

Institutional Review Board (IRB) Tip Sheet

IRB Structure

Under Federal regulations, the IRB must be a diverse group in terms of gender and racial background.

Specifically, the IRB must consist of:

- At least five members of varying backgrounds who are sufficiently qualified, not solely of one profession, and gender diversity
- At least one non-scientist
- At least one member not affiliated with institution
- Expertise on “vulnerable populations” (e.g., prisoners, children, pregnant women, etc.).
- Outside consultants

The responsibilities of an IRB

- Review and approve, require modifications, or disapprove all research
- Require that “Informed Consent” is in accordance with regulations.
- Require documentation of “Informed Consent” or opt to waive documentation in accordance with regulations
- Notify investigators, in writing, of decisions
- Conduct continuing review of research no less than once per year

A protocol is not approved until all required modifications are received and approved by the IRB. There may be no activity on the project until these modifications have been approved by the IRB, and the approval letter has been received by the PI indicating approval and permission to begin the study. The term of the approval will be indicated, as well as the date that the first progress report is due. Any special conditions that have been applied to the research will also be indicated in the approval letter. Each protocol will receive an IRB Protocol Number; this number must be included on all future correspondence.

Types of Reviews

I. Exempt: The term “exempt” means the research will be reviewed for approval by the IRB chair or designee and will not be subject to continuing review under federal regulations. The following categories of research will generally qualify as exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
 - Research on regular and special education instructional strategies; or
 - 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
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 2 above, if;
 - **The human subjects are elected or appointed public officials or candidates for public office**
 - **Federal statute(s) require 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 in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration project that are conducted by or subject to the approval of Department or Agency heads, and which are designated to study, evaluate, or otherwise examine:
Public benefit or service programs, **when the following criteria are met:**

- a. The program under study must deliver a public benefit (e.g. financial or medical benefits as provided under the Social Security Act) or service (e.g. social, supportive, or nutrition services as provided under the Older Americans Act);
- b. The research or demonstration project must be conducted pursuant to a specific federal statutory authority; and
- c. There must be no statutory requirement that the project be reviewed by an IRB.

6. Taste and food quality evaluation and consumer acceptance studies if:

- a. Wholesome foods without additives are consumed or
- b. 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 to the U.S. Department of Agriculture.

Note: *Protocols classified as exempt are not subject to continuing review. However, it is the investigator's responsibility to notify the IRB of any changes or modifications that are made in the research study design, procedures, etc. Such changes may necessitate a new IRB submission. Protocols approved as exempt will be assigned an IRB Protocol Number that must be referenced on all correspondence with the Office of the IRB.*

II. Expedited Review: research submitted for "expedited review" is not subject to meeting cycle deadline dates. Protocols are reviewed as they are submitted. The term "expedited" refers to the type of review mechanism that is employed and does not necessarily mean "quicker". If it is determined that a protocol does not meet the criteria for expedited review and required full-board review, deadline dates would apply to the resubmission.

Research is usually considered for "expedited" review if the following applies:

- **Presents no more than minimal risk to participants.**
- Does not involve certain vulnerable populations, namely, prisoners, persons over whom the researcher is in a position of authority, and mentally disabled.
- All procedures fall into one or more of seven categories designated as eligible for expedited review:
 1. Categories related to medical research (without INDA approval).
 2. Clinical studies of drugs and medical devices (without INDA approval).
 3. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
 4. Prospective collection of biological specimens for research purposes by noninvasive means.
 - Research involving materials that have been collected or will be collected solely for non-research purposes.
 - Collection of data from voice, digital or image recordings made for research purposes.
 - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies

III Full Board Review: refers to review at a convened IRB committee meeting where a quorum is present (a **quorum** is the presence of greater than half of the voting membership including at least one member whose primary concerns are in non-scientific areas). Approval of research is by a majority vote of the quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, or absence of a non-scientific member), the IRB may not take further actions or votes unless a quorum is restored.

Necessary when the research involves any of the following:

Prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively impaired adults as subjects;

1. The collection or recording of behavior which, if known outside of the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing to the subject;
2. The collection of information regarding sensitive aspects of the subject's behavior such as drug or alcohol use, illegal conduct, or sexual behavior;

Principal investigators of research requiring a full IRB review must submit the following:

- 1) An Application for Review of Human Subjects Research Form
- 2) Human Participant Research Review Form
- 3) And all accompanying documents as specified in the Application for Review of Human Subjects Research Form.

There are three possible outcomes for protocols reviewed by the full IRB

- 1) Approval
- 2) Accepted Pending Changes
- 3) Revise and resubmit
- 4) Denial.

A full review is based on your institutions IRB meeting and may take days to several weeks for a review of your application.

IRB Proposal (Institution Specific)

Education Human Subjects Protection

1. Submit a current curriculum vitae or resume
2. Complete the Investigator Responsibility Certification Form¹
3. Submit the appropriate submission application with your protocol

Tips for Writing the Proposal

- I. BASIC OUTLINE OF A RESEARCH PROTOCOL (Best to be written in bulleted format)
 - a. TITLE OF THE RESEARCH PROJECT
 - b. PROJECT SUMMARY
 - c. STATEMENT OF THE PROBLEM
 - d. JUSTIFICATION AND USE OF THE RESULTS
 - e. THEORETICAL FRAMEWORK (argumentation, possible answers, hypothesis)
 - f. RESEARCH OBJECTIVES
 - g. METHODOLOGY
 - i. Type of Study and General Design
 - ii. Sample Selection and Size, Unit of Analysis and Observation, Selection Criteria
 - iii. Proposed Intervention
 - iv. Data Collection Procedures, Instruments Used, and Methods for Data Quality Control
 - v. Procedures to Ensure Ethical Considerations in Research with Human Subjects
 - h. PLAN FOR ANALYSIS OF RESULTS
 - i. Methods and Models of Data Analysis according to Types of Variables
 - ii. Programs to be Used for Data Analysis
 - i. BIBLIOGRAPHIC REFERENCES
 - j. TIMETABLE
 - k. BUDGET (optional)
 - l. ANNEXES (Data collection instruments, elaboration on methods and procedures to be used, etc.)
-

Informed Consent:

Informed consent is a process that involves a comprehensive discussion between the investigator and subject in order to ensure the subject's understanding of a proposed research study. This process is documented and reinforced by a written consent form.

Informed consent is not valid unless the subject or the subject's legally authorized representative comprehends the information in the consent document. Consent forms should be written in simple language that is understandable to a lay person (as close to an eighth-grade reading level as possible). They should also be written in an easy to follow format. The patient/subject should be identified as "I/my" or "you/your" consistently throughout the consent form. If the consent form is written for a third party who is consenting on behalf of an individual (parent, legally authorized representative, etc.) then a sentence explaining that "you" or "I" refers to the patient should be included in the introduction. (It is best not use "you/your child" throughout). **Bold-faced** or underlined paragraph headings should be used for clarity.

Required Elements of a Research Consent Form

1. **Introduction**
 - o Additional Text for Cooperative Group Studies
2. **Purpose of Study**
3. **Expected Duration of Subject's Participation**
4. **Description of Procedures**
 - o Randomized, Cross-over, Double-blinding, Placebo Controlled Studies
 - o Washout Period
 - o Drugs and Devices
 - o Additional Procedures, Contraindicated Medications and/or Foods
 - o Birth Control
 - o Incomplete Disclosure/Deception
5. **Possible Benefits**
 - o For Randomized Studies Only
6. **Possible Risks/Discomforts**
 - o Blood-Drawing
 - o For randomized studies only
 - o Magnetic Resonance Imaging (MRI)
 - o Collection of Sensitive Information
 - o Unknown Side Effects
 - o Standard of Care/No Additional Expected Research Risk
 - o Drug Availability After Completion of Study
7. **Alternatives to Participation**
8. **Costs/Compensation**
 - o Marketable Products
9. **Compensation for Research-Related Injury**
 - o Additional Wording for Industry-Sponsored Studies
10. **Voluntary Participation**
11. **Privacy/Confidentiality**
 - o Special Confidentiality Wording for Studies with a Certificate of Confidentiality
12. **Contacts for Questions/Access to Consent Form**
13. **Summation/Signature**
14. **Physician's Statement**
15. **Additional Guidelines: Special Issues**

- [Research with Children](#)
 - [Sample Child Assent Form](#)
 - [Research with Decisionally Impaired](#)
 - [Sample Adult Assent Form](#)
 - [Sample Research Review Questionnaire](#)
 - [Addendum to Consent by Research Proxy for Continuing Participation in a Research Study](#)
16. [Genetic Testing and Tissue Banking](#)
-

Chart Reviews:

Exempt Chart Review Studies:

Review of existing patient records may be considered exempt if the records are collected **without identifiers or a link to identifiers**; specifically, there is no possible way to go back to the records at a later date.

Additionally, the record review must be conducted by an individual (investigator) who would normally have access to the records as part of the patient's routine clinical care.

In most cases, a retrospective chart review that **does not record identifiers** falls under the following allowable exempt category:

"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 in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects."

Generally, in order to submit this type of retrospective, anonymous chart review to the IRB for consideration, complete the following:

- [Proposal Cover Sheet](#)
- [Study Personnel/Required Education Sheet](#)
- [Retrospective Chart Review Research Plan](#)
- [Conflict of Interest Questionnaire](#)
- [Application for Determination of Exempt Status](#)

Or any other pertinent forms as designated by the institution's review board

Expedited Chart Review Studies:

For research involving **retrospective review** of patient records for which it is **necessary to collect identifying information or maintain a link to the data source**, a protocol for expedited review must be submitted to the IRB.

Based upon the details being collected and the risks to the patient, a waiver of obtaining informed consent/authorization **might** be granted by the IRB.

In order to submit a proposal for this type of chart review to the IRB for consideration, the following is required:

- [Proposal Cover Sheet](#)
- [Documentation of Required Education](#)
- [Retrospective Chart Review Research Plan](#)
- [Conflict of Interest Questionnaire](#)
- [HIPAA Compliance](#)
- Application for Approval of Research Involving Human Subjects [for Retrospective Chart Review Studies](#)

- Research Consent Form (if appropriate)

Or any other pertinent forms as designated by the institution's review board

Example of IRB websites

Northwestern University Office for the Protection of Research Subjects

<http://www.northwestern.edu/research/OPRS/>

Loyola University Chicago Office of University Research Services

<http://www.luc.edu/depts/uresearch/ours/home.htm>

DePaul University, Institutional Review Board for the Protection of Human Research Participants

<http://condor.depaul.edu/~gmichel/extra/WelcomeR.html>

University of Illinois at Urbana-Champaign,

Institutional Review Board for the Protection of Human Subjects in Research

<http://www.irb.uiuc.edu/index.html>

University of Chicago, Social & Behavioral Sciences Institutional Review Board (SBS IRB)

<http://humansubjects.uchicago.edu/sbsirb/>

HIPAA: Health Insurance Portability and Accountability Act of 1996

HIPAA resources for research involving the use of individually identifiable health information collected in a setting related to the patient care process:

<http://www.hhs.gov/ocr/hipaa/>

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

This article was developed by the ASHP New Practitioners Forum Science and Research Development Advisory Group. We appreciate your comments, feedback, and suggestions as we strive to capture issues and challenges affecting New Practitioners. Please send all feedback and comments to the New Practitioners Forum, at newpractitioners@ashp.org. Enjoy!