Federal Regulations & Institutional Responsibilities

This tutorial provides an introduction to the Federal Policy (Common Rule) and DHHS Regulations for the Protection of Research Subjects.

The Federal regulations are intended to implement the basic ethical principles governing the conduct of human subjects research. These ethical principles are set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). No one should be involved in human subjects research at any level without being familiar with these ethical principles.

The Belmont Report

The Belmont Report sets forth three basic ethical principles:
Respect for Persons
- Respect individual autonomy
- Protect individuals with reduced autonomy
Beneficence
- Maximize benefits and minimize harms
Justice
- Equitable distribution of research burdens and benefits

Application of the general ethical principles to the conduct of human subjects research leads to the following requirements:

Respect for Persons
- Informed Consent
- Privacy and Confidentiality
Beneficence
- Risk/Benefit Analysis
- Scientific Merit
Justice
- Review of subject selection

Introduction

Under Federal regulations, any institution engaged in Federally-supported human subjects research must commit itself in writing to the protection of those subjects.

This written commitment is called an Assurance of Compliance.

For human subjects research supported by the Department of Health and Human Services (DHHS), the Office for Human Research Protections (OHRP) must approve the institution's Assurance before the funds can be awarded.

Before OHRP can approve an Assurance, it must be satisfied that the Institutional Official, the Chair of the Institutional Review Board (IRB), and the Human Protections Administrator (Primary Contact) at the institution understand the responsibilities involved in an institutional program of human subject protection.
The purpose of this tutorial is to explain these responsibilities, as well as the informed consent process. OHRP will not approve an institution's Assurance unless these key individuals have completed this tutorial or equivalent training.

This tutorial consists of three modules:

- Federal Regulations & Institutional Responsibilities
- Investigator Responsibilities & Informed Consent
- Human Protections Program Administration & IRB Responsibilities

In order to qualify for an Assurance, the Institutional Official must complete Module 1. The Human Protections Administrator (Primary Contact) and the IRB Chair must complete all three modules. IRB members and investigators may take this tutorial, but this would not fulfill the education requirement in the institution's Assurance.

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Federal Regulations & Institutional Responsibilities

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The provisions of the Common Rule are identical to the DHHS Regulations (45 CFR 46, Subpart A).

DHHS regulations include additional protections for vulnerable populations as Subparts of 45 CFR 46:
Subpart B - Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization; Subpart C - Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research.

**Food and Drug Administration**

The Food and Drug Administration (FDA) has a separate set of regulations governing human subjects research (21 CFR 56 – IRBs and 21 CFR 50 – Informed Consent). The basic requirements for IRBs and for Informed Consent are congruent between the two sets of regulations.

Differences center on differences in applicability:

- The Common Rule is based on federal funding of research;
- FDA regulations are based primarily on use of FDA regulated products: drugs, devices, or biologics.

This tutorial will focus on the Common Rule. Institutions conducting research regulated by FDA should contact FDA for detailed guidance.

**Definitions**

- Research – A systematic investigation designed to develop or contribute to generalizable knowledge.
- Human Subject – A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

**Exempt Research**

Certain low-risk research is exempt from the requirements of the Federal regulations. These exemptions do not imply that investigators have no ethical responsibilities to subjects in such research; they mean only that IRB review and approval of the research is not required by Federal regulations.

In no case should investigators make the final determination of exemption from applicable Federal regulations or provisions of their institution's Assurance.

Institutions should adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations.

**Basic Protections**

The regulations contain three basic protections for human subjects:

- Institutional Assurances
- IRB Review
- Informed Consent
Institutional Assurances

What is an Institutional Assurance?

- The documentation of an institutional commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects.
- The principal mechanism for compliance oversight by OHRP.

Assurances

Federal departments and agencies will conduct or support research covered by the regulations (non-exempt) only if:

- the institution has an approved Assurance,
- the institution has certified to the department or agency head that the research has been reviewed and approved by the IRB, and
- the research will be subject to continuing review by the IRB.

IRB Review

The Institutional Review Board (IRB) is a committee established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

IRB Review

The IRB reviews, and has the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research.

The IRB conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year.

The IRB has the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB’s requirements, or that has been associated with unexpected serious harm to subjects.

Institutional Officials may not authorize or approve the conduct of human subjects research that has not been approved by the IRB. Research approved by an IRB may be subject to further review and approval or disapproval by officials of the institution.
Consent

Unless specifically authorized by the IRB, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Informed consent is the voluntary choice of an individual to participate in research based on an accurate understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.

Informed consent must be legally effective under applicable state law and must include the eight specific elements described in the Federal regulations.

Unless specifically waived by the IRB, informed consent must be documented in writing.

Detailed information on the Consent Process may be found in Module 2.

Institutional Responsibility

The responsibility for the protection of human subjects does not rest solely with the IRB. It is a shared responsibility between the Institutional Official, the IRB, and the investigator. Each has a crucial, yet distinct, role to play.

Institutional Official

The Institutional Official is the individual authorized to act for the institution and assumes on behalf of the institution the obligations in the institution's Assurance.

The Institutional Official is responsible for:

- Setting the "tone" for an institutional culture of respect for human subjects;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities as detailed in Module 2;
- Facilitating participation in human subject education activities;
- Serving as a knowledgeable point of contact for OHRP.

Administratively, the Institutional Official is typically responsible for:

- appointing the IRB members and Chair;
- providing the IRB with necessary resources and staff;
- supporting IRB authority and decisions.

Depending on the organizational structure at a given institution, other administrative arrangements may be appropriate.

Institutional Responsibilities

The Institution bears full responsibility for all research involving human subjects covered under its Assurance.
All requirements of the Federal regulations must be met for all Federally-sponsored research. In addition, for DHHS-sponsored research, the provisions in Subparts B through D of 45 CFR 46 must be met.

OHRP strongly encourages institutions to embrace the Federal regulations, regardless of sponsorship, and to commit to this standard in their Assurance.

**Institutional Responsibilities**

Institutions are responsible for:

- designating one or more Institutional Review Boards (IRBs) to review and approve all nonexempt research covered by the Assurance;
- providing sufficient resources, space, and staff to support the IRB's review and recordkeeping duties;
- providing training and educational opportunities for the IRB and investigators;
- developing policies and procedures which effectively and efficiently administer the human subjects program;
- ensuring that Assurances are in place and Certifications of IRB review are submitted to the appropriate authorities for all their DHHS-sponsored research, not only for themselves, but also for collaborating performance sites;
- implementing appropriate oversight mechanisms to ensure compliance with regulations and effective administration of the Human Protections Program.

All persons involved in human subjects research should be familiar with the following references: (Use the "Back" browser button to return to this page after reviewing each reference.)

The Common Rule and DHHS Regulations:
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

The Belmont Report:
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm

For institutions conducting FDA regulated research:

21 CFR 50:  http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html
21 CFR 56:  http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html

Where international research is involved:

Declaration of Helsinki
http://www.wma.net/e/policy/17-c_e.html

Operational Guidelines for Ethics Committees - World Health Organization
http://www.who.int/tdr/publications/

International Ethical Guidelines for Human Subject Research - Council for International Organizations of Medical Sciences (Not available online).

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance
Investigator Responsibilities & Informed Consent

Investigator Responsibilities

- Investigators have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of their institution's Assurance.
- Investigators are expected to be knowledgeable about the requirements of the Federal regulations, applicable state law, their institution's Assurance, and institutional policies and procedures for the protection of human subjects.
- conducting their research according to the IRB approved protocol and complying with all IRB determinations;
- ensuring that each potential subject understands the nature of the research and of the subject's participation and taking whatever steps are necessary to gain that comprehension;
- providing a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the institution.
- promptly reporting proposed changes in previously approved human subject research activities to the IRB. The proposed changes may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects;
- reporting progress of approved research to the IRB, as often as and in the manner prescribed by the IRB;
- promptly reporting to the IRB any unanticipated problems involving risks to subjects or others.

A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law. However, such activities will not be counted as research nor the data used in support of research, except to the extent required under FDA regulations. Investigators should consult with the IRB to ensure that activities that meet the regulatory definition of research undergo prior IRB review and approval.

Informed Consent

Informed consent refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.

The Consent Process

Informed consent is not a single event or just a form to be signed — rather it is an educational process that takes place between the investigator and the prospective subject. The basic concepts of the consent process include:
- full disclosure of the nature of the research and the subject's participation,
- adequate comprehension on the part of the potential subjects, and
- the subject's voluntary choice to participate.

General Requirements

- Informed consent must be prospectively obtained from the subject or legally authorized representative of the subject (if allowed by state law).
- Information must be conveyed in understandable language.
Subjects must be given sufficient opportunity to consider whether they want to participate.
Consent must be given without coercion or undue influence.
Subjects must not be made to give up legal rights or be given the impression that they are being asked to do so.

Comprehension

- Even if the IRB has approved a consent procedure, it is the investigator's responsibility to ensure that each potential subject understands the information and to take the appropriate steps necessary to gain that comprehension.
- Individuals may not be involved as research subjects unless they understand the information that has been provided.

Competency to Consent

- Informed consent must be legally effective under applicable State law. Only legally competent adults can give consent.
- In most cases, minors cannot give consent – only parents or legal guardians can give permission for minors to participate in research.
- Incompetent adults cannot give consent – this may include the developmentally disabled, the cognitively-impaired elderly, and unconscious or inebriated individuals. Only legally authorized representatives in accordance with state law can give permission for incompetent adults to participate in research.
- The evaluation of competence must be made on a case-by-case basis.
- In addition to obtaining permission from parents or legal guardians, provisions must be made for soliciting the assent of the children or incompetent adults.

Elements of Informed Consent

The Federal regulations detail specific elements of information which must be provided to each subject:
- description of the research and subject's participation, including the identification of experimental procedures;
- description of reasonably foreseeable risks;
- description of expected benefits;
- potentially advantageous alternatives to participation;
- explanation of confidentiality protections;
- explanation of compensation for injuries policy;
- whom to contact with questions about the research and research subject's rights;
- explanation that participation is voluntary.

Research and Procedures

The information provided to subjects should:
- make clear that the activity involves research and describe the overall experience that will be encountered;
- explain the research activity, including any parts that are experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues).
Risks

- All reasonably foreseeable risks, discomforts, inconvenience, and harms that are associated with the research activity, should be described.
- Investigators should be forthcoming about risks and not underestimate or gloss over reasonably foreseeable risks.
- If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.

Benefits

- Any benefits that subjects may reasonably expect to encounter should be described.
- Investigators should be frank about benefits and not overestimate or magnify the possibility of benefit to the subject. There may be no benefit other than a sense of helping the public at large.
- Payment to subject should not be listed or described in the Benefits section.

Alternatives to Participation

- Appropriate alternatives to participating in the research project, particularly alternatives that might be advantageous to the subject, should be described. For example, in drug studies, the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- Investigators should be reasonably specific about describing the nature and type of available alternatives. It is not sufficient simply to state that "the researcher will discuss alternative treatments" with the subject.

Confidentiality Protections

The regulations require that subjects be told the extent to which their personally identifiable, private information will be held in confidence. For example, sponsors, funding agencies, regulatory agencies, and the IRB may review research records. Some studies may need sophisticated encryption techniques to prevent confidentiality breaches or a Certificate of Confidentiality to protect the investigator from involuntary release (e.g., under subpoena) of subjects' names or identifiable private information.

Compensation for Injury

If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that the regulations do not limit injury to "physical injury." This is a common misinterpretation.

The regulations prohibit
(i) requiring subjects to waive any of their legal rights, and
(ii) leading subjects to believe they are waiving their rights. Consent language regarding compensation for injury must be selected carefully so that subjects are not given the impression that they have no recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
Contact Persons

The regulations require the identification of contact persons to answer subjects' questions about the research and their rights as research subjects. Subjects must also be informed as to whom to contact in the event of any research-related injuries.

These areas must be explicitly stated and addressed in the consent process and documentation.

A single contact person is not likely to be appropriate to answer questions in all areas. This is because of real or apparent conflicts of interest. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects may best be referred to persons not on the research team. These questions could be addressed to the IRB, an ombudsperson, an ethics committee, or other informed individual or committee. Each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

Voluntary Participation

The regulations require statements regarding voluntary participation and the right to withdraw at any time. Subjects must be informed that:

- participation is voluntary;
- subjects may discontinue participation at any time;
- there is no penalty or loss of benefits for not participating or discontinuing participation.

Additional Elements

Where appropriate, the following additional elements of informed consent shall be included:

- Currently Unforeseeable Risks;
- Termination of Participation;
- Additional Costs to Subjects;
- Consequence of Withdrawal;
- Informing of New Findings;
- Number of Subjects

Waiver of Consent

Under certain circumstances specified in the Federal regulations, the IRB may approve a consent procedure which does not include some or all of the elements of informed consent, or may waive the requirements for obtaining informed consent. To do so, the IRB must find and document that:

- the research involves no more than minimal risk to subjects;
- the waiver will not adversely affect the rights and welfare of subjects;
- the research could not practically be carried out without the waiver; and
- whenever appropriate, the subjects will be debriefed – provided with additional pertinent information – after they have participated in the study.

NOTE – FDA regulations do not provide for a waiver of consent, except in emergency situations
Documentation of Consent

Informed consent is documented by use of a written consent form approved by the IRB and signed by the subject or subject's legally authorized representative. A copy shall be given to the person signing the form.

The written presentation of information in the consent form is used to document the basis for consent and for the subject's future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

The information that is given to the prospective subject, or his/her representative, must be in language understandable to the subject or representative.

Consent forms should be written at a level appropriate to the understanding of the subjects to be enrolled; technical language should be avoided.

OHRP strongly discourages use of the "first person" in consent documents (e.g., "I have been fully informed about ..."). Such statements unfairly ask subjects to make statements that the subject is not in a position to verify (e.g., the subject has no way to verify that the investigator has provided full and complete information).

Waiver of Documentation of Consent

The IRB may waive the requirement for written documentation of consent in cases where:

- the principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research; and the consent document is the only record linking the subject with the research;
- OR
  - the research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting.

Documentation of Consent

The consent form is merely the documentation of informed consent and does not, in and of itself, constitute informed consent.

The fact that a subject signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent.

The Consent Process

Please also review the following additional guidance. Use your browser's "Back" button to return to this page after reviewing each reference.

- Informed Consent Checklist
  http://ohrp.osophs.dhhs.gov/humansubjects/assurance/consentckls.htm
- Informed Consent, Legally Effective and Prospectively Obtained
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc93-03.htm
- Informed Consent, Non-English Speakers
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ic-non-e.htm
- Certificates of Confidentiality
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/certconpriv.htm
- Contacts for obtaining a Certificate of Confidentiality
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/cert-con.htm
**Human Protections Administration**

All assured institutions should have a Human Protections Administration (HPA) program in place to ensure that human subjects involved in research are adequately protected and that the institution remains in compliance with the regulations. This applies equally to institutions with their own IRB, as well as to institutions who rely on another IRB.

Administrative procedures may be handled differently from one institution to another. The following describes procedures that many institutions follow to ensure effective administration and compliance with regulations.

**Human Protections Administrator**

Effective administration of a Human Protections Program requires the designation of a Human Protections Administrator who serves as OHRP's primary institutional contact person and has administrative responsibility for the program.

Institutions with a very small human research program may be able to assign other duties to the Human Protections Administrator, but that person's primary responsibility should be the Human Protections Program.

Depending on the volume of work, the administration of the program may fall to the Human Protections Administrator alone, or to an office staffed by many persons with differing areas of responsibility.

The administrative responsibilities for the HPA fall into three general areas:

- Communication & Education
- Recordkeeping & Reporting
- Monitoring & Oversight

**Communication & Education**

- The HPA is responsible for ensuring constructive communication among the research administrators, department heads, investigators, clinical care staff, human subjects, and institutional officials, as a means of maintaining a high level of awareness regarding the ethical conduct of research, and safeguarding the rights and welfare of subjects.
- The HPA arranges for ready access to the institution's Assurance, copies of pertinent Federal regulations, policies and guidelines related to the involvement of human subjects in research, as well as institutional policies and procedures.
- The HPA is responsible for educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects.

**Recordkeeping & Reporting**

- The HPA is responsible for ensuring that IRB records are being maintained appropriately and that the records are accessible, upon request, to authorized Federal officials. For institutions relying on another IRB, records may be retained at the IRB site.
For Federally supported research, the HPA is responsible for forwarding Certification of IRB approval of proposed research to the appropriate Federal department or agency.

The HPA is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval, except when necessary, to eliminate apparent, immediate hazards to the subject.

The HPA is responsible for ensuring the prompt reporting to the IRB, appropriate institutional officials, OHRP, and any sponsoring Federal department or agency head:

- any unanticipated injuries or problems involving risks to subjects or others;
- any serious or continuing noncompliance with the regulations or requirements of the IRB, and
- any suspension or termination of IRB approval for research.

Monitoring & Oversight

- The HPA is responsible for ensuring that appropriate oversight mechanisms to ensure compliance with the determinations of the IRB have been implemented.
- The HPA ensures that all cooperating performance sites in Federally supported research have appropriate OHRP-approved assurances and provide Certifications of IRB review to the appropriate Federal authorities.
- The HPA should ensure that performance sites cooperating in non-Federally supported research have, and can document, appropriate mechanisms to protect human subjects.
- The HPA ensures that cooperative IRB review arrangements are documented in writing in accordance with OHRP guidance.
- The HPA ensures that all independent investigators, who rely on the institution's IRB, have documented, in accordance with OHRP guidance, their commitment to the institution's human subjects protection requirements and to the IRB's determinations.

Institutional Review Boards

Review by an Institutional Review Board (IRB) is the cornerstone of an institution's program for the protection of human subjects. IRBs are responsible for ensuring that an institution meets the requirements of the Federal regulations, and that the rights and welfare of the subjects are adequately protected.

Although most institutions will have their own IRB, institutions have the option of relying on another IRB to review their research

Relying on Another IRB

An institution relying on another IRB has the following responsibilities:

- to ensure that the reviewing IRB is in compliance with the IRB requirements in the Federal regulations;
- to ensure that the particular characteristics of its local research context are considered, either (i) through knowledge of its local context by the reviewing IRB; or (ii) through subsequent review by appropriate designated institutional officials
IRB Responsibilities

IRB Authority

- The IRB reviews, and has the authority to approve, require modification in, or disapprove all research activities, including proposed changes in ongoing, previously approved, human subject research.
- The IRB has the authority to suspend or terminate the approval of ongoing, previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected, serious harm to subjects.

Continuing Review

- The IRB conducts continuing review of ongoing, approved research at intervals appropriate to the degree of risk, but not less than once per year.
- For approved research, the IRB determines which activities require continuing review more frequently than every twelve months.
- Continuing IRB reviews are preceded by receipt of appropriate progress reports from the investigator, including available, study-wide findings.
- Continuing review must be substantive and meaningful.

IRB Expertise

- The IRB must be familiar with the requirements of the Federal regulations, applicable state law, their institution's Assurance, and institutional policies and procedures for the protection of human subjects.
- The IRB must have effective knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent.
- The IRB must be able to properly judge the adequacy of information to be presented to subjects.
- The IRB must have the professional competence necessary to review the specific research activities coming before it.

Review of Performance Sites

- The IRB roster submitted to OHRP should include members knowledgeable about any other institution for which the IRB regularly conducts reviews.
- For performance sites for which the IRB does not regularly conduct reviews, the IRB must obtain effective input on the local research context from knowledgeable persons other than those conducting the research.
- The presence of such knowledgeable persons should be documented in the IRB minutes.

IRB Communication

- IRB decisions and requirements for modifications must be promptly conveyed to investigators and to the HPA in writing.
- The IRB must provide investigators with written notification of decisions to disapprove research that is accompanied by reasons for the decision, with provision of an opportunity for reply by the investigator, in person or in writing.
Criteria for IRB approval of research:

- risks to subjects are minimized;
- risks are reasonable in relation to anticipated benefits;
- selection of subjects is equitable;
- informed consent is sought from each subject;
- informed consent is appropriately documented.

Additional criteria where appropriate:

- data collection is monitored to ensure subject safety;
- privacy and confidentiality of subjects is protected;
- additional safeguards are included for vulnerable populations.

Expedited Review

- Some specified categories of minimal risk research may be reviewed by the IRB through an expedited review procedure.
- Expedited review may be carried out by the IRB chair or by one or more designated IRB members.
- All of the requirements for IRB approval of research apply equally to expedited review. Expedited review should not be viewed as a less rigorous review.
- Under expedited review, the reviewers may exercise all of the authorities of the IRB, except that the reviewers may not disapprove the research.

Expedited review procedures may be used for:

- research appearing in the published list of eligible research and found by the reviewer to involve no more than minimal risk;
- minor changes in previously approved research during the authorized approval period.

All other non-exempt research must be approved at a convened meeting of the IRB.

Convened Meetings

The IRB observes the following requirements for convened meetings:

- a majority of the members of the IRB must be present and at least one nonscientist must be present;
- if the required number of members is lost during a meeting, no action may be taken until it is restored;
- in order for research to be approved, it must receive the approval of a majority of those members present at the meeting.
- Scheduled meetings of the IRB should occur at intervals appropriate to the level of reviewed research and with sufficient frequency so that the IRB can adequately oversee the progress of the research it has approved.
- Convened meetings may be conducted by telephone conference call, provided that each participating IRB member has received all pertinent material prior to the meeting and can actively participate.
and equally participate in the discussion of all protocols. Minutes of such meeting must clearly document which members were present via conference call, and that these two conditions have been satisfied.

**IRB Minutes**

Minutes of IRB meetings must include:

- attendance at the meetings;
- actions taken by the IRB;
- the vote on these actions including the number of members voting for, against, and abstaining;
- the basis for requiring changes in or disapproving research;
- documentation of specific findings required by the regulations, and
- a written summary of the discussion of controverted issues and their resolution.

**IRB Recordkeeping**

IRBs shall prepare and maintain adequate documentation of IRB activities, including the following:

- copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
- minutes of IRB meetings;
- records of continuing review activities;
- copies of all correspondence between the IRB and the investigators;
- a list of IRB members;
- written procedures for the IRB;
- statements of significant new findings provided to subjects.

**Human Protections Administration**

All Human Protections Administrators and IRB Chairs should review the following references: (Use the "Back" browser button to return to this page after reviewing each reference.)

- Research that may be reviewed through an expedited procedure:  
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm
- IRB knowledge of local context:  
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/local.htm
- Institutions engaged in research:  
  http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm
- Continuing review – Institutional and Institutional Review Board responsibilities:  
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc95-01.htm
- ORHP Compliance Activities – common findings and guidance:  
  http://ohrp.osophs.dhhs.gov/references/findings.pdf