



THE INSTITUTIONAL REVIEW BOARD (IRB): A COLLEGE PLANNING GUIDE

AMERICAN PSYCHOLOGICAL ASSOCIATION
COMMITTEE ON ASSOCIATE AND
BACCALAUREATE EDUCATION

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INTRODUCTION

The American Psychological Association Committee on Associate and Baccalaureate Education (CABE) recognizes the need for Institutional Review Boards (IRBs) to review research that has been proposed at all academic institutions if (a) research with human participants is being conducted and (b) the institution receives federal or state money, such as research grants. Institutions can choose to establish their own IRB, use a commercial IRB, or use the IRB of a cooperating agency.

Protection of human participants is of the utmost importance for practical and ethical reasons. CABE created this document to help faculty and administrators at community colleges and at other colleges without an IRB who choose to establish one. Much of what is discussed in this document can be found on the website of the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP; <http://www.hhs.gov/ohrp>). We have attempted to summarize the basic DHHS policy for the protection of human research participants as specified in the Code of Federal Regulations (CFR) Title 45, Part 46, Subpart A (also known as the Common Rule, 45 CFR 46). We have also included information based on faculty members' experiences in establishing IRBs at other colleges in an attempt to provide the reader with some best practices, advice, and tips that may help make the process of starting an IRB as smooth as possible.

Disclaimer: The CABE IRB Planning Guide is intended to serve as a resource for psychology instructors who are interested in establishing an effective IRB. However, the DHHS Office for Human Research Protections (OHRP) is the authoritative source on IRBs.



THE IMPORTANCE AND VALUE OF AN IRB

As community colleges and other undergraduate institutions establish IRBs, many of the decision makers at those institutions are turning to psychology faculty members to offer guidance on the process. Many working in the field of psychology are aware of negative reports concerning IRBs in journals and on electronic Listservs over the years. In those reports, complaints have been lodged about the restrictiveness of IRBs (Salzinger, 2006), infringement of academic freedom (Hamburger, 2007), the ever-increasing reach of these boards (Gunsalus et al., 2006), and the lack of evidence to show that the entire IRB process has actually improved the safety of the research enterprise (Mueller & Furedy, 2001a, 2001b). Many reports show that IRBs can hinder research productivity. These reports may lead some who are considering starting an IRB at their own institution to believe that the task is too great or too difficult or that having an IRB will make conducting research not worth the effort. The truth is that the task of starting, and using, an IRB may not be as onerous as it appears, and IRBs do not have to be an obstacle to research (O'Brien, 2006).



An Additional Note About the Value of Establishing an IRB

It is important to note that the creation of an IRB does not address all of researchers' ethical issues. Researchers must be professional and adhere to the ethical codes of conduct that govern scientific research in general (i.e., the principles set forth in the *Belmont Report*) and their specific disciplines. For example, the American Psychological Association has an ethical code of conduct that includes standards for research with human participants (APA, 2010; <http://www.apa.org/ethics>). This ethical code governs research conducted by people in the field of psychology, whether or not an IRB exists at their institution. The fact that an institution did not previously have an IRB does not mean that researchers at that institution have been unethical; it means that the institution has not formally documented whether the research adheres to all regulatory requirements found in 45 CFR 46. Having an IRB allows an institution to formally document that the institution is following the generally accepted method of assuring that human research participants are protected.

The opportunity for undergraduate students to conduct research is a high-impact educational practice that is correlated with student success. In addition, instructors will find there is pedagogical value in having an IRB on campus. Having an IRB provides faculty with in-house experts who can talk to students about IRBs in their classes, describe the necessary training to serve as an IRB member, and demonstrate how and when to complete an IRB's official forms. Students may also gain by hearing the views of those who advocate for and/or oppose the IRB process and by learning more about the history of and rationale for IRBs, as well as empirical data on IRBs.

Having a properly composed IRB also makes research eligible for federal grants. All research (i.e., behavioral, social, educational, or otherwise) that uses human participants requires a review by a properly composed IRB to be eligible for federal grant monies. By starting your own IRB, you have the potential to open up more possibilities for research projects, giving faculty more opportunities for professional development and collaboration with faculty at other institutions.

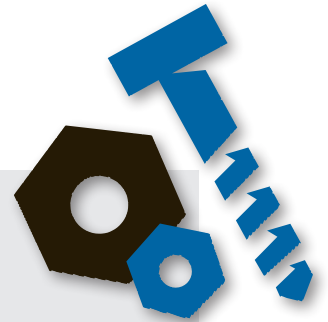
GETTING STARTED

Before you begin to set up an IRB, read and become familiar with the federal regulations that apply to research with human participants as specified in 45 CFR 46 and the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). An essential resource is the 100-page *Institutional Review Board (IRB) Guidebook* published by the Office of Human Research Protections (OHRP; <http://www.hhs.gov/ohrp>). This guidebook is available for purchase or free download from the OHRP website. The OHRP website has everything you need for creating your IRB.

Keep in mind that the basic job of the IRB is to protect the rights and welfare of human research participants and facilitate research by using the basic ethical principles from the *Belmont Report*.

THE NUTS AND BOLTS

This section summarizes some of the key federal regulations for establishing an IRB. Please keep in mind that this is a brief summary; be sure to refer to 45 CFR 46 for complete and specific information about these regulations.



Size of the IRB

According to federal regulations, the minimum number of people required for an IRB is five; however, you can certainly have more than five members. The number of members will most likely depend on the size of the institution and the IRB workload. The availability of potential members will also affect the number of members you choose to have on your IRB.

Your institution may have more than one IRB. Many universities have multiple IRBs that specialize in particular types of research. If you are working for a community college or other undergraduate college that has multiple campuses, it may be advisable to have multiple IRBs so that each campus has its own review panel. This may help speed up the review process for each individual proposal.

Composition

As noted above, an IRB must consist of a minimum of five members of varied backgrounds to facilitate diversity in its composition. Accordingly, if you are doing federally funded research, you will need to make sure that your IRB is composed of members who represent the following characteristics:

Scientific area. At least one member must work in science (e.g., biology, psychology, chemistry).

Nonscientific area. At least one member must work in a nonscience area (e.g., history, English, philosophy).

External to the institution. One member must come from outside the institution and not be affiliated with the institution.

Diversity of representation. An effort must be made to achieve diversity of representation, particularly if members of a “vulnerable population,” such as children or people with intellectual disabilities, are frequently a subject of study (see definitions in Appendix A). If such populations will be used, someone who has knowledge of or experience with those populations should participate as a member of the IRB.

Diversity of gender. The IRB should have both male and female representation.

Diversity of profession. The IRB should not have representation from just from one profession, such as psychology.

If you are not doing federally funded research, you have the freedom to choose alternative and sometimes more appropriate members for your IRB.

Other Considerations

- An IRB may not allow any member to participate in the review of any project in which the member has a conflicting interest. That would include researchers involved in the project and administrators involved in the grant applications.
- An IRB may invite individuals with expertise in specific areas to assist in the review of projects that require expertise that is not represented sufficiently on the IRB; however, they may not vote with the IRB.
- By definition, the IRB is a board, not a committee. As such, it means that members of an IRB are tasked with rendering decisions about research they review. In contrast, members of standing committees may or may not be tasked with rendering decisions—often, their purpose is to offer recommendations or organize information used to help others make decisions. The appointment process to an IRB often differs from the appointment process to other standing committees, as federal regulations include specific requirements about the membership of an IRB.

IRB Staff

Your institution will need to provide adequate staffing for the IRB. You may be able to designate a current employee as the IRB staff person, depending on the person’s current duties and the expected workload for the IRB. Depending on the number of research projects, you may need a full-time staff person for the IRB.

Key tasks for staff include:

- Answering questions regarding the IRB process,
- Assisting researchers in completing their IRB proposals,
- Tracking when ongoing research projects are due for their annual review,
- Communicating with the IRB regarding incoming proposals and/or other board responsibilities, and
- Maintaining documentation of completed training for IRB members and principal investigators (PIs).

IRB Members

The members of the IRB that come from current faculty and staff may need release time to perform the functions of the IRB. In particular, the chairperson of the IRB will likely have some administrative functions for the IRB and may need the time to perform them. This release time needs to be taken into consideration when considering cost. Additionally, you may choose to provide a stipend or reimburse travel time or mileage to your community representative.

Procedures for IRBs That Meet Federal Requirements

Your IRB will need to establish written procedures so that it is clear how the IRB will function. Before the IRB creates these procedures, considering how the IRB will fulfill its duties will be helpful. The questions below will likely need to be addressed; the answers to the questions will be based on your institutional organization and the anticipated volume of research conducted at your institution that requires IRB review.

Members of an IRB will determine the level of IRB review required for submitted research proposals (e.g., "exempt," "expedited," or "full" IRB review). Studies that meet the definition of "research" and that involve human participants may be considered exempt if they meet certain requirements.

A "full" IRB review is required when the research is defined as (a) a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (38 CFR 16.102d); (b) that involves human subjects (i.e., a living person about whom a researcher collects either identifiable private information OR data through an intervention or interaction); and (c) involves greater than minimal risk to those human subjects. A full IRB review usually requires attendance from a quorum of IRB-appointed members.

An "expedited" IRB review is selected when the research is defined as meeting the first two classifications noted above but involves no more than minimal risk to subjects OR is being reviewed strictly for minor changes to previously approved protocols in the research project. An expedited review procedure can be conducted by a subset of reviewers designated by the IRB chairperson from members of the IRB.

An "exempt" IRB review (see Appendix B) is selected when the research falls into one of the six approved categories of exempt research (45 CFR 46.101 [b]) and is not applicable to research in a covered research category (e.g., FDA regulation - 21 CFR 50.20). Exempt research does not mean that a research project has no review. Rather, for studies that are determined to be exempt, it means that the exemption (and its corresponding category) is documented in the IRB records and that the decision is communicated in writing to the investigator.

Accordingly, one of the first questions to consider is who on the IRB makes the determination that a proposed study is exempt (see Appendix B, Criteria for Exempt Status). Is the IRB chairperson solely responsible for that determination, or will a subcommittee screen all proposals for exemption?

- How will expedited or administrative review be conducted? Studies that pose minimal risk or proposals that are minor changes to studies that were previously approved by the IRB may not need to undergo a full IRB review.
- How will the IRB conduct initial and continuing review of research proposals? Studies that are ongoing (lasting more than 12 months) should have a follow-up review process at least once every 12 months.
- How will the IRB's decision be communicated to the PI?
- How will changes in proposed research activity be communicated to the IRB? If the IRB has already approved a proposal, will changes to that proposal require new review?
- How will unanticipated problems that pose subsequent risks to human participants be reported to institutional officials?
- What are the deadlines for submissions, and how often will the IRB meet?

Be sure that you give these kinds of questions some thought up front and then solicit

input from those people who are interested in either serving on the IRB or helping with the formation of the IRB. Most likely, you will also need to educate administrators at your institution about IRB regulations and procedures.

Educating IRB Members and Principal Investigators

IRB members and PIs need training and education in research ethics and current research regulations if they are going to be applying for federal funds. Most IRBs will choose to have some record of training, but it can be as innocuous as having researchers affirm that they have read the *Belmont Report*. If more extensive training is deemed necessary, it may be delivered a number of ways (e.g., a face-to-face class, an online class, a self-paced tutorial). The cost of providing training can vary widely. If you choose to have IRB members and PIs attend a face-to-face class, they need to have the time to participate, and you will need to provide a trainer. Online training costs also vary. There are online training modules that your institution can use for free or purchase and customize (see Appendix C for a list of inexpensive training options). As a psychologist, you may wish to review these training modules, as they are often quite naïve in their treatment of research methodology.

Setting up your own online training also has costs, such as the time of the person designing the website and the time of the experts needed to write the training modules. For institutions with limited time and/or budgets, the OHRP's *Institutional Review Board Guidebook* is a good place to begin in terms of deciding what material to include in a training course. The key information that needs to be delivered includes:

- The basic ethical principles underlying research with human participants as elucidated in the *Belmont Report*,
- The federal regulations for the protection of research participants, and
- The history and ethics of research with human participants.

Completion of training requirements should be documented and kept on file so that the institution can demonstrate that IRB members and PIs have been provided the relevant information. Although probably not necessary, this documentation can be acquired by requiring that IRB members and PIs take a test after reading all of the material that is provided to them.

Record Keeping

Federal records, whether in hard copy or electronic form, need to be maintained and easily accessible for at least 3 years after the research is completed. You may choose a significantly less cumbersome system for research that is not federally funded. Office space or computer space will need to be allocated for storage. These records include:

- Research proposals, sample consent documents, updates from the researchers, and documentation of unanticipated problems (as described by OHRP; see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.115>);
- Minutes of IRB meetings that document who attended; a record of voting; rationale for accepting, rejecting, or requiring changes to research proposals; and, where there is conflict among the IRB members, a summary of the issue and its resolution;
- Copies of communication, including email, between the IRB and researchers;
- List of IRB members, including their degrees, area they represent, relevant experience, and association with the college;
- IRB procedures and forms; and
- Evidence of training completion.



HOW MUCH WILL AN IRB COST?

The cost of the IRB depends on how much research the faculty, staff, and students at your institution are conducting and the nature of the research being conducted. Generally, faculty members serve on IRBs as part of their college service without additional compensation. If the volume of research is relatively low and/or most of the research qualifies as exempt (see Appendix B), the cost may be minimal. If the volume of research is high and/or the research involves more than minimal risk to participants, the additional record keeping may create greater costs.



WHAT IS A FEDERALWIDE ASSURANCE (FWA) AND DOES MY INSTITUTION NEED ONE?

A Federalwide Assurance (FWA) is a way that institutions can let federal agencies know that they intend to comply with the regulations for the protection of human research participants. An FWA is required of institutions engaged in nonexempt research with human participants that is conducted or supported by the DHHS. Because it is federalwide, it is accepted by other federal agencies and departments that have adopted the Common Rule and that support research with human participants.

What this means in practice is that, if you have a current FWA, a federal agency that is providing funding for research at your institution will not have to request information from the institution concerning the makeup, policies, or procedures of the IRB. They will already have all the information they need in the FWA. It can streamline the process of obtaining grant money for research. The downside of an FWA is the amount of documentation required. Filing the paperwork and maintaining the FWA may require more work than choosing not to have an FWA.

You can compose an IRB that meets the federal guidelines described in 45 CFR 46 without an FWA. You can also, if you choose, use an IRB from another institution that has an FWA if you need it because of your request for funding from the DHHS (which requires an FWA). An FWA is not currently required for funding from other federal sources; however, other agencies may require their own assurance in the absence of an FWA.

There are significant advantages to having an FWA, but institutions need to be aware of both the requirements and the terms of such an assurance. For additional information, your IRB and/or your institution's legal department should review the materials in the Assurances section of the OHRP website (<http://www.hhs.gov/ohrp/assurances>).



DOES ALL DATA COLLECTION AT OUR INSTITUTION REQUIRE IRB REVIEW?



Much of the data collected within or on behalf of an institution does not meet the regulatory definition of “research” and, thus, would likely not require IRB review. For example, many institutions often engage in projects that are best defined as quality improvement initiatives or program evaluation. Such projects usually do not meet the regulatory definition of research and thus would not need IRB review. However, if (a) the data being collected meet the regulatory definition of research and (b) the research is done using human participants (see Appendix A, Definitions), the study does require an IRB review. In addition, if one of the anticipated activities following the study is to disseminate the information, such as in a publication or conference presentation, the study may require an IRB review. When in doubt, the PI should submit an IRB proposal. Remember that the IRB is the institutional authority on research requirements, not the researcher or the institutional administration.



WHAT ELSE DO WE NEED TO KNOW?

It's difficult to convey everything you need to know to start an IRB at your institution in one document. Things will undoubtedly come up as you go along, some of which will be unique to your institution. However, here are a few of the more common IRB issues you should know:

- Information gathered exclusively for educational purposes (i.e., not for outside dissemination), such as in-class student surveys or class projects, do not meet the regulatory definition of research and therefore do not require IRB approval. Even if the faculty or students do not submit an IRB proposal for these educational activities, faculty are still responsible for demonstrating appropriate and ethical conduct in research and for ensuring that their students do the same.
- Investigators must recognize and follow additional policies and/or requirements of their institution and/or other institutions (or local, state, or federal agencies, school districts, etc.) as needed in addition to meeting IRB regulations.
 - In some cases, investigators at other institutions may wish to involve your institution's employees or students as research participants. Your institution should have a policy in place for determining when to allow use of your institution's resources for a research project originating at another institution. For example, your institution may decide that the investigator's home institution must first provide documentation of its IRB approval.
 - Similarly, if you want to use another institution's or agency's employees or students in a research project, you must find out what policy that institution follows. For example, if someone from College Y (CY) would like research access to students at Elementary School Z (ESZ), ESZ may have specific requirements prior to granting permission. School district policies vary, and other regulations may come into play when considering the conduct of research in schools.
- Again, the purpose of the IRB is to ensure protection of human subjects. It is not to judge the merits of a research proposal. If a proposal seems poorly conceived or incomplete, the IRB should not withhold approval if the proposal meets the regulatory guidelines for ethical treatment of its human participants. Just because you might do the study differently does not mean the proposal should not be approved. Relatedly, IRB members should not decline a proposal on the basis of political, religious, or moral perspectives that may be in conflict with the ideas presented in the research proposal.

ARE THERE SOME BASIC FORMS THAT CAN HELP US GET STARTED?

Appendix D includes sample forms to help you get started. Feel free to use these as a framework from which to build forms for your institution. These are the forms used by the Maricopa County Community College District in Arizona. Your institution may want to add or delete content as appropriate.

- American Psychological Association. (2010). *Ethical principles of psychologists and code of conduct (2002, Amended June 1, 2010)*. Retrieved from <http://www.apa.org/ethics/code>
- Gunsalus, C. K., Bruner, E. M., Burbules, N. C., Dash, L., Finkin, M., Goldberg, J. P. . . . Pratt, M. G. (2006). Mission creep in the IRB world [Editorial]. *Science*, *312*(5779), 1441. doi:10.1126/science.1121479
- Hamburger, P. (2007). Getting permission. *Northwestern University Law Review*, *101*(2), 405–492.
- Mueller, J. H., & Furedy, J. J. (2001a). Reviewing for risk: What’s the evidence that works? (Pt. 1). *Observer*, *14*(7). Retrieved from http://www.psychologicalscience.org/observer/0901/irb_reviewing.html
- Mueller, J. H., & Furedy, J. J. (2001b). The IRB review system: How do we know it works? (Pt. 2). *Observer*, *14*(8). Retrieved from <http://www.psychologicalscience.org/observer/1001/irbssystem.html>
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979, April 18). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved from <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>
- O’Brien, R. M. (2006). The Institutional Review Board problem: Where it came from and what to do about it. *Journal of Social Distress and the Homeless*, *15*, 23–46.
- Protection of Human Subjects, 45 CFR 46 (rev. 2009). Retrieved from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
- Salzinger, K. (2006). Behavior analysis in the real world. *Behavior and Social Issues*, *15*, 192–195.
- Shirey, M. R., Hauck, S. L., Embree, J. L., Kinner, T. J., Schaar, G. L., Phillips, L. A., . . . McCool, I. A. (2011). Showcasing differences between quality improvement, evidence-based practice, and research. *Journal of Continuing Education in Nursing*, *42*(2), 57–68. doi:10.3928/00220124-20100701-01
- U.S. Department of Health and Human Services. (n.d.). *IRBs and assurances*. Retrieved from <http://www.hhs.gov/ohrp/assurances>

DEFINITIONS

(Taken from the Code of Federal regulations, Title 45, Part 46, Subpart A)

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, 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.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

*Vulnerable populations include children, prisoners, pregnant women, or people with intellectual disability.

*People with intellectual disability are not officially considered a vulnerable population in the current code of federal regulations as there is no subpart devoted to this group. They are included here as their inclusion appears to be consistent with the spirit of the regulations. Be sure to refer to the current code of federal regulations for information concerning vulnerable populations.

CRITERIA FOR EXEMPT STATUS

The following list outlines the criteria for a project to be considered exempt. Keep in mind that exempt does not mean that the project need not be considered by the IRB. On the contrary, all research projects involving human participants need to be reviewed by the IRB. You may indicate on the submission form that you believe your project fits the exempt status criteria; however, the final determination is made by the IRB.

These criteria were taken directly from the Code of Federal Regulations, Title 45, Part 46, Subpart A.

- 1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 5 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 6 Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

APA AND OTHER RESOURCES

American Psychological Association (APA)

APA has excellent resources available [online](#) concerning conducting research with human participants. This page is a compilation of websites that address legislation, regulations, guidance, federal offices, ethics codes, and training resources related to human research protections.

Recommendations of the 2007 APA Presidential Task Force on Institutional Review Boards and Psychological Science

The Presidential Task Force on Institutional Review Boards was charged with identifying specific policies and practices that would assist IRBs and psychological scientists in reducing researcher–IRB tension.

IRBs and Psychological Science: Ensuring a Collaborative Relationship

This 2004 report of the APA Board of Scientific Affairs Working Group on IRB issues suggests specific strategies that IRB members, IRB administrators, and investigators can use to avoid potential conflict and facilitate the protection of human research participants.

Other Web Resources

Office for Human Research Protections (OHRP)

OHRP provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services.

OHRP offers a [free webinar series and supporting materials](#).

OHRP publishes the *IRB Guidebook*.

Health Resources and Services Administration (HRSA)

HRSA has produced [three video training modules](#) on protecting human subjects.

Collaborative Institutional Training Initiative (CITI)

The CITI Human Subjects Research Education Program, a nonprofit organization run through the University of Miami, has developed customizable online modules on the Responsible Conduct of Research (RCR). For more information, visit the [CITI RCR website](#).

National Institutes of Health (NIH) Office of Extramural Research

The NIH Office of Extramural Research has produced a [tutorial](#) called Protecting Human Research Participants.

IRBs and Research on Teaching and Learning

Frequently asked questions about the use of IRBs in research on the scholarship of teaching and learning.

Books About IRBs

- Amdur, R. J., & Bankert, E. A. (2011). *Institutional review board member handbook*. Boston, MA: Jones & Bartlett.
- Bankert, E. A., & Amdur, R. J. (2005). *Institutional review board: Management and function* (2nd ed.). Boston, MA: Jones & Bartlett.
- Buchanon, D., Fisher, C. B., & Gable, L. (Eds.). (2009) *Research with high-risk populations: Balancing science, ethics, and law*. Washington, DC: American Psychological Association.
- Chastain, G. D., & Landrum, E. R. (Eds.). (1999). *Protecting human subjects: Departmental subject pools and institutional review boards*. Washington, DC: American Psychological Association.
- Citro, C. F., Ilgen, D. R., & Marrett, C. B. (Eds.). (2003). *Protecting participants and facilitating social and behavioral sciences*. Washington, DC: National Academies Press. Retrieved from http://www.nap.edu/catalog.php?record_id=10638
- Dunn, C. M., & Chadwick, G. L. (2012). *Protecting study volunteers in research* (4th ed.). Boston, MA: Thomson Centerwatch.
- Kulakowski, E. C., & Chronister, L. U. (2011). *Research administration and management*. Boston, MA: Jones & Bartlett.
- Mazur, D. J. (2007). *Evaluating the science and ethics of research on humans: A guide for IRB members*. Baltimore, MD: Johns Hopkins University Press.
- Sales, B. D., & Folkman, S. (Eds.). (2000). *Ethics in research with human participants*. Washington, DC: American Psychological Association.
- Strand, C. M. (2009). Navigating institutional review boards when conducting school-based research. In L. M. Dinella (Ed.), *Conducting science-based psychology research in schools* (pp. 33–50). Washington, DC: American Psychological Association.

- | YES | NO | |
|------------------------------|--------------------------|--|
| 1. <input type="checkbox"/> | <input type="checkbox"/> | Does this project or study involve collection of data that identifies individuals (e.g., cohort databases include SSN# data on individuals, surveys, or interviews identifiable by name or student number etc.)? |
| 2. <input type="checkbox"/> | <input type="checkbox"/> | Will data identifiable by individual be shared with anyone (such as in a performance report for a funding source, conference presentations, published articles and reports, etc.)? |
| 3. <input type="checkbox"/> | <input type="checkbox"/> | Are the participants being offered one or more of the incentives to participate (such as money, extra credit for the class, etc.)? List the incentive(s) here: |
| 4. <input type="checkbox"/> | <input type="checkbox"/> | Is participation in this project or study voluntary for the individuals participating in the program or study? |
| 5. <input type="checkbox"/> | <input type="checkbox"/> | Will participants be fully informed about the benefits and any risks? |
| 6. <input type="checkbox"/> | <input type="checkbox"/> | Will participants be videotaped during the project or study? |
| 7. <input type="checkbox"/> | <input type="checkbox"/> | Will participants' privacy and personal information be protected? Briefly explain how privacy and information will be protected: |
| 8. <input type="checkbox"/> | <input type="checkbox"/> | Will participants be debriefed following completion of the project or study? |
| 9. <input type="checkbox"/> | <input type="checkbox"/> | Will participants, prior to the project, indicate informed consent to participate by completing and signing a written form? Sample is included? Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 10. <input type="checkbox"/> | <input type="checkbox"/> | Does the funding source have any potential for financial or professional benefit from the outcome for this study or project? If yes, please explain. |
| 11. <input type="checkbox"/> | <input type="checkbox"/> | Are data sources clearly identified (such as interviews, survey, existing project data such as services received, reports, grades, existing school records, focus group, etc.)? |

Check all that apply and estimate total number of individual participants in each relevant category about whom you will be collecting data on for your project or grant:

- | | |
|---|--|
| <input type="checkbox"/> College Students | <input type="checkbox"/> General Public |
| <input type="checkbox"/> Faculty | <input type="checkbox"/> Children and Youth under 18 |
| <input type="checkbox"/> Staff | <input type="checkbox"/> Other (specify category and number) |

Comments (optional):

I. Abstract Describing Project and Purpose: Briefly describe (a) the project or study and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used, design and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests, or other instruments are to be used, include a brief description and one copy of the instruments. **Note to Grant Projects Directors:** In the case of educational or training grants, data collected about the participants served, assessment testing, pre- and posttesting and other aspects of project evaluation plans are critical.

II. Methodology: Specify who the project participants or research subjects will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which individuals will be subjected. Use additional pages if necessary.

III. Voluntary Participation: Specify the steps that will be taken to insure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

IV. Confidentiality of Data and Privacy Protection: Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape, and audio materials.

V. Informed Consent: Attach a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to the participant.

VI. Risks to Participants: a) Describe any potential risks to participating individuals—physical, psychological, social, legal, or other; b) include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and c) in research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.

VII. Benefits: (a) Describe the benefits and/or any compensation that the participating individuals can expect and (b) describe the gains in knowledge that may result from the project or research study.

VIII. Human Subjects Research Protection Exemption Categories: Federal law 45 CFR 46.101(b) identifies the six (6) EXEMPT categories listed below using the language found in the legislation. *Check all that apply to your project or study and explain why your proposed project or study falls into the category.*

NOTE: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Special Note to Grant Project Directors:

In most cases, your grant projects are not what we traditionally think of as research studies. Nevertheless, the participant data, pre- and posttests of student learning, and other information you generate, compile, analyze, and report on in carrying out project activities and project evaluation are now considered Human Subjects Research by federal funding agencies. As you review the exemption categories listed below, think about the data you are collecting and reporting for the participants you serve and other data you will be using for project evaluation purposes.

(1.) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Please provide an explanation as to how your research falls into this category:

(2.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Please provide an explanation as to how your research falls into this category:

(3.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Please provide an explanation as to how your research falls into this category:

(4.) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Please provide an explanation as to how your research falls into this category:

(5.) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or levels or payment for benefits or services under those programs.

Please provide an explanation as to how your research falls into this category:

(6.) Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed or b) if a good is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspective Service of the U.S. Department of Agriculture.

Please provide an explanation as to how your research falls into this category:

Attachments: Attach all that apply to your proposal. (Check the ones you've included with proposal.)

- Informed Consent Form(s): first page(s) on letterhead
- External support proposal or award letter
- Letters of approval from cooperating entities
- Research methods (research design, data source, sampling strategy, etc)
- Questionnaires, surveys, or other data-gathering forms
- Letters, flyers, questionnaires, etc., that will be distributed to the study subjects
- Copy of thesis/dissertation, approved proposal, or prospectus
- If the research is part of a research proposal submitted for federal, state, or external funding, submit a copy of the FULL proposal

Notes:

- 1) The information should be in sufficient detail to allow the IRB to determine if the study can be classified as EXEMPT under Federal Regulations 45 CFR 46.101(b).
- 2) Be sure to send electronic copy of the application and materials to: IRB Office at District Office. (A district server will be set up in the fall for this purpose. Call if questions, 731-8128.)

Certification and Signatures

In making this application, I certify that:

- 1) I have successfully completed the IRB Required Tutorial.
- 2) I have read and understand the protocol and method of obtaining informed consent, as outlined by the MCCCCD IRB Reference Document, and will follow them during the period covered by this research projects.
- 3) I intend to comply with the letter and spirit of MCCCCD IRB Policies.
- 4) I agree to comply with federal, state, and local laws regarding the protection of human participants in research.
- 5) I will submit any future changes to the research project to the IRB for review and approval prior to implementation, as these may alter the exempt status of the project.
- 6) I agree that any new findings that develop during the course of this study that may affect the risks and benefits to participants will be promptly reported to the IRB in writing.
- 7) I agree that any adverse events that occur in the course of this study will be promptly reported to the IRB in writing.
- 8) I agree and understand that records of the participants will be kept for at least three (3) years after the completion of the research.
- 9) I may begin research when the IRB gives notice of its approval.

Signature of Principal Investigator: _____ Date / /

Printed Name:

Co-Investigator (Name):

Approval by Faculty Sponsor (e.g., dissertation, thesis, special project). I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the IRB.

Signature of the Faculty Sponsor: _____ Date / /

Printed Name:

Approval by the College or District (Department Chair, Dean, Vice President, Vice Chancellor, or Other Primary Administrator). I confirm the accuracy of the information stated in this application. I am familiar with and I approve of the procedures that involve human participants.

Signature of Department Chair, Dean, Vice President, Vice Chancellor or Other Primary

Administrator:

Date / /

Printed Name:

For IRB OFFICE Use Only:

This application has been reviewed by the MCCCCD IRB as:

Approved, Categories:

Approved, Subject to Restrictions:

Tabled (insufficient information for IRB to make a final decision)

Disapproved:

Authorizing Signature: _____ **Date:** ____/____/____

Printed Name: _____

IRB 2016

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