J-PAL
ABDUL LATIF JAMEEL POVERTY ACTION LAB

Collaborating with the Institutional Review Board (IRB)

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Objectives:

1. What the IRB is and what it does.
2. International research.
3. How the IRB protects participants.
4. Strategies for communicating with the IRB

What the IRB is

- The Federal regulations often referred to as the Common Rule or Subpart A of regulatory requirements of 45 CFR 46; establishes that an IRB exists to ensure the ethical protection of participants from the reasonably foreseeable risks of harm caused by research.
- The Common Rule is the codification of the ethical principles of Belmont: respect for person, beneficence and justice.
- May be part of an academic institution; a medical facility; a federal, state, or local agency; or any other organization or commercial entity.
- The singular mission of an IRB is the protection of participants in research.

International research

1. International research is not different from domestic research. Belmont still applies.
2. Cultural norms will always be a focus of attention and respect for culture needs to come across in the research proposal.
3. Research in another country may involve observing or recording illegal activity.
4. What constitutes a “vulnerable” populations may be more broadly defined.
5. Equivalent protections.

What an IRB does not do:

1. Manage, approve or monitor grants or mechanisms for funding the research.
2. Develop financial conflict of interest disclosures or management plans.
3. Develop Non-disclosure agreements or data sharing agreements such as data transfer or data use agreements.
4. Determine compliance with Family Educational Rights and Privacy Act (FERPA).

Note: HIPAA compliance may or may not be an IRB responsibility depending on if the IRB is the privacy board for the covered entity.

Protection of participants in research:

Three focal points:

- the identifiability of the data or information being used or collected in the research;
- the sensitivity of those data as it relates to the identifiability; and
- the probability and magnitude of harm as it relates to the sensitivity of the data and the overall benefits of the study.

Protection of participants: the review process

1. Is it research activity that meets the definition of "human research"?

   Is the research activity a systematic collection of information, intended to produce generalizable knowledge, *about* humans, social behavior or the social environment.

2. If it is human research:

   a. Is it federally funded?

   b. Is the researcher an agent and is the institution engaged?

Protection of participants: the review process (cont.)

3. Is it exempt or non-exempt?
    a. What is the level of risk as it relates to the probability and magnitude harm?
    b. What is the identifiability and the sensitivity of those data?
    c. Is informed consent needed?

Strategies for communicating with the IRB:

1. Know your IRB. Use the approved protocol template.
2. Provide a detailed description of what the research is proposing to do with participants and / or their identifying information.
3. Specify roles and responsibilities of the study team members and individual collaborators and collaborating organizations.
4. Provide a clear data management plan.
5. Be specific about the identifiability and the sensitivity of the data.
6. If applicable, identify the type of data sharing agreement and the process for establishing it.
7. Use the language of the IRB.