



# Mitigating Ethical Risks

## PURPOSE

This document provides guidance for those conducting human subjects research on ways to mitigate risks to participants across the project cycle, from inception to close-out.

Researchers are responsible for ensuring that any risk to participants is minimized to the full extent possible before beginning research activities. Additionally, the overseeing Institutional Review Board (IRB)<sup>1</sup> will consider whether “risks<sup>2</sup> to subjects are reasonable in relation to anticipated benefits... and the importance of the knowledge that may be reasonably expected to result,” before granting approval.<sup>3</sup>

## GENERAL TIPS FOR MINIMIZING RISKS<sup>4</sup>

### Psychological Risks:

Remind participants of their right to withdraw from research or limit their participation if they become uncomfortable, provide counseling or psychological support for those who experience distress, and thoroughly debrief with participants after research sessions are completed.

### Social Risks:

Protect confidential data collected as well as the fact that the subject is participating in the research project itself.

### Legal Risks:

Protect confidentiality of research data and ensure all relevant local laws, including age of consent and mandatory reporting, are followed.

### Physical Risks:

Carefully follow protocols, have trained individuals conduct research procedures, closely monitor participants' health status, recruit appropriate populations, and provide clinical care when needed.

## PLANNING STAGE

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<sup>1</sup> The ethics committee responsible for reviewing and approving research conducted with humans to safeguard the rights and welfare of participants

<sup>2</sup> Per federal regulations, risk is measured both by the magnitude of a potential harm or discomfort and the probability that it will occur

<sup>3</sup> [45 CFR 46.111\(a\)\(1,2\)](#)

<sup>4</sup> Adapted from [NIH Research with Human Subjects Training](#)

### **The Research Team:**

- Recruit and employ staff with appropriate skills and experiences necessary to properly carry out research activities. Literacy level, language and translation skills, and gender (i.e., female researchers working with female participants) are all important considerations when building a team.
- Ensure all members of the research team are properly trained to work with the specific subject population. Conduct intensive staff trainings on the protocol and how to appropriately answer questions related to the study, methods to obtain truly informed consent and minimize potential coercion, context-specific cultural sensitivity, relevant local laws, and the importance of assuring privacy and confidentiality.
- Where possible, have research staff sign confidentiality agreements, which stipulate that breaches of confidentiality will result in termination. Additionally, develop and train staff on protocols for reporting and responding to breaches of confidentiality. Staff should be able to report such breaches safely and confidentially without threat of repercussion.

### **Study Design:**

- Consider the timing of the research. Will the study interrupt school, holidays, religious obligations or harvest season? When working with children, plan the study according to the local academic year. Ensure that participation will not conflict with school attendance, worship or standard work schedules to avoid causing additional stress for the subject.
- Work with local staff to develop contextually-appropriate tools and instruments. Whenever possible, utilize previously validated tools and adapt for the context in which they will be applied.
- Consider non-traditional survey and data collection methods. Tools like Audio Computer Assisted Self-Interviewing (ACASI) have been used by IRC and Population Council to conduct interviews in low-resource settings when working with historically non-written languages or when unable to find enough literate staff to serve as in-person interviewers. Because respondents complete the survey or questionnaire independently without the need for an interviewer, this type of tool is especially well-suited for research on sensitive topics.
- Ensure subject selection and inclusion and exclusion criteria are equitable so as to not exacerbate any local tensions between groups.
- In studies that involve treatment and control groups, allow the control group to receive the intervention after post-tests or endline data collection are complete. This approach addresses the ethical concern of withholding the treatment from some participants.
- Confirm that all personally identifiable information to be collected is absolutely necessary to the research. Do not collect any unnecessary identifiable information in order to minimize the risk of breach of confidentiality.



### Engaging the Community:

- Ensure efforts to engage community leaders and obtain their support of the study do not reveal details about sensitive topics to be addressed through the course of data collection.
- Confirm that communication and feedback mechanisms are in place to immediately flag areas where study procedures may inadvertently exacerbate local tensions or conflict.

## OPERATION STAGE

### Informed Consent:

- The informed consent process should emphasize the voluntary nature of study participation and the subject's ability to withdraw from parts or all of the research at any time. Researchers should make every effort to minimize coercion and undue influence while providing participants with information on the purpose and procedures of research as well as potential risks and benefits. For more detailed information on the consent process, please refer to the [Informed Consent Checklist](#), [Consent Form Guidance and Template](#), and [Guidance on Obtaining Meaningful Informed Consent](#).
- Ensure there is a process in place should a participant choose to withdraw from the study, which should be described in clear and appropriately translated language to all participants during the consent process.

### Data Collection:

- Identify private, safe spaces in which to conduct any data collection involving participants, including interviews, focus groups, and surveys. If any study tools, such as tablets, are likely to draw outside attention, make efforts to minimize their visibility in public spaces.
- During data collection, on-site research staff should be responsible for monitoring the space to ensure privacy and confidentiality is maintained. In the event that privacy is breached, have a contingency plan in place. This may involve pausing the activity or switching to a dummy questionnaire until privacy is re-established. Reschedule the activity to a later date if necessary.
- Before and during data collection activities such as interviews, remind participants that they can skip certain parts or stop the activity at any time should they feel uncomfortable. Researchers should be trained to identify signs of distress and stop activities accordingly if a participant seems unable to continue.
- Introduce sensitive topics or questions to the participant with normalizing statements so that they do not fear judgment for answering in a certain way.
- When dealing with sensitive topics, schedule a debriefing between the researcher and participant in order to look for any sign that the participant may need to be referred to clinical or psychological services. When applicable, provide participants with information about how to



obtain professional assistance, as well as means of confidential support provided by the IRC. It may also be helpful to have trained professionals available near the location of the activity.

- If the research appears to be causing more than minimal risk to the subject, or exceeding the expected amount of risk or harm initially anticipated, the study team should submit a Reportable Event Form to the IRB and halt research activities until the project's IRB can address the issue.

## THE CLOSING STAGE

### Data Management

- When handwritten-notes, paper surveys, or audio tapes are used in data collection, immediately transfer hard copies to locked storage that are only accessible by the research team. If possible, transfer the data to a password protected computer and destroy hard copies to limit the risk of breach of confidentiality.
- Ensure all data are stored on password-protected and encrypted devices so that the information can only be accessed by the research team.
- Anonymize or de-identify data as early as possible in accordance with the research design to minimize the possibility that confidential data could be leaked.
- Participants must provide additional consent if any of their data is to be shared beyond the original scope described in the initial consent form. It should be made clear who will have access to this information, how it will be used, and what efforts will be taken to maintain confidentiality.

### Publication of Findings

- Closely consider whether research participants could be in any way identified by the data included in publication, even when no personally identifiable information is included. Geographic details and age ranges along with many other more general forms of demographic information can provide unintentional hints linking subjects to the research.
  - A publication may, for example, include the name of the area or village where the research took place and information on subjects over the age of 70. If however, there are only a handful of people over 70 living in that area, it might be possible to link the subject to the data. To minimize risks to subject, remove any such identifying details or context clues whenever possible.

## MINIMIZING RISKS WITH VULNERABLE POPULATIONS

### Research Involving Children

#### *General Guidance*

- The IRC has a zero tolerance policy regarding the abuse and exploitation of children. When research involves child participants, all IRC workers, visitors, sub-grantees, suppliers/sub-contractors, and implementing partners must review and comply with IRC's Child Safeguarding



Policy.

- For further guidance on allowable risk levels and the consent process, please reference [Federal Regulations on Research Involving Children](#).<sup>5</sup>

#### *Informed Consent*

- Consult local laws to determine the legal age at which someone can provide consent to participate in research. When working with children under the age of consent, researchers must obtain the assent of the child as well as the consent of their parent(s) or guardian(s).<sup>6</sup>
- The child should not participate in the study if the researcher does not feel that that they are consenting of their own free will, but rather due to pressure from their family or community. Additionally, children should not continue to participate in the research if it becomes apparent to the team that they are doing so out of fear, obligation, or guilt. Consult with in-country child protection staff and the overseeing IRB to determine the best course of action in such a case.

#### *Child Protection Procedures*

- A list of relevant health and protection services must be maintained for referral whenever working with children.
- IRC staff must immediately report suspicion or allegations of child abuse or exploitation or policy non-compliance in accordance with the IRC's Global Reporting Guidelines.
- When working with individual children, make sure wherever possible that more than one adult is present.
- During long-term studies, children may grow attached to the researchers. Make certain that the child understands the timeline of the study and the reason why the researchers will no longer be in their life after the completion of the study.

#### *Use of Image*

- Ensure that images taken of children are accurate and respectful of children's privacy and dignity. Children must be adequately clothed in images. Obtain informed consent from children and their caregivers before taking photographs of them, and restrict use of images of child beneficiaries to professional, respectful, awareness raising, fundraising, publicity, and programmatic purposes. Any image or recorded case history of a child must not place him or her at risk or render him or her vulnerable to any form of abuse.

### **Research Involving Refugees and IDPs**

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<sup>5</sup> [45 CFR 46 Subpart D](#)

<sup>6</sup> Consent of one parent is needed for research that does not involve greater than minimal risk or involves greater than minimal risk, but presents the prospect of direct benefit to the subject. Consent of both parents is required in all other cases unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.



### *Context*

- Investigators should build an early understanding of the environments in which they will conduct research, whether it be a temporary host community, IDP camp, or permanent resettlement location. Account for the demographic make-up of the area, underlying tensions between groups, and power dynamics in order to best protect refugee participants from risk of unfair treatment or retaliation by the surrounding community.
- Migrant populations face an inherent risk of trafficking due to unstable economic and living situations. Ensure researchers are trained to recognize and respond to victims of trafficking and other forms of physical, mental, or emotional abuse.

### *Power Dynamics*

- Remain cognizant of perceived power imbalances between researchers and participants. Refugee populations living in camps often believe that researchers or personnel connected with outside NGOs have the power to affect their financial assistance or chances of resettlement. Make every effort to explain to participants that participation, or lack thereof, in the research will have no impact, positive or negative, on benefits or assistance.
- Refugees may face heightened consequences in the event of a breach of confidentiality. At times, for example, camp authorities have punished refugees who were found to have shared instances of malpractice or neglect in the camp system with outside researchers. Because of the refugee's inherent power disadvantage in such an environment, confidentiality becomes even more paramount to their safety.
- When possible, create an agreement with the refugee groups which gives them the authority to sign-off on materials such as reports and images before release. This approval mechanism enhances the consent process and transfers some of the power and ownership of the research back to the participants.<sup>7</sup>

### *Consent*

- Ensure that refugee subjects are able to consider what participation in research might mean at a later stage in their life. Many are eager to share their stories while living in a camp, but might not understand the implications of seeing their image or story in a book or advocacy campaign once they are resettled elsewhere.
- Strive for complete transparency and set realistic expectations for participants about what can and cannot be likely expected to come of the research. Unfulfilled expectations and the mishandling of sensitive issues may increase the risk of retraumatization for the participant.

## **Research Involving Pregnant Women**

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<sup>7</sup> This guidance was adapted from [“‘Stop Staling Our Stories’: The Ethics of Research with Vulnerable Groups.”](#) See article for more information reciprocal research and the ethics behind working with refugees and IDP populations.



- Refer to [federal regulations](#) which provide additional protections for research involving pregnant women, fetuses, and neonates.<sup>8</sup>
- Women who are pregnant, nursing, or caring for young children may face increased physical and mental risk from participation in research. Investigators should take into account the different nutritional demands on a pregnant or nursing woman's body, as well as the risk of triggering post-partum depression should a study cause emotional discomfort or additional stress on the new mother.
- This population may also be in greater need of financial or nutritional support for themselves and their children, making them increasingly vulnerable to coercion. Investigators should consider this risk of coercion when deciding whether or how much to offer participants in terms of compensation.

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<sup>8</sup> [45 CFR 46 Subpart B](#)

