

## **Appendix D: Institutional Review Board (IRB) of the Urban Institute**

### **Overview**

The Urban Institute takes seriously its ethical responsibilities in the performance of research involving human subjects. It is the Institute's policy that all research involving human subjects adhere to the following principles:

- Subjects are informed of the purposes of the research, the types of data to be collected, and the methods used to safeguard the confidentiality of sensitive data. In some research, possible risks to subjects may require formal informed consent.
- Adequate provision is made to protect the privacy of subjects and to maintain the confidentiality of data.
- Risks to subjects are minimized to the extent possible within the research design.
- Risks to subjects (from the research) are reasonable in relation to anticipated benefits (from the research).
- The selection of subjects is as equitable as possible (so that the burdens and benefits of the research are fairly distributed) and particular attention is paid to research involving vulnerable populations.

Federal regulations require research involving human subjects to ensure adherence to these principles and in certain circumstances to be certified by a formally established "institutional review board." Accordingly, the Institute has established the Institutional Review Board (IRB) to make certain that its research practices and procedures effectively protect the rights and welfare

of human subjects according to the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46).<sup>1</sup>

The Urban Institute's Institutional Review Board is appointed by the executive Vice President, who is designated the "institutional signatory official." The IRB consists of a chairperson who presides over matters before the IRB, an IRB administrator who has overall responsibility for managing matters coming before the IRB, and four primary members, one of whom is not otherwise affiliated with the Urban Institute and one other of whom has responsibilities primarily in non-scientific or non-research areas.

### **IRB Review Process**

The Urban Institute's IRB has the authority to review and to approve, require modifications to secure approval, suspend, or disapprove all research activities involving human subjects. Every research project is required to complete and submit a Screening Sheet to the IRB at the time the funding proposal is prepared. This Screening Sheet is used to determine whether full IRB review or expedited review is required prior to the start of data collection. Similarly, a revised screening form is required for any project collecting new primary data not previously reviewed.

For projects that require either a full IRB review or an expedited review, principal investigators are responsible for preparing review materials and completing the review process prior to the start of any relevant data gathering. IRB reviews require preparation of brief descriptions of project methodology, risks to subjects and plans to mitigate such risks, data confidentiality and security plans, and informed consent procedures.

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<sup>1</sup> The UI IRB is registered as Federal-Wide Assurance (FWA) # 00000189. This FWA is accepted by the government in lieu of a Multiple Project Assurance (MPA).

In preparation for IRB review, the UI principal investigator must prepare a package of materials that includes the following components:

- Summary of the study's purpose, methods and procedures to be used, the study population and what is required of the subjects.<sup>2</sup>
- Statement of whether the research involves the collection of private or sensitive data and/or requires the use of data or records linked to individual identifiers; and if identifying information is to be collected, description of data security procedures.
- Assessment of any potential risks - physical, psychological, social, employment, legal or other - and the likelihood and seriousness of such risks; and description of procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness.
- Discussion of the potential benefits to individual subjects and to society in general as a result of the planned work; and indication of how the benefits outweigh the risks.
- Description of consent procedures to be followed, including how and where informed consent will be obtained.
- A sample staff confidentiality pledge to be used by all research staff having contact with human subjects or sensitive project data.

Project directors with research involving IRB review are required to notify the IRB in writing, if any material and relevant changes in the project occur subsequent to IRB review. And the status of every project involving IRB oversight is reviewed annually by the IRB.

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<sup>2</sup> If the study population consists of special groups such as prisoners, children, and the handicapped or mentally disabled, the economically or educationally disadvantaged or other groups whose ability to give voluntary informed consent may be in question, it is necessary to provide the rationale for using this particular population and to describe additional safeguards that will be instituted to protect the rights and welfare of these subjects.

If an adverse event – that could pose unanticipated potential harm to a research subject -- occurs during a project, the principal investigator is required to submit a written report to the IRB within three working days, along with information about any anticipated repercussions and any proposed or actual resolution taken. The IRB may temporarily discontinue a research project until a thorough investigation has been conducted. Dependent on the investigation, the IRB may request changes to a research project or permanently discontinue the research project.

### **Human Subjects Training**

The Urban Institute has also established human subjects training requirements to ensure that all staff members fully understand and adhere to procedures for protecting human subjects. All research staff, center administrative staff, contracts staff, and IT staff are required to complete the human subjects training. New staff are required to complete the training within 45 days of starting work. The IRB will not conduct a review for a proposed project unless the principal investigator has completed this training.