Informed Consent in Action: Facilitator Guide

Informed Consent in Action is a 60-minute training DVD designed to demonstrate good practices for recruiting participants and obtaining informed consent in community-based research. Five experienced community researchers share lessons learned. Vignettes show what informed consent "looks like" and filmed group discussions highlight key points and raise issues for further discussion.

The DVD begins with a brief Introduction and ends with a brief summary of Advice from Our Experts. Five segments cover: The Process of Recruitment (Scenarios 1-5); Information (Scenarios 6-8); Alternatives to Signed Consent Forms (Scenarios 9-10); Understanding (Scenarios 11-12); and Voluntariness (Scenarios 13-14). This Facilitator Guide summarizes each segment of the DVD and provides discussion questions and key summary points for each vignette. Additional discussion questions are also provided for use in conjunction with study protocol-specific training.

Introduction (4:00)

We meet our main characters, five expert community research partners and a few academic researchers. Our main characters meet Mark, who is producing and directing a training DVD for community research partners who will be recruiting participants for research studies and obtaining informed consent.

The Process of Recruitment (19:24)

"Recruit and enroll only those individuals who meet study inclusion and exclusion criteria."

Opening Scene/Group Discussion (@0:00 – 1:07)

Mark asks, "How do you find people to participate in research studies?" Our experts explain the importance of the eligibility criteria, that is, the rules for who can be included and who must be excluded from a research study. They provide examples of inclusion and exclusion criteria and explain the connection between these criteria and strategies for finding appropriate research participants.

➢ Scenario 1 (@1:08-3:47)

Someone is Interested But Does Not Meet Eligibility Criteria

Deborah is recruiting county residents for a research study on cancer screening. The study involves attending an educational program and completing a few surveys. Participants must be African American and over 50 years old. Deborah goes to a senior event to recruit participants. She meets the event organizers, sisters Sandra and Gloria, and explains the purpose of the study, the eligibility criteria, and the requirements of participation. Sandra and Gloria both express interest in participating. However, Gloria does not live in the county where the study is taking place. Deborah thanks Gloria for her interest but respectfully tells her that unfortunately, she is not eligible. *A brief group discussion of Scenario 1 follows @ 3:48-4:01.*

Scenario 1 Discussion Questions

- What is meant by eligibility (or inclusion/exclusion) criteria?
- Why might people want to participate in research even if they are not eligible?
- What strategies might you use to explain to someone that they are not eligible for a research study?
- Where else might Deborah go to recruit participants for this study?

Protocol Specific Questions

- What are the eligibility (or inclusion/exclusion) criteria for STUDY X?
- Why might people want to participate in STUDY X even if they are not eligible?
- What strategies might you use to explain to someone that they are not eligible for STUDY X?
- Where will you be going to recruit participants for STUDY X?

➢ Scenario 2 (@4:02 – 7:53)

Participants Can Be Hard to Find

Ronnie is going door-to-door, administering a household survey on asthma. He has a list of addresses that he is supposed to survey, but he is frustrated because no one is home. Ronnie ends up giving the survey to some parents who are picking their children up from school, even though he knows this is not following the protocol. His supervisor, Steve, reminds Ronnie of the importance of following the protocol, which he learned in training.

Group Discussion (@7:54- 9:33)
Researchers have scientific reasons for determining the number and type of participants needed for a particular study. The most important responsibility of those who recruit research participants is to make sure that everyone enrolled meets the eligibility criteria. Ronnie explains how he carefully documents his attempts at recruiting participants so that the researchers will know what he has been doing and how hard he has been working (even when the numbers may not show it). Mark asks the group for examples of different kinds of eligibility criteria, which include geography, age, gender, race/ethnicity, and medical conditions. The group also discusses studies that use multiple, complex criteria.

Scenario 2 Discussion Questions

- What should Ronnie have done in this situation?

Protocol Specific Discussion Questions

- What challenges might you encounter in recruiting participants for STUDY X?

➢ Scenario 3 (@ 9:20 – 12:01)

Medical Screening to Determine Eligibility for Research Participation

Carlos is with a nurse at a health club giving blood pressure screenings. Men with pre-hypertension (blood pressure that is high, but not *too* high) are eligible to participate in a research study. Matthew is interested in having his blood pressure taken, but only because he wants the $20 that is being offered to eligible participants. After checking twice, the nurse tells Matthew his blood pressure is 140/90, which is quite high and over the limit for study eligibility. She tells him to see a doctor as soon as possible. Matthew is confused because he thinks having high blood pressure means he can be in the study. Carlos explains that Matthew's blood pressure is so high that participation in the study would not be beneficial and perhaps may even be dangerous.

Group Discussion (@12:01-12:35)
Mark asks about challenges in recruiting research participants. Our experts highlight the importance of clarifying criteria and determining eligibility early on in the conversation with a potential research participant.

Scenario 3 Discussion Questions

- What other information should Carlos have given Matthew before the nurse took his blood pressure?
- Is Matthew a research participant?
- Should Matthew have been asked to provide written informed consent before having his blood pressure taken?
- The nurse tells Matthew that he should see a doctor soon to address his high blood pressure. When he says that he doesn't have a doctor, she provides him with a list of resources. Did she do enough? Should she have done more to help him?

Protocol Specific Discussion Questions

- How will potential participants be screened for STUDY X?
- What resources, if any, should be provided to potential participants or individuals who are screened to participate in STUDY X?

➢ Scenario 4 (@12:35-14:17)

A Potential Participant Misunderstands Eligibility Criteria

Regina sits at a table at a community center, recruiting people with diabetes for a weight loss study. She mistakenly assumes that the woman who sits down to talk to her has read the sign and understands that the study is only for people with diabetes. Regina is very thorough in her description of the study requirements – and the many benefits of participating – but neglects to ask the woman if she has diabetes. When Regina hands her some forms to review, she then notices that having diabetes is a requirement for study participation. She becomes angry with Regina for wasting her time.

Group Discussion (@14:17-16:08)
The group discusses how it can sometimes be difficult to tell people that they can't participate in a research study. Eligibility criteria do not always make sense to those outside of the study. This includes not only potential participants but also community research partners. Regina raises a key point: Community partners are often tasked with delivering researchers' messages. This is why, Carlos says, it's critical that those who are going to be recruiting and obtaining informed consent understand the ethical

and/or scientific reasoning behind the inclusion/exclusion criteria. You need to ask questions before you go out into the community, because you don't know what questions someone might ask you.

Another important point is raised in this discussion: participating in research is different from receiving services. The focus of research is trying new things and collecting data to see if something works. Even when services are part of the research, there may not always be a benefit to research participation. And even if inclusion criteria are broad, resources are limited, so not everyone who is interested may be able to participate.

Scenario 4 Discussion Questions

- How do you balance explaining the details of a study honestly with making it seem attractive to participants?
- How is participating in research different from receiving services? How is asking someone to participate in research different from offering services?
- As Regina says, community research partners are often in the position of having to explain the research – and the researchers' intentions – to community participants. What are some of the challenges of being in this position?

Protocol Specific Discussion Questions

- What are the ethical and/or scientific reasons for the eligibility (inclusion/exclusion) criteria for STUDY X? How would you explain this to a potential participant?

➢ Scenario 5 (@16:08 -18:13)

Eligibility Criteria May Be Complicated

Sarah attends a training session led by John, the principal investigator on a study with complicated eligibility criteria. The study is looking for children who are younger than one year old and who have no other siblings. The study will follow these children for several years to track school performance. John explains that all the children need to be approximately the same age when they enroll in the study so that comparisons can be made. He also explains why children are being enrolled at such a young age when the study is interested in school performance.

Discussion (@18:13-19:24)

Sarah discusses that she was nervous to ask a question at training, a little embarrassed even, but ultimately was glad she did. John admits that the amount of information presented at a training session can be overwhelming, and that researchers rely on your questions to help them do a better job explaining the study.

Scenario 5 Discussion Questions

- What are the eligibility criteria for the study presented in this scenario?

Protocol Specific Discussion Questions

- What questions do you have about the eligibility (inclusion/exclusion) criteria for STUDY X?
- What questions do you anticipate that potential participants in STUDY X might have about eligibility (inclusion/exclusion criteria)?

Information (13:51)

"Provide potential research participants with accurate information and enough details about the study to help them decide about participating."

Opening Scene/Group Discussion (@0:00 –2:17)

When Mark asks the experts about informed consent, Ronnie starts by discussing the informed consent form. He explains that while laws dictate what information must be included and require researchers to be truthful, the consent form is not a binding contract for participants. The signature provides assurance that an individual has learned the details of the study before they agree to take part, but research participation is always voluntary, and a participant can withdraw at any time (more on this later).Ronnie shares that when he first got involved in research, he thought he could just give people the consent form and they would read it on their own. This draws laughter from the group.

- **Scenario 6 (@ 2:15-5:10)**

An Example of Poor Informed Consent

Ronnie sits on a park bench with Shawn, discussing a study for injection drug users. Ronnie definitely downplays the requirements of being in the study, which will take place over several years and requires multiple surveys and many visits to a health clinic to have blood drawn for different kinds of tests, including HIV. Shawn seems primarily interested in the $15 that he'll get today for completing the first survey. Ronnie asks Shawn to sign the consent form – and he does – but it is clear that Shawn is not fully informed. Later we see Ronnie calling Shawn to reschedule a missed research visit. Shawn appears irritated. He thought he had completed the study. Ronnie is also irritated. There might be one less research participant in the study.

Group Discussion (@5:10-5:30)

Ronnie explains the importance of fully explaining all the requirements of a study to a potential participant, especially when a study requires a long-term commitment and multiple study visits. You might be able to get someone to sign the consent form today, but if they don't know what they are signing up to do, they might not show up in the future. For many studies, if a participant does not complete all the requirements, it's the same as if they were never in the study.

Scenario 6 Discussion Questions

- What were some of Ronnie's mistakes?
- What could Ronnie have done to ensure that Shawn better understood the study?
- Where should conversations about research participation and informed consent take place?
- How are consent forms different from contracts and other legal documents that we are used to signing in everyday life?
- What should you do if someone seems focused on the money they will receive for participating in research? Does this mean that you should not enroll them?

Protocol Specific Discussion Questions

- Where should conversations about research participation and informed consent for STUDY X take place?

➢ Scenario 7 (@5:30-9:51)

Examples of Valid Informed Consent

Ronnie is recruiting again for the same study. This time, he is in a quieter location seated across from a young woman, so he can review the consent form with her. He is much more thorough in his explanation of study requirements and risks and provides multiple opportunities for questions. The young woman has some concerns about the blood tests required by the study. Ronnie explains the study's privacy protections and limitations and gives her a few days to think about participating before signing the consent form. Then we see Ronnie talking to another young man, who like Shawn, is very interested in the money he will receive for participation. This time, rather than exploiting that interest, Ronnie slows him down and presents some of the risks of participation – in this this case, risks to privacy. The young man seems a bit surprised, and realizes that there's more at stake here than the money. He'll be sharing a lot of personal information. Ultimately, he decides to participate.

Scenario 7 Discussion Questions

- What did Ronnie do better this time?
- What are some of the risks of research participation?
- What are some of the pros and cons of having research participants sign the consent form right away, versus taking some time – even days – to go home and think about participation?

Protocol Specific Discussion Questions

- What are some of the risks of participating in STUDY X?
- What are some of the benefits of participating in STUDY X?
- What are some of the requirements of participating in STUDY X that might be difficult for participants to do?
- Should participants be asked to sign the consent form right away, or should they be told to think about it for a few days?

Brief Introduction Discussion Re: Next Topic (@9:52-10:17)
The group discusses research with medical records and the fact that some people are particularly sensitive about researchers looking at their medical records.

➢ Scenario 8A (@10:18-12:10)

A Participant Withdraws from a Study

Deborah gets an angry phone call from a young woman who signed a consent form for participation in a research study earlier that morning. She signed the form before she realized that the researchers would be collecting information from her medical records as part of the study. She is quite upset about this part of the research and wants to withdraw from the study completely.

➢ Scenario 8B (@12:10- 12:52)

What to Do When Something Goes Wrong

Upset about the angry phone call, Deborah calls Lucy, the study's principal investigator. Lucy and Deborah meet to discuss how to handle the situation. They decide to contact the woman again to reassure her that researchers have not looked at her medical record and provide her with documentation of her withdrawal. They also decide to report the event to the Institutional Review Board (IRB).

Group Discussion (@12:50-13:51)
Lucy discusses the importance of dealing carefully with participants who have complaints. She also explains the role and purpose of the Institutional Review Board (IRB). She emphasizes that all research must be reviewed and approved by an IRB before recruitment can begin.

Scenario 8 Discussion Questions
- Why might some people be concerned about researchers collecting information from their medical records?
- What would you do if you received an angry phone call from a research participant?

Protocol Specific Discussion Questions
- In what other situations should you consult immediately with the director or principal investigator of your research project?

Alternatives to Signed Consent Forms (7:32)

"In some cases, a signed consent form may not be required."

Introduction/Group Discussion (0:00-1:10)
Mark asks if every person in every study always has to sign a consent form. The group discusses some situations when a signed consent form is not required.

➢ Scenario 9 (@1:10- 3:40)

Conducting Survey Research Over the Phone

Sarah is conducting a survey over the phone. Since she is not ever meeting participants face-to-face, she cannot get their signature. And, since the study is anonymous and the risk of participating is low, she does not need to get written informed consent. But she still must tell participants the purpose of the study and potential risks, and she must give them an opportunity to decline participating. When calling, she discusses the purpose of the survey and informs the person on the other line how long the survey will take and what kinds of questions she will be asking if they agree to participate. She also lets them know that participation is voluntary and that they can refuse to answer any specific question with which they are not comfortable. She asks them at various points in the conversation if they agree to continue and gives them opportunities to ask questions.

Scenario 9 Discussion Questions
- Why didn't Sarah have to get a signed informed consent form from participants in this study?
- What makes a study "low risk"?

Protocol Specific Discussion Questions
- Is signed informed consent required for STUDY X? Why or why not?

➢ **Scenario 10 (@4:00-end)**

Protecting Research Participants From Social Risks

Carlos is recruiting day laborers for a study of working conditions. He informs a couple of guys about the study, but does not require them to sign anything. Because participants may be discussing illegal or dangerous labor practices by previous or current employers, and because the participants may be undocumented, serious harm could result to participants in the event of a breach of confidentiality. Therefore, in this case, *not* having them sign a consent form provides protection. This way, no one can find out the names of the participants in the study. However, participants must still be informed of all the risks and requirements of study participation.

Scenario 10 Discussion Questions

- Why didn't Carlos have to get a signed informed consent form from participants in this study?
- What were the main risks in this study? How did not having participants sign a consent form protect them from these potential harms?

Protocol Specific Discussion Questions

- Is signed informed consent required for STUDY X? Why or why not?

Understanding (8:36)

"Make sure participants really understand what they have been told about a study."

Opening Scene/Group Discussion (@0:00-2:15)
Mark asks the group how you know if a research participant understands what they are signing up for and what you can do to help research participants better understand. Our experts propose strategies for enhancing participant understanding, emphasizing that informed consent should be a two-way conversation.

➢ **Scenario 11 (@2:15-4:46)**

A Participant Who Cannot Read

Sarah discusses study participation with a man whose odd behavior suggests that he may not be able to read the consent form. She knows from training that he can still participate, even if he's not able to read. She also knows that because she can't rely on the written consent form, she needs to really make sure that he understands what she's asking him to do. She also doesn't want to embarrass him. She goes through the details of the study with him, sends him home with information, and suggests that he discuss participation with a family member before making his decision.

Scenario 11 Discussion Questions

- What might indicate (e.g., statements or non-verbal cues) that a person doesn't understand the information being presented to them?
- Should research participants ever be required to demonstrate (e.g., by correctly answering questions or passing a test) that they understand what they have signed?
- What do you think of the way Sarah responded when she figured out that the man she was recruiting couldn't read? Would you have done anything differently?
- What can you do to make sure that participants understand the requirements of a research study?

Protocol Specific Discussion Questions

- What would you do if during the process of recruitment and informed consent, it appeared that the person you were talking to could not read?
- Can someone who is not able to read participate in STUDY X?

➢ Scenario 12 (@ 4:45-8:36)

Research Versus Practice

The group discusses certain things about research that participants often have difficulty understanding. Ronnie discusses how explaining the difference between research and medical care can be particularly challenging. Shawn (the same research participant that appeared in Scenario 6) meets Ronnie at the health clinic for a study-related blood draw. Shawn has a wound on his leg and wants the nurse to look at it. Ronnie and the nurse explain that she is there only to draw blood for the study and that she cannot treat Shawn's leg because she doesn't have the necessary supplies. Ronnie discusses how it is important to make sure that study participants understand that being in research does not mean free medical care. He also addresses the limits of assisting study participants with their medical or other needs.

Scenario 12 Discussion Questions

- What are some things about a research study that might be difficult for a potential participant to understand?
- What do you think of the way Ronnie responded when Shawn showed the nurse the wound on his leg? Would you have done anything differently?
- How might you explain the difference between research and medical care to a potential research participant?
- What do researchers owe research participants? What are the limits of what researchers and research staff members can do to help research participants?

Protocol Specific Discussion Questions

- What are some of the aspects of STUDY X that might be particularly difficult for a potential participant to understand?
- What should you do if a study participant asks for help with something – for example, getting medical care, or finding a job or child care?

Voluntariness (6:48)

"Make sure that people feel like they can really say NO. Respect decisions not to participate or to stop participating in research."

Opening Scene/Group Discussion (@0:00-1:37)
The group explains that when you are responsible for recruiting participants and obtaining informed consent in research, it is NOT your job to get everyone/as many people as possible to say yes or sign the consent form. It's a bit more complicated than that. Your job is to give them all the information they need to make an informed decision on their own – one that is in their best interest. As Deborah puts it, "Informed consent is not a sales job." The group also discusses that people have different reasons for participating in research.

➢ Scenario 13 (@1:30-3:10)

Making Sure People Can Say No

Regina emphasizes how important it is to make sure that saying "no" is a real option for potential participants. She plans to recruit women from her local community center; she's been working out there and knows a lot of people. But, in talking to a few of these women, she realizes how hard it is for some people to say "no" to someone they know. She decides instead to just put up some of the study recruitment posters at the center and leave it at that.

Scenario 13 Discussion Questions

- How do you balance meeting a study's recruitment goals with ensuring voluntary participation?
- What are some of the reason people might not want to participate in research?
- What are some of the reasons it might be hard for someone to say "no" to research participation?
- What are some ways to ensure voluntariness in a research study?
- When might it be better to recruit participants using methods like posters or flyers rather than asking them in person?

Protocol Specific Discussion Questions

- What are some of the reasons people might not want to participate in STUDY X?
- What are of the reasons it might be hard for someone to say "no" to participating in STUDY X?
- What are some ways to ensure that people participate voluntarily/don't feel pressured to participate in STUDY X?

➢ Scenario 14 (@3:10-6:00)

Saying "No" to Research and Concerns about Relationships and Services

Sarah works at an after-school program. She is recruiting children from the program for a research study. Sarah talks to Raquel, the mother of two children who attend the after-school program. Raquel has some concerns because the program aims to prevent risky behavior, and she feels her children might be too young. On the phone with her husband, Raquel questions whether they really have a choice to participate in the research. They don't want the kids to lose their spot in the after-school program. Raquel expresses this concern to Sarah, who reassures her that whether or not she agrees to allow the children to participate in the study will not affect her relationship with the after-school program.

Group Discussion (@6:00-6:48)

When recruiting people you know, special considerations for ensuring voluntariness are needed. Personal and professional relationships can affect people's perceptions of their true ability to say "no." In so many other areas of life, there are consequences for saying "no." But there should not be such consequences in research, because as we have learned, research is different. There are special rules.

Scenario 14 Discussion Questions

- Why did Raquel think that she didn't have a choice about enrolling her children in the research study?
- Would it be fair to require all the children in the after school program to participate in the research study? Why or why not?

Protocol Specific Discussion Questions

- Are there any types of people who are being invited to participate in STUDY X who might feel like they don't have a choice to participate?
- What can be done to make sure people know they have a choice?

Advice From Our Experts (5:06)

In this last segment, we hear words of wisdom from our experts:

- Before you start talking to potential participants, you should know all the study materials and details backwards and forwards. You will need to be able to answer any questions that people might have, and think on your feet if you run into any problems.
- When you are recruiting participants for a research study, you have two main goals. ONE: Identify and invite only eligible participants. And TWO: Obtain valid, voluntary informed consent. Doing it right – in a way that provides accurate information and respects people's right to say NO – is more important than recruiting lots of people. So, no short cuts.
- Some days, it may seem that your primary job is to get as many people as possible to sign up. In fact, some days it may seem that this is the only thing the researchers you are working with care about: "How many people do we have?" But the MOST important thing is voluntary informed consent.
- Asking people to participate in research isn't always easy. Not everyone will be happy to talk to you or want to participate. And some people may rudely brush you off. It's important to be prepared for this and realize that there's not much you can do about it. This rejection comes with the territory. But it's not your job to convince people to do something they don't want to do.
- You have an important role in helping researchers figure out the best ways to recruit participants and obtain valid informed consent. Recruiters who are out in the field are the first to realize if a study's recruitment protocol is not working as planned, or if information on a consent form is not understandable by the people the study aims to recruit.
- If something is not working, or does not seem right, speak up and share your insights with your university academic partners. This can serve to better protect participants and enhance their experience of participation. It can also help your study meet its recruitment goals.
- Ensuring that participants really understand the research and give their informed consent freely can make the entire research experience better – both for the participant and for the research team.
- For many people living the United States, English is not their first language. Some studies may be able to hire people who speak other languages. But in some studies, especially those that are small or have limited resources, it may be necessary to exclude non-English speakers from participating. Although excluding people based on their ability to speak English is not ideal, it is disrespectful- and could even be harmful – to enroll someone to participate in something that they don't understand.
- Written materials, like the consent form, should not be translated "on the spot" by research staff or family members. If members of non-English speaking communities are going to be targeted for the study, then all the study materials, including the consent form, should be translated ahead of time and approved by the institutional review board.
- If you take the time to help participants understand the research, there is less of a chance that they will be surprised or upset by anything that happens in the research.
- Good informed consent improves trust. When participants trust you they will tell you the truth and take time to think about their responses.
- If you provide detailed information, participants will feel comfortable asking you a question if there is something they do not understand. Their understanding may also increase the chances that they don't miss research-related appointments.
- When participants respect you, they will be more likely to show up for scheduled appointments on time or call when they are not able to make it to a scheduled meeting. Your interactions with participants will be more satisfying if you take the time to explain all the important details up front.

For more information on CIRTification or Informed Consent in Action, please contact:

Emily Anderson
emanderson@lumc.edu or
cirtificationresearchtraining@gmail.com