

PART 6

DESIGNING ETHICAL RESEARCH

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QUESTION #55

How Do I Ensure That Eligibility Criteria Are Appropriate and Fair?

Eligibility criteria for a research study consist of inclusion and exclusion requirements. Inclusion criteria are those characteristics that an individual must have in order to be eligible to participate in the research study. Exclusion criteria are characteristics that would prohibit participation. For example, a research study may require participants to be within a certain age range, such as from 18 to 25 years old. A study may require that participants have had a particular experience, such as growing up in a single-parent household; or have a particular health condition, such as diabetes. Additionally, a research study may exclude individuals with particular experiences or medical conditions. Exclusion may be based on the fact that participation would be too risky. For example, a research study of an exercise program with older adults may exclude those with heart conditions.

Exclusion may also be appropriate if there is good reason to believe that the experiences (and therefore the data) of individuals with certain characteristics will differ significantly from the experiences of a broader group—and there will not be enough individuals who share these characteristics (or enough resources) to make meaningful conclusions. For example, a small research study that aims to describe the college experience of hearing-impaired adolescents may reasonably exclude individuals who have other physical limitations.

In determining appropriate eligibility criteria, you must consider the scientific objectives of the research study as well as ethical principles, particularly the risk–benefit balance and justice. Research must be scientifically sound. If your eligibility criteria are too broad or too narrow, your ability to interpret and generalize your results may be limited. If your results are meaningless, then participants' time has been wasted, and they have possibly been subjected to risk for no good reason. Your inclusion and exclusion criteria must be justified in your research proposal. Importantly, inclusion and exclusion criteria should never be based on convenience. Eligibility criteria should be determined based on what is known about the phenomenon to be studied.

More questions? See #15, #27, and #50.

QUESTION #56

What Strategies Can I Use to Ethically Recruit People to Join My Research?

There is no one optimal recruitment strategy to recommend for all studies. Many studies require multiple strategies. The best strategies for a given study depend on the scientific aims as well as eligibility criteria, number of participants needed, time frame, and available resources. Be sure to check the recruitment policies of your institutional review board when you are developing your recruitment materials and approaches.

When recruiting for your study, you should protect individuals' privacy and avoid using approaches that will (1) identify an individual as being part of a specific group, (2) suggest that the individual engages in certain behaviors, or (3) give the impression that the individual has a specific condition. Protecting prospective participants' privacy is particularly important if the group, behaviors, or condition is stigmatized in any way.

Prospective participants may be approached through a variety of indirect or direct methods. Indirect methods include flyers; other types of announcements posted in public places; and radio, newspaper, television, or Internet advertisements that alert interested individuals to a study opportunity. Interested individuals call you, or your study staff members, to learn more about the research while choosing the amount of privacy they want when placing that call, such as calling from their home when they are alone. Methods that limit direct contact are most respectful of personal privacy but may not yield as many participants.

Direct recruitment methods include personalized letters, emails, telephone calls, and in-person requests. Direct methods may target individuals identified in a specific population. For example, in a community survey, phone numbers associated with addresses in certain zip codes may be randomly selected and called. Direct methods may also be used to reach those likely to meet eligibility requirements. For example, you may want to send letters to all parents of children participating in a school lunch program, with permission from school administrators. When using direct recruitment methods, you should explain to the prospective participants how they were identified and inform them that participation in research is

voluntary. Although direct methods typically yield more participants, such solicitation may be considered by some to be an invasion of privacy.

Depending on the type of research study and the eligibility criteria, you may recruit at specific locations or sites. These may include schools, health care centers, organizations that deliver social services, businesses, and community centers or places where people who meet eligibility criteria are likely to be found. Direct or indirect means of recruitment may be used at such sites. Depending on the location, you may need to get permission from an authorized individual associated with the site. Health care institutions must follow HIPAA privacy laws (see Question #26) and may have additional specific privacy policies outlining guidelines for accessing patient records for research purposes. If individuals will be recruited in person—for example, at a community event—interactions should take place in a quiet, private location so that others cannot hear personal information being shared.

When recruiting for research through partner organizations, it is important that individuals who are approached about research participation understand and trust that refusal to participate will not compromise their relationship with the organization or affect the care or services they receive. If a partner organization's employees or volunteers will be involved in recruitment, these individuals must be appropriately trained regarding ethical standards for research. Partner organizations may have policies regarding sharing individuals' contact information with researchers, and researchers must respect these policies. It may be preferable for information about your research study to be sent directly from the partner organization.

There are pros and cons of having individuals from a partner organization make initial contact with prospective participants about research participation, rather than having the researcher make the initial contact. On one hand, the prospective participant may know and therefore feel more comfortable with an individual from the partner organization, such as a teacher or service provider. This may lead to better understanding of the research and a more valid informed consent. Also, given the organization's access to individuals who may meet the eligibility criteria, staff members at partner organizations can likely share information about your study with prospective participants one-on-one in a private place and provide information about how to enroll to those who are interested. Lastly, because the staff members are already informed of the prospective participant's health status or reasons he or she is obtaining the specific services, the individual's privacy is likely not violated (although some individuals may not like to be approached about research participation). On the other

hand, the prospective participants may have a harder time saying “no” to someone they know.

Ideally, whoever approaches individuals about research participation should not be in a position of power over them. Concerns about potential undue inducement must be balanced with privacy considerations and the need for adequate informed consent. For example, a researcher should determine whether it is better to have employees at a social service agency invite their clients to complete a survey, or whether the agency should mail surveys directly to clients asking them to send it back to the researcher in a stamped, pre-addressed envelope. Each of these options has risks and benefits. Clients may feel pressure to participate because they are being asked by someone from whom they receive services. On the other hand, if the survey is mailed home, they will not have an opportunity to ask questions about the purpose and potential risks of the survey.

“Snowballing” is another recruitment approach. This is when participants identify people they know who they think will likely meet the eligibility criteria. When this approach is used, it is best for the participant to give the researcher’s contact information to individuals rather than to give the researcher the individuals’ names and contact information. That way, those who are interested can directly contact the researchers. It is a violation of individuals’ privacy to give their information directly to researchers.

Many universities have subject pools that can be accessed to identify individuals meeting specific eligibility criteria. These pools will have guidelines regarding how participants can be identified and contacted.

More questions? See #57, #58, and #68.

QUESTION #57

When Is It Appropriate to Pay Participants for Taking Part in Research?

It is almost always ethically acceptable to offer some compensation, including monetary payment, to research participants. In some studies, offering money may be necessary to incentivize individuals to participate, especially if the research is particularly time-consuming or otherwise burdensome. For example, participants may be hesitant to enroll in research when research visits are frequent. Payment is not meant to offset the risks of the research, nor should it be presented as a benefit of the research. Rather, payment is considered reimbursement for participants' time, inconvenience, and transportation costs traveling to the research site or a "thank you" gesture recognizing participants' contribution. Small token items such as pens or tote bags are also appropriate incentives.

Researchers, ethicists, and institutional review board (IRB) members have expressed concerns that payment could lead some individuals to ignore research risks, thereby diminishing their ability to provide voluntary informed consent. This might happen if an individual decides to join a study because the amount of money provided is too high to turn down—an offer "too good to refuse."

Investigators can address concerns that compensation may be difficult to refuse by ensuring that the risks of any research study are appropriately minimized and communicated to prospective participants (an ethical requirement for all research), and that the payment amount is appropriate for the time and burdens associated with research procedures. The IRB will need to approve the incentive amount you plan to offer participants.

Some research institutions require that research participants provide personal information (and, in some cases, even Social Security numbers) in order to receive cash or check payments. This should be mentioned in the consent form as it increases the potential harms that may result from a data breach. It may also deter certain individuals from participating, including undocumented immigrants, other individuals who do not have Social Security numbers, or individuals concerned about identity theft. In

lieu of cash or check payments, some studies compensate participants with gift cards. This practice is generally acceptable; but it may disadvantage certain individuals, such as those not able to easily reach a particular business to redeem their gift card.

For research with children, you can provide an incentive to the children, which could be a small payment or gift, if approved by your IRB. You should also consider whether payment should be provided to parents, as parents might incur costs, such as from transporting their children to and from a research clinic. The amount provided to parents should be appropriate to cover their costs, so as not to negatively influence parents' decisions about their children's participation. IRBs and organizations who work with children may have different policies regarding payments to children and/or their parents.

More questions? See #14, #56, and #58.

QUESTION #58

How Do I Determine the Appropriate Amount to Pay Research Participants?

Unfortunately, there is little guidance available to help researchers to determine suitable payment amounts. Few institutional review boards have established formal policies. Researchers at your university or in your department may have a general “rule of thumb” amount or range that they use. Some researchers multiply the local minimum wage by the estimated number of hours that will be spent in research participation. In reality, the range of payments offered varies greatly. If you are looking to recruit the same types of participants as other nearby researchers, it is important to recognize that researchers’ prior payment practices influence participants’ expectations, particularly if you are working in a heavily researched population.

Ethical considerations aside, ultimately, the amount that any researcher can pay participants will depend on the resources available and the costs of other research tasks, such as interviewer or data entry costs. It may be the case that using incentive payments can decrease other costs, such as the costs of recruitment materials or follow-up calls to schedule or reschedule research appointments. Payment to participants may therefore be a cost-effective means of achieving a sufficient sample size. In cases where the number of participants needed for a given study is quite high but budgets are small (or it’s just not feasible to pay everyone), a lottery may be acceptable. In a lottery, participants who complete study requirements are entered with a certain chance to win a limited number of prizes (cash or other). The true chances of winning must be clear in the consent form or information sheet.

More questions? See #49, #56, and #57.

QUESTION #59

What Ethical Issues Should I Consider When Conducting Focus Group Discussions?

The primary ethical consideration in focus group research is whether gathering data in the group setting will pose greater risk to participants than conducting individual interviews. Risks to consider include informational risks (risks to privacy and confidentiality), social risks (risks to relationships), and emotional and psychological risks.

Collecting data in the presence of other participants limits your ability to completely protect participants' privacy and confidentiality, as you cannot control what participants share with others once the focus group is over. For this reason, you should inform prospective participants of this risk during the informed consent process. Additionally, you should consider the topics that will be covered during the group discussion. Research on any sensitive topic poses risks to participants' privacy and confidentiality as well as their personal comfort. Therefore, as a general rule, participants are not asked to discuss sensitive personal topics in focus groups. Rather, researchers use in-depth interviews to ask about topics that are likely to be sensitive.

Even when you do not plan to discuss sensitive topics, you should take steps to protect participants' privacy during focus groups, such as using first names only or pseudonyms. However, because the group meets face-to-face, even if participants do not reveal their real names, there is the potential for future recognition by the researcher and by other participants. Therefore, true anonymity is not possible and should never be promised. Even if you conduct focus groups over the telephone or online, participants may believe such forums are anonymous, but complete anonymity is not possible because all participants hear each other's voices.

It is common to audio record focus groups, transcribe the recordings, and analyze the transcripts; some researchers video record focus groups. Recording the discussion ensures the accuracy of data. However, recording poses potential additional risks to confidentiality; faces and voices can be recognizable, especially for individuals with unique voices because of

accents or speech impediments. Any identifying information, such as the mention of specific places or people's names, should be redacted from transcripts during transcription. (See Questions #22 and #23 for best practices in maintaining privacy and confidentiality.)

Social risks are possible if there are preexisting or ongoing relationships among focus group participants. In the group setting, there is much more of a chance that potentially damaging personal information (for example, discussion of illegal behavior) or negative comments (for example, complaints about services) could get back to a third party (such as a service provider or an employer). What if, for example, in a focus group of recipients of state benefits, an individual discloses that she routinely lies on forms in order to keep her benefits? Even if confidentiality is promised by the researchers, another participant could share this information with a caseworker. If it is possible that focus group participants may disclose information that could be damaging if learned by a third party, it may be preferable to conduct individual interviews instead of focus groups.

Researchers use focus groups because when participants hear others' views and experiences, it may help them think differently or more deeply about an issue, resulting in more valuable comments from all participants. Focus group moderators should ensure a safe space for such sharing; but they must also be aware that participants may become upset by another focus group member's statements or when sharing their own personal experiences (which, as a general rule, is not the purpose of a focus group). Some participants may reveal more than they had intended to share. People sometimes feel more comfortable disclosing private, sensitive information to strangers than to friends or family. However, too much disclosure may lead them to become upset or to feel regret after the focus group. If a participant becomes upset, it may be difficult for researchers to notice because of the focus group setting. Depending on the research topic, referrals for local services or care may be needed for participants who become upset.

Several best practices can limit disruptions and ensure the comfort and safety of all participants. Before starting a focus group, tell participants that it is important that they demonstrate respect for others' views, talk only one at a time, wait to be called on, and do not talk about what was said in the focus group outside of the focus group. Focus group participants should be reminded that participation is voluntary, that they do not have to answer a particular question if they do not want to, and that they can stop participating and leave at any time. It should be made clear that their personal comfort takes precedence over their participation in the focus group at all times.

More questions? See #12, #17, and #100.

QUESTION #60

What Ethical Issues Should I Consider When Conducting Participant Observations?

Participant observation allows researchers to obtain data that may not be accessible through other data collection methods, such as interviews or surveys. Participant observation may involve brief observations of superficial activities or ethnographers embedding themselves in a community for several years. Each participant observation study is different; therefore it is difficult to apply ethical standards uniformly. However, people generally do not like to be “spied on,” and some past research ethics scandals in social and behavioral science research involved observational research. In planning your observational research, consider the venue in which you will conduct your observations. What level of privacy do people in that venue generally expect?

If you are collecting data in a manner that does not allow for the identification of individual participants, your observational study will likely be considered exempt from federal research regulations oversight, and informed consent would not be required. For example, you might observe people’s viewing behavior at an art museum and simply note numbers and basic demographics.

The more details you collect that could potentially make an individual identifiable—and the more private and sensitive the information you collect—the greater the risk posed by the research. If you must collect personally identifiable information as part of your observational research, written or verbal informed consent, or a request for a waiver of informed consent, may be necessary.

Another important ethical consideration is whether and when to reveal your identity as a researcher during the observation. This depends on the extent of the interaction between you and those you are observing. If the observation does not require you to interact with the participants, and you are not collecting any identifiable information, it is generally ethically acceptable for you not to reveal your identity as a researcher. However, if you are interacting with those you are observing, such as engaging in a

conversation with them to elicit certain responses, you will likely need to obtain informed consent.

Covert observational research, in which a researcher spends an extended period of time in a particular setting pretending to play some role other than researcher, has raised many ethical objections. Those being studied have no knowledge that they are being studied. Covert research requires considerable ethical justification, given the overwhelming violation of the right to privacy. It can be justified only on the basis of the social benefit of the research. The scientific argument supporting covert observations is that individuals may change their behavior if they know they are being watched. However, there are important ethical considerations, such as the requirement of respect for persons in research, betrayal of public trust, potential harm to participants, exploitation of vulnerable individuals and groups, strain on the researchers of maintaining their cover, and the potential for harm if the researcher is discovered.

Covert observation that involves interacting with participants may be justified if the interaction is brief, and if the research data could not be collected in any other way. For example, you may want to pose as a customer at convenience stores to see if store clerks ask to see identification for the purchase of alcohol. Institutional review boards may have different views on the acceptability of studies like these, because of the potential for clerks to become upset for being observed without their knowledge—and potential harm to you, the researcher.

You may also intentionally or unintentionally observe illegal behavior during your research. If this is a possibility, you should plan in advance for how you will handle this, including whether your study will qualify for a Certificate of Confidentiality (see Question #25).

More questions? See #21, #37, and #72.

QUESTION #61

What Are Some of the Ethical Issues Raised by Deception in Research, and When Is It Ethically Acceptable to Use Deception?

Deception has been used in social science research since the early part of the 20th century. Ethical controversy erupted in the 1970s, after participants in the obedience studies of Stanley Milgram experienced psychological harm. Deception research has the potential to negatively impact public trust in research because, in general, people do not like to be deceived.

Deception in research can take different forms. Indirect deception occurs when the true purpose and goals of a study are not completely communicated to participants. In other cases, deception may be direct; for example, participants may be purposefully misled or given false information about an essential component of the study's procedures or given false feedback about their performance on certain tests or tasks.

According to the American Psychological Association's Code of Ethics, four conditions must be met in order for deception to be ethically acceptable:

- 1. The study will make a significant contribution to scientific knowledge.** Participants may not be deceived in pursuit of answers to frivolous questions.
- 2. The phenomenon of interest cannot be studied using other (nondeceptive) means.** Imagine you are seeking to study employment biases. You ask participants to evaluate potential job candidates who are identical on all qualifications but who differ by race, gender, and/or age. Alerting individuals to the purpose of the study will almost certainly influence their responses, as most people do not want to be perceived as being biased.
- 3. The use of deception is not expected to cause significant harm or emotional distress to participants.** In deciding whether

to use deception in research, consider the type, probability, and magnitude of the potential risks of deception. Also consider the extent to which you are infringing on participants' autonomy by not giving them true or complete information. Deception may be considered an invasion of privacy because it may cause people to reveal things about themselves that they would prefer to keep private. If—such as in studies that involve false feedback—participants are led to believe something about themselves that is not true, this may be demeaning and have negative effects on self-esteem.

- 4. Participants will be debriefed, and the deception will be explained as soon as possible.** Whenever direct deception is used in research, no matter how seemingly benign, a debriefing process is required. During the debriefing process, you should explain the true purpose of the study to participants; give them an opportunity to ask questions about the study; give them a chance to withdraw their data from analysis; and, if appropriate, assess them for any emotional distress or psychological harm, and provide them with appropriate resources. When deceptive measures are employed to elicit certain behaviors, participants should be reassured that their responses—for example, succumbing to the pressure to conform—are normal. Good debriefing can offset potential negative effects such as becoming upset or embarrassed.

More questions? See #7, #11, and #37.

QUESTION #62

What Ethical Issues Should I Consider If My Intervention Research Includes a Control Group?

In some studies, behavioral interventions or other social programs are evaluated to determine whether they are effective. Most scientists, including social and behavioral scientists, consider a randomized controlled trial (RCT) to be the gold standard for answering such research questions. In RCTs, some participants are randomly assigned to an intervention group and some participants are randomly assigned to a control group. Individuals in the intervention group receive the experimental intervention. Individuals in the control group do not receive the experimental intervention; they may receive the standard-of-care intervention, if one exists, or no intervention at all.

In a two-arm RCT, participants must understand that they have a chance of being randomized to a control group or to the unproven, experimental intervention group, and that being in either group carries different, unique risks. Therefore, consent forms—which are almost always required when a study includes randomization to an intervention, unless the intervention is brief and benign, such as playing a game—must adequately explain the various study arms and the chance of being randomized into one group or another.

If the experimental intervention is determined to be effective (for example, it improves educational achievement or prevents teen pregnancy), it may be ethically desirable to deliver the intervention to individuals initially assigned to the control group after the formal study period is over.

Conducting an RCT in a community-based setting poses unique challenges. Community members may want that intervention to continue after the formal study period is over if the research shows that it is effective. Funding may not be immediately available to continue the intervention—especially if policy change is required to provide that funding or to revise practice standards. Community research partners may become frustrated,

feeling that benefits are being withheld from their communities. Researchers may be sympathetic yet lack the resources needed to help communities identify the funding to continue programs. This is an important ethical issue that should be discussed early on in any community–academic partnership.

More questions? See #15, #16, and #40.

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What Ethical Issues Should I Consider When Conducting Research in a Defined Community?

Some research studies may involve a geographic community or a group of individuals who share a socially meaningful characteristic, such as race, ethnicity, disease status, or formal group membership. Examples of such groups include Appalachians, African-American women, people with diabetes, graduates of Harvard University, or children living on the West Side of Chicago. Because group membership may be easily determined, individual participants may be readily identifiable. Thus, participants in research conducted in a defined community may be more vulnerable to risk of disclosure of private information as well as the subsequent social harms.

When conducting research with a defined community, there are group-level risks as well as individual risks to consider. Group-level risks involve the potential for harm to all group members, regardless of individual research participation. Risks to nonparticipants include the potential for findings to stigmatize anyone who is a member of the community. For example, you may conduct a survey and find that Community A has a rate of self-reported prescription drug abuse that is 5 or 6 times higher than other surrounding communities. It is possible that upon learning this information, individuals from this community will be assumed by others—friends, family members, current or future employers—to be prescription drug abusers. This could result in social or economic harm to anyone who lives in Community A, not just to those who took the survey. The smaller the community is, and the more sensitive the data being collected are, the greater such risks.

Researchers must also consider the potential for research to pose risks to a community as a whole. In the 1990s, a geneticist working with an anthropologist collected blood samples from members of the Havasupai tribe in Arizona. There were fewer than 1,000 living tribe members at the time. The original purpose of the blood collection—as stated in the consent form—was to look for a genetic predisposition to diabetes. However,

without either permission from tribal leaders or individual informed consent from participants, the researcher also conducted research on schizophrenia and shared samples with students and colleagues. One published analysis determined that the Havasupai's ancestors had migrated over the Bering Strait from Asia. This information contradicts the Havasupai's origin story, in which the original tribe members were from the base of the Grand Canyon. The publication of this information was potentially detrimental to group cohesion, as well as to individual tribe members' identities.

Given these potential risks, researchers conducting studies on a defined community must consider whether they have an obligation to engage members of that community in the design, conduct, analysis, and dissemination of the research. Arguably, the ethical obligation for such engagement is higher in defined communities because of the additional risks, as well as the potential benefits of community input on development and implementation.

More questions? See #11, #64, and #65.

What Is the Relationship Between Community Engagement and Research Ethics?

Traditionally, nonscientists have not been involved in the design or implementation of research studies or the interpretation of results. However, during the last few decades, academic researchers increasingly engage prospective participants and communities in planning and implementing research studies. Various forms of community engagement emerged in response to instances of abuse of research participants, out of recognition that research is often improved when communities are involved, and due to a perceived growth in “helicopter research”—in which researchers come into communities, collect data, and leave without informing them of the results. Although community engagement may not be possible or appropriate in all studies, and not all research topics or questions lend themselves to engagement, researchers should consider how the community could be involved when they begin thinking about a new research topic.

Community-based participatory research (CBPR) and participatory action research (PAR) are two specific approaches for engaging communities in the design and conduct of research, each with a defined history and literature. There are also many other approaches for involving prospective participants and communities in research development, implementation, and data interpretation. The umbrella term “community engagement” encompasses various strategies to involve nonresearchers who are stakeholders in the research results (often referred to as “community partners”).

Different engagement methods are appropriate in different circumstances. Methods of community engagement may include

- holding open forums (“town hall meetings”) to get broad, general input;
- establishing advisory boards to help design the research by giving input on specific issues and strategies;

- conducting formative research with prospective participants and members of their community to gather data to inform the research's study design and procedures;
- getting prior input on question wording from individuals similar to those who will take a survey, to increase validity of findings;
- hiring and training community members to serve as recruiters, data collectors, interviewers, and/or interventionists; and
- designating community leaders as co-investigators.

Community engagement in research has potential scientific, ethical, and community benefits. Engaging stakeholders in the identification and development of specific research questions and agendas can ensure that issues that are important to communities are studied and increase the real-world utility of results. Community engagement may lead to better data, which in turn should lead to improved community health. Community engagement may also improve enrollment and response rates. For example, engaging known, trusted community organizations in recruitment efforts can encourage participation and, perhaps, lead to faster enrollment, saving time and money.

Community engagement can also enhance the ethics of research by increasing transparency between researchers and communities, improving the informed consent process, and identifying individual- and community-level risks and ways to minimize those risks. Meaningful community engagement can also develop community capacity to conduct research and apply results.

Determining whether and to what extent you might engage communities in your research depends on many factors. Community engagement first and foremost can be thought of as a philosophical or ideological commitment to respecting the expertise of nonscientists, to building community capacity, and to advocating for change. Although involving communities is likely important for many kinds of research, if you plan to conduct research with a disenfranchised community, or suspect that your research may impact a defined community, you should consider engaging the community. If you are conducting research with populations who are hard to reach or are particularly suspicious of research due to past bad experiences, community engagement is also likely necessary. You may be able to partner with existing community organizations to conduct your research, or you may need to identify informal community leaders and representatives and bring them together. Keep in mind that those people who best represent the “community” may not always be readily identifiable, enthusiastic about research, or able to dedicate the necessary hours. Importantly,

researchers should engage with the community early in the planning process so that there is time to adequately incorporate community input.

Advocates of community engagement argue that involving communities makes research more ethical. Although community engagement does demonstrate respect for a community and its values, and it may remedy some of the problems that arise when conducting research within communities, community engagement is not without its own ethical challenges. Researchers are not used to sharing decision making or data ownership, therefore, these negotiations may be challenging. Community partners may perceive researchers as speaking a different language, which may hamstring even the most well-intentioned efforts at genuine engagement and power sharing. Community partners, particularly advocacy groups, may have very different goals than academic researchers, complicating shared decision making. Expectations regarding research risks, efforts to minimize risks, and the potential for individual- and community-level benefits must be clearly defined before research begins.

Community engagement in research may also pose specific risks to research participants. When someone is invited to participate in research by people they know or on whom they depend for services, this may threaten their voluntary participation and the informed consent process. Problems with data integrity may also arise if those responsible for data collection are not trained in scientific methodology, have ideological conflicts of interest, or do not have adequate power in their roles—for example, if they fear they might be fired if they do not recruit enough participants. Community partners who are responsible for data collection or intervention delivery may experience distress, for example, when they are not able to offer an intervention they feel is beneficial to someone randomized to the control group.

When engaging community members in research, it is important for researchers to demonstrate respect for the expertise that they bring to the table. Be genuine in your efforts to listen to community input and incorporate that input into your research plan. Expect to hear things that may challenge your assumptions about the topic you are studying.

Community partners who have responsibilities for research design and/or data collection and analysis—whether they are formally employed by your institution or not—will need to complete research ethics training if they will interact with study participants and/or their data. It is important that all community partners, regardless of their specific role, understand the foundational ethical principles of research.

More questions? See #27, #63, and #65.

QUESTION #65

What Does Cultural Competence Mean, and How Do I Apply It to Research Ethics?

Simply put, cultural competence involves demonstrating respect for differences. In the context of research ethics, cultural competence requires that researchers do not blindly apply ethical principles to research conducted in cultures that may have different interpretations of respect, benefit, or justice.

For example, in the United States, a country founded on an ideal of independence, autonomy means something very specific. In research, this translates to individual informed consent, often utilizing a formal signed document. Conceptions of autonomy may vary worldwide as may the comfort level with signing documents. As a result, the informed consent process may need to be altered in order to demonstrate respect for participants in a different culture. Although the ultimate decision about research participation should lie with the participants themselves, community and family have a significant role in decision making in many cultures. Additionally, the concept of individual consent or signing documents may be unfamiliar. In such cultures, favoring privacy over communal decision making, or requiring individuals to sign documents does not respect their autonomy and does nothing to protect their rights.

How do you ensure that you are being culturally competent in conducting your research? Partner with local researchers. Ask questions about cultural norms and expectations. Listen and learn from your partners. Understand that different cultures also have distinctive norms regarding privacy, confidentiality, and modesty. These must be respected in research, while still adhering to standard ethical principles and relevant research regulations. For example, having a male research assistant ask female participants questions about reproductive health matters may be perceived as extremely disrespectful, and may even be traumatic for research participants from certain cultures.

Use participants' preferred language, but keep in mind that language is about more than just translating materials for non-English speakers. All

research documents—flyers, consent forms, surveys and other instruments, intervention materials—should reflect how the people you are trying to reach think, talk, look, and act. Photos, examples, and vocabulary can affect enrollment rates, the completeness and accuracy of responses, and—most importantly—participants' comfort.

Communication also includes nonverbal cues, such as body language. Different actions carry different meanings in different cultures. For example, direct eye contact may be used as a sign of respect or attentiveness, or it may be completely avoided out of a desire to show respect.

Much has been written about the benefits of having culturally matched research team members. However, cultural competence or congruence cannot be assumed just because of the way someone looks. Proficiency in a foreign language does not equate to cultural competence.

Truly becoming culturally competent takes time and effort. The best way to learn about a culture is to ask people to share their culture with you. Cultural competence cannot be learned by reading a book. It requires active engagement and humility. When working in unfamiliar cultures, collaborating with community partners who can share information about the cultural norms of prospective participants will be necessary. In some cases, formative research prior to full implementation may be required in order to determine the most culturally appropriate research methods, strategies, and communications. Carefully listening and observing will go a long way in helping you demonstrate cultural competence.

More questions? See #46, #54, and #66.

QUESTION #66

What Ethical Guidelines and Regulations Should I Consider When Conducting Research in Another Country?

United States researchers conducting research in other countries are generally bound by U.S. regulations as well as the regulations of the country in which they are working. Often this means that research must prospectively be reviewed by both a U.S. institutional review board (IRB) and an ethics review board in-country, if the other country has such a mechanism for research oversight. Consult with your institution's IRB as soon as possible to ensure a timely and appropriate review. Your collaborators should be familiar with the process at their own institutions.

As a researcher, it is your responsibility to know the rules and regulations of the country in which you are working. The U.S. Office of Human Research Protections (OHRP) also compiles a list of international and country-specific laws, regulations, and guidelines related to human research, available on the OHRP website. Several guidance documents also exist to inform the ethical conduct of research from an international perspective. Many are available online.

Different countries may have different standards regarding issues such as privacy protections or informed consent procedures. It may not be obvious how to adhere to both, or which standard supersedes which, for a particular issue. Determining how to develop recruitment strategies, consent processes, and confidentiality protections that satisfy the standards of both or all countries in which you are conducting research will require early and ongoing discussion with your local collaborators, as well as with all IRBs that will be reviewing your research.

More questions? See #46, #54, and #76.