

## EVALUATION BRIEF

# Understanding the Institutional Review Board (IRB)

January 2008

### What Is an IRB?

An IRB is a committee set up by an organization to review, approve, and regulate research conducted by its members, on its premises, or under its sponsorship.<sup>1</sup> The National Research Act, passed by Congress in 1974, directed all institutions receiving federal support for research and evaluation studies—including universities, public schools, hospitals, and nonprofit organizations—to establish IRBs. The primary responsibility of an IRB is to ensure that the risks faced by human participants in research are minimal. If an IRB determines a research project to pose more than minimal risk, the IRB may ask the researcher to revise the study design. In some cases, the IRB may refuse to approve a study if the research is deemed harmful to participants, careless, or unethical.<sup>2</sup>

An IRB consists of at least five members with varying backgrounds in respect to race, gender, cultural background, and profession. IRB members must have expertise in the areas of research they review, and at least one member of the IRB must be a representative of the greater community, rather than the affiliated institution.<sup>3</sup>

### What Does an IRB Do?

IRBs review any proposed research protocol involving human subjects, including medical research and all behavioral or social research studies, which includes evaluation research. A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.<sup>4</sup> Human subjects can include clients, program participants, members of an organization, constituencies, or the general public. IRBs also make sure provisions are in place to protect vulnerable populations such as children, prisoners, pregnant women, and the cognitively impaired.

IRBs ensure that research investigators satisfy the following requirements:

- (1) Risks to subjects are minimized.
- (2) Risks to subjects are reasonable in relation to any anticipated benefits to subjects and the importance of the knowledge the study is expected to produce.
- (3) Selection of subjects is equitable, in regards to the problems of research involving vulnerable populations.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.



- (5) Informed consent will be appropriately documented.
- (6) When appropriate, the research plan makes adequate provisions to monitor the data collected in order to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<sup>5</sup>

### How Can I Find Out Whether My Project's Evaluation Needs IRB Approval?

To decide whether your evaluation needs IRB approval, you must consult the guidelines on protecting human research subjects from the following sources: (1) your funding agency,<sup>a</sup> (2) your agency, organization, or institution, and (3) your evaluator (if using an external evaluator) and his or her affiliated institution.

#### *Step 1. Consult Your Funding Agency's Guidelines*

Most often, your funding agency will provide guidance on whether your evaluation needs IRB approval. It is increasingly common for funding announcements to include specific information about obtaining IRB approval; some even require applicants to describe plans for gaining IRB approval in their proposals. For example, the following excerpt from a recent Children's Bureau program announcement instructed applicants on the need to obtain IRB approval:

Evaluation plans that include obtaining identifiable private information about clients may involve non-exempt human subjects research and require compliance with the HHS Protection of Human Subjects regulations (45 Code of Federal Regulations (CFR) Part 46). Applicants proposing such research are asked to describe: (a) the procedures for protecting the privacy of clients and insuring the confidentiality of data collected about clients; and (b) the process for obtaining institutional review board (IRB) review of the proposed evaluation plans. While IRB approval is not required at the time of award, applicants proposing non-exempt human subjects research will be required, as a condition of award, to hold a Federal-wide Assurance (FWA) approved by the Office for Human Research Protections (OHRP) and to provide certification to ACF that an IRB designated under the FWA has reviewed and approved the research prior to enrolling any subjects in the proposed evaluation. Certifications of IRB approval may be submitted to ACF using the form at <http://www.hhs.gov/ohrp/humansubjects/assurance/OF310.rtf><sup>6</sup>

If your project is receiving funding from multiple sources, your project will need to satisfy the requirements of each funding source. For example if your project is receiving both State and Federal funding, your project will need to meet the requirements of the State funding agency as well as the Federal government.

#### *Step 2. Consult Your Own Agency's Guidelines*

In addition to satisfying the requirements of your funding agency, you must also consider the requirements of your own agency, organization, or institution. In cases where the funding agency does not require IRB approval, your agency (i.e., the agency that is fiscally responsible for the grant) may still require IRB approval. For example, a

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<sup>a</sup> This document was developed for project staff and evaluators of programs receiving discretionary grant funding through the Department of Health and Human Services (HHS). Therefore, the funding agency is assumed to be HHS.



university may require an evaluation to undergo IRB review even when the funding agency does not. Some IRBs will require all research projects to submit an application for review, regardless of whether the investigator believes the research is exempt from review. The safest bet—for the investigator, sponsoring agency, and the IRB—is for the IRB to decide which research projects require IRB review and which projects are exempt from review.

*Step 3. Consult Your Evaluator's Institutional Guidelines.* If your project is utilizing an external evaluator that is affiliated with an IRB, the evaluators may need to obtain IRB approval from their IRB as well. For example, if you have contracted with the social work department of your local university to conduct the evaluation, the university may require that the evaluation obtain IRB approval from the university's IRB, in addition to the IRB governing the agency's research and evaluation studies.

Most likely, your project will only need to secure IRB approval from a single IRB, but your project must meet the requirements for protection of human subjects as determined by the funding agency, the project agency, and the evaluator's institution.

### Does My Funding Agency Require IRB Approval?

All agencies under the umbrella of Health and Human Services, including the Children's Bureau, are subject to the Code of Federal Regulations known as 45 CFR Part 46. These regulations establish the role of IRBs in protecting human subjects, the criteria for obtaining IRB approval, the types of research both covered by and exempt from the regulations, and additional protections for special populations. **Your project is subject to the Code of Federal Regulations and must obtain IRB approval if your evaluation will utilize identifiable private information.**

Figuring out whether your project is required to obtain IRB approval is a two-step process: (1) you must first determine whether your project will utilize private information, (2) then you must determine whether this private information is also considered identifiable.

#### *Step 1. How do I determine whether my evaluation will use private information?*

Private information includes:

- Information collected about a person's behavior that occurs when a person typically expects that no observations or recordings are taking place. Since observations or recordings are taking place, the behavior is no longer private. Examples could include observations or recordings of a child's behavior, parent child interactions, or the demonstration of skills acquired in a training program.
- Information provided by an individual for a specific purpose that a person typically expects will not be made public. Examples could include information disclosed in an intake or other assessment, information otherwise found in a case file, and information obtained through pre/post tests.

#### *Step 2. How do I determine whether my evaluation will use identifiable information?*

Private information, as described above, is considered *identifiable* private information, when the investigator is able to link the information back to the individual.<sup>7</sup> When a participant's name, address, telephone number, social security

number, or other identifying piece of information is disclosed, the investigator is able ascertain the individual's identity, either directly (i.e., through a name) or indirectly (i.e., through a phone number).

### Is Coded Data Considered Identifiable Private Information?

The term "coded data" refers to data where any identifying information (that would enable the investigator to learn the identity of the individual attached to the data) is removed from the data and replaced with a code containing numbers and/or letters. The data are considered coded because a key to decipher the code exists, enabling the investigator to link the identifying information back to the private information.

In evaluation research, data are often coded to protect the confidentiality of respondents. Coded data are still considered identifiable because an investigator can potentially learn the identity of the individual, either directly or indirectly.<sup>8</sup> **If the data are collected along with names, addresses, or other personally identifying information at any time, the possibility exists for the evaluator to link the information back to the individual and the data are considered identifiable.** Therefore, demonstration projects that plan to provide the evaluator with coded data must still obtain IRB approval. Furthermore, in most demonstration projects, project staff and evaluators share some evaluation tasks, such as data collection, analysis, report writing, and dissemination of findings. When this is the case, the same Federal regulations regarding research apply to both the project staff and evaluators.<sup>9</sup>

### When Is an Evaluation Exempt from IRB Review?

If your evaluation is not utilizing identifiable private information, your project most likely will not need IRB approval. Research utilizing the following types of data (and only these types) is typically exempt from IRB review:

1. Data, documents, and records that are publicly available. Examples of public data include AFCARS or NCANDS data or public court records.
2. Data that is recorded by the investigator in a way that the subjects cannot be identified, either directly or through identifiers linked to the subjects.<sup>10</sup> An anonymous survey, where respondents do not provide their name or any other piece of identifying information, cannot be linked back to respondents (as long as there is no coding key).

### What Is the IRB Review Process?

Obtaining approval from an IRB requires submitting a detailed research proposal. Before submitting a proposal, contact your IRB to learn about their specific requirements for submission, including the suggested format and required documentation. In general, the components of a research proposal for IRB approval include the following:

- A description of the study and its purpose;
- A description of the population to be studied and how its members will be selected for the study;
- A description of the interventions that researchers plan to implement, if any;
- Enumeration and description of the data collection methods to be used;



- Information about how proposed subjects will be informed about the study and what will happen to them if they agree to participate;
- An assessment of the risks and benefits of the research to participants and to the general population;
- A description of how the researcher intends to protect the identity of participants;
- A statement assuring participants that their participation is voluntary;
- A statement assuring participants of their right to participate or withdraw at any point without consequences to themselves or their families;
- The address and phone numbers of the researchers and of the responsible people in the researchers' institutions; and
- Copies of all informed consent forms and recruitment materials.<sup>11</sup>

In general, investigators receiving Federal funds must complete training on the protection of human subjects before obtaining IRB approval. This requirement can be satisfied by taking a short online tutorial sponsored by the National Cancer Institute. To access this training, visit the following website: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>.

If the IRB determines that your evaluation poses minimal risk to human subjects and adequately protects its participants, your proposal will be approved. However, the IRB can ask investigators to revise their proposals to address any areas of concern. When submitting your research proposal, leave plenty of time for the review process. As most IRBs are affiliated with a university, many operate on an academic calendar and do not meet during breaks. Your project's ability to obtain approval may be delayed if the IRB requires that you submit revisions to your proposal.

### **Is My Project's Evaluation Eligible for an Expedited IRB Review?**

The IRB will determine whether your evaluation will receive a full board review, an expedited review, or is exempt from review. Evaluations of demonstration projects that are utilizing identifiable private information, and therefore require IRB approval, are eligible for an expedited IRB review.<sup>12</sup> An expedited review consists of an abbreviated review procedure, most often conducted by only the IRB chairperson. Research employing survey, interview, focus group, or program evaluation methodologies are eligible for but are not guaranteed to receive an expedited review. Demonstration projects are eligible for an expedited IRB review because they are deemed to present only minimal risk to human subjects. However, if an IRB determines an evaluation to pose more than minimal risk to its participants, the IRB can require the evaluation to obtain approval through the regular full-board review procedure.

### **Do I Need to Submit a Renewal Application Every Year?**

The IRB approval period is for a maximum of one year.<sup>13</sup> You must submit a renewal application to the IRB on a yearly basis, usually between thirty and sixty days before the project expiration date. If your project does not receive approval to continue the evaluation, you will have to stop all research-related activities, including data collection and analysis. An interruption in data collection can significantly impact an evaluation, as data collection activities are often scheduled to coincide with programmatic activities.

### If My Project Is Not Affiliated With an IRB, How Can I Find One?

Projects sponsored by universities, medical facilities, correctional facilities, and large social services agencies will most likely have their own IRB. Projects that are not connected to an IRB associated with their agency must nevertheless obtain IRB approval. IRBs connected to public institutions, such as hospitals and universities, will often review research protocols from non-affiliated agencies in the community, in addition to research proposed by their institution. Consult your local college or university, as they almost always have an IRB. If you cannot locate an IRB affiliated with a public institution in your community, you may be able to use a private IRB (also called an independent or commercial IRB). Private IRBs are run by for-profit organizations and review research protocols for a fee. You can search for IRBs in your state—both public and private—by logging on to the following website:  
<http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>

### Who Is Responsible for Obtaining IRB Approval, Project Staff or the Evaluator?

According to the Federal regulations, the agency receiving the funding is the institution that must receive IRB approval. Even if all evaluation research activities are subcontracted out to a university or other research entity, **the agency receiving Federal funding must secure IRB approval because the awardee institution bears the ultimate responsibility for protecting subjects involved in the research conducted under the award.**<sup>14</sup> However, you must also satisfy the requirements of your agency's IRB and your evaluator's IRB.

### Additional Resources

The Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46), is available on the following website:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

The Office for Human Research Protections of the Department of Health and Human Services has published further guidance on research involving coded information which includes official definitions of terms found in 46 CFR 45, such as "research," "human subject," and "identifiable private information." The document is available on the following website:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

The Western Institutional Review Board has developed *A Guide for Researchers* which includes information about conflicts of interest, informed consent, and suggested guidelines for writing a research protocol. The guide is available on the following website:  
[http://www.wirb.com/content/foot\\_wirb\\_handbook.aspx](http://www.wirb.com/content/foot_wirb_handbook.aspx)

Consult your IRB for information on their submission guidelines, timelines, and specific review procedures. Many IRBs post information about the proposal process online and even accept proposals through their website.

Contact your Federal Project Officer or James Bell Associates for more specific guidance on obtaining IRB approval for your project.

1 Schensul, J. and M. LeCompte. (1999). *Designing and conducting ethnographic research*. London: Altamira Press.

2 Babie, E. (2001). *The practice of social research*, 9th edition. Belmont, CA: Wadsworth, page 476.



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- 3 Protection of Human Subjects, 45 C.F.R. § 46.107 (2005).
  - 4 Protection of Human Subjects, 45 C.F.R. § 46.102 (2005).
  - 5 Protection of Human Subjects, 45 C.F.R. § 46.111 (2005).
  - 6 Department of Health and Human Services. (2007). Funding Opportunity Number HHS-2007-ACF-ACYF-CA-0023.
  - 7 Department of Health and Human Services. (2004). Guidance on research involving coded private information or biological specimens, page 2.
  - 8 Department of Health and Human Services. (2004). Guidance on research involving coded private information or biological specimens, page 3.
  - 9 Department of Health and Human Services. (2004). Guidance on research involving coded private information or biological specimens, page 3.
  - 10 Department of Health and Human Services. (2004). Guidance on research involving coded private information or biological specimens, page 5.
  - 11 Schensul, J. and M. LeCompte. (1999). Designing and conducting ethnographic research. London: Altamira Press, page 189-190.
  - 12 Protection of human subjects: categories of research that may be reviewed by the Institutional Review Board (IRB) through an expedited review procedure. 631 .F.R. 60364-60367 (1998).
  - 13 Protection of Human Subjects, 45 C.F.R. § 46.109 (2005).
  - 14 Department of Health and Human Services. (1999). Engagement of institutions in research.  
<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>, accessed December 21, 2007.