Promise Neighborhoods Technical Assistance on
Institutional Review Board (IRB) Approval

The US Department of Education notified grantees of the time-sensitive need for IRB approval **before** proceeding with research covered by IRB. Sites should consider their options for moving forward with IRB approval:

1. Use your organization's existing IRB (usually for university-based grantees)
2. Set up your own IRB (likely not an option given the time-sensitivity and burden)
3. Borrow the IRB of a local partner or university
4. Contract with one of the commercial IRBs available to review proposals within a set timeframe for a fee

This document contains more information on option 4, as well as a further description of the IRB process and package requirements for review.

Contract with a commercial IRB available to review proposals within a set timeframe for a fee:

Grantees can search the Office for Human Research Protections (OHRP) Database for Registered IRBs at the following site: http://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc.

According to these websites, commercial IRB fees can range from $500 for an expedited review to $1,200 for a full review. Turnaround time can range from same-day service for an expedited review to six days for a full review. More information on specific processes and fees is available on the sites.

IRB Review Process

An **IRB** is a group of five or more individuals whose primary responsibility is to protect the rights and welfare of research subjects. IRBs review proposed research and have the authority to approve, require modification in, or disapprove research activities subject to the regulations. There are two types of IRB review for covered activities. Through a screening form, the IRB will assess which review is most appropriate for the submission.

An expedited IRB review is generally limited to projects involving human subjects where no linked personal identifiers are being collected, the study population is not vulnerable, and there is minimal risk (physical, reputational, or financial) to any human subject involved. An expedited review package should provide (see below for a more in-depth explanation of each item):

- A brief discussion of the research to be conducted,
- Informed consent procedures,
- Risks to participants,
- A data security plan,
- A sample staff confidentiality pledge,
- A copy of your survey/questionnaire, if applicable, and
- IRB screening form or any other administrative forms required.

Expedited reviews usually require fewer reviewers and (if your package is complete) can be approved in a day or two. Approval is normally good for one year from the date signed. If the project is expected to

go beyond the 12 month approval period – or if there is any substantive change to any aspect of the project – you must go back to the IRB requesting renewal for each year or approval of the change to the project.

A full IRB review is required for any project involving human subjects where personal identifiers are being collected, or the study population is vulnerable (children, prisoners, pregnant women, immigrants), or there is more than minimal risk to any human subject should sensitive information about them or their participation in the research be disclosed. A full review package should include the following information:

- Research overview: background, research objectives, funder name, research partners, data collection methods, sites to be visited, and any other relevant information
- Informed consent procedures: forms used, description of process
- Risks to participants: description of possible risks to participants
- Data security plan: explains how data will be collected, stored, transmitted, and secured during each step. Will PGP data encryption be employed? If mailed, will trackable means be used? Who will have access? Are there "work arounds" that have been considered as alternatives to collecting sensitive data such as SSN's, names and addresses, etc.? If hard copies are filed, where are the files stored, are they under lock and key, where are the keys stored, who has access?
- Staff confidentiality pledge: a copy of the pledge to be used
- Questionnaire/survey/focus group script: at least a draft of the instrument in development and the IRB will need to review the final product before it is administered
- Any other relevant information, e.g., if another organization is a research partner and their IRB has reviewed any aspect of the work to be performed, please provide a copy of that approval.
- Research team: biographies for the PI and other senior researchers conducting the work
- IRB screening form or any other administrative forms required

Upon review, an approval certificate will be issued that is usually good for 12 months from the date signed (unless the IRB decides the level of risk requires more frequent renewal). If the project is expected to go beyond the 12 month approval period – or if there is any substantive change to any aspect of the project or new survey/data collection instruments developed – you must go back to the IRB requesting renewal for each year or approval of the change to the project.

Covered Activities and Review Timeline:

Sites should discuss their specific project plans with their chosen IRB to determine:

1. Which type of IRB review may be required for each activity and
2. Whether IRB approval should be fully completed before undertaking each activity.

It may be possible to sequence IRB approval as activities and data collection instruments are developed. For example, the IRB may review and approve an initial research protocol while certain materials,

including surveys and consent forms that will be developed over time as part of the project, may be submitted to the IRB as they are developed, on condition that approval is obtained prior to the use of the materials. An IRB familiar with social science or education research would be helpful in these considerations (some IRBs focus on other areas, such as biomedical research). The following Promise Neighborhood activities are identified by the Urban Institute as possible covered activities for IRB (an IRB screening form will help detail this information for your chosen IRB). Urban consulted the Department's Protection of Human Subjects Coordinator on these activities and those thoughts are also included for each activity below.

- Collecting personally identifiable information from administrative data sources, including school district records, on students under 18 years old and linking those data in a case management system for the purpose of tracking program performance and measuring outcomes.
    - Use of directly or indirectly identifiable student records for research purposes are, in this context, likely to be covered research and need to have human subjects research approval prior to accessing and using that identifiable data.
- Collecting personally identifiable information through an intake process for the purpose of providing services to families with children and individuals (adults and children) and linking those data in a case management system for the purpose of tracking program performance and measuring outcomes.
    - In some cases, routine non-research activities can move ahead while waiting for IRB review. Depending on the specifics, this activity may fit into the category of things that a site is doing anyway as part of its normal operations—if these are not activities initiated for purposes of the research.
- Collecting anonymous survey data on neighborhood residents, including specific information on children under 18 years old, for the purpose of tracking program performance and measuring outcomes.
    - Some projects may include a mix of covered and exempt research activities. If any portion of the research includes nonexempt human subjects research, then the entire study needs human subjects approval before any of the research can begin.
    - Pre-human subjects research activities such as preparing surveys, identifying potential research sites and populations can go ahead while working on human subjects approval for the "human subjects research" activities.
- Collecting anonymous survey data in schools on students under 18 years old for the purpose of tracking program performance and measuring outcomes.
    - Same considerations as neighborhood surveys above.