BASIC INSTITUTIONAL REVIEW BOARD (IRB) REGULATIONS AND REVIEW PROCESS 2

Basic Institutional Review Board (IRB) Regulations and Review Process

1 Introduction

The purpose of this module is to provide a basic understanding of the human subject protection regulations that govern the participation of human volunteers in research in the United States. By end of the module you will be able to:

- Describe the role, authority, and composition of the IRB.
- List the IRB requirements for conducting research involving human subjects.
- Describe the types of IRB review.
- Describe the process of working with the IRB.
- Identify other regulations and regulatory groups that require compliance based on the type of research being conducted.

2 IRB Role, Authority, and Composition

2.1 The Role of the IRB

An Institutional Review Board (IRB) is a review committee established to help protect the rights and welfare of human research subjects. Regulations require IRB review and approval for ***research involving human subjects*** if it is funded or regulated by the federal government. Most research institutions, professional organizations, and scholarly journals apply the same requirements to all human research. Although federal regulations refer to IRBs, an institution may have chosen a different name for this committee.

To clarify when IRB review is required, let's define some terms:

- **Research:** Federal regulations define research as: "a systematic investigation designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)] If an investigator is unclear about whether a planned activity is research, the investigator should contact his/her IRB office.
- **Human Subjects:** The Department of Health and Human Services (DHHS) regulations define a human subject as "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." [45 CFR 46.102 (f)]

  Note: Some state laws include deceased individuals and fetal materials as "human subjects." Check with the local IRB about the definition of a human subject that applies in the state where the research will be conducted.

- **Private Information** includes:
  - Information about behavior that occurs in a setting in which the individual can reasonably expect that no observation or recording is taking place.
  - And information that has been provided for specific purposes, other than research, where the individual can reasonably expect that it will not be made public (e.g., a medical record.) [45 CFR 46.102(f)].

- **Coded Private Information or Biological Specimens.**
  DHHS Office of Human Research Protection (OHRP) policy considers private information or specimens to be individually identifiable when they can be linked to specific individuals either directly or indirectly through coding systems. DHHS OHRP guidance states that only a knowledgeable person or entity is authorized to determine if coded specimen or data constitute research. An investigator cannot make that determination. [OHRP DHHS Guidance on Research Involving Coded Private Information of Biological Specimens, August 2004.]

- **Clinical Investigation**: The Food and Drug Administration (FDA) defines clinical investigation as "any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration, or is not subject to requirements for prior submission to the Food and Drug Administration, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit." [21 CFR 56.102(c)]

2.2 The Authority of the IRB

Federal regulations stipulate that an IRB can:

- Approve research.
- Disapprove research.
- Modify research.

- Conduct continuing reviews.
- Observe / verify changes.
- Suspend or terminate approval.
- Observe the consent process and the research procedures.

2.3 The Composition of the IRB

Federal regulations dictate that the IRB membership will include:

- At least five members.
- Member of both sexes.
- Members that come from varied professions.
- At least one member whose primary concerns are in nonscientific areas.
- At least one member whose primary concerns are in scientific areas.
- At least one member who is not otherwise affiliated with the institution.

The regulations also stipulate that the IRB membership will include:

- Reviewers with experience and expertise in all of the areas of research being reviewed. At its discretion, an IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- Diversity of backgrounds.
- Sensitivity to community attitudes.
- Knowledge of institutional commitments and regulations, applicable laws, and standards of professional conduct.
- Knowledge and experience with vulnerable populations.

Note: If an IRB reviews research that involves vulnerable subjects, the IRB must consider the inclusion of an individual who has knowledge of, and experience with, these vulnerable subjects. The regulations may also require a voting IRB member who has relevant research expertise (for example, research involving prisoners). IRBs may call experts to help with problematic reviews, but those persons may not vote on the disposition of the application. If an IRB member has a conflict of interest, that member cannot be present for the review of that project except to provide the IRB with information as requested and may not vote on that project.

3 IRB Requirements for Human Subjects Research

3.1 IRB Requirements

Institutions and IRBs vary in the practices that assure they meet the federal regulations and in the details of the standards they apply. What follows are the *minimum* federal requirements. Institutions and/or IRBs may add additional protections or procedures to these minimum requirements.

IRB applications usually contain, at a minimum, information that allows IRB members to assess:

- **Risk / anticipated benefit analysis.**
  - Identification and assessment of risks and anticipated benefits.
  - Determination that risks are minimized.
  - Determination that risks are reasonable in relation to potential benefits.

- **Informed consent.**
  - Informed consent process and documentation.

- **Assent.** The affirmative agreement of a minor or decisionally impaired individual to participate in research.
  - Assent process and documentation.

- **Selection of subjects.**
  - Equitable selection in terms of gender, race, ethnicity.
  - Benefits are distributed fairly among the community's populations.
  - Additional safeguards are provided for vulnerable populations susceptible to pressure to participate.

- **Safeguards** that ensure that subject recruitment does not invade individuals' privacy and that procedures are in place to assure that the confidentiality of the information, collected during the research, is monitored.

- **Research plan for collection, storage, and analysis of data.**
  - Clinical research studies often include data safety monitoring plans and/or data safety monitoring boards (DSMB). IRBs will review the plans to ensure they are adequate to protect human subjects.

- **Research design / methods** that are appropriate, scientifically valid and therefore, justify exposing subjects to research risks.

- **Additional information about identification**, recruitment and safeguards if the research involves special populations.

- **In addition, the IRB must review:**
  - The qualifications of the principal investigator (PI) and scientific collaborators.
  - A complete description of the proposed research.
  - Provisions for the adequate protection of rights and welfare of subjects.
  - Compliance with pertinent federal and state laws/regulations and institutional policy.

3.2 Responsibilities of the Principal Investigators and Research Staff

Principal investigators and research staff have specific responsibilities. They are required to:

- Protect the rights and welfare of human subjects who participate in research.
- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- Inform research staff of the regulations governing research and the institutional research policies.
- Ensure that all research activities have IRB approval and other approvals required by the institution before human subjects are involved.
- Implement the research activity as it was approved by the IRB.
- Obtain the informed consent of subjects before the subject is involved in the research and document consent as approved by the IRB.
- Maintain written records of IRB reviews and decisions and obtain and keep documented evidence of informed consent of the subjects or their legally authorized representative.
- Obtain IRB approval for any proposed change to the research protocol prior to it's implementation.
- Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
- Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
- Make provisions for the secured retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.

- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions.

- Notify the IRB regarding the emergency use of an investigational drug or device within 5 working days of the administration of the test article.

3.3 If IRB regulations are not followed, consequences could include:

- Suspension of research project.

- Suspension of all of a PI's research projects.

- Inability to use data or publish results.

- Notification of sponsors, regulatory agencies and funding agencies of noncompliance.

- Debarment by FDA from using investigational products.

- Inability to receive funding from federal grants.

- Additional monitoring and oversight by the IRB and/or third party monitoring of research activities.

- Termination of employment.

- Loss of licenses.

- Immediate shut-down of ALL research at an organization.

3.4 Consequences of Not Following IRB Regulations

These are not theoretical consequences. Some or all of these consequences have occurred at sites where human subjects research was conducted improperly or without IRB approval.

4 The Types of IRB Review

Contact the IRB office for the guidelines for submitting an IRB application. The IRB will provide guidance in implementing federal regulations. The IRB can be a resource for investigators and staff. Under federal regulations, there are three possible IRB review procedures:

1. **Full Committee Review.**

2. **Expedited Review.**

3. **Review for Exemption Status.**

4.1 Full Committee Review

Full committee review is the standard type of review described in the Federal regulations. It must be used for the initial review of all studies that are not eligible for expedited review or exemption status. The procedures and conditions for **full committee review** require that:

- The review must be conducted at a convened meeting of the IRB. A majority of IRB members (a quorum) must be present at the meeting.
- At least one member whose primary concerns are in nonscientific areas must be present at the meeting (in addition, FDA policy requires that a physician be present).
- In order to approve research, the IRB must determine that all of the requirements specified in 45 CFR 46.111 (and if applicable, 21 CFR 56.111) are satisfied.
  See: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm and www.fda.gov/oc/ohrt/irbs/appendixc.html.
- A majority of the members present at the meeting must approve the research.
- IRB members who have a **conflict of interest** in a research project may provide information to the IRB, but cannot participate in the review. Members with a conflict do not count toward the quorum for that review.
- The IRB must notify investigators and the institution in writing of its decision to approve, modify or disapprove the research.
- IRBs must keep detailed documentation of meeting activities including attendance, voting on actions, the basis for the actions, and a written summary of the IRB discussion of controverted issues and their resolution.

Although not specifically addressed in the regulations, IRBs may employ a "primary reviewer system". In such a system, all IRB members receive basic information about the research application, but a "primary reviewer" with experience and/or expertise in the study area is assigned to conduct a thorough review of the IRB application and any accompanying documentation (e.g., an Investigator's Brochure or grant application). The "primary reviewer" will then report his/her findings for discussion at a convened meeting of the full board.

Reviewers may contact the investigator with questions or suggestions prior to the meeting. The IRB may ask that investigators attend the IRB meeting or be available by phone to answer questions that may arise at the meeting.

4.2 Expedited Review

Federal regulations permit the IRB chairperson or one or more experienced members to review a study if it involves no more than minimal risk for the subjects and if it fits within certain categories. The term "Expedited Review" only describes the process by which an IRB submission can be reviewed. The information the expedited reviewer(s) is required to consider is the same as if the submission were receiving Full Committee Review.

The Federal Regulations establish two main criteria for an expedited review. There are:

- The research may not involve more than "minimal risk".
    - "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.” ([45 CFR 46.102(i)] and [21 CFR Part 56.102(i)])
- The entire research project **must be consistent** with one or more of the following federally defined categories (quoted from the OHRP, the IRB oversight agency, guidance document on Expedited Reviews.)

Some institutions/IRBs have additional requirements. Check with the IRB office for more information about how expedited review is handled by your IRB.

4.3 Research Categories that Qualify for Expedited Review

Federal Regulations establish 9 categories that IRBs may use to invoke the expedited review process. Institutions may adopt some or all of the categories when determining if a research activity can be appropriately reviewed by an expedited review process. Categories 1 through 7 pertain to both the initial and to the continuing IRB review. Categories 8 and 9 pertain only to continuing review. The 9 categories are listed below. Follow the hyperlinks for more details about each category. Hyperlinks will open in a new browser window. Close the new window to return here.

4.3.1 Category 1

Clinical studies on drugs or medical devices for which an investigational new drug (IND) or an investigational device exemption (IDE) application is NOT

required. Similarly, a study with a cleared/approved medical device that is being used in accordance with its cleared/approved labeling. More details

4.3.2 Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. More details

4.3.3 Category 3

Prospective collection of biological specimens for research purposes by noninvasive means. More details

4.3.4 Category 4

Collection of data through noninvasive procedures routinely employed in clinical practice provided that:

- The noninvasive procedure must not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves.
- Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples of noninvasive procedures are:
Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy

- Weighing or testing sensory acuity.
- Magnetic resonance imaging.
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography

Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. More details

4.3.5 Category 5

Research involving data, documents, records, or specimens that:

- Have been collected.
  or
- Will be collected solely for non-research purposes (such as for medical treatment or diagnosis).

Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is ***not*** exempt. More details

4.3.6 Category 6

Collection of data from voice, video, digital, or image recordings made for research purposes. More details

4.3.7 Category 7

Research on individual or group characteristics or behavior. More details

4.3.8 Category 8

Continuing review of research previously approved by the convened IRB **where**:

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; ***and*****,** the research remains active only for long-term follow-up of subjects,

  Or where:
- No subjects have been enrolled and no additional risks have been identified.

  Or where:
- The remaining research activities are limited to data analysis. More details

4.3.9 Category 9

Continuing review of research not conducted under an investigational new drug (IND) application or investigational device exemption (IDE) and where categories two (2) through eight (8) do not apply. More details

4.3.10 Expedited Review Process

The IRB chairperson or one or more experienced IRB members, designated by the Chair, can conduct an expedited review. IRB members with a conflict of interest can not be designated to serve as an expedited reviewer. In conducting the review, a determination must be made that the research meets the conditions for expedited review procedures.

The reviewer conducting the expedited review may exercise all of the authorities of the IRB with one important exception, the reviewer may not disapprove research. To approve a research activity, the reviewer must make the determination that all of the requirements specified in Federal regulations (45 CFR 46.111 and 21 CFR 56.111) are satisfied. The reviewer (s) may either approve the research, require modifications (to secure approval) or refer the research to a convened IRB meeting for review in accordance with the "full committee review" procedures described in section 2 above, and set forth in DHHS regulations at 45 CFR 46.108(b) and 21 CFR 56.108(c).

Expedited procedures can also be used to review minor modifications of previously approved research. [45 CFR 46.110(b) and 21 CFR 56.110(b)]

4.4 Review for Exemption Status

Federal regulations specifically define 6 categories of human subjects research that are ***exempt*** from the other provisions of the regulations. Federal Guidance indicates that applying exempt status to a project is a decision to be made by the IRB and that investigators can not make this determination for themselves. Therefore, institutions / IRBs have established procedures to certify that a project is exempt. Check with the IRB office to find out who has been granted authority to make the exemption determination. *Note: the determination must be made prior to initiation of research or of the activity; it cannot be made retroactively.*

4.5 Research that is Exempt

The following six categories of research are eligible for exemption status, [**45 CFR 46.101(b)**]: See the hyperlinked material for the regulatory details and conditions associated with each category. The links will open in a new browser window. Close the new browser window to return here.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. More Details

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. Some Observations studies do not qualify

for exemption More Details,

3. Research not exempt under "2" above, may still qualify for an exemption if the human subjects are elected or appointed public officials or candidates for public office. More Details

4. Research involving the collection or study of freely available de-identified existing data, documents, records, pathological specimens, or diagnostic specimens. More Details

5. Research and demonstration projects conducted by heads of government departments or agencies which are designed to evaluate public programs. More Details

6. Taste and food quality evaluation and consumer acceptance studies. More Details

4.6 When Exempt Review is Not Appropriate

According to the DHHS regulations 45 CFR 46, NO research involving prisoners, as subjects, can be exempted.

4.7 Additional HIPAA Requirements that Indirectly Impact Exemption Review

The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. [45 CFR 160 and 164]. If an IRB has been given the responsibility to consider HIPAA in research issues and if the research potentially falls under the purview of HIPAA, an IRB will be applying not only the 45 CFR 46 exemption categories but also determining if HIPAA applies. In some cases, HIPAA applicability requirements are more stringent than DHHS exemption requirements and in other cases less stringent. A research project that is exempt from the human research subject IRB requirements may not be exempt from HIPAA provisions. Also, a project that is not exempt from IRB might be exempt from HIPAA. See the DHHS OHRP "Guidance on Research involving Coded Private Information or Biological Specimens," and the NIH and guidance entitled "Institutional Review Boards and HIPAA Privacy rule".

5 Process of Working with the IRB

5.1 Criteria for IRB Approval

Federal policy lists **Basic Criteria** that the IRB must apply [45 CFR Part 46.111 and 21 CFR Part 56.111] when reviewing research involving human subjects. To approve a research project, the IRB must determine that:

- The risks to subjects are minimized.
- The risks are reasonable in relation to any anticipated benefits to the subject, and to the advancement of knowledge.
- The selection of subjects is equitable.
- Informed consent will be sought.
- Informed consent will be documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.

In addition, there are specific requirements regarding the informed consent process. These will be detailed in Module 3, "Informed Consent".

The IRB must determine that these conditions exist at the time of initial review and at each subsequent review conducted by the IRB

5.2 Types of IRB Submissions

1. **Application for initial review:** The first request for approval of a specific project is the application for initial review.
2. **Application for continuation review:** The IRB must re-review studies at a minimum of once every 365 days. An IRB may require review more frequently depending on the IRB's assessment of the study's risk/benefit ratio. The review may be a full or expedited review.
3. **Amendments or modifications:** Changes can not be made to approved studies, including the informed consent document, without prior IRB review and approval. The review may be full or expedited, depending on the magnitude of the change and the effect of the change on the risks / benefit ratio.
4. **Reports:** The IRB may require a report for:
    a. Adverse events or unanticipated problems involving risks to subjects or others.

b. Incidences of noncompliance.
c. Deviations from an approved study protocol and violations of the terms of approval.
d. Data Safety and Monitoring Report summaries.

5.2.1 Application for Initial Review

The initial review may be either a "Full Committee" or "Expedited" review.

5.2.2 Application for Continuation Review

The IRB must do substantive continuing review and must consider the same issues as during initial review. Specifically:

- When conducting a continuation review, the IRB uses "Full Committee Review" procedures unless the research meets the expedited review criteria.
- To approve research, the IRB must determine that all the requirements for initial approval (specified in 45 CFR 46.111 and 21 CFR 56.111) continue to be satisfied.
- IRB should review, at a minimum, the protocol and any amendments as well as a status report including:
  - The number of subjects accrued.
  - A description of adverse events, unanticipated problems, withdrawal of subjects, complaints, summary of relevant new information.
  - A copy of current informed consent document.

Follow the link to view the latest GUIDANCE FROM OHRP ON IRB CONTINUATION REVIEW.

It is an investigator's responsibility to know when IRB approval will expire. However, most institutions/IRBs, as a courtesy to their investigators, send out reminders that IRB approval is about to expire. Sometime during the first year of IRB approval, investigators will receive a request to complete a progress report for continuing review by the IRB. It is an investigator's responsibility to complete the continuing review request, submit it back to the IRB in a timely manner prior to the end of the current IRB approval period.

If a protocol's approval expires before the IRB completes its Continuation Review, the investigator should stop all procedures that are not needed to ensure the health and safety of the research subjects.

5.2.3 Amendments and Modifications

All amendments and modifications to a study need IRB approval before they are implemented. If the investigator wants to change *anything* in the research that would impact the subjects, such as recruitment procedures, key personnel, inclusion/exclusion criteria, research procedures, the informed consent document / process, or data elements collected, the investigator must obtain IRB review and approval prior to implementation of the changes. The only exception are changes necessary to immediately protect subjects' safety, as noted in 21 CFR 56.108(a)(4) and 56.115(a)(1). If an investigator is unsure about reporting changes to the IRB, he/she should call the IRB office and ask for guidance. The IRB office can also provide investigators instructions for submitting a request to modify an IRB approved research

5.2.4 Reports of Unanticipated Problems / Adverse Events / Noncompliance to the IRB

Federal reporting requirements for IRBs, investigators, and funding sponsors are confusing and contradictory. Consequently, IRBs tend to develop their own idiosyncratic reporting requirements, based upon their interpretation of both FDA and OHRP guidance. This poses some difficulty for investigators because if the project is funded, the sponsor may have reporting requirements that differ from the IRB policy and procedures.

At a minimum, to ensure compliance, the investigator is responsible for:

1. Determining the IRB requirements for reporting with respect to what needs to be reported, when it should be reported, and the procedure for submitting the report.

2. Setting up systems to ensure that reportable events are identified and submitted to the IRB in a timely manner.

Examples of the type of events that may be reportable include:

- An unanticipated problem which may be defined as any unexpected event that affects rights, safety or welfare of subjects. The event could be physical such as an adverse drug experience or adverse device effect. The event could also involve some harm or risk (i.e. breach in confidentiality or harm to a subject’s reputation).

- Serious adverse event which may be defined as a death, life-threatening adverse drug or device experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent disability/incapacity, or a cognitive anomaly/birth defect.

- Protocol exceptions which may be defined as enrollment of a research subject that fails to meet protocol inclusion/exclusion criteria.

- Protocol deviation which may be defined as a departure from the protocol as approved by the IRB for a single subject.

- Data and Safety Monitoring Plan or Board summary reports.

- Complaints concerning subject rights submitted by subjects or concerned parties, family members, or study personnel.

The IRB will use the reports to assess whether the risks/benefit ratio is still reasonable, whether changes in the informed consent document or study procedures are needed, or whether re-consent is necessary. IRB requirements for reporting vary regarding what should be reported, when the reports should be submitted, and the format of the reports. Check with your IRB to determine its specific requirements.

5.3 Additional Reporting Requirements

Besides the IRB, the Principal Investigator (PI) has a variety of entities to which he/she is responsible for reporting. Minimum reporting requirements for each entity are:

Entity	PI Reporting Requirements
Research Subject	While it might not be considered reporting in the strictest sense, the *informed consent process* is a report to the potential subject about the research, both before the research begins and on an ongoing basis throughout the study. Also, if new information becomes available during the research that might impact the subject's willingness to participate, an investigator is obligated to provide the subject with that information. This information will also need to be reported to the IRB. The IRB office can provide guidance on how additional information should be reported.
Institution	Most institutions have reporting lines set up so that the investigator makes reports to the IRB and it falls upon the IRB to keep the institution informed. However, check with the local IRB to make sure that the investigator does not have direct responsibility for reporting incidents to the institution.
Sponsor	Adverse events should be reported immediately to the sponsor. Investigators should also check with the sponsor about proposed changes that might be made to the study, based on the adverse event that has occurred or preliminary findings. The sponsor also should be told about serious or ongoing noncompliance in a study.
FDA	Adverse events should be reported directly to FDA if the research is PI-

	initiated (without external sponsorship) and falls under the FDA's purview.
DSMB	If your project has a Data Safety and Monitoring Board, check your DSMB plan for reporting requirements.

5.4 Record Keeping

The signed informed consent document is one of the most critical research records the investigator needs to obtain and keep. It provides verification that the research was explained to the subject and that the subject understood and voluntarily agreed to participate in the research study. Investigators are responsible for retaining signed consent documents, IRB correspondences, and research records for at least 3 years after the completion of the research activity. However, local institutional policy or sponsoring agency requirements may dictate that records be kept longer. Check with the sponsor and IRB office to make sure that the minimum 3 years retention requirement meets their needs.

The FDA regulations specify unique document retention requirements for FDA regulated studies [see 21 CFR Part 312.62 (c)]. These requirements must be met for FDA regulated studies.

6 Other Regulations and Regulatory Groups

6.1 Funding and Regulatory Agencies

Depending upon the nature of your research and the agency that funds your research there are a number of other regulations, policies and procedures that may need to be considered. Below is a brief description of selected regulations, regulatory bodies, and funding agencies that may oversee your research. Funding agencies and /or your local IRB offices can also provide guidance on whether any additional requirements apply to a research activity. Hyperlinks will open in a new browser window. Close the new browser window to return here.

Funding Agency / Regulatory Agencies	General Regulations
DHHS The Department of Health and Human Services (DHHS) is responsible for one group of human	The DHHS 45 Code of Federal Regulations (CFR) Part 46 applies to all human research submitted to or funded by Department of Health and Human Services and is applied to all human research by most large institutions. Subparts include: **Subpart A:** Basic Federal Policy for the Protection of Human Subjects

subjects federal regulations.	**Subpart B:** Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research **Subpart C:** Additional Protections for Prisoners **Subpart D:** Additional Protections for Children
NIH The National Institutes of Health include funding agencies that provide federal funding for biomedical research. NIH requires grantees conducting certain types of clinical research studies to have either data safety monitoring plans and/or data safety and monitoring boards. In general NIH policy requires that a Data and Safety Monitoring Board be established for all phase III randomized clinical trials.	(1) NIH Policy for Data and Safety Monitoring. (2) Policy for the National Cancer Institute for Data and Safety Monitoring of Clinical Trials. (3) Essential Elements of a Data and Safety Monitoring Plan for Clinical Trials Funded by the National Cancer Institute. (4) Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials.
OHRP The Office for Human Research Protections is the DHHS oversight body that provides guidance to IRBs and investigators conducting human subject research.	OHRP Policy and Assurances guidelines, regulations, ethical principles, IRB Guide Book, OHRP/OPRR Reports, FAQs, and other materials relevant to the protection of human research subjects are available from the Office for Human Research Protections Website.
FDA The Food and Drug Administration	The Food and Drug Administration (FDA) has numerous regulations directly impacting informed consent. See Guidance documents, information sheets and regulations indirectly impacting IRBs and investigators.

oversees the use of all drugs, devices, biologics, etc. including their use in research with human subjects.	
ICH/GCP. International Conference on Harmonization / Good Clinical Practices.	Human subject research that is conducted in international settings may have additional requirements that must be met such as, International Conference on Harmonization / Good Clinical Practices
Department of Education.	Research that is funded by the Federal Department of Education may have additional requirements that must be met.
Department of Veterans Affairs.	Research involving human subjects recruited from or conducted in a Veterans Affairs facility must also meet the requirements as set forth in the VA Manual 1200.5
Other Federal Agencies.	Each federal agency may have additional policies, procedures, requirements, etc. that must be applied to research involving human subjects. Examples are the Department of Defense, Department of Energy, and National Science Foundation .

6.2 Assurance Requirements

If DHHS regulations apply to research being conducted at an institution, the institution must have an "Assurance" on file with the DHHS Office for Human Research Protections (OHRP). The Assurance outlines the institution's responsibilities for meeting the requirements for 45 CFR 46.103 and documents how the institution will protect the welfare and rights of research subjects based on federal regulations. The Assurance encompasses:

- A statement of principles.
- Designation of IRBs.
- A list of members on the IRB.
- Written operating procedures for the human subject protection program.
- Training in human subject protections.

Everyone on the research team has a responsibility to understand the institution's written policies and procedures.

6.2.1 Contact the IRB office to:

- Ensure the organization is registered with OHRP if federal dollars are funding the research.
- Obtain the Federal Wide Assurance (FWA) or Multiple Project Assurance (MPA) number. Alternatively, this information can be found on the OHRP Website.
- Determine FWA requirements for multi-sites research activities.