

## HUMAN SUBJECTS PROTECTIONS IN COMMUNITY-ENGAGED RESEARCH: A RESEARCH ETHICS FRAMEWORK<sup>1</sup>

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**ABSTRACT:** IN THE 30 YEARS SINCE THE BELMONT Report, the role of the community in research has evolved and has taken on greater moral significance. Today, more and more translational research is being performed with the active engagement of individuals and communities rather than merely upon them. This engagement requires a critical examination of the range of risks that may arise when communities become partners in research. In attempting to provide such an examination, one must distinguish between established communities (groups that have their own organizational structure and leadership and exist regardless of the research) and unstructured groups (groups that may exist because of a shared trait but do not have defined leadership or internal cohesiveness). In order to participate in research as a community, unstructured groups must develop structure either by external means (by partnering with a Community-Based Organization) or by internal means (by empowering the group to organize and establish structure and leadership). When groups participate in research, one must consider

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risks to well-being due to process and outcomes. These risks may occur to the individual *qua* individual, but there are also risks that occur to the individual *qua* member of a group and also risks that occur to the group *qua* group. There are also risks to agency, both to the individual and the group. A 3-by-3 grid including 3 categories of risks (risks to well-being secondary to process, risks to well-being secondary to outcome and risks to agency) must be evaluated against the 3 distinct agents: individuals as individual participants, individuals as members of a group (both as participants and as non-participants) and to communities as a whole. This new framework for exploring the risks in community-engaged research can help academic researchers and community partners ensure the mutual respect that community-engaged research requires.

**KEY WORDS:** human subjects protections, research ethics, risks, moral agency, autonomy, community, community-engaged research, community-based participatory research; academic-community partnerships

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**T**HE NATIONAL COMMISSION FOR THE Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) was established in 1974 to identify the underlying ethical principles that would be the foundation for human subjects protections (HSP) in biomedical and behavioral research. In its 1979 Belmont Report, the National Commission identified and described 3 underlying principles—respect for persons, beneficence, and justice—that were to be operationalized by the requirements of informed consent, an assessment of risks and benefits, and the fair selection of research subjects (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The focus was on the protection and rights of the individual subject. The National Commission also wrote other reports focused on vulnerable populations (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1976; 1977), and these reports, in conjunction with the

Belmont Report, were incorporated into the federal regulations that are the basis for HSP in the United States (Department of Health and Human Services, 1981; revised 2009.)

In the 30 years since the Belmont Report, the role of the community in research has evolved and has taken on greater moral significance. Although the Belmont Report and the federal regulations derived from it were developed to provide guidance for both biomedical and behavioral research, they have been most useful in providing guidance for clinical trials that enrolled ideal patients under very controlled circumstances. Social science and behavioral researchers have long been critical that the requirements found in the federal regulations are cumbersome when applied to the type of research they perform and fail to consider the different types of risks that their research may pose (DeVries, DeBruin, & Goodgame, 2004; Eckenwiler, 2001; Morahan et al., 2006; Reynolds, 2000). Similar concerns are raised by researchers who attempt to ensure that research findings from phase 1 translational research (traditional bench to bedside research) are applicable in the community, where patients and their environments are less ideal. Such translational research now spans a continuum from T-1 (bench to bedside) to T-2 (extension of clinical trials into the community), to T-3 (which focuses on the development of Clinical Practice Guidelines and the research required to promote dissemination and diffusion of best practices), and T-4 (which focuses on determining the health impact of the new treatment on the health of the population) (Khoury et al., 2008). Specifically, academic and community research partners who engage in community-based translational research beyond T-1 express reservations that the federal regulations are not designed to regulate the types of research that must be conducted in order to understand and effectively modify human behavior to improve population health (Flicker et al., 2007; Malone et al., 2006). When writing the federal regulations, the National Commission did not anticipate that translational research would be performed with the active engagement of individuals and communities rather than merely upon them (Dresser, 2001). While such research may involve fewer direct process risks of physical harm, such research exposes individuals to risks of emotional, psychological and social harms, risks that may be compounded if outcomes reflect adversely on the communities about which and in which the research occurs (Eckenwiler, 2001; McGovern, 1998).

Another evolution since the writing of the Belmont Report is how justice should be conceived as a requirement of research. In the Belmont Report, justice focused

on ensuring an equitable distribution of risks and benefits. This required both that those involved in research should be the beneficiaries of the research; and that the inclusion and exclusion criteria are fair for those individuals similarly situated. The growth of community collaboration encourages a broader conception of justice. While community-engaged research is concerned about fairness in distribution, at its core community-engaged research is focused on non-distributive components of justice often referred to as social justice (Powers & Faden, 2006). Social justice includes ensuring that research priorities reflect the health needs of all socioeconomic communities, particularly vulnerable communities; and promoting institutions and social practices that support capacities for self-determination and ensure respectful interactions. This is best achieved if the individuals and communities who are the object of the research participate as partners at all stages of the research process: from agenda-setting to the development of policies based on the findings.

Collaboration with communities in research occurs along a continuum, the whole of which we will call Community-Engaged Research (CEnR), the terminology now used by the National Center for Research Resources (NCRR) at the National Institutes of Health (NIH). For many researchers and community partners, the ideal partnership model is the Community-Based Participatory Research (CBPR) model (Yale CARE, 2009). CBPR is not a methodology *per se*, but rather an orientation to research whose goal is that the academic researcher and community research partners are equal partners in all phases of research (Israel et al., 1998). Many research activities between academic institutions and communities, however, exhibit variable degrees of community participation and engagement and variability in the roles performed by the stakeholders. One literature review found four types of active community-academic research partnerships: one controlled by the academic researchers; one controlled by the community; one in which the academic researcher partners directly with the community; and one in which the academic researchers partner with one or more community-based organizations (CBOs) who represent various communities (Lesser & Oscós-Sánchez, 2007). Often the particulars of cases dictate different degrees of engagement, and we use CEnR to refer to all research that embraces collaboration among stakeholders whose common goal is to improve health (CTSA Community Engagement Committees, 2009).

The rising interest in CEnR generally can be seen as emergent moral sensitivity of the research community

to the value of engaging with the communities in which they seek to do research. The evolution was also spurred on by individuals and communities who have become cognizant of the value of the data, samples and information that they provide, and demand a greater degree of benefit-sharing and the right to engage as partners and participants (Dresser, 2001). CEnR can be best understood, then, as a bi-directional effort to respectfully and effectively translate clinical research into the community (CTSA Community Engagement Committees, 2009; Dresser, 2001). Collaborative partnerships incorporate the experiential knowledge brought to research by communities and their members, help ensure the effectiveness of treatments in real-world settings, and respect the research participants as ends-in-themselves—as individuals and groups with their own goals, values, beliefs and needs (Dresser, 2001).

This manuscript presumes the value of active community engagement and the intention of the investigator to engage the community in the process. It offers a research ethics framework focused on the risks intrinsic to the CEnR process, risks that were not fully envisioned by the National Commission (Childress, Meslin, & Shapiro, 2005). These risks are analyzed from the perspectives of the individual and the group, requiring an analysis of group structure and function. Potential benefits also accrue from the CEnR process at the levels of the individual and the group, and these are important because an analysis of risks cannot be fully appreciated outside of a benefit: risk analysis. Although groups or communities are not “human subjects” under the federal regulations governing research, it is essential for academic-community partnerships to address these issues as part of a comprehensive human subjects protection (HSP) program.

### Method

A seven-member writing team convened to develop a framework for providing HSP in CEnR. The team consisted of one academic researcher and one community research partner; four with specialization in human subjects protections with three who self-identify as ethicists and one in research subject advocacy; and one research associate with interest in HSP. Through iterative collaboration, the writing group developed a taxonomy and framework for the risks presented by CEnR. Implications were explored, and appropriate safeguards discussed. Two stakeholder meetings were held with numerous academic researchers, community research partners, community activists and other HSP program personnel.

At the first meeting, 6 additional academic researchers involved in CEnR were invited, as were 10 community research partners/community activists and 8 persons engaged in HSP. The stakeholders were asked to give presentations about the process of CEnR from the perspectives of the academic research partner and the community research partner respectively. Some were asked to describe the benefits, burdens, incentives and obstacles faced by those involved in CEnR, while others were asked to discuss specific ethical challenges that arise when doing research with communities that are both partners and participants. There were both large group and small group break-out sessions to give all attendees a chance to express themselves. Following this meeting, the writing team developed a taxonomy of risk, with a particular focus of exploring the breadth of risks faced by disparate groups. At the second stakeholder meeting, the writing group (minus the research subject advocate) met with 5 additional academic researchers involved in CEnR, 7 community research partners/community activists and 7 HSP experts to seek feedback on the ethical framework and supplemental documents developed to serve community-academic partners and HSP program personnel respectively. While there was much overlap in the participants who attended the first and second meetings, we intentionally made some changes to increase the diversity of viewpoints. All stakeholders at the second meeting were asked to comment on written drafts and most were asked to give oral presentations regarding strengths and weaknesses of the three documents.

### Definition of Community

Although it is common to hear people talk about the “African American Community” or the “South Side of Chicago community” or the “HIV community,” these entities are not established communities with internal structure, but groups of individuals with a shared characteristic (race/ethnicity, geography or disease respectively). Individuals belong to many such groups, some of which they belong to voluntarily, and others involuntarily, some of which they embrace, and others which are imposed upon them. Group membership may be defined at birth or later in life because of the development of some particular attribute. Traits may be permanent, due to genetic inheritance, or may be transient due to changing preferences or geographic mobility.

A community, by contrast, is a structured group—a group with its own social structure often with identifiable leaders. Communities may be formed because of

a shared characteristic, trait, experience, belief, attitude, interest, or historical event; but earn their status because they have an internal structure, identifiable leadership, and sustain themselves over time. Some communities are local; others are not defined by geography. Some communities have existed for centuries, others are newly formed, and others still are formed only for service delivery. Individuals are members of many groups simultaneously and have greater or lesser affiliation to particular groups at different times in their lives. Individuals may not even identify with certain groups, but others may ascribe membership to them. There may also be significant overlap of traits and membership between various groups.

The inherent variability in the definition and constitution of “community” is central to ethical analysis in CEnR. For the purpose of this article, we distinguish between structured groups—communities that exist irrespective of the research and have their own organizational structure and leadership, and unstructured groups that may exist because of a shared trait but do not have defined leadership or internal cohesiveness (Hausman, 2008a). Whereas established communities exist over time and have identity as a specific entity, members of an unstructured group may have no sense of shared identity and may even reject group association, even if third-parties define a group based on the particular trait. When referring to “the African American Community” which is an unstructured group and not a community by our definition, we place the word in quotes (e.g., “Community”).

Sometimes, academic researchers want to work with members of an unstructured group, and these groups can be empowered to have structure (or at least a subset of the group can be structured) for the purpose of the research. The structure may come externally (e.g., by partnering with a Community-Based Organization, or CBO) or internally (e.g., by empowering the group to organize and establish leadership). We therefore use the term community to refer both to pre-existing structured groups (established communities) as well as to unstructured groups that are structured for the purpose of the research either by external or internal sources. For example, we would consider a particular neighborhood Hispanic association to be a structured group (established community) while patients with obesity served by a hospital system to be an unstructured group. However, an unstructured group can develop structure. For example, obese patients may join together to become a formal organization (e.g., Overeaters Anonymous at the University of X) to provide mutual support to its members, to improve its negotiations with the hospital

system, or to become an active partner in obesity research. When an unstructured group develops structure and leadership, it becomes a community and can engage as a research partner with academic researchers.

### A Taxonomy of Risks in CEnR

The basic mission of HSP has been to minimize risks to the subject (risks to well-being) while preserving individual rights and autonomous decision-making (agency). Risks to well-being focus on physical risks, although for some research the potential social and psychological risks to individuals have also been identified as significant (Prentice & Gordon, 2001) and these risks often may have greater salience when research moves into the community. Risks to well-being can be due to the “process” (the risks that occur in the process of doing the research) as well as the risks that occur due to the “outcomes” of the research (Hausman, 2008a; 2008b). These risks may occur to the individual *qua* individual, but there are also risks that occur to the individual *qua* member of a group and also risks that occur to the group *qua* group (Hausman, 2008a; 2008b). The risks to the individual as a member of a group, like risks to the individual *qua* individual, may occur due to the research process (e.g., harms that occur when one is labeled and recruited because of membership in a group) and due to outcomes (findings about a group that are then attributed to the individual members). Risks to individuals as members of group can occur either by self-identification as a group member or by external identification as a group member. Risks to individuals as members of groups can occur whether or not a particular individual actually participates in the research; that is, the risks to the group may result in labeling of non-participants as well as participants. Risks to the group *qua* group are not commensurable with the accumulated risks to individual members; that is the risks to groups are not simply the sum of the risks to each individual in the group. Risks to structured groups (communities) include potential disruptions to the community’s structure (internal relationships), or function (both internal and external relationships), caused by the group’s collaboration with the researchers (process risks) and by findings that either prove or disprove the significance of a particular belief or trait (outcome risks) (Hausman, 2008a; 2008b; May, 1987).

In CEnR, risks to agency can be risks to individual agency or group agency. Risks to individual agency are addressed through the informed consent process and documented by the signing of a consent form. The process involves a robust discussion of risks, including both process and outcome risks that the research poses to the

TABLE 1. Risks to Well-Being and Agency at the Individual and Group Levels.

	Process Risks to Well-Being {1}	Outcomes Risks to Well-Being {2}	Risks to Agency {3}
Individual {A}	Physical and psychosocial risks of the research interaction	Physical and psychosocial risks of research findings	Risk of undermining personal autonomy/authority
Individual by group association {B}	Physical and psychosocial identity risks of the research interaction	Physical and psychosocial identity risks of research findings	Risk of group decisions undermining personal autonomy/authority. Risk of individual decisions undermining group autonomy/authority
Community {C}	Risks to group's structure and function because of engagement in research	Risks to group group's structure and function because of research findings	Risk of undermining the group's moral and sociopolitical authority

individual and to the groups with which he identifies, as well as a delineation of benefits and alternatives. Risks to group agency are addressed by the relationship-building that is required to form a partnership and may be formalized by the development of, and agreement about, a memorandum of understanding (MOU). If the academic researchers interact disrespectfully with a group and its individual members, the group's agency may be challenged, or even disregarded. For example, a researcher who devalues the cultural concerns expressed by a community's leadership and insists upon imposing his own method of recruitment may leave the community members unsure of their leader's moral authority or responsiveness to their needs. This in turn may have repercussions for relationships between community members and their leadership, between community members themselves; and even between the community and its relationship with other communities beyond the research context.

Table 1 delineates the three categories of risk: risks to well-being secondary to process, risks to well-being secondary to outcome, and risks to agency. It categorizes these risks to individuals as individual participants, but also to individuals as members of a group (both as participants and as non-participants), and to communities as a whole. Examples of each category as they apply to research participants are offered following the table. The table, however, also applies to academic researchers and community researchers. While researchers (both from the academic institution and the community) are not at risk for individual physical harms, threats to their moral agency arise from risks to reputation and trust. These risks are not limited to these researchers as individuals, but also to these researchers as members of the institutions to which they are affiliated, and to the broader research community.

The role of structure and lack of structure can be understood in reference to Table 1 as follows. Broadly speaking, both structured and unstructured groups are

susceptible to B-1, B-2 and B-3 risks, but only structured groups (communities) are susceptible to C-1, C-2, and C-3 risks. The community risks may be due to the research process (C-1, if participation causes internal strife), or to the outcomes (C-2, if the participation leads to findings that stigmatize or cause friction within the group). To the extent that the researcher-community partnership is not based on mutual respect, the community exposes itself to disrespect of its group authority by its participation {C-3 risks}.

As the above taxonomy demonstrates, engaging a group as a research collaborator greatly complicates the social and ethical dynamics of research beyond engaging individuals separately. Although individual research participants are members of various groups, and the process and outcomes of the research may have direct relevance to these groups {B-1 and B-2}, in CEnR, the community is a research partner and participant which raises concerns regarding (1) the process and outcome risks to the community {C-1 and C-2}; (2) the process and outcome risks to individuals through association with the defined group {B-1 and B-2}; (3) the risks to group agency {C-3}; and (4) risks to individual agency due to group decisions with which an individual may not agree {B-3 and C-3}. When engaging a community as a research partner, potential benefits and risks to the group should be included in the consent process to the extent that they are foreseeable.

*Examples of Risks*

BOX A-1

In a research interaction there are physical and psychosocial risks to participating individuals. For example:

- Blood is drawn for a sample; there is a risk of bruising.
- A drug is administered; there is a risk of adverse effects.
- A survey is performed; there is a risk of emotional distress.

BOX A-2

When the findings of research conducted on individuals are reported, there are physical and psychosocial risks to those individuals. For example:

- A patient experiences adverse clinical effects from an experimental drug trial and her condition is worsened. There is the risk that her poorer health status now makes her ineligible for other available therapies.
- A participant is informed she has tested positive for a genetic predisposition. There is the risk that she will incur psychological difficulty or damage to her social relationships.

BOX A-3

When an individual participates in research, there are risks to the individual's moral agency (autonomy). For example:

- Blood samples are taken as data for a cholesterol study to which the participant has agreed; but the samples are then used as controls for a genetic study on aggression without her knowledge—an area of genetic study that she does not support.

BOX B-1

When an individual or group participates in research, there may be risks to an individual who can be associated with a group—both participating and non-participating individuals. For example:

- In Native Hawaiian culture, blood is correlated with power. If blood samples are taken for a research study, participants may be at risk for being stigmatized by their cultural community.
- A study is underway exploring the high occurrence of Sexually Transmitted Infections in North St. Louis. Because of the group finding, an individual resident of North St. Louis might be labeled as likely to have an STI infection to explain vague symptoms which may delay proper diagnosis or may cause him social embarrassment.

BOX B-2

When the findings of research are reported and traits are ascribed to a group, there are risks to individuals who can be associated with the group whether or not they participate. For example:

- Studies showed a prevalence of the BRCA1 and BRCA2 genes, genes linked to breast cancer, in persons of Ashkenazi Jewish heritage (Streuwing et al., 1997).

The increased risk is ascribed to any woman who self-describes as Ashkenazi Jewish, whether or not she participated in the research (Merz et al., 2002), and this may result in higher insurance premiums.

- Expatriate Native Americans maintain group association by their biological heritage. Any study of genetic factors that enrolls these individuals can produce findings that, once ascribed to the genetic group, are ascribed to all associated individuals of that group, both on- and off-reservation and in- and out-of-study.

BOX B-3

When a group chooses to engage or not to engage in research, there are risks of the associated individual's moral agency being undermined. For example:

- The leader of an established community has established ongoing relationships with a research institution. He hears about a project and thinks it would be great if his community participated. Members hear about the project and are not interested as they believe that there are more important health priorities. However, they feel pressured to participate given that the leader has promised the cooperation of the community.
- The leader of a disease group has a bad personal experience with a researcher. The researcher now proposes a research project that may be of significant benefit to the group. The leader claims it is too dangerous and refuses to provide access. The other members of the disease group are unaware of the opportunity.

BOX C-1

When a community engages in the research process, there are risks to the group's cohesiveness and structure. For example:

- A community engages in research. Conflict arises within the community's leadership regarding the direction and extent of the group's participation. One leader loses respect within the group and is ousted. This disruption may adversely impact overall group cohesiveness or impair group effectiveness in any of its capacities.

BOX C-2

When the findings of research are reported, there are risks to the engaged group itself. For example:

- A genetic study of blood samples from the Havasupai Native American tribe traced the tribe's origins to Asia with migration across the Bering Strait to what is now Arizona. The Havasupai have traditionally

believed their origin as a people to be the Grand Canyon (*Havasupai Tribe of Havasupai Reservation v. Arizona Board of Regents*, 2008). Because the theory is contrary to the people's collective belief, it threatens their community's identity.

- Research found evidence of elder abuse among one Navajo community (Brown, 1989). The most prevalent form of abuse cited was neglect. The findings spurred self-critique and discord within the community because of its potential adverse impact on group solidarity and social traditions.
- A study of an isolated genetic community in Greece identified community members who were heterozygote carriers for Sickle Cell Disease (Stamatoyannopoulos, 1974). The community understood the condition to be very undesirable. Following the study, families came to require that their children investigate whether potential mates were carriers of the trait. In this way the traditional social operation of the community was disrupted.

#### BOX C-3

When an established community (structured group) engages in research, there are risks to the group's moral agency. For example:

- The Havasupai tribe grew concerned about diabetes in their community and sought to participate in a research study to address the issue. Investigators collected blood samples for the study and concluded that genetic factors were not the primary contributors to the community's diabetes problem. Unbeknownst to the tribe, the researchers used these blood samples to study genetic factors for conditions other than diabetes, including evolutionary biology and schizophrenia. The data may also have been shared with researchers at other institutions. The group's agency was harmed because they had not given consent for these additional uses of its samples.
- The Sephardic Jewish Congregation Mikvé Israel-Emanuel on the Caribbean island Curaçao is the oldest synagogue in continuous use in the Western Hemisphere and an isolated cultural community consisting of a few hundred individuals. In the 1960s, the synagogue's Board of Directors commissioned Dr. Isaac Emmanuel to write a comprehensive history of the congregation, but retained the right to prevent publication of unfavorable descriptions to protect the community as a whole and its individual members (Emmanuel & Emmanuel, 1970). More recently, an anthropologist named Alan Benjamin was involved in a lengthy negotiation with the congregation and its members to

develop a contract that would allow him broad access but again gave the community the authority to restrict publication to minimize potential harms to the community (Benjamin, 2002).

### Partnering with Communities

Partnership or collaboration, the fundamental commitment of CEnR, is conceptually distinct from both community consent and "community consultation". Community consent refers to permission given by a community to allow research to proceed. This consent may be critical for access and expresses at least some acceptance of the research project, but does not necessarily entail community involvement in any other stage of the research. In federal regulations promulgated in 1996 for emergency research, "community consultation" referred to the requirement to communicate with a community about emergency research for which the researchers sought waiver of consent (Department of Health and Human Services, 1996). The main goal is to inform the community about the research project and to gain its acceptance. However, the phrase "community consultation" is also used in the research ethics context to refer to the engagement of communities as a preliminary stage of engagement as a means to develop trust and build relations, to ensure that the research is of interest to the community, and/or to ensure that the researchers have appropriate language in consent forms. This latter conception of community consultation is more consistent with the focus on active community engagement in CEnR in which the community or community representatives play an active role in the research design, implementation, and analysis.

Partnerships in CEnR are quite different from the relationships formed in a traditional clinical project where the investigator and an individual form a research-participant relationship unencumbered by the participant's relationship to the structured and unstructured groups to which the participant belongs. Within this researcher-participant relationship, the focus is on potential physical and psychosocial harms and on respect for agency for the individual participant, without consideration of the harms that may accrue to groups of which she is a member. Group consideration is limited to the justice concern of whether individuals exposed to harms are members of the group expected to benefit from the knowledge gained. In contrast, harms in community-engaged research can arise from the multiple and complex relationships of individual group members to the researcher(s), the relationships of individuals to the groups in which they are members, the relationships of these groups to the

academic researcher(s), and the impact of group identification on the self-image of individuals (King, Henderson, & Stein, 1999).

How partnerships are created in CEnR and what additional psychosocial benefits and risks they may create will depend, in part, upon whether the group is structured or unstructured before the research is proposed, and the extent to which the leadership is inclusive and responsive (Montanaro, 2009). Partnerships require that groups are structured in order to possess and exercise agency (Nickel, 1997). Respect for agency focuses not only on the authority of the individual to provide consent, but also on the agency of the community as a moral entity and its authority with respect to its own members (and their individual agency), and in its relationship with greater society.

The engagement of groups as partners in research brings into focus the tension between the agency of the group and its individual members {B-3}. When researchers seek to partner with a structured group (that is, an established community), there are often easily identified persons to contact and with whom to establish point-of-contact relationships. Leaders of established communities may be determined by democratic means (e.g., the election of state governors) or by contract (e.g., the hiring of a clergyman by a church) or informally (e.g., everyone looks to the most vocal member to express their views). The legitimacy of the leader may be strong or weak, and this may cause cohesiveness or distress in the group. This is not to say that the leader of an established community is necessarily the right person with whom to negotiate research collaboration, but that the leader can delegate or encourage the community to select the leaders with whom the academic researchers should negotiate. This does not imply unanimity within the community in order for the research partnership to be legitimate. However, the less unanimity that exists about research participation within a community, the greater the risk that individuals may feel their agency to decide whether or not to participate in the research is threatened by their association with the group {B-3}. Thus without unanimity (which will always be rare) individual and group agency are in tension.

To facilitate collaboration with an unstructured group, the researchers may elect to provide the group with structure or help to empower the group to structure itself. To the extent that a group develops structure, the group becomes a community. When a group becomes a community, it becomes vulnerable to C-type harms, although established communities (communities that exist irrespective of the research) may be at greater risk for these C-type harms because the threat of dissolution and

factions is potentially more destructive when a group has a long and rich shared history.

Academic researchers may collaborate with an unstructured group by partnering with a CBO that will provide the leadership to facilitate community engagement. For example, a CBO that provides services to homeless people may find it useful to partner with researchers to document the health needs of this community. The leaders or group representatives may or may not be members of the community that they serve, and the individual clients may seek services from a number of CBOs with overlapping missions to address their needs. CBOs will differ in the degree to which they are responsive to the needs of their clients and inclusive in engaging their members in active participation and it behooves the academic researchers to ensure that the CBOs will remain respectful of and committed to clients who refuse to participate. The majority of risks to the members of an unstructured group represented by a CBO are A- and B-level risks.

The decision of a CBO to participate in research gives its individual clients greater negotiation power than they would have if academic researchers directly interacted with the individuals. This is true even if the group does not identify itself as an established community, but only as a group structured because of a shared need or mission. By serving as a conduit to the participants, the CBO can work with the academic researchers to focus on research that is designed to (1) address the actual needs of the community; (2) reduce harms due to lack of cultural sensitivity; and (3) provide some asset building either during or after the research is completed. The academic researchers also benefit because the CBO can facilitate recruitment for the academic researchers and can improve the research design because of knowledge of the group's culture and mores.

If there is no third-party source that empowers members of a group to function as a structured group, academic researchers may elect to create structure for a group and they may assign or select group leaders in order to engage in research with a community. If the leadership is selected by the researchers, there is the risk that the leader is not legitimate from the perspective of the group members. Therefore, it may behoove the researcher to empower the group and promote an internally developed group structure before attempting a research partnership. These unstructured groups that are structured by the research team may be the most vulnerable research collaborators because they often represent vulnerable populations who lack the resources or capacities to structure themselves and lack a third party resource focused on their needs and interests.

Even when a group partners with academic researchers, individual members still have individual agency and must decide for themselves whether or not to participate. To the extent that some individual members may feel some pressure to conform to the group, individual and group agency are in tension. Alternatively, when groups decide not to participate, individual members may choose to engage in similar research as individuals, again placing individual and group agency in tension. For example, if the tribal leaders of a Native American community decide that the community will not participate in a particular diabetes research project, the researchers may still enroll Native American participants who live in the city and do not feel obligated to abide by the tribal leaders' decisions. Clearly a comprehensive HSP program must be aware of these agency concerns and academic researchers must have a plan to ensure that the agency of individuals and the agency of the community are being adequately respected.

#### *Non-Participant Third Parties*

Regardless of the extent to which an individual member identifies with a community, an individual member may have his or her social identity challenged by the research findings discovered through participation of others who share a particular trait (Hausman, 2008a). Non-participants may be susceptible to B-1, B-2, and B-3 risks depending on the research project. For example, the development of a test to identify carriers of Tay-Sachs disease is relevant to both observant Ashkenazi Jews and non-observant Ashkenazi Jews. While it may be only those Ashkenazi Jews who are members of an established religious community (e.g., a neighborhood synagogue) who provide blood samples and are therefore at risk for the process risks of research participation {A-1}, both research participants and non-participants are at risk for (1) the process risks that accrue due to their affiliation with a "labeled" group {B-1}; (2) the outcome risks that accrue due to the identification of an abnormal mutation that is found within the Jewish community {B-2}; and (3) the need to decide whether or not to personally undergo genetic testing for reproductive decision-making {B-2}. The meaning of being a carrier may differ between these groups because the likelihood of marrying within the at-risk community and the attitude towards prenatal testing and pregnancy termination are different. Even those Ashkenazi Jews who are not married or not contemplating children may experience the outcome risk to social identity and potential for stigma by this research {B-2}.

Some members of "the Ashkenazi Jewish community" are not members of an established community; that is,

they are not members of a particular synagogue, but they still share a particular ancestry and religion (traits) with those who are. When a synagogue collaborates with academic researchers, the voices of the larger unstructured Jewish community may not be heard. For example, if the leader of the synagogue (the Rabbi) agrees to his community's participation in a genetic study of cancer risks, this may have consequences for whether individuals of the unstructured group are even offered the opportunity to participate {B-3}, although the outcomes may have direct impact on them {B-2}. The congregants, on the other hand, may feel compelled to participate even if it is contrary to their own preferences {B-3}. On the other hand, if the Rabbi rejects the research opportunity for his particular synagogue, those who belong to the synagogue may feel compelled not to participate regardless of the individual's own preferences {B-3}. If a particular community does reject the research opportunity, the researchers may seek to recruit Ashkenazi Jews from the general population who are not members of a synagogue in a more traditional researcher-participant encounter. These Ashkenazi Jews may participate without the benefit of "community" support or "community" negotiations for dissemination considerations or benefit-sharing, and their participation may have implications for the members of the synagogue even if the synagogue's leadership chose not to partner with the researchers {B-2}. In these ways there are threats to individual and group agency and well-being whether or not one belongs to a structured subset (synagogue) of the larger "Jewish community" (more accurately, the group of individuals who share a common Jewish heritage or ancestry), and whether or not one participates in the research.

#### **Benefit: Risk Ratio**

Although we have focused on the risks associated with CEnR, an exploration of risks alone is inadequate, because risks must be weighed against benefits. CEnR requires a comprehensive benefit: risk assessment that addresses the process, outcome and agency harms to individuals and to communities, the frequency and magnitude of these potential harms, and the impact that the frequency and magnitude of potential benefits may have on the toleration of risks. That is, in CEnR, both risks and benefits must be understood from the perspective of the individual participant, the individual as a member of a group, and the group itself. For instance, in a clinical drug trial, a participant may be told that there are potential health benefits for him {A-1 and A-2} or, if not, perhaps that data gathered from his participation may

benefit future patients {B-2}. In CEnR, there may be benefits to individual participants {A-1 and A-2}, to members of the group who participate {B-1 and B-2} (and even to members who do not participate {B-1 and B-2}) as well as benefits to the group through its participation {C-1 and C-2}. Benefits to the group may include social support through group participation {C-1}; greater understanding of the variability of a condition around which the group identifies {C-2}; greater understanding of the intersection of certain diseases with environment (e.g., why individuals who live near toxic dumps are at increased risk for health problems) {C-2}; or empowerment of the advocacy group in sharing in the decisions regarding study design {C-3}. The advocacy group may be strengthened by its own appreciation of its power to successfully negotiate and partner with academic researchers {C-1}, and by its ability to use its group cohesiveness/identity to lobby for greater resources for research on their health condition {C-2} or greater resources for its members {B-2} (including those who did not participate). The partnership may also lead to some identifiable benefits to communities, including employment for some individual members {B-1}.

Groups will place different emphasis on the distribution of benefits (e.g., whether to individuals or to the group) as well as to the distribution of risks. Groups will also place different emphasis on whether and how to minimize risks to individual members. As such, different structured groups may come to very different conclusions about the potential value of the same research project. It is also the case that individual participants, non-participant group members, and group leaders may evaluate risks and benefits quite differently. Some of this may be based on individual personality traits such as risk-aversion or one's attitude about social change; some of this may be based on the risks one experiences in other activities of daily living; and some may be based on historical experiences that lead to distrust about research in general.

Groups may also be able to demand additional benefits from research collaboration that individual participants in non-partnered more traditional research might be unable to negotiate. In traditional research, the research benefits are usually of two types: (1) advancement of scientific knowledge generally, and/or (2) experimental treatment for the participants. In CEnR, benefits may accrue not only from research participation and from the discoveries made, but also from the benefits to the community in terms of job opportunity, empowerment, access to services and resources, and collaboration in a research endeavor. And as a structured group, the group may have greater power to insist

upon greater benefit-sharing or in obtaining commitments to maintain the benefits even after the research data are collected.

In CEnR, the primary goal of the research partners may be less focused on novel research findings and more focused on the utility or efficacy of adopting or incorporating specific health care measures at the "community" level. However, whereas the academic partners may be focused on proving generalizability of a given intervention in a less than ideal research environment, the community partners may be focused on whether its members have access to the intervention, even if its efficacy is still being debated. This need not be problematic as the community partners and academic researchers do not need to share the same goals, although their goals do need to be compatible.

In traditional research, conflicts of interest (COI) arise when the academic researcher's primary interest (valid scientific discovery) is unduly influenced by a secondary interest (e.g., economic gain). In CEnR, the academic researchers, the community research partners, and/or the researcher-community partnership may have conflicts of interest that may influence their motivation for research participation or collaboration. Each party should be transparent about what it hopes to gain from the research collaboration and conflicts of interests must be disclosed in order to ensure a fair partnership {C-3}.

### Concluding Thoughts: 360 Degrees of Human Subjects Protections in CEnR

Risks to research participants can be focused at the level of the individual, of the individual as a member of a group, or at the level of the group. These risks include process, outcome and agency risks, risks that may be dynamic over the course of a partnership. It is ethically imperative that these risks are addressed because, practically, research with communities requires this level of mutual respect to be successful. In an accompanying article, we examine the issues that both the academic researchers and the community research partners must address throughout the CEnR process (see "The Challenges of Collaboration for Academic and Community Partners in a Research Partnership: Points to Consider," this issue).

We believe the new Clinical and Translational Science Award (CTSA) infrastructure presents a valuable opportunity to create sustainable partnerships between academic researchers and community research partners and to create an HSP program that can accommodate CEnR processes. To ensure that the rights and safety of

all subjects are promoted, and that the benefit: risk ratio is favorable, a variety of HSP mechanisms exist. In a second accompanying article, we consider how an integrated and comprehensive HSP program can address the potential individual and group risks and harms of collaborative research (see “Nine Key Functions for a Human Subjects Protection Program for Community-Engaged Research: Points to Consider,” this issue).

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