Research Ethics Reconsidered in the Context of Community-Engaged Research:

Proposed Revisions to the Belmont Report and Federal Regulations Guiding the Protection of Research Participants

Contents

Introduction **1**

National Collaborative Team 1

2015 Proposed Revisions to the 1979 Belmont Report **3**

Preamble 3

Part A. Boundaries Between Practice and Research 5

Part B. Basic Ethical Principles: Proposed Additions and Revisions 5

Part C. Application: Proposed Additions and Revisions 8

2015 Proposed Revisions to the Code of Federal Regulations **10**

Terms and Defintions 10

Vulnerable Populations 11

Institutional Review Board (IRB) Membership 11

Categories of Research that are Exempt from IRB Review 12

Criteria for IRB Approval of Research 13

Informed Consent 13

Adhering to Laws and Procedures of Tribal/Sovereign Nations 13

Consideration of Long-Range Effects of Applying Knowledge Gained 13

Other 13

Acknowledgements **14**

References **15**

Introduction

Community-engaged research (CEnR) represents a shift from conventional research approaches that identify individual community members as research subjects to engaging with community members and the organizations that represent or serve them as research participants and partners. As a result of the wide scale adoption of CEnR principles and strategies, researchers and communities have grown dissatisfied with the regulations designed to protect the rights and welfare of individual study participants, persuasively arguing that such regulations do not sufficiently include nor operationalize the ethical considerations of CEnR.

Earlier work conducted by our National Collaborative team found that the Belmont Report, published in 1979 as the regulatory framework for the ethical conduct of all research with human participants, does not cover a wide range of ethical issues that arise in CEnR, and thus Institutional Review Boards (IRBs) that follow it may not provide a complete ethical analysis. For example, the Belmont Report does not include the CEnR commitment to community benefit nor do most institution-based IRB application forms query community perspectives regarding the justification for the study or what the benefits may be, if any, for the involved community.

Therefore, our goal in this project was to propose revisions to the Belmont Report and the federal regulations for research involving humans in light of the realities of CEnR. The ethical framework presented within the Belmont Report is intended to inform the federal regulations, which apply to most federally funded research conducted in the United States. These regulations inform the practices followed by Institutional Review Boards (IRBs).

In this document we present our proposed changes. These revisions build off of our previous research including a Greenwall Foundation funded survey that identified and described 109 community-based research ethics review processes (CRPs) from across the United States and an NIH funded cross-case study of five diverse CRPs. The revisions were further developed through a second Greenwall Foundation funded effort that included a review of the relevant literature,[1] four in-person feedback sessions held with CRP reviewers and other stakeholders followed by a national online survey of stakeholders with a vested interest in CEnR and/or research ethics.

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1 See page 15 for listing of the main articles that informed the proposed changes

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2015 Proposed Revisions to the 1979 Belmont Report

Our proposed revisions to the Belmont Report include a re-drafted Preamble and Part A, including both revised and new text.

In broadening the interpretation of the three guiding principles in Part B, we found that their applications are no longer limited to the three areas specified in Part C of the original Belmont Report: Informed Consent, Assessment of Risk and Benefits and Selection of Subjects. Additionally the revised applications of the principles often involve intersections of all three principles rather than representing instances of a single principle in operation. For these reasons we recommend that Part C no longer be organized by these three areas. Ethical research practices instead must be informed by all three principles. Additionally, we posit three core capacities for all individuals engaging in CEnR which, like the principles are often all required in overlapping ways during the course of research.

As an additional overarching change, we advocate for 1) replacing "subjects" with "participants", and 2) including "community" whenever the text talks about considerations regarding the individual participant. At times this may entail simply substituting "individual" with "individual and community," or "participants" with "participants and their communities." In other sections, parallel content specific to community considerations will need to be added. This new content is presented in the proposed changes listed below. Worth noting is that some of the language listed below contains verbatim text from the original Belmont Report.

Preamble

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions and resulted in harms to both individuals and communities. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes intended to assure that research involving human participants would be carried out in an ethical manner. During this same time, there were significant research abuses in the U.S. with many different vulnerable populations (within prisons, mental health institutions, institutions for children in poverty, and historically disadvantaged communities) as brought to light by Henry Beecher's landmark article in 1966, the New York Times breaking news of the 40 year U.S. Public Health Service study of untreated syphilis in Tuskegee, Alabama, and more recent conflicts between university researchers and tribal communities. While these research abuses made headlines, numerous other harms occur on a regular basis to both individuals and communities, which do not garner the same attention in the media. Close study of these cases makes it clear that a researcher's good intentions and basic research ethics principles and regulations are not sufficient to guide ethical research practices. We need a more responsive statement of research ethics, one that takes diverse perspectives and lived experiences into account.

The Nuremberg code consisted of rules, some general, others specific, which guide the researchers or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Further, the existing rules

and guiding principles focus primarily on individuals. Lessons learned in the intervening decades show ethical principles must also consider impact (harms and benefits) to communities, as defined by the people involved themselves. People from different backgrounds and experiences can interpret principles differently – what is seen as a harm for one person is not considered a harm for another, for example. Communities can also be defined geographically, racially, culturally, by disease condition, or otherwise. With this in mind, it can be challenging to have a set of rules or principles guide a diverse practice such as all research involving humans.

Three principles, or general prescriptive judgments, that are relevant to research involving human participants are identified: Respect for Persons and Communities, Beneficence, and Justice. Other principles may also be relevant.

Thirty-five years after the original drafting of these principles, we return to reconsider the guidance offered in light of the significant changes in research technologies and methodologies, historic and current research practices and abuses, and their evolving ethical considerations.

Since the 1979 edition of this Report, research and societal expectations have become much more participatory. The original framing of individuals engaged in research as "subjects", and hence, passive objects of study, is no longer tenable in the current climate.

We have revised the articulation and operationalization of the original Belmont principles through the lens of a relational, diverse, and participatory social context in which research now occurs. In addition to the re-conceptualized Belmont principles, we underscore three core capacities: humility, relational integrity, and accountability. These capacities are integral to all research involving human participants and are thus expected of researchers as they engage in research practices:

- **Humility:** Researchers recognize the limitations of their own experience and perspectives, and respect the diverse ways of knowing and considerable strengths that exist within communities. Humility requires a willingness to learn from others different from yourself, not assuming you already know what's best, and being open to a range of ways to proceed in research.
- **Relational Integrity:** Researchers recognize and respect how trustworthy relationships take time and resources. These relationships occur over time, and often extend beyond the scope of a particular study. Power imbalances must be considered and made transparent, including what is at stake for each party.
- **Accountability:** Researchers are accountable to the regulations and rules guiding research, as well as to any relational agreements established among study partners (e.g., partnership principles, memoranda of understanding). Individual researchers need to be accountable for institutional integrity and be ready to advocate for change when institutional processes risk disrupting trustworthy relationships.

Principles cannot always be applied to resolve particular ethical problems. The objective of outlining principles and capacities is to provide tools that will guide the resolution of ethical problems arising from research involving human participants. We therefore assert that this revised Belmont Report be treated as a living document, and remain responsive to the ever-evolving nature of research technologies and methodologies as well as the social and cultural contexts of people engaged in research.

Part A. Boundaries Between Practice and Research

It is important to distinguish between research and practice that involves human participation. The distinction between research and practice is often blurred where there are novel techniques or therapies being tried in practice. What counts as practice-based research and what is simply innovative practice is not always clear. Emerging research strategies such as learning healthcare organizations, pragmatic clinical trials, participatory-action research, and partnership-based research are particularly challenging to characterize as they apply research methods in practice-based or community settings.

For the most part, the term "practice", in settings of biomedical, behavioral, or social inquiry, refers to interventions that are designed solely to enhance the well-being of an individual person. By contrast, the term "research' designates an activity that is systematically designed to permit conclusions to be drawn. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. While these distinctions will continue to be challenged on a case-by-case basis, they remain a reasonable guideline for determining whether outside ethics review is warranted. While research and practice may occur concurrently, the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human participants and communities.

Part B. Basic Ethical Principles: Proposed Additions and Revisions

1. Respect for Persons and Communities

- A critical addition for the 2015 revision to principles guiding research ethics is that we recognize that respect is to be garnered by communities as well as individuals, and individuals as members of communities.
- Underlying assumptions for this addition include: individuals are members of communities and that such community identification(s) by self or others may necessitate additional ethical considerations; and, that communities themselves, beyond the level of individual members, are entitled to respect as autonomous social groups.
- The principle of respect guides us to carefully consider communities in whatever manner communities may define themselves (e.g., geographically, racially, culturally, by disease condition, or otherwise). While some communities are discernibly autonomous (e.g. sovereign tribal nations) with formal processes in place through which researchers must obtain community consent prior to recruiting and consenting individual research participants, other types of communities exist that are entitled to equal respect even in the absence of a formal community-recognized consent process. Respect for communities in this latter context may require participatory engagement with members of the identified community prior to research in order to develop study methods that minimize the potential for harm to individuals, community members (participants and non-participants), and the community as an entity itself.
- As the original Belmont Report asserts, "respecting persons is often a matter of balancing competing claims urged by the principle of respect itself." By adding respect for persons AND communities, we must consider additional protections due to the diminished autonomy (vulnerability) of some communities and populations that may be necessitated by factors such as historical mistreatment,

disadvantaged social and political status, inadequacy of resources and supports, degraded environments, and the complex interactions of these factors over the life course. Vulnerability must not be regarded as a characteristic of the community or population itself. Decisions concerning additional protections due to vulnerability for either individuals or communities should be "periodically reevaluated and will vary in different situations."

- Any determinations about vulnerability of individuals or communities should be done in consultation with members from that community. That is, decisions regarding "protections" should not be made by those external to the community without community input.
- Respect also requires that we consider how membership in a community may expose individuals to additional risks. Risks can arise when individuals are targeted for research due to an actual or perceived membership in a given community, or when the research process or outcomes stigmatize the community and/or when it conflicts with the shared values or beliefs of the involved community. These risks to the individual potentially can impact individuals regardless of their participation in the research. Researchers should identify potential stigmatizing risks in consultation with members of the involved community, and discuss them as part of the informed consent process.
- In addition to risks to individuals based upon actual or perceived membership in a community, respect also demands us to consider risks to the involved community. Community-engaged research points us to recognize the importance of equitable partnerships that recognize the community's expertise and time, and the importance of the research process and outcomes respecting the community's social and cultural context. Researchers must also consider how research can create conflict and tension within the community, and must take measures to reduce this possibility. For example, research findings can result in stigmatizing or further marginalizing a community, or increase divisiveness among its members.

2. Beneficence

- A critical addition for the 2015 revision to principles guiding research ethics is that we recognize that beneficence must be viewed through the lens of potential benefits and harms for communities as well as individuals.
- Individuals and communities must be treated in an ethical manner not only by respecting their decisions and protecting them from individual and group harms, but also by making efforts to secure both personal and community well-being.
- For research involving identified communities, beneficence also entails the community determining whether and how proposed research is important, relevant, and valuable. Such commitments fall under the principle of beneficence.
- In this document, beneficence is understood as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) minimize or eliminate harm and (2) maximize possible benefits. These complementary expressions apply to three levels of consideration: individual, the individual as a community member, and the community as a whole.
- For research involving communities, it is critical that the involved community have the right to determine what constitutes benefits and risks, and what represents a justifiable risk/benefit ratio. How this determination occurs will vary across communities. In some instances, the process will entail researchers listening and carefully considering the experiences and knowledge of the elders,

leaders or other community members. For example, the community may want to identify upfront (before any research begins) how a particular study's findings may translate into actions to benefit the community, such as through community capacity building and policy changes that address a community-identified concern or priority.

- The obligation of beneficence requires us to consider both the short and long-term consequences of the research process and outcomes. In the case of particular studies, researchers, community members and members of their institutions or organizations are obliged to give forethought to the maximization of benefits and the reduction of risk.

- No person or group can truly represent the views of every member of a community. Researchers must take precautions against assuming the involved stakeholders or individuals who hold formal leadership positions within the community represent the voice for the entire community. Precautions may entail, for example, hosting community forums or conducting listening sessions, to ensure a broad understanding of concerns and priorities.

3. Justice

- A critical addition for the 2015 revision to principles guiding research ethics is that we expand the principle of justice beyond distributive justice to include responsive justice, which is inclusive of considerations of redistribution, recognition, and responsibility.

- Hence the expanded questions of justice include:
  - Who ought to receive the benefits of research and bear its burdens?
  - Who decides what is experienced as a benefit or burden, given that different individuals and communities have different relationships to research and healthcare, and the institutions where those practices often originate?
  - Where does responsibility reside in a society with historic inequities and injustices to account for these imbalances in our current practices?

  These are questions of justice, in the sense of considering equitable access to research, recognizing the community's varied experiences with research, and responsibility to share power and resources. Equal access and opportunity to participate in research does not create a just outcome alone; issues of equity must be considered.

- To better highlight the extent of the abusiveness of the U.S. Public Health Service study of untreated syphilis in Tuskegee, and the federal government's sanctioning of it, the Belmont Report must include appropriate name and timeframe (1932-1972). Currently the Belmont Report refers to it as Tuskegee syphilis study, which fails to highlight the responsibility and role of the U.S. Public Heath Service.

- Injustices continue into the present day with the under-representation in research of whole communities such as indigenous people, ethnic groups, and protected classes[2] and as a result, their health status remains largely unchanged. When one group – institutionally based researchers – has the power to make decisions, determine protocols, decide what counts as harms and benefits, and distribute resources, inequities remain in the system.

2 "Protected classes" refer to those groups of people named in federal anti-discrimination law. See here for the index of protected classes: http://www.eeoc.gov/laws/types/index.cfm

- To address injustices, we need to develop policies that include affected communities in the decision-making processes that guide research and address their unique community priorities. This obligation comes from responsive justice: redistributing power and decision-making power, recognizing perspectives that are not yet heard, and for the group with predominant power and privilege (researchers and IRBs) to have the responsibility to assure community voices are included in decision-making.
- To achieve equitable participation, researchers may need to earn trust and cultivate partnerships with some historically disadvantaged groups before they will voluntarily engage with research.

Part C. Application: Proposed Additions and Revisions

- While the primacy of informed, voluntary choice of individuals to participate in research should remain, we submit that the principle of respect for persons and communities will require additional actions in many research contexts. Our assumption is that there are many ways to demonstrate respect, beyond informed consent, including developing a partnership agreement.
- Where appropriate, communities (via community representatives and/or leaders) should also be consulted and asked to give permission to conduct research that has the potential to have a community impact. There may be community-specific processes to pursue, for example, some communities have their own ethics review process that specify additional considerations.
- It is essential to consider potential risks and benefits of research to the individual and the community as a whole. Attention must also be given to the potential risks and benefits that may arise from an individual's membership to the community being studied or involved in the research process.
- The assessment of risks and benefits requires a careful review of relevant information, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the researchers, it is a means to examine whether the proposed research is properly designed taking into account the potential benefits and harms that may impact individuals and communities. These considerations should not be based solely on the researchers' assumptions regarding the involved individuals and community, and instead respect the involved community by ensuring its explicit role in determining what are the potential risks and benefits. For a review committee, it is a method for determining whether the risks that will be presented to participants and communities are justified and that the researchers have carefully considered the different levels of potential risk and benefit. For prospective participants, the assessment will assist the determination whether or not to participate.
- Risks and benefits of research may affect the individual participants, the varied communities of the individual participants, and society at large (or special groups of participants in society). Current codes and Federal regulations require that risks to participants be outweighed by the sum of both the anticipated benefit to the participants, if any, and the anticipated benefit to the involved society in the form of knowledge to be gained from the research. Current understanding of benefits prompts us to also consider what are the potential benefits to the involved community, which may include how the research will address a potential community identified concern or priority.

- Respect and justice considerations require that individuals from communities be consulted as the systematic assessment of risks and benefits are "balanced".
- It remains true that no particular group should bear the burdens of research, and no particular group (only) should gain the benefits. Diversity in participation and access to benefits is a necessary obligation of conducting research.
- In addition, responsive justice requires researchers and research review bodies to include the perspectives of those who are or may be impacted by the research to make determinations of fairness, respect, benefits, and harms.
- Finally, respect and justice together applies to a shift in viewing participants as partners in research rather than the "subject" of research. Community participation in the key decisions made during every phase of the research (development, implementation and dissemination) and equitable allocation of the research budget and resources are two examples of the application of justice in research.

Title 45 – Public Welfare
Department of Health and Human Services
Part 46 – Protection of Human Research Participants

Our proposed revisions to the federal regulations are categorized below as bulleted points. In some instances the bullets represent additional content, and in other instances modifications of the existing regulatory language. These proposed revisions align with our proposed changes to the Belmont Report.

Terms and Defintions

The current terminology, "human subject", is used throughout the regulations. We propose this be changed to "human or research participant" in order to demonstrate and respect one's active role in research.

- Replace the term "Institution" with the term "Institution, Organization, or Group" to move away from the presumption that all research is conducted by institutions when it is also conducted by community groups and/or community-based organizations.
- Use the culturally appropriate term "researcher" rather than "investigator." Researchers are defined as individuals who conduct research, whether they hold an advanced degree or not. In other words, the definition is broadened to also include community-based individuals, students and trainees who conduct research. The regulations currently suggest researchers are professionals or students only.
- Include a description of community to include:
    - No one definition exists.
    - It is dynamic and inclusive.
    - It is not defined solely by geography.
    - It can refer to a group that self-identifies by age, ethnicity, gender, sexual orientation, disability, illness or health condition.
    - It can refer to a common interest or cause, a sense of identification or shared emotional connection, shared values or norms, mutual influence, common interest, or commitment to meeting a shared need.
- Include a statement regarding the importance of recognizing the different kinds of risks posed and benefits afforded to an individual or group (i.e., social, economic, legal, physical, psychological).
- Include "the community involved in or impacted by the research" wherever the individual research participant is mentioned in the regulations. The phrase "the community involved in research" is defined as the community that is participating in the research and/or the communities that are most likely to be affected directly by the research, its conduct and/or its findings.

Vulnerable Populations

- We propose that the category "vulnerable populations", which currently include "children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons" to include historically marginalized populations, such as native/tribal communities, LGBTQ individuals, racial and ethnic groups, and individuals who are socially disadvantaged. We furthermore propose that "handicapped or mentally disabled persons" be referred to as "people experiencing a physical, emotional, behavioral, or mental disability."
- Although we recommend an expansion of the category of "vulnerable populations", the term itself risks being patronizing, if it does not recognize the systematic marginalization, harms, and oppression that exist within historic and current research practices. Rather than attributing characteristics to a particular group, greater emphasis must be placed on the ongoing mistreatment of certain groups due to their social status. This category needs further work, as we appreciate there are legal implications, as well as political and social implications of the term and who is included within it.

Institutional Review Board (IRB) Membership

- The IRB must be sufficiently qualified through the experience and expertise of its members to not only safeguard the rights and welfare of individual research participants, but of the communities involved in the research.
- Expand the definition of "diversity" in IRB membership to include ethnicity (the requirements currently include diversity among race, gender, cultural backgrounds and sensitivity to such issues as community attitudes). Furthermore, no IRB may consist entirely of members of one racial/ethnic group, unless it only reviews research that is conducted with only that racial/ethnic group.
- At least 1/3 of each IRB's membership must be "unaffiliated individuals" who are not currently nor have ever been affiliated with the institution/organization conducting the research and who are not part of the immediate family of a person who is or has ever been affiliated with the institution/organization (e.g. retired from said institution/organization). At least two of these "unaffiliated individuals" must be community members (community-based individuals with experience and expertise in community engagement, community-based research and/or community concerns about research). This is an expansion from the current language in the regulations that state "each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution."
- We propose that the IRB be required to include as voting members two or more members who are knowledgeable about or have first-hand experience working with communities engaged in research, thus giving greater voice and power to these individuals. These voting members can be community- or academic-based individuals.
- If an IRB regularly reviews research that involves one or more identified communities (e.g., defined by race, ethnicity, gender, sexual orientation, geography, etc.), the IRB must include as voting members two or more members who are knowledgeable about and experienced in working with these communities. These voting members can be community- or academic-based individuals.

- Under an expedited review procedure, the review may be carried out by two or more experienced reviewers designated by the chairperson from among members of the IRB, including at least one community member of the IRB. Current regulations specify only that one or more experienced reviewers conduct such reviews.

- Community members and unaffiliated members of the IRB must be selected outside of the institution's/organization's and/or funder's influence to prevent a conflict of interest. For example, the current group of unaffiliated members could review applications for these positions and recommend which to accept.

Categories of Research that are Exempt from IRB Review

- We propose that "research involving pathological and diagnostic specimens" be pulled out from the exempt category altogether due to past harms caused by this exemption (e.g., when specific communities were identified with the specimens and/or when cultural/community customs were not taken into account leading to significant harm on community and individuals).

- Due to circumstances, some communities, cultures, and situations may warrant a full panel review. Several categories of research that are currently exempted from IRB review can potentially pose risks to communities. As a result, they should not be automatically considered exempt. Rather, community risks must be assessed in these cases and mitigated for the research to proceed.

  - *Research involving the collection or study of existing data, documents, or records, [recommended removal of "pathological specimens or diagnostic specimens"], if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects"* – these existing sources of data could potentially pose risks to communities. For example, data collected for one purpose that individuals consented to that are now being used to study a different question that may be contentious or offensive.

  - *Research involving the use of educational tests, survey procedures, interview procedures or observation of public behaviour, if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."* – Depending on how the information is analyzed and presented it could potentially pose risks to communities. For example, if a particular data set, while not containing individual identifiers, can be linked to a particular community and leads to conclusions about the community, this could result in both harm to the community and harm to any individual associated with that community.

- We propose that IRBs thoroughly examine research proposals before determining exemption status, particularly if any "vulnerable populations" are involved. This will help ensure the research proposal will not override cultural or other critical considerations relevant to the involved community. For example, some of the above exempt categories could be harmful if associated with a particular community and/or ethnic group, and therefore would require IRB review.

Criteria for IRB Approval of Research

- We propose that the phrase "the community involved in the research" is defined as the community that is participating in the research and/or the community/ies that is/are most likely to be affected directly by the research, its conduct and/or its findings.

Informed Consent

- Community-level review and support must be granted along with individual consent where appropriate. Evidence must be provided that the community involved in the research is supportive of the research (e.g., approval by a community IRB or other community-based review entity, approval by a community advisory board, community leader letters of support, etc.). For tribal/sovereign communities, this must include evidence of community consent for the study (e.g., a tribal resolution). If the study does not warrant community review, the researcher should justify the absence of community consultation.
- Individual informed consent forms must include a description of any reasonably foreseeable risk to the community involved in the research.

Adhering to Laws and Procedures of Tribal/Sovereign Nations

- Currently, the regulations require compliance with any state or local laws or regulations, which provide additional protections for human research participants. We propose adding compliance with pertinent tribal/sovereign laws or regulations, with these laws and regulations taking precedence.

Consideration of Long-Range Effects of Applying Knowledge Gained

- IRBs must assess research risks and benefits to both the research participant and the communities involved in the research, including potential long-range effects of applying the knowledge gained in research as they relate to the communities involved in research.

Other

- We propose that the general public has an opportunity to provide comments on the list of categories of research that may be reviewed by the IRB through an expedited review procedure or deemed exempt from review. The public currently does not have opportunity to comment on categories, and there may be local circumstances that make some categories non-exempt.
- We propose that the IRB report out its findings and actions to all involved researchers and their institutions/organizations/groups involved in the study (e.g., co-investigators and/or designated individuals of participating institutions/organization/groups). Currently, the IRB communicates with the corresponding researchers and critical information may not be shared in a timely manner with other stakeholders (i.e., community partners).

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Listed below are key articles that significantly informed our proposed revisions to the Belmont Report and federal regulations.

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