

CARE: Community Alliance for Research and Engagement, Ethical Principles of Engagement Work Group, and the Yale Interdisciplinary Center for Bioethics present “Community-Based Research: New Ethical Challenges”

Keynote, Dr. Jeremy Sugarman, MD, MPH, Harvey M. Meyerhoff Professor of Bioethics and Medicine, Berman Institute of Bioethics and Department of Medicine, The Johns Hopkins University
“The Ethics of Engaging Communities in the Health Research”

Dr. Jeremy Sugarman began his keynote address explaining the perspectives from which his view points come – ethics of HIV prevention research (especially the Ethics Working Group of the HIV Prevention Trial Network), research in the emergency setting (especially the Resuscitation Outcomes Consortium), and genetics research (notably a project called AGREE: Accessible Genetics Research Ethics Education), and a book he co-authored on the changing notions of justice and fairness in communities, *Beyond Consent*. Drawing on these influences, Dr. Sugarman outlined some general considerations related to community engagement – its types, its power, and its moral hazards, followed by a more focused discussion of one type of community engagement, namely community consultation. This included a discussion of recommendations and requirements for it, how it differs from community consent, its various types, and its ethical goals.

Calling on the conference members to clarify what type(s) of community engagement they seek to foster, Dr. Sugarman listed some examples, such as advocacy groups, which largely began out of the context of the AIDS movement, Community Advisory Boards (CABs), community “members” on IRB’s, as well as community sensitivity, preparedness, and permission. In addition, the conference needs to address the unique issues surrounding both community-based research (CBR) and community-based participatory research (CBPR). While the attendees seek to bridge the gap between the ivory tower and the community, but the myriad ways of doing this need to be clarified and made explicit before one begins discussing specific strategies. As he admitted throughout his talk, Dr. Sugarman seeks to make more complex areas that will become stagnant if left unexamined or are simply assumed.

In all of these types of community engagement, it is important to bear in mind that the ongoing revolution of technology and media impacts the way communities communicate and ought to revolutionize the ways researchers engage communities. By harnessing the power of social media researchers ought to seek to join conversations that are already taking place, as opposed to approaching the community from “on high” with a previously decided hypothesis to evaluate. If two-way dialogues are to be developed, then the communities ought also be allowed to help shape and drive the research. Rather than maintaining an “us vs. them” mentality in approaches to research, Sugarman stressed the need to openly and humbly engage the community and determine, alongside community members, the research that *needs* to be done.

Community engagement can be powerful. The early drug trials for AIDS, the first watershed example that Sugarman cited, fueled disease-based activism once it became clear that research could be therapeutic. Involving those who were diagnosed could clearly shape the research process. The growth of this view is epitomized in the 2007 guidance document issued by UNAIDS and the WHO, “Ethical considerations in biomedical HIV prevention trials.” This document required community consultation for HIV trials with all research stakeholders,

although the identities of the research stakeholders and the community(ies) remain unclear. Part of this conference's mission is to clarify these key definitions.

Expanding on his theme of power related to community engagement, Sugarman cited the contrasting research examples of genetic screening for Tay Sachs Disease (TSD) in Ashkenazi Jews and Sickle Cell Disease (SCD) in African-Americans that resulted in polar opposite effects on stigma and discrimination. If genes, such as TSD, SCD, and BRCA 1/2 are prominent among distinct communities, research stakeholders need to identify and seek to protect the possibilities of discrimination in housing, insurance, etc.

The powers of stigma, discrimination, and community control arise in unique and often heightened ways throughout international collaborative research. Dr. Sugarman used two concrete examples to highlight important issues. One revolved around a malaria vaccine in Africa. Once the researchers engaged the community, there was broad support for the research. This initiated a second problem, where recruitment had to be limited. The tribal leaders and community decided on drawing short and long sticks to decide who could enroll. In addition, since there was so much support for the research gaining informed consent from those who drew the long sticks was delayed by a few days. This alleviated the communal pressure of those who "got" to enroll. Sugarman praised these methods because the researchers were willing to change their preconceived plans and were open to the community's culture and suggestions.

A second example included a vaginal microbicide, which encountered culturally sensitive issues in the depiction of recruitment and enrollment activities. For example, in a recruitment brochure, a depiction of the woman on the cover was adjusted to reflect cultural norms. These studies highlight ways to successfully engage communities, but it is also important to be aware of the moral hazards possible in community engagement. Sugarman listed four main issues: 1. inappropriate or incomplete representation (in IRB's, or broader research discussions); 2. tyranny of the majority; 3. tyranny of the articulate, where those who speak differently, or not "academic speak," are unable to express their views; and, 4. self-interest among groups in the community that may divert the research to serve only their group and not the wider community.

Dr. Sugarman then focused on community consultation which has been employed in a variety of research settings, such as aboriginal and epidemiologic research, international collaborative research, and HIV-related research. This conference can learn and build on these important foundations, rather than trying to re-invent the wheel. In addition, it is important to remember that not all cases where community consultation is employed are necessarily contentious and the results of the research can be profoundly important.

For example, the fact that we now commonly see lifesaving automatic defibrillators in communal settings, such as defibrillators in shopping malls, resulted from research conducted in the emergency setting when consent was not possible, but would require community consultation before it is conducted. For research in the emergency setting when it is not possible to get consent, the IRB process in the US already includes certain requirements that go beyond other research: additional protections of rights and welfare, public disclosure of the research, a data monitoring committee, and the contact of family members. It is important to remember, however, that seeking advice and information in a community does not qualify as consent or permission when these are required.

Dr. Sugarman concluded his talk with four ethical goals of community consultation, since it is important to note for *what* we are seeking before we discuss *how* to do it. These included enhanced protection, enhanced benefits, legitimacy of the community's involvement, and shared

responsibility that allows both researcher and community to be equally engaged. These are four significant goals and they are discussed in the working groups, described below.

Based on questions from the audience, Sugarman was able further to explain some of his points. First, questions surrounding community research arise in multi-site as well as single-site trials. In both cases, integrating both the local and global communities becomes complex. For example, “Does a CSW in Thailand speak for a CSW in Manhattan?” A second point contended that it seems as if we seek to better safeguard and care for those outside the US than those within. Sugarman pointed out programs at the University of Pittsburgh (CRAB) and Johns Hopkins (Environmental Justice Partnership) that are seeking to partner with American communities. Finally, an audience member wondered whether there is a trend toward developing a set of standards for protecting communities akin to those that exist for human subjects. While there have been proposals in some settings, such as genetics research and research in the emergency setting, Sugarman urged attendees at the conference to address whether such an approach is needed and if so, how it might be operationalized.

Working Groups

In order to enable true community-university collaborations in research to operate, partners must develop a set of mutually agreed upon definitions, policies and procedures. Each of the Work Groups today is charged with answering questions about a key functional element of this relationship with the goal of identifying answers that will permit such partnerships to conduct mutually beneficial research.

Group 1

Seeking to define “community” and “community-based research” and provide guidelines of legitimate forms of the latter, this working group acknowledged the myriad forms that communities take and the fluidity that must be inherent within any definition. All communities, however, are guided or unified by some purpose, broadly considered, whether it is an interest, a lifestyle, religious affiliation, activities, or such commonalities as population, geography, environment, and ethnicity/race. In addition, researchers ought to be aware that people often belong to multiple communities, and that strata exist within each community; one voice of that community might not speak for the entire community. Identifying leaders or a leadership structure within communities that are characterized by credibility and trust is crucial for consulting them as representatives of their community. Nonetheless, the complexity of this question remains - “Who represents the community?”

The fluidity of these definitions ought to be acknowledged, since it is unclear what research on human beings is *not* community based. It is best to bear in mind a continuum between clinically based research and community based research, rather than a strict delineation

Starting with this working definition of community, the group then discussed distinct characteristics of community-based research. Over against clinically based research, which focuses on addressing a medical need, often reflects higher sensitivity, and is not required to involve women and minorities or seek a community’s benefit, community based research usually seeks to address a public health concern. It is broadly applicable and the study itself does (or ought to) reflect to some degree the resources and needs of the particular community, rather than

a solely medical or academic hypothesis. Those “researched,” rather than being passive subjects, are incorporated into the research process..

Within community based research, community based participatory research (CBPR) seeks to engage the community at a higher level, where community leaders drive, organize, and are built into the research methods. In the this type of research, the community chooses topics, develops projects, collects data, translates the basic intervention(s) into appropriate language, applies the research toward changes in behavior and practice, and seeks to impact policy. The “systems approach” of CBPR pursues these avenues in research of broader systems, such as transportation, safety, economics, and the toxic or built environment.

Group 2

The second group was charged with the task of identifying central tenets for ethical principles of community-university partnerships in research. Building on the foundation set by Dr. Sugarman’s suggestions, this group made explicit the ethical goals of these partnerships: enhanced protection beyond that which exists in research that is not community based; enhanced benefits for the communities; legitimacy; and, shared responsibility. They also acknowledged the importance of the ethical principles from the Belmont Report – beneficence, justice, and respect. Efforts to achieve these goals can be separated into two main foci – implementing and maintaining *parity* and focusing on long-term *sustainability*. Efforts that seek parity in the community-university research partnership include:

- gaining *authentic input* from key members in the community
- addressing the *diverse agendas* that come from a variety of sources in both the community and university
- recognizing that science has a *mutuality* to its development, such that openness to input does not sacrifice scientific rigor or evidence-based and theory-driven research
- obtaining *honest expectations* with regards to the limits of the research from both sides
- promoting *open communication and dialogue*, for example through record keeping and documentation
- maintaining a *consent process* on two levels, with gate keepers for access to the community as well as consent of individuals
- respecting *community identity or diversity* and *cultural competency* in developing partnerships
- involving both parties at an *early stage* in the research, which allows for more genuine community engagement
- developing a *living document* with agreed-upon guidelines that respect the dynamic and changing nature of the partnership.

The last effort above serves as a helpful bridge to the efforts that look toward the long term in promoting sustainable relationships beyond single project collaborations. These strategies include:

- identifying the “*go-to*” *members* of the community for authentic feedback and allowing them to give voice to the community’s needs and priorities
 - this can be enhanced by developing a *database* of potential collaborators and authentic voices, utilizing social networks

- setting up *infrastructures and processes* at the community and university level for review and ongoing work
- developing the researchers' community competence and the community's competence of research through *training and education*
- planning *dissemination* that involves all partners of the research
- implementing ideas of *flexibility* where the project can be initiated from either partner, such as *co-investigators* or *shared authorship*
- developing a *university resource center* that facilitates working within the community on diverse projects
 - this may include: guidance and training; templates for budgets, dissemination, agreements, mou's, etc.; an ombudsman role of mediation between community and researchers; and, a library of de-identified case studies for training and problem-solving.

Group 3

The third working group was charged with considering new methods of community and IRB review of CBR. All of these suggestions and models are meant to empower the community in the research review process.

Having discussed ways in which the research review process takes place in various university and community settings, the group divided their suggestions into four areas of responsible players: IRBs, community review models, researchers, and institutions.

For IRBs, it is important to

- define the scope of each individual IRB (e.g. the unique scope of the Yale Medical School IRB vs. the IRB on Yale's main campus). The scope of its role as well as its applicability can often become confused.
- educate both the community and the researchers regarding the IRB process, since some schools have multiple IRBs, some have one, and sometimes outside IRBs are involved.
- enhance the quantity and expertise of IRB community members. Education and training can be provided for the community member(s), and a diverse membership of laypersons and disciplines ought to characterize the IRBs.
- require proof of community review in the researcher's proposal, via MOAs or letters of support from the community entity involved in the research.
- provide infrastructure support for community agencies.

A recurring issue for IRBs is the recruitment of community members to sit on the boards. Most often this takes place by researcher or IRB member contacts and "word of mouth." Beyond these typical methods, numerous other opportunities exist:

- The institution could create an official and funded position for interacting with the local community that includes recruiting valuable and insightful members of the community
- Many cities have volunteer bureaus, on which the opportunity for serving on the IRB could be listed.
- Community based organizations (CBOs) and their boards as well as elected officials and their offices could be contacted to attract new members to represent the community on the IRB.

In considering possible community review models, no one in the room was aware of a community IRB that exists completely independent of a research university or hospital, although this is a possible model.

Other models identified include:

- The Lawrence, MA city government model consisting of an office (which a facilitator of this group holds) to serve as mediator and special relations person to the community and researchers;
- The creation of a community advisory board, akin to the scientific advisory board that already exists on many IRBs to review studies before they reach the IRB proper. In the same way that all IRB members cannot possibly be experts in all scientific disciplines, they should not be expected to be well-versed in all community issues;
- The use community consultants who consult with IRBs according to their area of expertise. As previously mentioned, one community has many strata, so IRBs might incorporate certain experts who would only be consulted for individual studies. For example, a local advocate in domestic violence might be part of the review process of a protocol addressing substance abuse and domestic violence, but it might be untenable to make that person a permanent member of the IRB.

In addition to the IRB and community roles, the researchers bear responsibilities to engage the community:

- Early engagement with the community, rather than appearing “out of the blue” with a hypothesis, ought to be a part of the researcher’s activities;
- Contact with city government and community agencies, either through public relations persons or officials, would also improve the researcher’s relationships with the community and empower the community and scientific rigor of the research with knowledge of the boundaries to which they can commit the institution they are representing, so as not to create false promises or expectations;
- Researchers could also seek to not only educate themselves about the community in which they hope to research, but also try to become a member of it in ways that do not directly relate to their research, such as volunteer opportunities;
- Dissemination of research findings to the community is an essential building block of community trust.

The institutional demands of improved CBR are myriad as well:

- Official training of their researchers as well as internal dissemination of community knowledge would support the researchers in their task and begin to promote better CBR as a highly regarded value;
- Mentorship programs, taking advantage of the experienced researchers at the university, could also enhance collaboration that often gets ignored amidst busy schedules and over-extended professionals;
- An institutional awareness of the community issues and the important community officials already working on these issues would also begin to change the research culture and to promote greater community awareness and respect.

This institutional support could help insure that the research proposals being brought to the IRBs perform ethical CBR.

The group identified the following beginning activities to enhance community input into the research, understanding that resources on all sides are always more limited than desired:

- The IRB can require a letter of support from the community agency involved in the research;
- The IRB can seek consultation from a community advisor on community-based research;
- The community can support IRB recruitment of community representation on IRBs
- The university and community can jointly develop educational sessions on understanding the community, and understanding research
- Consultative support to community entities can be provided by the University on the conduct of research, and ways to develop the infrastructure to support it.

Finally, possible standards for IRB approval ought to keep in mind the following foci for community:

- the relevance and benefit to the community; possible legal issues or harm to the community;
- the acceptability of the research to the community; the feasibility of the research in the community;
- the required and available resources (financial or other); and,
- whether or not the targeted population is appropriate for the research.

Having provided these suggestions for IRB involvement in CBR, it is always important to bear in mind a common theme that has arisen throughout this conference – flexibility – since all communities and institutions are unique. Openness to this overarching theme may provide the foundation out of which these ideas can succeed.

Group 4

This work group was asked to identify essential training approaches and educational material for researchers and community leaders. The group agreed that the concepts of community and community-based research are largely new to both academia and to community members and that a collaborative approach to the development of appropriate curricula and training be tailored to different target audiences. The group was given 4 questions to help with this task.

- 1) What are the essential training components for parties interested in undertaking research in community settings, both from the perspective of the University and the Community partner?
- 2) What training methods are most effective at teaching the fundamentals of developing collaborative working relationships with community organizations?

The group answered questions 1 and 2 together by stating the beliefs that community engagement needs to be integrated institutionally, it needs to reflect the values of research beyond clinical trials, and that the community-university partnership ought to strive for *reciprocity*. The resulting training approaches will promote dialog for reciprocal learning and understanding and will focus on the development of mutual benefit, respect, and trust.

And, that both Community and University involvement be characterized by:

- High levels of Transparency,
- Humility
- Listening and Responsiveness (in that order)

3) Outline the key topic areas for the development of on-line training components (cultural competency)? And what is the necessary technical assistance to support the on-line education? The group outlined a two-pronged training approach to question 3:

- a. First, an online component which will include universal items that all university and community members will be exposed to.
- b. Second, a more comprehensive and dynamic component to focus on communication skills, cultural and community sensitivity, partnering mechanisms, and problem solving techniques to help manage diverse partnerships. This second training approach can include the following:
 - role-plays,
 - deliberation and discussion
 - sharing stories (through films, videos, or pod casts (cf. NPR's "Story Core"))
 - community events (potluck meals, concerts, etc.,)

4) Define the overall process for developing the training approach—identify potential obstacles that must be overcome in order for this process to be successful.

In answering question 4, the group restated the need for a major **paradigm shift** in how community work is viewed within academic settings. Group members spoke about the need for sustained support within the institution to promote the new paradigm. Here is a list of suggested institutional changes:

- Create a "hub" where information can be shared across the university/state/globe
- Create an office of community engagement (for health and social determinants) within the university
- Fold into established educational and training requirements a community internship for students and junior faculty