SNU Institutional Review Board
Guidelines for Review of Research
Involving Human Subjects
The Southern Nazarene University Institutional Review Board (SNU IRB) operates in accordance with federal regulations 45 CFR 46. The SNU IRB reviews all research involving human subjects that is sponsored by units of SNU or research involving human subjects that is conducted on the SNU campus which involves personnel (faculty, staff and/or students) and/or facilities of these units. The nature and composition of the IRB human subject, the categories and criteria of review, and the procedures and decisions of the IRB are presented in these guidelines.

Two Federal agencies, the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), have published complete sets of regulations regarding the review of research involving human subjects In most respects, the regulations parallel each other, and the SNU IRB acts as the reviewer of research covered by both agencies. These regulations apply to all research involving human subjects that is conducted or otherwise subject to regulation by, but not limited to, any Federal Department or Agency that has adopted the regulations.

Structure & Responsibilities

Structure:
The composition of the SNU IRB has been designed to meet regulatory requirements and to ensure the complete and sensitive review of all projects submitted. The SNU IRB is composed of at least 5 members. The members are primarily SNU faculty with at least one representative from each of the units. Such representation provides a diversity of viewpoints and promotes the complete and adequate review of human subject research activities. The IRB also includes at least one individual whose primary concerns are in nonscientific areas, and at least one community representative having no affiliation with the University. A prisoner representative has also been appointed to the IRB to assist in the review of research concerning the prison population. The IRB may also call upon outside expertise whenever it receives especially sensitive projects.

Responsibilities:

Review: The IRB reviews all research involving human subjects.

Policies/Procedures: Policies and procedures for review of human subject research are developed in consultation with the IRB.

Education: The IRB provides information regarding IRB policies and procedures, and also provides regulations and forms to investigators via the SNU web site, informational brochures, seminars, and meetings.

Records and Files: The IRB maintains a record of review proceedings and decisions, in accordance with Federal and University guidelines, for at least three (3) years following termination of the projects.

Definitions

Defining Research:
As stated in the regulations, Research is any systematic investigation designed to develop or contribute to generalizable knowledge. Any activity that meets this broad criterion and that is conducted by SNU faculty, staff, or students, or that uses SNU facilities, personnel or students is considered research. It does not matter whether the activity takes place within and as a part of (however large or small) some other activity (such as a demonstration or services programs) or whether the research is the whole of a project.

Defining the Human Subject:
Regulations define a Human Subject as a living individual about whom an investigator obtains either:

a) data through intervention or interaction with the individual, or

b) identified private information.
Intervention generally includes both physical procedures by which one gathers data (e.g., venipuncture) and manipulations of the subject (or the subject's environment) that are performed for research purposes. Much more common are interactions which include communication or interpersonal contact between the investigator and the subject. Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place. Thus, the individual will have provided the information for specific purposes and can reasonably expect that the information as associated with his or her identity will not be made public.

Research

Some Tests for Research:

When dealing with data gathering within the context of training, demonstration, or service projects, you may want to ask yourself several questions to determine if any aspect of your work is research as it might be related to human subjects review:

➤ Will you seek out subjects (or settings that contain subjects) for your training, demonstration, or service project, rather than the subjects seeking the service or training from you in their normal pursuit of professional services?

➤ Do you anticipate in advance of conducting the project that you will analyze, interpret, and disseminate the findings of your investigation?

➤ Might the knowledge you gain from your encounter with the subjects be applied beyond the service of a training project to a similar encounter so as to lead to a new procedure or process?

If you answer yes to any one or more of these questions, then your training, demonstration, or service project has a research component.

Theses and Dissertations:

A special class of data record that is always research is the thesis or dissertation. By accepting a thesis or dissertation, the University disseminates its contents for use by others. Therefore, a thesis or dissertation that involves the use of humans must always be submitted for review or for certification of exemption from review by the IRB.

Some Instances of Non-Research:

There are numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations. Some examples are:

➤ Data gathering for classroom training in research methods for which the only foreseeable purpose is teaching. In other words, neither the instructor nor the student can foresee or anticipate any dissemination of the data gathered beyond the classroom situation.

➤ Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to improve services or operations. In other words, no dissemination of the information outside the unit or institution is foreseen or anticipated.

➤ Evaluation data gathered for a contractor about a project or operation for which he or she is responsible, if neither the research nor the contractor intends or anticipates the dissemination of the data.

All these categories of data gathering fail to be research because there is no foreseeable dissemination of the data. Any record of the data (or interpretations and analyses of the data) remains private (used only for purposes that are appropriate to the class, institution, or agency in the normal conduct of its work).

Some Forms of Interaction in Research:

The idea of interacting with a human being is perhaps the key idea in determining whether or not he or she is a subject with respect to the regulations. All forms of interaction are included by the regulatory definitions. Among the most common types of research interactions are:
➢ Mail questionnaires or surveys
➢ Personal interviews, structured or unstructured, with or without recognized instruments
➢ Personal (i.e., face-to-face) surveys
➢ Telephone interviews and surveys
➢ Classroom instruments, evaluations, or exercises
➢ Examination of private records (e.g., medical, psychological, or school records)
➢ Observations of public behavior by identifiable individuals (e.g., in a classroom)

**Common Forms of Research Requiring Submission:**

From the list of types of interaction, we can see that many common forms of research that present little, if any, risk to human beings nevertheless require review or certification of exemption simply because the research has human subjects. Some of the more common types are:

➢ Oral history
➢ Case studies of events or individuals if interviews are involved
➢ Workplace and school observations whether activities are controlled or uncontrolled
➢ Surveys for information, attitudes, opinions, and similar matters for publication or for report to a federal, state, or local governmental agency

**Consent**

**Informed Consent:**

The need for informed consent and the development of a legally effective consent document is a vital step in the design of research involving human subjects. Except as detailed below, regulations require that the investigator obtain the informed consent of the subject, or the subject’s legal representative, prior to the subject’s involvement in the research. This applies to all categories of research.

**Basic Elements of Informed Consent:**

A consent form guideline should be used when preparing the consent form for the research. Examples of approved consent forms are available from the IRB office, Science Room 433. A copy of the consent form should accompany the IRB application. The basic elements to be included in a legally effective informed consent document are as follows:

➢ A statement describing the study, its purpose, the duration of the subject’s participation, and a description of procedures identifying those which are experimental (if any)
➢ Description of any foreseeable risks or discomfort to subject and any benefits which may be reasonably expected. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and if so, where further information may be obtained
➢ Possible alternative methods of treatment (if relevant)
➢ A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained. A statement of whom to contact for answers to pertinent questions about the research subject’s rights
➢ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and the subject may discontinue participation at any time without penalty or loss of benefits
Waivers and Alternatives

The IRB may approve a consent procedure which does not include, or modifies, some or all of the basic elements, or may waive the requirement to obtain informed consent under the following conditions (45 CFR 46, 117(c)(1)-(2)):

The research cannot practically be carried out without the waiver, and either

- It is a research demonstration project that is both:
  - a) directed or approved by state, local, or tribal governments, and
  - b) concerns only administration-regulatory issues in service programs;

  OR

- It is research that involves no more than minimal risk and will give subjects pertinent information at the end (if appropriate), and the waiver will not adversely affect subjects’ rights or welfare.

The IRB may waive the requirement to document informed consent if it finds either

- The only record linking the subject and the research would be the consent document and the principal risks would do potential harm resulting from a breach of confidentiality;

  OR

- The research presents only minimal risk and involves no procedures for which consent is normally required outside of the research context.

In cases where consent or documentation is waived, the investigator may still be required to prepare a statement (information sheet), containing the basic elements of the consent form which describe the project, for distribution, to the subjects.
CONSENT FORM GUIDELINE

The example below is for your convenience in preparing a consent form

I, __________________________, hereby authorize or direct __________________________ or associates or assistants
(Participant’s name) (Researcher’s name)
of his or her choosing, to perform the following treatment or procedure:

NOTE: The researcher should include the following elements in his/her description of the procedure:
1. Procedure – describe the general procedure. Specifically indicate (if relevant) that portion
   of treatment or procedure that is experimental.
2. Duration of subject’s participation.
3. Extent, if any, to which confidentiality of records identifying the subject will be maintained.
4. Possible appropriate alternative methods of treatment (if relevant).
5. Possible discomforts or risks.
6. Possible benefits for subjects/society.

This is done as part of an investigation entitled __________________________

The purpose of the procedure (or treatment) is __________________________

“I understand that participation is voluntary, that there is no penalty for refusal to participate, and that I am
free to withdraw my consent and participation in this project at any time without penalty after notifying
the project director.”

I may contact __________________________ at phone number __________________________. I may also
contact the SNU IRB, 6729 N.W. 39th Expressway, Bethany, OK 73008; (405)491-6323.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given
to me.

Date __________________________ Time (am or pm) __________________________
Signature of Participant __________________________ Person authorized to sign for subject (if required)
Witness (if required) __________________________ Witness (if required) __________________________

“I certify that I have personally explained all elements of this form to the subject or his/her representative
before requesting the subject or his/her representative to sign it.”

Project Director or his/her authorized representative

NOTE TO RESEARCHER(S): There are circumstances under which (a) some or all of the elements in
the above form may be altered or waived and/or (b) the requirement for the consent form to be signed may
be waived. See 45 CFR 46, Sections 46.116 and 46.117, or contact the IRB at (405)491-6323
§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any
medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth
above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; and

(2) The research could not practically be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practically be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)
§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)
Categories

Once you have determined that your proposed research involves human subjects, and the need for informed consent, the next step is determine the appropriate category of review of your IRB application.

Categories of Human Subject Research:

There are several categories of human subject research and each subject follows a different review procedure.

Exempt Category

Research that the regulations specifically exempt from review does not require full review by the IRB, however, such research must be certified as exempt. Exempting an activity from review does not absolve the investigator(s) from ensuring that welfare of subjects is protected and that methods used to gain subject consent and provide information are appropriate. Exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. Criteria for exempt research are as follows:

- Research conducted in established or commonly accepted educational settings involving normal educational practices, such as:
- Research on regular and special education strategies
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects
- Research involving survey or interview procedures except where responses are recorded in such a manner that the human subjects can be identified (directly or through identifiers linked to the subjects), and either:
  - The subjects’ responses, if they became known outside the research could reasonably place the subjects at risk of criminal liability or civil liability, or be damaging to the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standings or employability;
  - The research deals with sensitive aspects of the subject’s own behavior that could be damaging to the subject’s reputation, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- Research involving the observation (including the observation by participants) of public behavior, except where observations are recorded in such a manner that the human subjects can be identified (directly or through identifiers linked to the subjects), and either:
  - The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability,
  - The observations deal with sensitive aspects of the subject’s own behavior that could be damaging to the subject’s reputation such as illegal conduct, drug use, sexual behavior, or use of alcohol.

This exemption does not apply to research involving children, except for research involving observation or public behavior without interaction.

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

Research that the Federal government has found to present minimal risks to subjects is eligible for expedited review. Expedited reviews are conducted by at least two members of the IRB assigned according to expertise in the area of research to be reviewed. Upon evaluation of the project, the IRB may require review by the full committee. Criteria for determining expedited review are as follows:

- Collection of hair and nail clippings in a nondisfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction
- Collection of excreta and external secretions including sweat, uncanunlated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during delivery
- Recording data from subjects 18 years of age or older using noninvasive procedure routinely employed in clinical practices. This includes the use of a physical sensor applied either to the surface of the body or used at a distance that does not involve the input of matter or significant amounts of energy into the subject or invade the subject’s privacy. It also includes such procedures as weighing, testing, sensory acuity, electrocardiograph, electroencephalograph, thermograph, detection of naturally occurring radioactivity, diagnostic echograph, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves, etc.).
- Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older in good health and not pregnant
- Collection of both supra- and subgingival plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
- Voice recording for research purposes, such as investigation of speech defects
- Moderate exercise by healthy volunteers
- Study of existing data, documents, records, pathological specimens, or diagnostic specimens
- Research on individual or group behavior or characteristics of individuals (such as studies of perception, cognition, game theory, or test development) where the investigator does not manipulate the subject’s behavior and the research will not involve stress to subjects
- Research on drugs or devices for which an investigational new drug exemption or an investigational device is not required

Expedited - Special Population

If researchers feel they have an application that represents minimal risk with a special class of subjects, they may elect to mark the IRB application as Expedited and next to that option write in the phrase Special Population. (Full Board Review Required).

All research which does not fit either exempt or expedited review criteria must be reviewed by the entire IRB. Additionally, research initially submitted for exemption or expedited review may be required to undergo Full Board Review.

Specially Protected Individuals

Current government regulations recognize four groups of vulnerable subjects for whom additional guidelines have been prepared. These are:

- Children
- Pregnant Women and Fetuses
- Prisoners
- Mentally disabled
See specific guidelines for research involving children. Although some exemptions apply for research involving these subjects, particularly for children, Full Board Review will be required for most research projects.

If your research involves one of the other types of vulnerable subjects, please contact the IRB office, Science 433, for further information.

**The Review Process**

The individual initiating a program involving human subjects is responsible for ensuring appropriate committee review before submitting an off-campus proposal or undertaking any program activities. The review process and time will vary with the category of research (exempt, expedited, full board).

The principal investigator(s) is/are responsible for preparation of the Application for Review of Human Subjects Research. This application should be prepared for all categories of research. A copy of the project proposal, or thesis, or dissertation proposal, must be attached. Signatures of the investigator(s), department head, and college research director are required.

The application should be submitted to the IRB Executive Secretary, Science Room 433.

**Types of Reviews**

**Exempt Review:**

Applications for exempt research are sent for review to one reviewer to certify exemption. This process takes three to five working days depending on the reviewer’s workload.

**Expedited Review:**

Expedited research applications are sent for review to two (2) IRB members. The reviewers are selected based on expertise; however, applications are not reviewed by a member from the originating department. Review time is approximately 2 weeks.

**Expedited Review - Special Population:**

For applications involving special classes of human subjects; the IRB will initially have them reviewed by two IRB members for determination if the research represents minimal risk (as defined by the Federal Regulations and determined by those IRB members). If that test is met, then the application will be sent to two more IRB members for review. At least one (preferably two) IRB members will have experience with those special classes of subjects. One of the four IRB members will be appointed by the IRB chair or executive secretary to coordinate reviews and consolidate a single document to be sent back to the principal investigator by the executive secretary. Review time is approximately four weeks.

**Full Board Review:**

Applications requiring Full Board Review are first sent to two IRB members for review of the application’s completeness and to determine the need for additional information. After receipt of any requested information or changes, application is then submitted for review by the full IRB. A full board application must be complete before review is initiated, including receipt of any revisions requested by the preliminary review. Total review time can range from three to six weeks.

**Review Criteria and Results**

**Criteria:**

In general, criteria for approval or disapproval of the proposal are as follows:

- **Risk:** Risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose the subjects to risks; and, when appropriate, by using procedures already being performed on the subject for diagnostic and treatment purposes.
➢ **Risk vs. Benefit:** The risks to the individual subject must be accepted when measured against
  
  o the possible benefit to him/her,
  
  and
  
  o the importance of the knowledge to be gained.

➢ **Subject Selection:** Selection of subjects should be equitable.

➢ **Informed Consent:** The method to obtain consent and the substance of the information upon which the subject bases his/her consent to participate in a research study must be adequate to assure informed consent.

➢ **Safety and Privacy:** Appropriate safeguards must be provided to protect the privacy of subjects and to maintain the confidentiality of data gathered.

*Results:*

The review committee may take one of the following actions in regards to applications for review:

➢ **Approved:** The IRB may approve or certify exemption of the project as submitted.

➢ **Pending Revision:** To receive approval, the listed pending items must be revised.
§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (j) of §46.101 of subpart A are applicable to this subpart.


§46.402 Definitions.

The definitions in §46.102 of subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the
applicable law of the jurisdiction in which the research will be conducted.

(b) **Assent** means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) **Parent** means a child's biological or adoptive parent.

(e) **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.