

7.6 EVALUATING PEER PROGRAMS: PROTECTION OF HUMAN SUBJECTS AND EVALUATION

► IRB RESOURCES ON THE WEB

The role of the Institutional Review Board (IRB) is to ensure that human subjects involved in research and evaluation activities are not placed at undue risk or coerced into participating.

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm : Use the IRB Guidebook, produced by the federal department of Health and Human Services (HHS), to become familiar with the issues and concepts that underlie IRB regulations.

<http://www.hhs.gov/ohrp/qualityfaq.html>: This website has a list of frequently asked questions that describes HHS/OHRP's thinking on quality improvement activities and human subjects research

<http://www.hhs.gov/ohrp/assurances/> : Use this HHS website to search for a local registered IRB or to consult a list of frequently asked questions about IRB registration

<http://phrp.nihtraining.com> : Use this National Institutes of Health online training to become certified in human subjects protection

The role of the HIPAA is to ensure patient confidentiality.

<http://hab.hrsa.gov/publications/hippa04.htm>: Use this resource guide for HIV services providers to become familiar with the Privacy Rule as it pertains to CARE Act grantees.

A crucial step in developing a peer program is to secure necessary approval for all phases of program implementation, evaluation, data collection, and data analysis. Obtaining approval from an Institutional Review Board (IRB) may be necessary depending on the design of the evaluation, the type of data that is being collected and analyzed, how the results will be used, and who is participating in the evaluation. The purpose of an IRB is to ensure that human subjects who are involved in research and evaluation activities are not placed at undue risk and are participating in activities with informed consent and without coercion. This section describes the role of the IRB and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in the protection of human subjects and patient confidentiality.

Some evaluation activities may be considered quality improvement (QI). QI refers to measures to continuously monitor and improve the quality and efficiency of services by systematically assessing program components. QI is built into routine program activities, so that service providers and administrators are engaged in monitoring and improving progress toward program objectives and goals. QI typically involves the review of patient or client records and/or anonymous surveys.

All staff members, including peer workers, who are involved in the collection, storage, or analysis of QI data must be trained to understand and comply with all guidelines concerning patient/client confidentiality, the Health Insurance Portability and Accountability Act (HIPAA), and the protection of human subjects in research (see below).

Although QI shares many characteristics with research, the two endeavors are essentially distinct. QI initiatives generally examine internal processes and work to generate solutions to process-type problems, and often have a limited, internal audience. Another criterion of QI initiatives is that the majority of clients are likely to benefit from the knowledge gained, and the clients are not subjected to additional risks or burdens beyond general clinical practice. QI initiatives may not typically be seen as research. Helpful criteria have been proposed for differentiating **QI and research** (Reinhardt, 2003)

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The table below helps to outline these distinctions.

Institutional Review Board (IRB)

In the United States, IRBs are governed by Title 45 CFR (Code of Federal Regulations) Part 46. Legislation in the mid-1970's provided the guidelines for IRBs and defined their roles and responsibilities for the review of research activities subject to regulation by the federal Department of Health and Human Services (HHS). The Office for Human Research Protections in HHS regulates and oversees IRBs. For more information see: http://www.hhs.gov/ohrp/irb/irb_guidebook.htm.

To determine whether IRB regulations apply to an evaluation program, two questions need to be answered: 1) do the evaluation activities constitute research; and 2) do the activities involve human

subjects. Each term has a technical definition within OHRP. For example, research means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”¹

Human subjects means “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.”¹

It is possible that some evaluation projects will require an IRB approval, while others may not. Likewise, some research projects will need IRB oversight while others

DIFFERENCE BETWEEN QI AND RESEARCH

Criteria	Quality Improvement	Research
Intervention	Accepted practice or treatment intervention not previously implemented	New, untried practice or treatment intervention
Risk	Absence of risk to participants	Presence of risk, however slight, to participants
Audience	Primary audience is the organization Information is applicable only to the organization	Primary audience is the scientific community and consumers Information is generalizable

¹<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>

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<http://hab.hrsa.gov/publications/hippa04.htm>

Use this resource guide for HIV services providers to become familiar with the Privacy Rule as it pertains to CARE Act grantees.

<http://privacyruleandresearch.nih.gov/>

This HHS National Institutes of Health website provides HIPAA resources and educational materials.

may not. The best way to address the issue, again, is to contact an IRB representative and discuss the proposed project activities to determine if they meet the definitions of “research” and “human subjects.”

Where are IRBs and who serves on them?

Most colleges and universities maintain IRBs, since these institutions routinely implement research funded by federal agencies involving human subjects. IRBs can also be found in most state and county health offices, and within medical clinics and social service agencies. There also are private IRBs that charge a fee for the review process. IRBs have guidelines about the types of applications they will accept for review. For example, universities may not review an application if it does not involve any of their staff, faculty, or students. The composition of an IRB is outlined in federal regulations. An IRB must have at least five members—some with and some without research expertise. IRBs should also include men and women from diverse professional fields and there should be at least one scientist and one non-scientist. At least one non-scientist member is not affiliated with the organization. The goal is to have a diverse board that understands research as well as local community standards and conditions. To find a local IRB, visit the Department of Health and Human Services website at <http://www.hhs.gov/ohrp/assurances/>.

Criteria for IRB approval of research

An IRB representative can help determine if the evaluation activities meet the criteria for IRB review. If an application to a local IRB is required, the board members will consider whether all of the following conditions are met in the proposed activities: 1) risks to subjects are minimized, 2) risks to subjects are reasonable in relation to anticipated benefits (to participants or society), 3) selection of subjects is equitable, 4) informed consent will be sought from each prospective subject or the subject’s legally authorized representative, 5) informed consent is appropriately documented, 6) the research plan provides for

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monitoring the data collection process to ensure the safety of participants, and 7) there are adequate provisions to protect subject privacy and maintain confidentiality of data collected.

Training in the Protection of Human Subjects

Regardless of whether evaluation efforts qualify as research, it may be helpful to have all parties that are involved in evaluation certified in human subjects protection. Check with a local IRB and ask about completing human subjects protection training. Most trainings, if not all, can be completed online. A curriculum offered by the National Institutes of Health (NIH) takes about 90-120 minutes to complete. It includes reading materials and a number of quiz questions. Successfully completing the quiz questions allows the participant to print a certificate documenting completion of the curriculum. The course can be found at: <http://phrp.nihtraining.com>.

HIPAA Guidelines

In all aspects of evaluation, patient confidentiality must be maintained and the Health Insurance Portability and Accountability Act (HIPAA) guidelines need to be followed carefully. The HIPAA privacy rule covers all protected, personally identifying health information.

The HIPAA privacy rule covers **individually identified health information** which is any health information that can be used to identify an individual. **De-identified information** is not covered by the privacy rule.

There are 18 identifiers that must be removed from data (such as medical record data) in order for it to be considered de-identified. These include name, social security number, dates of service and medical record number, among others. The organization should review the HIPAA guidelines put out by HRSA at the following site: <http://hab.hrsa.gov/publications/hippa04.htm>.

This information will help determine if the program is in compliance with HIPAA regulations. It may also be necessary to also discuss this with a project officer.

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► FOR MORE INFORMATION

Additional Evaluation Sections

- [7 Evaluating peer programs: Introduction](#)
- [7.1 Choosing the outcomes to measure](#)
- [7.2 Logic models for peer programs](#)
- [7.3 Data collection methods](#)
- [7.4 Analyzing and disseminating evaluation results](#)
- [7.5 Evaluation and resource planning](#)
- [7.6 Protection of human subjects and evaluation](#)

Resources

- [Sample forms for documenting peer work](#)
- [Logic Model Brainstorm \(The Lotus Project\)](#)
- [HIV primary care quality assurance program summary \(Kansas City Free Health Clinic\)](#)
- [Process evaluation plan \(People to People\)](#)
- [HIV patient satisfaction survey-English and Spanish \(Kansas City Free Health Clinic\)](#)
- [Treatment adherence survey \(Kansas City Free Health Clinic\)](#)
- [Communicating and reporting plan \(Kansas City Free Health Clinic\)](#)
- [Focus group guidelines \(Kansas City Free Health Clinic\)](#)
- [Peer focus group guide \(Massachusetts Department of Public Health\)](#)
- [Example of a qualitative study design and interview guide](#)
- [Additional evaluation resources and websites](#)
- [Validated evaluation instruments](#)

This section is part of the online toolkit *Building Blocks to Peer Program Success*. For more information, visit http://www.hdwg.org/peer_center/program_dev.