should produce useful new knowledge, which could “be applied to improve general health outcomes, either through the development of novel solutions/interventions or by providing information that can help advocate for appropriate policy change.”

Those supporting the importance of community initiation of research stated that “community-driven” is the principle that “is the holy grail,” which might be difficult to implement because it is “one of the trickiest components of community-based research from an academic perspective.” Comments of even those panelists who supported this principle revealed the challenges of applying it to all translational research. One of the stated challenges was the diversity among communities and their needs, as well as the difficulty in identifying appropriate individuals who can speak for the community. Another challenge was related to the knowledge and power differentials between academic and community partners, which may make it difficult for community to initiate research.

Finally, qualitative findings also revealed a challenge of applying the ethical principles of CEnR to all translational research projects. Several participants indicated that while such principles may be important for late stages of translational process, they may not be as vital for basic science projects taking place in a lab setting or for exploratory or developmental research projects that are in the early stages of development.

## DISCUSSION

Our study was designed to explore expert opinion on the applicability of ethical CEnR principles to translational research. Two out of five principles that apply to community at large and three out of four principles that apply to research team members were deemed important by both panels and the combined sample. Participants agreed that ethical translational research projects may be those where relevant stakeholders are engaged in the process of conducting research, and especially in the interpretation and dissemination of study findings;<sup>21,26</sup> where trust among research team members is being built on an ongoing basis;<sup>11,28</sup> where culturally consonant<sup>17,18</sup> and scientifically valid<sup>30</sup> projects are prioritized; and where community at large is informed about study risks and benefits.<sup>24,25</sup> The expansion of the ethical focus of research is consistent with the growing importance of stakeholder engagement in the conduct of research and illustrates a systematic approach to incorporating community and patient perspectives into scientific practice, such as the one endorsed by PCORI.<sup>47</sup>

Nonetheless, our findings also illustrate new ethical challenges associated with active stakeholder engagement in research<sup>3</sup> and suggest that translational researchers may have concerns about the feasibility of active stakeholder involvement. A relatively high degree of consensus among participants about the importance of these novel ethical principles stands in contrast to their divergent opinions regarding their achievability. Indeed, out of the five principles that were deemed important to the definition of ethical translational research, only one principle (“grounded in trust”) was consistently deemed feasible in our study. Moreover, some of the principles that characterize the conduct of ethical CEnR, such as “based on equal partnership” and “community-driven,” were consistently deemed uncertain in terms of both importance and feasibility, suggesting that the practical challenges of ensuring “equal” partnership and defining what “community-driven” means may have prevented experts from assigning higher ratings to these principles.

However, it is important to note that differences between the panels on the feasibility of some of these principles and a substantial number of principles consistently deemed uncertain does not mean that translational research should ignore them. In contrast, high prevalence of uncertain feasibility ratings may suggest that participants were not sure about the best ways of achieving and measuring these ends because these principles are relatively new and have rarely been discussed in the context of translational research ethics in the literature. Moreover, because translational research is a diverse field,<sup>3</sup> some of our participants were uncertain about the applicability of these novel ethical principles to all translational projects, regardless of the fact that translational science as a discipline has become more stakeholder-engaged.<sup>6,7</sup>

The most robust finding of our study is the importance of trust as an ethical principle for translational research. Transparency and trustworthiness in the relationships among academic and community partners are a prominent theme in CEnR<sup>48,49</sup> and translational science<sup>50</sup> literatures that seek to explain low levels of public trust in science, particularly among minority and under-resourced communities. Mistrust of science and underrepresentation of ethnic minorities in health research<sup>51</sup> have been partly attributed to ethical misconduct in research involving minority participants,<sup>51–54</sup> and the involvement of community partners in all aspects of research is assumed to facilitate trust-building in science among community at large. Therefore, results of our study suggest that translational research could become a critical venue for reducing mistrust in science and scientists. This finding is particularly interesting because our experts reached agreement on the importance and feasibility of using trust as an ethical principle to guide translational research.

Moreover, our results suggest that the increasing use of CEnR models may be shifting both scientific practices and concepts of research integrity. While the academic panel considered that being “culturally appropriate” and “forthcoming with community about study risks and benefits” are important and feasible components of ethical translational research, the mixed panel agreed that being “scientifically valid” and “ready to involve community in interpretation and dissemination” may make translational research ethical. Traditional models of research integrity, including those typically monitored by Institutional Review Boards, focus on protecting the rights of individual research subjects enrolled in research, and thus it is noteworthy to see the endorsement of cultural appropriateness, community

benefit, and risks to community at large as key issues for translational science to consider. The endorsement of these principles, which have been particularly critical to CEnR models, suggests that ethical priorities characteristic of participatory science may be influencing the norms of a broader group of translational science stakeholders.<sup>17</sup> Therefore, our findings may be suggestive of the development of a new scientific model where, in addition to protecting the rights of participating study subjects (e.g., assessing the integrity of data collection procedures), translational researchers are expected to take into account interests of their research team members and larger community (e.g., consider interests of those who are not study subjects).

Although important, timely, and interesting, results of our exploratory study should be interpreted with caution. While our sample was large, compared to traditional 9-person modified-Delphi expert panels,<sup>46</sup> it was not necessarily representative of all translational science stakeholders. Although we invited non-academic translational science stakeholders, the majority of our panelists represented the academic perspective and had previous CEnR experience. Moreover, while the panels included translational science stakeholders focused on treatment development, implementation, and population health, the panels underrepresented the viewpoints of bench and basic science researchers and drew almost half of their participants from public or population health fields. This may have skewed the results in the direction of a focus on issues of relevance to community at large. To mitigate the sample limitations and to evaluate replicability of our findings, we identified ethical principles endorsed by both panels and the combined sample. Indeed, the endorsement of trust as being important and feasible to the ethical conduct of translational research by both panels further validates the addition of this principle to the list of ethical priorities for further research. Furthermore, in an attempt to foster debate and discussion among participants, we deliberately used strong language in describing some ethical principles. The use of the term “must” instead of “should” could have affected participants’ ratings, possibly by making panelists less likely to assign higher scores. Future efforts to replicate this study should take this limitation into account. Finally, not all Round One participants provided Round Three ratings. Participant attrition, however, is a common limitation of Delphi studies.<sup>55</sup> Therefore, we caution that this was an exploratory study, its results are suggestive rather than definitive, and these findings should be replicated in samples that better represent the population of translational researchers. In particular, future research efforts should recruit more bench and basic science researchers and those without CEnR experiences, for example, by engaging with professional societies, such as the Association of Clinical Research Professionals.

Regardless of these limitations, our findings have a number of potential implications for health research, research review and oversight, and policy:

- Translational researchers, their funders and sponsors, and Institutional Review Boards should be aware of the extent to which ethical principles that move beyond the traditional Belmont principles and extend beyond study subjects are redefining the ethics of translational research.
- The field of translational research may benefit from the development of measurement strategies that can assess the implementation of novel ethical dimensions, such as trust, cultural appropriateness, and equal partnership.

- Translational researchers may benefit from further training and opportunities for consultation to learn more about ethical principles like trust, equal partnership, action orientation, and community-driven that are commonly used in CEnR.
- Specifically, consultation strategies and process-oriented trainings could be useful to support translational researchers in their efforts to extend protections to members of the research team and community at large.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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## Abbreviations

<b>CEnR</b>	Community-Engaged Research
<b>NIH</b>	National Institutes of Health
<b>PCORI</b>	Patient Centered Outcomes Research Institute

## References

1. Schmittiel JA, Grumbach K, Selby JV. System-based participatory research in health care: An approach for sustainable translational research and quality improvement. *The Annals of Family Medicine*. 2010; 8(3):256–9. [PubMed: 20458110]
2. Braun L, Daudt HM, Watson P. Overcoming the translational roadblocks: A cancer care and research model. *Clinical and Translational Medicine*. 2014; 3(1):1–7. [PubMed: 24460977]
3. Sofaer N, Eyal N. The diverse ethics of translational research. *The American journal of bioethics*. 2010; 10(8):19–30. [PubMed: 20694901]
4. Smith, SA.; Blumenthal, DS. Translating research to practice. In: Blumenthal, DS.; DiClemente, RJ.; Braithwaite, RL.; Smith, SA., editors. *Community-based participatory health research: Issues, methods, and translation to practice*. New York, NY: Springer Publishing Company; 2013. p. 181-94.
5. Westfall JM, Mold J, Fagnan L. Practice-based research—“blue highways” on the nih roadmap. *JAMA*. 2007; 297(4):403–6. [PubMed: 17244837]
6. Emmons KM, Viswanath K, Colditz GA. The role of transdisciplinary collaboration in translating and disseminating health research: Lessons learned and exemplars of success. *Am J Prev Med*. 2008; 35(2):S204–S10. [PubMed: 18619401]
7. Estape ES, Mays MH, Harrigan R, Mayberry R. Incorporating translational research with clinical research to increase effectiveness in healthcare for better health. *Clinical and Translational Medicine*. 2014; 3:20. [PubMed: 25024819]
8. Hebert JR, Brandt HM, Armstead CA, Adams SA, Steck SE. Interdisciplinary, translational, and community-based participatory research: Finding a common language to improve cancer research. *Cancer Epidemiology Biomarkers & Prevention*. 2009; 18(4):1213–7.
9. Becker, AB.; Israel, BA.; Gustat, J.; Reyes, AG.; Allen, AJ. Strategies and techniques for effective group process in CBPR partnerships. In: Israel, BA.; Eng, E.; Schulz, AJ.; Parker, EA., editors.

Methods in community-based participatory research for health. 2. San Francisco, CA: John Wiley & Sons; 2013. p. 69-96.

10. O'Fallon LR, Dearth A. Community-based participatory research as a tool to advance environmental health sciences. *Environ Health Perspect.* 2002; 110(Suppl 2):155–9. [PubMed: 11929724]
11. Kraemer Diaz AE, Spears Johnson CR, Arcury TA. Variation in the interpretation of scientific integrity in community-based participatory health research. *Soc Sci Med.* 2013; 97:134–42. [PubMed: 24161098]
12. Shore N. Re-conceptualizing the belmont report: A community-based participatory research perspective. *Journal of Community Practice.* 2006; 14(4):5–26.
13. Mikesell L, Bromley E, Khodyakov D. Ethical community-engaged research: A literature review. *Am J Public Health.* 2013; 100(12):e7–e14. [PubMed: 24134352]
14. Smith R, Monaghan M, Broad B. Involving young people as co-researchers: Facing up to the methodological issues. *Qualitative Social Work.* 2002; 1(2):191–207.
15. Wing S. Social responsibility and research ethics in community-driven studies of industrialized hog production. *Environ Health Perspect.* 2002; 110(5):437. [PubMed: 12003746]
16. Bromley E, Mikesell L, Jones F, Khodyakov D. From subject to participant: Ethics and the evolving role of community in health research. *Am J Public Health.* 2015; 105(5):900–8. [PubMed: 25790380]
17. Glass KC, Kaufert J. Research ethics review and aboriginal community values: Can the two be reconciled? *Journal of Empirical Research on Human Research Ethics: An International Journal.* 2007; 2(2):25–40.
18. Jacklin K, Kinoshameg P. Developing a participatory aboriginal health research project: “Only if it’s going to mean something”. *Journal of Empirical Research on Human Research Ethics.* 2008; 3(2):53–67. [PubMed: 19385745]
19. Brown P, Morello-Frosch R, Brody J, et al. Institutional review board challenges related to community-based participatory research on human exposure to environmental toxins: A case study. *Environmental Health.* 2010; 9(1):39. [PubMed: 20637068]
20. Flicker S, Guta A. Ethical approaches to adolescent participation in sexual health research. *J Adolesc Health.* 2008; 42(1):3–10. [PubMed: 18155024]
21. Story L, Hinton A, Wyatt SB. The role of community health advisors in community-based participatory research. *Nurs Ethics.* 2010; 17(1):117–26. [PubMed: 20089631]
22. Whittle J, Fletcher KE, Morzinski J, et al. Ethical challenges in a randomized controlled trial of peer education among veterans service organizations. *Journal of Empirical Research on Human Research Ethics.* 2010; 5(4):43–51. [PubMed: 21133786]
23. Brugge D, Kole A. A case study of community-based participatory research ethics: The healthy public housing initiative. *Science and Engineering Ethics.* 2003; 9(4):485–501. [PubMed: 14652901]
24. Buchanan DR, Miller FG, Wallerstein N. Ethical issues in community-based participatory research: Balancing rigorous research with community participation in community intervention studies. *Prog Community Health Partnersh.* 2007; 1(2):153–60. [PubMed: 20208234]
25. Hyatt RR, Gute DM, Pirie A, Page H, Vasquez I, Dalembert F. Transferring knowledge about human subjects protections and the role of institutional review boards in a community-based participatory research project. *Am J Public Health.* 2009; 99(Suppl 3):S526–31. [PubMed: 19890152]
26. Marshall PA, Rotimi C. Ethical challenges in community-based research. *The American journal of the medical sciences.* 2001; 322(5):241–5. [PubMed: 11721794]
27. Michener L, Cook J, Ahmed SM, Yonas MA, Coyne-Beasley T, Aguilar-Gaxiola S. Aligning the goals of community-engaged research: Why and how academic health centers can successfully engage with communities to improve health. *Acad Med.* 2012; 87(3):285. [PubMed: 22373619]
28. Sharp RR, Foster MW. Community involvement in the ethical review of genetic research: Lessons from american indian and alaska native populations. *Environ Health Perspect.* 2002; 110(Suppl 2): 145–8. [PubMed: 11929722]

29. Santos L. Genetic research in native communities. *Prog Community Health Partnersh.* 2008; 2(4): 321–7. [PubMed: 20208312]
30. Khanlou N, Peter E. Participatory action research: Considerations for ethical review. *Soc Sci Med.* 2005; 60(10):2333–40. [PubMed: 15748680]
31. Anderson EE, Solomon S, Heitman E, et al. Research ethics education for community-engaged research: A review and research agenda. *Journal of Empirical Research on Human Research Ethics.* 2012; 7(2):3–19. [PubMed: 22565579]
32. True G, Alexander LB, Richman KA. Misbehaviors of front-line research personnel and the integrity of community-based research. *Journal of Empirical Research on Human Research Ethics.* 2011; 6(2):3–12. [PubMed: 21680972]
33. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA.* 2000; 283(20): 2701–11. [PubMed: 10819955]
34. Freedman B. Scientific value and validity as ethical requirements for research: A proposed explication. *IRB: Ethics and Human Research.* 1987; 9(6):7–10. [PubMed: 11650779]
35. Hasson F, Keeney S, BAM, McKenna H. Adv Dip Ed R. Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing.* 2000; 32(4):1008. [PubMed: 11095242]
36. Sawford K, Dhand NK, Toribio J-AL, Taylor MR. The use of a modified Delphi approach to engage stakeholders in zoonotic disease research priority setting. *BMC Public Health.* 2014; 14(1): 182. [PubMed: 24552445]
37. Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: Characteristics and guidelines for use. *American Journal of Public Health.* 1984; 74(9):979–83. [PubMed: 6380323]
38. Dalal SR, Khodyakov D, Srinivasan R, Straus SG, Adams J. Expertlens: A system for eliciting opinions from a large pool of non-collocated experts with diverse knowledge. *Technological Forecasting & Social Change.* 2011; 78(8):1426–44.
39. Khodyakov D, Hempel S, Rubenstein L, et al. Conducting online expert panels: A feasibility and experimental replicability study. *BMC Medical Research Methodology.* 2011; 11(1):174. [PubMed: 22196011]
40. Claassen CA, Pearson JL, Khodyakov D, et al. Reducing the burden of suicide in the U.S.: The aspirational research goals of the national action alliance for suicide prevention research prioritization task force. *American Journal of Preventive Medicine.* 2014; 47(3):309–14. [PubMed: 24750971]
41. Khodyakov D, Savitsky TD, Dalal S. Collaborative learning framework for online stakeholder engagement. *Health Expectations.* 2015; 10.1111/hex.12383
42. Rubenstein L, Khodyakov D, Hempel S, et al. How can we recognize continuous quality improvement? *International Journal for Quality in Health Care.* 2014; 26(1):6–15. [PubMed: 24311732]
43. Barber C, Marshall D, Alvarez N, et al. Development of cardiovascular quality indicators for rheumatoid arthritis: Results from an international expert panel using a novel online process. *The Journal of Rheumatology.* 2015; 42(9):1548–55. [PubMed: 26178275]
44. Barber C, Marshall D, Mosher D, et al. Development of system-level performance measures for evaluation of models of care for inflammatory arthritis in Canada. *The Journal of Rheumatology.* In Press.
45. Barber C, Patel JN, Woodhouse L, et al. Development of key performance indicators to evaluate centralized intake for patients with osteoarthritis and rheumatoid arthritis. *Arthritis Research & Therapy.* 2015; 17(322):1–12. [PubMed: 25566937]
46. Fitch, K.; Bernstein, SJ.; Aguilar, MD., et al. The RAND/UCLA appropriateness method user's manual. Santa Monica: RAND Corporation; 2001. Contract No.: MR-1269-DG-XII/RE
47. Frank L, Basch E, Selby JV. The PCORI perspective on patient-centered outcomes research. *JAMA.* 2014; 312(15):1513–4. [PubMed: 25167382]
48. Lucero, J.; Wallerstein, N. *Sage handbook of conflict communication: Integrating theory, research, and practice.* 2. Thousand Oaks, CA: Sage; 2013. Trust in community–academic research partnerships: Increasing the consciousness of conflict and trust development.

49. Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based research: Assessing partnership approaches to improve public health. *Annu Rev Public Health*. 1998; 19:173–202. [PubMed: 9611617]
50. Sankaré IC, Bross R, Brown AF, et al. Strategies to build trust and recruit African American and latino community residents for health research: A cohort study. *Clinical and Translational Science*. 2015;10.1111/cts.12273
51. Moreno-John G, Gachie A, Fleming CM, et al. Ethnic minority older adults participating in clinical research developing trust. *J Aging Health*. 2004; 16(5 suppl):93S–123S. [PubMed: 15448289]
52. Metzler MM, Higgins DL, Beeker CG, et al. Addressing urban health in Detroit, New York city, and Seattle through community-based participatory research partnerships. *Am J Public Health*. 2003; 93(5):803–11. [PubMed: 12721148]
53. Christopher S, Watts V, McCormick AKHG, Young S. Building and maintaining trust in a community-based participatory research partnership. *Am J Public Health*. 2008; 98(8):1398–406. [PubMed: 18556605]
54. Corbie-Smith G, Thomas SB, St George DMM. Distrust, race, and research. *Arch Intern Med*. 2002; 162(21):2458–63. [PubMed: 12437405]
55. Keeney, S.; McKenna, H.; Hasson, F. *The Delphi technique in nursing and health research*. John Wiley & Sons; 2010.
56. Basger BJ, Chen TF, Moles RJ. Validation of prescribing appropriateness criteria for older Australians using the RAND/UCLA appropriateness method. *BMJ Open*. 2012; 2(5)

## A Brief Commentary

### Background

The transfer of new discoveries into both clinical practice and wider community calls for reliance on interdisciplinary translational teams that include academic and non-academic investigators, which may require a re-consideration or expansion of the meaning of ethics in translational research.

### Translational Significance

Our findings suggest that the ethical principles that move beyond the traditional Belmont principles (e.g., grounded in trust, cultural appropriateness, community involvement) may be redefining the ethics of translational research and show that there is still much uncertainty about how these principles should be best achieved in practice.



**Table 1****A Two-Step Approach for Determining Group Results**

In the first step, the existence of disagreement among participants was determined. To do so, the value of Interpercentile Range (IPR), or the range of responses that fell between the 70th and the 30th percentiles, was calculated. Then, the value of the Interpercentile Range Adjusted for Symmetry (IPRAS), which is a measure of dispersion for asymmetric distributions, was determined and compared to the value of IPR. If  $IPR > IPRAS$ , the existence of disagreement was established.<sup>46,56</sup> Disagreement automatically produced an uncertain group rating.

In the second step, if there was no disagreement, the value of the median was used to determine whether the panel rating was positive, negative, or uncertain. A median score between 7 and 9 on a 9-point response scale indicated a positive rating displayed to participants in green font (see Online Appendix A). A positive rating meant that an ethical principle was considered important or feasible. A median score between 1 and 3 indicated a negative rating, meaning that an ethical principle was not important or not feasible, was displayed to participants in red font. A median between 4 and 6 indicated an uncertain rating, which was displayed in blue font.

**Table 2**

Demographic and Background Characteristics of Study Participants (%)

Demographic and Background Characteristics	Academic Panel (n=33)	Mixed Panel (n=30)	P value for difference in means	Combined Sample (n=63)
<b>Gender</b>				
Male	27.3	30.0	0.811	28.6
Female	72.7	70.0		71.4
<b>Race</b>				
White	81.8	86.7	0.729	84.1
Black	6.1	6.7		6.4
Asian	6.1	0.0		3.2
Other	6.1	6.7		6.4
<b>Hispanic</b>				
Yes	9.1	16.7	0.462	12.7
<b>Degree</b>				
Bachelor's degree	3.0	10.0	0.753	6.4
Master's degree	9.1	3.3		6.4
Professional degree	9.1	6.7		7.9
Doctorate degree (PhD)	54.6	56.7		55.6
Professional (MD) and doctorate degree (PhD)	24.2	23.3		23.8
<b>CEnR Experience</b>				
Yes	100.0	80.0	0.009	90.5
No	0.0	20.0		9.5
<b>Translational Research Type*</b>				
Pre-clinical/bench research	0	6.7	0.654	3.2
Treatment/intervention discovery & development	30.3	30		30.2
Health services/implementation research	27.3	16.7		22.2
Population health research	42.4	46.7		44.4
<b>Group</b>				
Researchers	100.0	63.3	<0.001	82.5
Community members	0.0	23.3		11.1
Other	0.0	13.3		6.4
<b>Organization</b>				
University	75.8	56.7	0.013	66.7
Community-based organization	0.0	16.7		7.9
Healthcare services agency/organization	0.0	10.0		4.8
Other (e.g., non-profit research institution)	24.2	16.7		20.6

Notes:

\*Participants were asked the following question: “Which statement best describes the type of research you typically conduct or are most familiar with?”

- Pre-clinical or “bench” research directed at mechanisms and presentations of human disease [Pre-clinical/bench research].
- Testing basic science discoveries for clinical effect and/or applicability [Basic science discovery].
- Testing new interventions in human subjects under controlled environments to form the basis for clinical applications and evidence-based guidelines [Treatment/intervention discovery & development].
- Research on the application of new interventions or therapies in general practice. Research that yields knowledge on best ways to implement new medical interventions in the clinic [Health services/implementation research].
- Investigations of factors and/or interventions that influence the health of populations; research that ultimately results in improved health of the public [Population health research].

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**Table 3**

## Importance of Ethical Principles

Academic Panel	Mixed Panel	Combined Sample
<b>Ethical Principles Deemed Important</b>		
Culturally appropriate (M=9)	Culturally appropriate (M=9)	Culturally appropriate (M=9)
Scientifically valid (M=9)	Scientifically valid (M=9)	Scientifically valid (M=9)
Grounded in trust (M=8.5)	Grounded in trust (M=9)	Grounded in trust (M=8.5)
Forthcoming with community about study risks and benefits (M=8)	Forthcoming with community about study risks and benefits (M=9)	Forthcoming with community about study risks and benefits (M=8.5)
Ready to involve community in interpretation and dissemination of findings (M=7)	Ready to involve community in interpretation and dissemination of findings (M=7)	Ready to involve community in interpretation and dissemination of findings (M=7)
Beneficial to community (M=7)	Action-oriented (M=7)	Beneficial to community (M=7)
		Action-oriented (M=7)
<b>Ethical Principles Deemed to be of Uncertain Importance</b>		
Community-driven (M=6)	Community-driven (M=6)	Community-driven (M=6)
Based on equal partnership (M=6)	Based on equal partnership (M=6)	Based on equal partnership (M=6)
Action-oriented (M=6)	Beneficial to community (M=6)	

Note: M=Median response

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**Table 4**

## Feasibility of Ethical Principles

Academic Panel	Mixed Panel	Combined Sample
<b>Ethical Principles Deemed Feasible</b>		
Grounded in trust (M=7)	Grounded in trust (M=7)	Grounded in trust (M=7)
Culturally appropriate (M=7)	Ready to involve community in interpretation and dissemination of findings (M=7)	Culturally appropriate (M=7)
Forthcoming with community about study risks and benefits (M=7)	Scientifically valid (M=7)	Scientifically valid (M=7)
<b>Ethical Principles Deemed to be of Uncertain Feasibility</b>		
Action-oriented (M=6)	Action-oriented (M=6)	Action-oriented (M=6)
Community-driven (M=6)	Community-driven (M=6)	Community-driven (M=6)
Scientifically valid (M=6)	Culturally appropriate (M=6)	Forthcoming with community about study risks and benefits (M=6)
Ready to involve community in interpretation and dissemination of findings (M=6)	Forthcoming with community about study risks and benefits (M=6)	Ready to involve community in interpretation and dissemination of findings (M=6)
Beneficial to community (M=6)	Beneficial to community (M=5)	Beneficial to community (M=5)
Based on equal partnership (M=4)	Based on equal partnership (M=5)	Based on equal partnership (M=4.5)

Note: M=Median response

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