This module covers the application of research ethics in community-engaged research. The core ethical principles are the same as in biomedical research. However, since researchers using a community-engagement approach form partnerships and collaborate with community organizations, the ethical questions can be different from those commonly encountered in biomedical research.
Introduction

Working with community organizations on collaborative research adds another dimension of ethical issues for researchers to consider. Researchers must be open to understanding communities’ values and priorities when conducting research collaboratively with community organizations.

This module introduces ethical concepts and considerations for conducting community-engaged research.
Community-engaged research is a different approach from much of the research done at medical schools and other health research institutions. Community-engaged research involves working with community agencies and organizations, building partnerships, and collaborating to STUDY health problems that affect a community. In the process researchers learn about communities and community organizations and community organizations learn about research and researchers. Because the research is conducted in “the real world” of a community results may be more easily translated to practice.
The term “community” can be vague and may refer to a neighborhood, city, county or other geographical area made up of many different groups who think of themselves as communities. It can also refer to groups with interests or health issues in common who do not share a geographic location. Although a “community” is defined by at least one commonly-shared characteristic, individuals and groups that make up a community may also be diverse by socioeconomic status, religion, race, or ethnicity.

How do researchers work with “the community” when it may be made up of many different groups?

Who represents “the community?”

Elected officials formally represent the entire community in governmental affairs: city council and county commission members, aldermen, the mayor and others. Outside of this formal representation there are agencies such as the local health, mental health, and housing departments that provide services for residents and may advocate in their interests.

At the community level there are organizations of residents around common interests, needs, service provision and political issues. These may be neighborhood associations, non-profit service organizations, advocacy groups, unions or political organizations. Examples include: support organizations for victims of domestic violence; political groups supporting causes such as clean environmental policies; tenant organizations; associations to advocate for fair treatment and enforcement of existing laws (such as the NAACP or NCLR the National Council of La Raza); organizations of new immigrants who want to help each other; etc. Faith based community organizations such as churches, synagogues and mosques also represent the interests and values of their members.

Because such community-based organizations have governance structures, leadership and memberships they are able to form formal partnerships with researchers for community-engaged research projects. Partnerships with community organizations make the ambiguous term “the community” specific: these organizations with identifiable interests, concerns and members represent segments of the larger community.
What should researchers do when:

- Community values are different from those of the researchers and conflict with the planned research methodology?
- Members of community partner organizations have different perceptions of what constitutes “risk”?
- Releasing research results may stigmatize an entire community?

The process of developing equitable working partnerships with organizations that are outside of the academy may raise ethical questions that researchers have not considered before. Researchers must be open to understanding communities’ values and priorities when conducting research collaboratively with community organizations.
This module covers the ethical principles that guide research with human subjects and how they may be applied to community-engaged research. Community-based research involves protecting individuals from research risks, as well as considering community-level concerns. Community-engaged research involves partnerships with community organizations and agencies, groups that may see the process and consequences of research very differently from the researchers. Conducting research with community partners may involve decisions about ethical behavior in relationships where power and control are not equal among partners.
1. Ethical Principles of Research

Learner objectives:

- Identify and describe the 3 ethical principles that guide research involving human subjects
- Identify the ethical principles that guide community-engaged research
- Identify the group that reviews research protocols for community-engaged research
The Belmont Report 1979

- **Respect for persons**
  - individual autonomy
  - protection for individuals with reduced autonomy
- **Beneficence**
  - Analysis of risks and benefits, minimization of risks
- **Justice**
  - equitable distribution of burdens & benefits

The Belmont Report was developed in response to the discovery of research abuses, such as those of the Nazis and of US researchers (the Tuskegee syphilis study, Willowbrook State School and others). Scientists, ethicists, funders, the Federal Government and others concerned with research realized that there needed to be agreed upon fundamental ethical principles guiding research with humans.

The ethical principles established in the 1979 Belmont Report were used to develop Federal regulations for the protection of human subjects (1981). After their acceptance by 17 Federal Agencies or Offices, these regulations (codified at title 45, part 46 of the code of federal regulations) became known as the Common Rule (1991). Institutions established Institutional Review Boards (IRBs) to oversee and enforce these regulations for the conduct of research. Research with human participants that receives Federal funding must comply with the Common Rule and regulations promulgated by the Office of Human Research Protections (OHRP). Certain types of research are specifically exempt from these regulations.

The Belmont principles of respect for persons, beneficence and justice are the core values that should guide how researchers conduct research. They are the foundation for human research protections and for the development of regulations that apply to community-engaged research as well as to traditional biomedical research.

The ethical principles governing community-engaged research are the same as those used for any research with human participants. Community-engaged research must meet the same standards and comply with the regulations that govern biomedical research, such as clinical trials. Community-engaged research must be reviewed by an IRB.”

The next section will explore how biomedical research, including some community-engaged research, may present different dimensions of ethical questions.
Scientists, ethicists, funders, the Federal Government and others concerned with research realized that there needed to be agreed upon fundamental ethical principles guiding research with humans. In response to concerns about unethical research on vulnerable subjects—such as prisoners of war, children and the institutionalized—the Belmont Principles focused on protecting *individuals* from research abuses.
The Belmont principles have guided the protection of individuals participating in research since their development in 1979. However, since the 1980s research approaches have increasingly included collaboration with communities. Some researchers and ethicists have criticized the existing system of human subjects protections for its sole focus on individual protections and lack of explicit protection or consideration for communities.
Limitations of the Belmont Principles for Community-engaged Research

- Use a biomedical framework
- Focus solely on the rights of the individual
- Lack ethical precepts for:
  - community collaboration and consideration of culture
  - the ethical conduct of research with community partners
  - community level risks

Many researchers who use a community-engaged research approach have found that the biomedical framework and the individual rights orientation of the current system of human subjects protections make including community concerns challenging.

The biomedical framework is the system of thought practiced by most researchers in health and medicine. It follows the scientific method and primarily uses quantitative data. The biomedical framework has a strong heritage of belief in scientific objectivity and impartiality rather than the post-modern approach of multiple truths and viewpoints common to the social sciences. Many Community-engaged researchers are also based in biomedical research: the two approaches are not mutually exclusive. The Belmont Report was written to guide medical and behavioral research and the language used is “researcher” and “subject”: a reflection of the biomedical approach.

Since the 1980s ethicists have critiqued the Belmont Report’s focus on the individual and the lack of protections for the community. In 1999 bioethicist Charles Weijer wrote: “I believe a fourth ethical principle must be added to those found in the Belmont Report: the principle of “respect for communities.” In 2001 the National Bioethics Advisory Commission “proposed that regulatory oversight for research with human subjects be extended beyond the protection of individual research participants to include the protection of social groups.”

(Risberg, Hamberg et al. 2006; Weijer 1999; National Bioethics Advisory Commission 2001; Sharp, Foster et al. 2002)
What kind of differences exist between Individuals & Communities for ethical decision making?

- How are individuals different from communities and community organizations?
- In what ways are the risks and benefits of research different for individuals than for communities?

Conducting research with community groups as partners brings some different ethical dimensions to the research enterprise. Identifying the research risks and benefits for communities requires conceptualizing communities as entities that may be harmed or helped by research. The community level risks and benefits may be different from the risks and benefits for individuals.

How does this difference affect ethical decision making? Why would communities need protection? How should ethical decisions be made when individual concerns and community concerns are in conflict?
For example, an individual may decide to risk temporary discomfort (providing a blood sample) and enroll in a study that measures blood lead levels of residents who live in different city neighborhoods. If a resident’s blood lead level is high the study will provide treatments to reduce it: an individual benefit.

At the community level, when results are released neighborhoods with high blood lead levels may be stigmatized as “unhealthy.” Residents may move out of the neighborhood to escape the lead exposure and others may not want to move in for the same reasons, causing a decline in the neighborhood: a community level risk.

Yet findings of elevated blood lead levels in a neighborhood may make it eligible for special lead abatement funding to remove the sources of lead: a community level benefit.
Generally autonomous individuals are able to weigh the benefits and risks of participating in research and make a decision based on their own understandings of the research, their own values and interests and their own circumstances. These decisions are personal and, although in some cases may affect family and friends, primarily affect the person making the decision.

If an individual decides to participate in a research project he or she signs a consent form. If an individual is not capable of giving consent—due to health, mental competency or other conditions—he or she is protected as provided for in Federal regulations.
Deciding what organization represents “the community” can be difficult. Should it be elected officials? the mayor or county commissioners? Or should a coalition of community organizations represent the community? What if the community is not geographically based, such as an interest group?

Since communities are made up of people who may hold different views and priorities, ethical decision making is more complex. Instead of one person weighing the benefits and risks of participating in research based on their own understanding, there may be many people making a decision on whether or not their community should participate in a research project.

As covered earlier, community organizations and agencies represent parts of the community, although few claim to represent ALL community members. Community-engaged researchers generally form partnerships with community organizations and agencies who share concerns about the health issue under research. Sometimes community organizations or agencies contact researchers about community health issues.
As of 2009 the US Office of Human Research Protections (OHRP), which maintains regulatory oversight over human subjects research, had not established additional guidelines or recommendations specifically for community-engaged research. However they have discussed the need for a clarified and consistent policy on IRB exemption or expedited review of Community Based Participatory Research (CBPR) projects.

Some agencies, funders and academic institutions have established recommendations for conducting Community-engaged research that include guidelines for securing approval FROM and formalizing partnerships WITH community organizations. But these recommendations apply only to their own research projects and are not nationally accepted or mandated.

http://www.hhs.gov/ohrp/sachrp/mtgings/mtg03-08/minutes.html
Incorporating a **communitarian approach** to the interpretation of the Belmont Principles would broaden their scope and encourage researchers and IRB members to consider some aspects of the conduct and consequences of research on the community-level. Reinterpreting the Belmont Principles’ existing focus on individual protections to include community-level protections would include consideration of issues such as these on the slide above.
The communitarian approach is not a separate ethical system, it is one approach among many in the field of biomedical ethics. The communitarian approach would expand on the ethics articulated in the Belmont Report and move the focus from solely the individual to include the community within which he or she lives or is a member. The rights of the individual are still protected, but a communitarian approach expands ethical considerations to the community level and informs new ethical questions.

The following slides show how each of the Belmont Principles can be reinterpreted with the communitarian approach.

(adapted from Callahan, D. Individual Good and Common Good: a communitarian approach to bioethics. 2003. Perspectives in Biology and Medicine, 46(4):496-507.)
Applying the communitarian approach to the principle of Respect for Persons would encourage researchers to work with community organizations and agencies to discuss the possible community-level risks and benefits of the proposed research.

Many researchers who conduct community-engaged research develop a Memorandum of Understanding (MOU) also known as a Memorandum of Agreement (MOA) with community organizations or agencies that outlines possible risks and benefits at the community-level as well as the responsibilities of researchers and of community partners. A MOU is not recognized by IRBs as responding to Federal regulations. However, when officers or Board members of a community organization or agency sign an MOU they acknowledge the possible risks and benefits of the research and agree how their organization will participate.
Belmont Principle:
Beneficence
maximize benefits & minimize risks

Risks & benefits at the community-level should be considered in addition to the risks & benefits to individual participants.

Risks and benefits to the community:
• May be different from risks & benefits to individuals
• Should be considered in addition to the risks & benefits to individuals
• Perceptions of risk & benefits may be different among researchers, community organizations and community members

Open discussion and negotiation among researchers and community organizations can contribute to each group's understanding of how others perceive risks and benefits.
Everyone involved in the research must recognize and understand the risks & benefits to individuals and to communities.

Questions to ask:

• Can the level of risks be determined? Have the main partners (researchers and leaders of community organizations and agencies) explored ways to reduce these risks?

• Can the benefits be identified, communicated and discussed among all partners?

• Can the main partners create a project environment where all are able to openly discuss and weigh the risks & benefits to individuals and to the community?
Researchers, community organization members and IRB members may have different interpretations of concepts in the Belmont Report. Such as “risk”.

The concept of “risk” depends very much on context: the world people live in day to day. When community organizations and agencies are involved as collaborators in research their understandings of “risk” may be different from those of researchers from academic institutions. With community-engaged research, different understandings need to be discussed and negotiated.
The Belmont Principle of Beneficence, reducing risks and maximizing benefits, may be understood differently by researchers, community members, community leaders, IRB members and university administrations.

For example, researchers in San Francisco, California formed partnerships with community organizations in 2 inner-city neighborhoods. Community groups were concerned about high rates of tobacco use and researchers worked with them to develop ways to investigate contributing factors. Local convenience stores commonly sold single cigarettes that made cigarettes more accessible, especially to minors, even though sales of single cigarettes were against state law. Because of their low cost and easy availability single cigarettes had also been identified as posing a barrier to those who were trying to stop smoking.

Community organizations wanted to find out how common this practice was. They proposed having organization members systematically visit neighborhood stores to observe single cigarettes sales. Since waiting in each store to observe a sale would take too much time, community members proposed to attempt to buy a single cigarette in each store. Buying a single cigarette was not against the law: selling the cigarette was.
The university IRB would not approve this protocol because, among other reasons, they considered that exposing illegal behavior would put community organization members at risk. The community residents did not consider buying single cigarettes from local convenience stores to be a personal risk. The community-engaged researchers supported the personal risk assessment of the community residents. Even after the local Attorney General wrote a letter stating that attempting to buy a single cigarette was not considered “entrapment” and that no store owner or clerk would be prosecuted for activities related to the study, the IRB would not approve the protocol.

This example demonstrates the different perceptions of minimizing personal risk and maximizing benefit among an IRB, researchers and community organization members who are part of a research partnership. The community organizations thought that information on the prevalence of single cigarette sales would enable them to work to stop this practice and thus remove a barrier for those in the community trying to stop smoking. This would benefit individuals and the community, especially considering the health affects of second hand smoke.

The IRB saw the project as exposing individuals to risk and did not accept the community organizations members’ risk assessment. Nor did the IRB accept the steps that the researchers took to minimize or eliminate the possible risks (such as the letter from the local Attorney General). The project did not receive IRB approval for this activity.

Belmont Principle: Justice
fair distribution of burdens & benefits

The Belmont Report includes:

• Justice considerations at the individual and social level
• the need to distinguish between groups who can and can not bear the additional burdens of research
• Research should benefit the community and not exploit it

The Belmont Report’s principle of Justice has always applied at the social level. The Belmont Report considers Justice in terms of affecting groups of people as well as individuals and provides guidance on how to decide if burdens and benefits are shared in a just way.

(The Belmont Report (1979) Section C.3.)
In this hypothetical example a group of researchers want to conduct a study of a new blood pressure medication which may be effective for a week or more for people with particular genetic make ups. The researchers want to form partnerships with community organizations active in near-by low-income neighborhoods so these groups can advise them and participate in the research. The researchers want these organizations to recruit participants; assist with data collection; and distribute study results locally. The community organizations would be partners in the research project and receive a subcontract to do this work. They would be part of the research team. The community organizations would not simply "help" the researchers, they would be responsible for their commitments and receive payment.

Study participants would receive free medication, monitoring and compensation for their time. For community members who need care for hypertension participation would be an individual benefit, even though participation in medical research may also include individual risks.

If approved this new genomically tailored medication is expected to be costly. Since these communities are predominantly low-income most residents' medical care and prescriptions are covered by Medicare or Medicaid, others have no medical coverage. Because of high cost, study participants may not have access to the new medication after the study is over.

Included in the Belmont Principle of Justice is the concept that research should benefit the community and not exploit it. Study participants would be taking on risk with little hope of receiving benefits at the conclusion of the study or in the future. Risks and benefits would need to be weighed by the IRB, which would need to determine if this low-income community was being exploited.
Sections 1 and 2 focused on the Belmont Principles and how they can be reinterpreted to apply to ethical decisions at the community-level. Section 3 focuses on other ethical issues researchers need to consider when conducting community-engaged research as well as the ethical dimensions of the partnership process.
Community values and ethics

May determine if community organizations and community members:

- Trust researchers
- Will consider participating in a study
- Can collaborate as partners in research

Values and ethics are an integral part of culture. Understanding the values of different segments of a community, represented by its community based organizations, is an on-going process. Long term relationships generally result in deeper understandings of community history, ethics and values. Communities are seldom homogeneous, instead they comprise different groups who have different histories and values. Although the specific values and ethics of groups within a community may differ, generally there are many shared values. Knowing the values of the community organizations, agencies and groups who are the primary partners is essential for a successful partnership and facilitates productive research.
Consider the following hypothetical example. A group of HIV/AIDS researchers want to study the reported rise of HIV infections among rural African Americans. The researchers want to find organizations within the community where they can easily access African Americans and decide to work through churches. They call 20 ministers from two rural counties near the University and ask them if their congregations might be interested in a free HIV screening study. None of the ministers agree to work with the researchers. Some ministers are insulted; the rest are polite, but refuse to participate.

Because researchers had not spent time in these communities or talked to others who had, they were unaware that in many rural areas HIV/AIDS remains an illness that few will talk about. In many rural areas most churches (both African American and white) view HIV/AIDS as punishment for having sex outside of marriage or for homosexual activity; both in their views morally wrong. To the ministers, to assist with a screening study for HIV/AIDS would be a moral affront to their congregations. Simply by asking for assistance the researchers violated the values of these churches and lost opportunities for forming partnerships.

The different interpretations of the moral meaning of HIV infection demonstrate not only the need for potential partners to get to know each other, but also how community organizations, such as churches, may have deeply held beliefs that preclude them from helping facilitate participation by their members in certain health research. Yet, every community is different and it is important not to assume that all similar communities have the same values and ethical beliefs.
Some standard research methods may look very different from the community perspective than they do from the perspective of trained scientists. For example, community organizations and agencies commonly refuse to participate in research that involves control groups who do not receive treatment or intervention. They may view excluding a control group from receiving a potential benefit as unfair to members of that group. Resources are scarce in many communities and research resources can be viewed as a kind of service which should be available to everyone. Sometimes using a design where the control group receives a delayed intervention or treatment is a compromise that researchers and community organizations can accept.

This community view may also apply to studies that provide different treatments or interventions to groups for comparison and to studies that use random assignment of participants.
Suppose researchers want to study whether regular low-impact exercise during pregnancy will improve birth outcomes among Latinas. They form a partnership with the Latino organization. Researchers explain that they want to enroll pregnant women into the study and that half will participate in a special exercise program and the other half will not.

Many of the Latino community organization members think that all pregnant Latinas should be able to join the exercise program. They reason that if the researchers think it will be better for the health of babies, then everyone should be able to attend so all their babies can benefit. The organization leadership agrees and asks the researchers to use women who don’t attend the exercise program as the comparison group. The community organization’s core belief is that anyone who wants to join the study should be able to; otherwise the program only provides benefits to selected community members and is not fair. Unlike scientists, the community organization and its members are not primarily concerned with possible bias in the results, instead they are concerned that every pregnant Latina receive the advantage the exercise program may provide.

Different values and beliefs contribute to this situation. Beyond a simple lack of communication, the researchers interpret the principle of beneficence differently than do the community organization members and leaders. Researchers view the study benefits on a broad scale: contributing to generalizeable knowledge of how Latina women can improve pregnancy outcomes. Community organization members view the benefits of the research on a local scale: how will the research benefit the pregnant women in the Latino community now?

Each group is using their own ethical beliefs and their values to guide their decisions as they balance risk and benefits. In the eyes of the researchers the principle of beneficence is met: from the community perspective it is not.
Because of past bad experiences or misunderstandings with researchers, some community organizations, agencies, and native American tribal councils have developed their own research approval processes. Often, the Board of Directors will conduct a review of research proposals. Community organizations and researchers can work together, if needed, to revise the research plan to make it acceptable to all parties. This collaborative process can be a way for researchers to explain important aspects of research methods and design to organization members and to respond to any concerns. Such communication and negotiation can contribute to developing strong partnerships and lead to innovative solutions to research challenges.


In order to receive approval to work with a community organization researchers often must agree to rules and guidelines developed by that organization. This is analogous to the rules and guidelines that universities, foundations and governmental agencies have for research. Community organizations may also develop standards for research partnerships to establish acceptable practices and procedures.

Examples:

• El Centro Hispano is a community-based organization in North Carolina which provides services to and represents the Latino community. They require researchers to submit proposals to the El Centro Board of Directors and receive approval before the organization will work with them.

• The Akwesasne Mohawk Nation in northern New York state established a Research Advisory Council (RAC) in 1995 to review and comment on research proposals. They developed standards for research protocols with requirements to help researchers collaborate with the Native American community.

• Many county Health Departments require that all research proposals which involve them as partners be approved by their Board of Health before the proposals are submitted to funders.

• School Boards and School administrators generally have a stringent review process for research done in the schools.
Power and control are unavoidable issues in partnerships of all kinds. When working with communities, all members of the partnership should try to identify and understand the existing power dynamics and work towards an equitable balance of power. This is an ongoing process, not an issue that is discussed once and then put aside as finished.
Partnerships exist within the context of a society and generally duplicate societal power imbalances. For example, in the United States money and power confer status to individuals and to groups. Researchers from a large academic institution will likely be perceived as having more power than community organizations or cash-strapped municipal agencies. In fact, most colleges and universities do have more power and access to funding than many community organizations.

For community-engaged research projects the academic researchers usually receive the grant funding and control that funding—since they must report on it to the university and to the granting organization. If one group controls all the funding then collaboration and partnership may be difficult because of the imbalance in power.

Yet there are many valuable and necessary elements of a research study in addition to funding. In community-engaged research the support of community organizations and agencies is often an essential element of the proposal and is required for funding. Community organizations can advise on: appropriate methods to reach community members; development of research instruments, such as surveys; the recruitment of research participants, and can influence how community members view the study. In a partnership, all contributions are valued, not only the funding.

Building strong partnerships requires commitment and open communication. Recognizing and discussing issues concerning funding and valuing other contributions can help address power imbalances.
Because there is no established protocol for obtaining community or community organization consent, researchers and community organizations and agencies have looked for other means to address this issue. The Memorandum of Understanding (MOU) can help researchers and community organizations think through some ethical issues. A MOU does not need to cover explicitly ethical concerns, but it can specify how researchers and communities will work together.
A Community-engaged research approach presents some ethical questions which are different from those common to biomedical research. The Belmont Report remains the ethical guide for protecting research participants and a communitarian reinterpretation can help in applying these principles on a community-level. The regulations that govern research with human participants apply to Community engaged research as well. Community partnerships can foster an awareness of different perceptions, priorities and values among researchers and community organizations.
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References


