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...information for program designers and program staff on the importance of institutional review boards and protecting the rights of individuals who participate in research studies.

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INSTITUTIONAL REVIEW BOARDS (IRBs): WHAT ARE THEY, AND WHY ARE THEY IMPORTANT?

Part 7 in a Series on Practical Evaluation Methods

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BACKGROUND

Many out-of-school time programs conduct evaluations. As part of an evaluation, program participants (including children, their parents, and program staff) may be asked to provide information. Researchers refer to these individuals as *human subjects*, and it is essential to protect their privacy, rights, confidentiality, and privileges. Organizations conducting research work with institutional review boards (IRBs) to ensure these protections. As it is, many out-of-school programs have conducted small-scale informal evaluations without prior approval from an IRB because the programs may have lacked information about IRB approval or awareness about these issues. This brief intends to allay the fears or concerns that out-of-school time program practitioners may have about the IRB review process by discussing the importance of IRBs and providing guidelines for their use in out-of-school program research.

WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

An **Institutional Review Board (IRB*)*** is a group of people that monitors research designed to obtain information from or about human subjects. Members of an IRB come from multiple research disciplines and from the communities in which the research is conducted.

Human subjects[1] are individuals from whom an investigator or researcher obtains information and data through direct interaction—such as in-person interviews or surveys—or through another source, such as administrative or program records. The overall purpose of an IRB is to make sure that all the necessary steps are taken to safeguard the privacy, confidentiality, rights, and privileges of those individuals who participate in and share information for the study.

The U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) regulate IRBs. All IRBs have the authority to approve, disapprove, or require revision of research designed to collect data from or about individuals,[2] subject to the rules outlined by the OHRP and the FDA. If research uses state or federal funds, then IRB review is legally required. IRBs require researchers to submit protocols that describe the proposed research and data collection activities. Further, these boards often conduct periodic reviews of funded research to ensure that these activities are carried out in the manner specified. Most large universities and hospitals that conduct research regularly have established their own IRBs. When out-of-school time programs conduct research with participants in programs that are funded by the federal or state governments, they may be required to submit materials to a federal or state IRB as well. Even if IRB review is not required by the government, most out-of-school time organizations that conduct research and evaluation decide to obtain IRB approval. This reduces the risk of complaints, legal

problems, or negative publicity if problems arise. Working with an IRB also assures programs that their evaluation procedures protect study participants.

WHY ARE IRBS IMPORTANT?

- ***In out-of-school time programs, IRBs ensure that, when data are being collected for research, the welfare, rights, privileges, and confidentiality of participants who agree to be a part of the study are protected.*** In response to abuses of human subjects in several historic studies, a government commission established a formal structure for IRBs. Notorious research, such as the Tuskegee Institute Syphilis Study, prompted the development of certain principles to guide research using human subjects.[3] In this study, from 1932 to 1972, federally-funded investigators at the Tuskegee Institute observed African Americans through the natural course of syphilis, but withheld available treatment. Partly as a result of these previous abuses, in 1979, the Belmont Report, produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established the IRB system. That system is governed by three principles: *Respect for persons; beneficence* (that is, the research must maximize the benefits, while minimizing the risks, to the participants and society); and *justice* (which means that the research does not exploit any group to benefit another).[4]

- ***In out-of-school time programs that conduct research about children, IRBs provide special protection.*** Certain vulnerable populations are given special protections in research, and children constitute one such group. IRBs ensure that a parent or guardian provides approval for any research involving children (under age 18). Children are also required to *assent* to participate, that is, they must understand the study and any risks involved and agree to participate in the research. However, a child's assent cannot be obtained until a parent or legal guardian gives permission for their child to participate in the research.[5] There are two types of consent:
  - **Active Consent.** Parents typically provide active consent, in which they sign and return a consent form indicating that they approve or disapprove of their child's participation in the study.
  - **Passive Consent.** Under special circumstances, parents may be allowed to give passive consent as an alternative to active consent. When a study uses passive consent, a consent form and detailed information about the study are distributed, usually by mail, to parents. If the parents do not return the form, the parents are deemed to have granted passive consent.[6] Passive consent may be allowed when written parental consent has been legally waived or the procedures for obtaining consent have been altered, based on review from an IRB.[7]

Special Issues When Conducting Research with Children

There are **four** categories of research in which children are allowed to participate:

- Research that does not involve greater than minimal risk[8] (for example, a survey given to youth about their participation in extracurricular activities);
- Research that involves more than minimal risk but will have direct benefit to the subjects[9] (for example, a survey given to youth about the knowledge they gained from a program that addresses risky sexual behavior in order to tailor the next level of the program to meet their needs);
- Research that presents more than minimal risk with no direct benefit to the subject, but will produce generalizable knowledge about the issue that is being studied[10] (for example, interviews with youth about their participation in illegal activities to produce research knowledge about risk factors of delinquent youth); and
- Research that will aid the understanding, prevention, or alleviation of problems that affect the health or welfare of children.[11]

What Are the Different Types of IRBs?

There are three types of IRBs, and they all share the common goal of protecting the rights of human subjects who participate in research:[12]

- **Local Institutional Review Boards**. Local IRBs are affiliated with the institution or organization conducting the research (for example, a university or hospital) and are usually located in or near the study site.
- **Central Institutional Review Boards**. Central IRBs are used with research that involves large, multisite clinical trials (for example, cancer research conducted at different places) that go beyond the expertise that may exist in the local community.[13]
- **Commercial Institutional Review Boards**. Commercial or independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects. The use of commercial review boards recently has become more common.

When Do Programs Need to Use an IRB?

If a program is not affiliated with a local IRB and it plans to collect confidential data from children, staff, and parents for research that is funded using state and/or federal funds, that program is legally required to contract with an independent IRB to ensure that the confidentiality, rights, and privileges of study participants during research are protected. Failing to do so could leave a program vulnerable to legal action.

- If a program is working with an external evaluator, the evaluator may have a local IRB or be aware of an independent IRB to recommend for the study and can help to prepare the necessary protocols.
- If a program is conducting its own evaluation, it is important for the program to select an IRB carefully to ensure a thorough review of materials and to ensure that the program's research includes the necessary human subject protections.

How Do Programs Work With an IRB?

If a program contracts with an external research organization to do an evaluation, that organization can work with the program to handle the IRB process. If a program plans on conducting research without the aid of an external research organization, that program may want to consult with a lawyer to determine if an IRB review is legally required. Any such program should review its human subjects research policy before proceeding with research. Programs considering obtaining IRB approval should follow four important steps:

Step 1: Form a working group that represents staff and board members to work with the evaluator. The purpose of taking this step is to get staff, board members, and the evaluation team to understand the role and importance of an IRB. The working group will also develop an IRB plan that draws together information about the program and clarifies what data are going to be collected. If a program is using an external evaluator, the evaluator will work primarily with this working group to complete the IRB process.

Step 2: Decide if an IRB review is needed for the particular project. If confidential or sensitive data are going to be collected, the working group is likely to determine that IRB approval is necessary. Any research activity involving the collection of private and confidential data for research purposes requires approval from an IRB if funded by state or federal funds. The IRB approval process can seem overwhelming and burdensome, which may deter an organization from seeking approval; however, IRB approval is necessary to assure the program staff, board members, parents, and others that the research meets high standards for protecting the interests of the participants involved.

Step 3: Select an IRB that has experience in social science research. Most out-of-school time programs will want to select an IRB that is familiar with how social science research is conducted (not just how biomedical research is conducted). It may also be useful to choose a commercial IRB that understands the issues around data collection in out-of-school time programs and has experience working with such programs. IRB reviews may start around $1,500 per review. Typically, nonprofit organizations are required to pay this fee. **Table 1** provides a list of possible commercial institutional review boards that may serve as a useful starting point for programs searching for an IRB.

Step 4: Prepare documents for IRB review. If it is decided that an IRB is necessary for the project, the next task is to gather the necessary documentation that will be submitted for IRB consideration and approval. Programs should be sure to speak to the designated IRB committee about the specific information that they require and the specific format they require for the submitted materials. Items submitted to an IRB for approval generally include the following:[14]

- Drafts of informed consent forms that will be used in the study. Informed consent forms explain the purpose of the study, describe it briefly, and identify any possible risks to participants. These forms must be signed and should include evidence of the child's assent and a parent's consent for the child to participate.
- A document that lays out the procedures that will be in place to minimize risk and not put participants in unnecessary danger. For example, programs will want to describe when and where data collection will take place. Programs will also want to describe the use of incentives (if any) that they plan to use in the study, how questionnaires will be collected and coded to protect respondents' privacy, and whether they will seek active or passive consent.
- Copies of the data collection instruments (surveys) to be used and of the protocol to be followed.
- If risks are present, information that shows that such risks are reasonable in comparison with the expected benefits. For example, programs will want to describe potential risks and procedures to protect confidentiality. Programs also will want to describe exactly where data will be stored once collected and who will have access to data files.
- Possible resources for use in the event of an emergency. For example, programs will want to identify the resources that may be used in the event of any unforeseen circumstances.

REMEMBER THE 4 STEPS WHEN WORKING WITH AN IRB

Step 1: Form a working group that represents staff and board members to work with the evaluator.
Step 2: Decide if an IRB review is needed for the particular project.
Step 3: Select an IRB that has experience in social science research.
Step 4: Prepare documents for IRB review.

NEXT STEPS: ADDITIONAL RESOURCES FOR PROGRAMS

The following resources provide useful information about institutional review boards and how to prepare documents for IRB approval:

Nesbitt, L.A (2004). *Clinical Research: What It Is and How It Works*. Sudbury, Massachusetts: Jones and Bartlett Publishing. This comprehensive guide is designed to teach programs the essentials about IRBs and help improve services to research participants.

National Institutes of Health, Office of Human Subjects Research – Information sheets/forms. The Office of Human Subjects Research provides many helpful fact sheets on conducting research that requires IRB review.
Available online at: http://ohsr.od.nih.gov/info/info.html

The National Science Foundation. (2006). *Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research.* This practical guide is designed to help behavioral and social science researchers decipher the federal regulations pertaining to research with human subjects.
Available online at: http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp

Citizens for Responsible Care and Research: A Human Rights Organization (CIRCARE). (2007). *Commercial Institutional Review Boards.* This online guide offers a list of commercial institutional review boards as a resource for programs that are not affiliated with a local IRB.
Available online at: http://www.circare.org/info/commercialirb.htm

Bankert, E.A., & Amdur, R.J. (2003). *Institutional Review Board: Management and Function*. Sudbury, Massachusetts: Jones and Bartlett Publishing. This text offers an informative, in-depth review on how institutional review boards should operate to ensure that human subjects are protected.

Table 1: Sample Listing of Commercial Institutional Review Boards

Allendale Investigation Review Board Web site: http://www.circare.org/info/commercialirb.htm Phone: 201-934-0995	Hill Top Research, Inc. Web site: www.hill-top.com Phone: 513-239-2320
ARGUS Institutional Review Board Web site: http://www.argusirb.com/ Phone: 520-296-6994	Independent Investigational Review Board Inc. Phone: 954-327-0778
Asentral, Inc. IRB Web site: www.asentralirb.com Phone: 978-462-6415	Independent Review Consulting, Inc. Web site: www.irb-irc.com/ Phone: 415-485-0717
Aspire IRB, LLC Web site: www.aspire-irb.com/ Phone: 619-460-0108	Institutional Review Board Services Web site: www.digiserv.com/irbs Phone: 305-940-3053
Beam Institutional Review Board (Beam IRB) Web site: www.beaminstitute.com/ Phone: 888-618-5781	IntegReview, Inc., Ethical Review Board Web site: www.integreview.com Phone: 512-326-3001
Biomed IRB Web site: www.biomedirb.com Phone: 619-282-9998	Liberty IRB, INC. Web site: www.libertyirb.com Phone: 386-740-9278
Chesapeake Research Review, Inc., Web site: www.chesapeakeirb.com/us/default/aspx Phone: 410-884-2900	Midlands IRB Web site: www.midlansirb.com Phone: 913-385-1414 or 800-636-4445
CHSD Independent Institutional Review Board Phone: 619-576-4008	New England Institutional Review Board Web site: www.neirb.com/ Phone: 781-431-7577
Clinical R&D Services IRB Web site: www.clinicalrdservices Phone: 973-696-0824	Patient Advisory Council, Inc. Web site: www.pacirb.com Phone: 251-479-5IRB
Coast IRB Web site: www.coastirb.com 949-218-9969	Quorum Review Inc. Web site: www.quorumreview.com Phone: 206-448-4082
Copernicus Group IRB Web site: www.copernicusgroup.com Phone: 919-465-4310 or 888-303-2224	RCRC IRB Web site: www.rcr-irb.com Phone: 800-688-2132
Essex Institutional Review Board, Inc. Web site: www.essexirb.com Phone: 908-236-7735	Schulman Associates, Institutional Review Board, Inc. Web site: www.sairb.com Phone: 513-761-4100
Ethical Review Committee Phone: 916-421-0008	Southwest Independent IRB Phone: 817-922-9308
Ethicon IRB Web site: www.ethiconirb.com Phone: 512-260-7983	St. Davids Human Research Review Board Phone: 1-877-398-5012
Fox Commercial Institutional Review Board, Ltd. Web site: www.foxirb.com/ Phone: 217-492-1369	Sterling Institutional Review Board Web site: www.sterlingirb.com Phone: 770-690-9491 or 1-888-636-1062
Goodwyn Institutional Review Board Web site: www.goodwynirb.com/Home.htm Phone: 513-793-8900	Western Institutional Review Board Phone: 1-800-562-4789

[1] Parvizi, J., Tarity, T., Conner, K., & Smith, B. (2007). Institutional review board approval: Why it matters. *The Journal of Bone and Joint Surgery*, *89*-A (2), 418-426.
[2] U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Institutional review boards and protection of human subjects in clinical trials. Retrieved May 10, 2007, from http://www.fda.gov/cder/about/smallbiz/humans.htm
[3] Parvizi, J., Tarity, T., Conner, K., & Smith, B. (2007).
[4] Ibid.
[5] American Journal of Evaluation. (2005). The complexity of the IRB process. Some of the things you wanted to know about IRBs but were afraid to ask. *American Journal of Evaluation, 26*(3), 353-361.
[6] Hollman, C.M. & McNamara, J.R. (1999). Considerations in the use of active and passive parental consent procedures. *Journal of Psychology*, *133*(2), 141-157.
[7] Ibid.
[8] U. S. Department of Health and Human Services, National Institutes of Health, Office of Human Subjects Research. (2006). Research involving children: Information Sheet 10. Retrieved June 7, 2007, from http://ohsr.od.nih.gov/info/sheet10.html
[9] Ibid.
[10] Ibid.
[11] Ibid.
[12] Parvizi, J., Tarity, T., Conner, K., & Smith, B. (2007).
[13] Ibid.
[14] The institutional review board - Discussion and news forum. Module Two: The role of the institutional review board. Retrieved May 10, 2007, from http://www.irbforum.org/documents/documents/Module2.pdf