

Portland State University
Human Subjects Research Review Committee

Purpose and scope

Portland State University (PSU) is responsible for the rights and welfare of human subjects involved in research sponsored or conducted by the university. In order to meet this responsibility, the University established the Human Subjects Research Review Committee (referred to hereafter as the Institutional Review Board or IRB). Members are charged with reviewing all research conducted under the auspices of PSU that involves human subjects to ensure adequate protections are in place.

1.1 Applicability

All faculty, other employees and students at PSU who propose to use humans as subjects in research and related activities must have approval from the IRB prior to conducting the research. In addition, these policies apply to any entity who contracts with PSU for services or who wishes to conduct research on PSU property or that involves students and/or employees.

1.2 Federal Authority

Portland State University has an assurance to conduct human subjects research in accordance with regulations set forth by the United States Department of Health and Human Services Office of Human Research Protections

Federal wide assurance:	FWA00000091
Expires:	October 19, 2010

1.3 Definition of Research

Research is defined as any systematic investigation designed to develop or contribute to generalizable knowledge.

A **systematic investigation** is one that applies a defined set of questions or steps across a number of individuals or points in time in order to answer a research question. Systematic investigation may be a characteristic of both research and non research projects. For example, a quality improvement process may be a systematic investigation but may not meet the criteria of resulting in generalizable knowledge.

Generalizable knowledge refers to knowledge that is intended to be applied beyond the research setting (program) or individual. Findings that are intended to be published or presented to audiences outside of the research setting are considered research for the purpose of human subjects review.

1.4 Definition of Human Subject

A **human subject** is a living individual about whom an investigator obtains data, either from intervention or interaction with the individual, or through records which contain identifiable private information.

2.0 Designation of Institutional Review Board (IRB)

Portland State University has two IRBs that are responsible for providing oversight for all research activities involving the use of human subjects. All review procedures meet or exceed the requirements set forth in 45 CFR 46 and 21 CFR 50 & 56. The activities of the IRBs are facilitated by the Research Integrity Coordinator, whose office is within the Office of Research and Sponsored Projects and who reports to the Vice Provost for Research and Sponsored Projects.

2.1 Membership of the IRB

Each IRB may be composed of faculty, research staff, graduate students and community members. The IRB may use, as necessary, non-voting members and consultant reviewers to provide specific expertise needed for the review of an application. PSU and federal regulations require that there be a minimum of 5 regular voting members. PSU's IRB will have a maximum of 10 members, including the Chairperson, on each IRB. Each IRB will have at least one member unaffiliated with the University (community member). At least one member on the IRB must have primarily non-scientific concerns; this is someone not primarily functioning as an investigator, such as a lawyer, ethicist or member of the clergy; thus, often this person fills, as well, the role of community member. The IRB may also have at least one graduate student member. Each IRB will be appointed such that the members have varying backgrounds based on experience, disciplinary expertise and diversity in terms of gender, racial and cultural background.

The Research Integrity Coordinator and the Associate Vice Provost for Research and Sponsored Projects will annually review existing IRB membership and provide recommendations to the Vice Provost for Research and Sponsored Projects regarding recruitment, retention or dismissal of members. This review includes examination of attendance, expertise, affiliation and diversity. Thus the membership and composition of the IRB is periodically reviewed and adjusted to meet regulatory and organizational requirements.

The IRB may invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond that available on the board (e.g. research with prisoners, child abuse, domestic violence.)

IRB members will be nominated through the University's procedure for committee assignments. All new or continuing members are appointed by the Vice Provost for Research and Sponsored Projects. Members are appointed for three years. Members may be asked to serve a longer term at the recommendation of the Research Integrity Coordinator.

The Chairperson(s) are nominated by the Research Integrity Coordinator and the Associate Vice Provost for Research and Sponsored Projects from among individuals at the University with the experience and skills to conduct the meetings. Appointments are made by the Vice Provost for Research and Sponsored Projects and appointments of all members and the Chairperson(s) are confirmed by the President of the University. Appointments are made for three years.

Each appointed IRB member will complete an on-line Human Subjects Training program before participating in a review.

3.0 Management of the IRB

The IRB meetings are presided over by the Chairperson. The Chairperson will confer with the Research Integrity Coordinator regarding the agenda for meetings and consult on meeting minutes and documentation sent to investigators.

Each IRB member is expected to attend IRB meetings regularly, read and analyze all applications sent prior to the meeting, and serve as primary reviewer as assigned. Acting as primary reviewer includes preparing a thorough critique of the application, contacting the investigator for additional information prior to the meeting and presenting the application to other members of the IRB at the meeting.

Members may be asked to perform expedited reviews outside of the IRB meetings. They will be given two weeks to review an application and are expected to do so in a timely manner.

IRB members will recuse themselves from discussion of any application in which they have a vested interest (e.g. principal investigator or other affiliation with the project) except to provide information as requested by the IRB.

Investigators may not request a specific IRB member as primary reviewer, although they may comment on which reviewer may have related expertise.

3.1 Functions of the IRB

The IRB will review all research involving human subjects conducted by faculty, other employees and students of PSU, or conducted on PSU property, or under PSU affiliation. The IRB may also review applications from non PSU entities at the discretion of the Research Integrity Coordinator. A fee may be charged for service to outside entities in conjunction with Oregon University System procedures.

Applications will be submitted to the Office of Research and Sponsored Projects and reviewed by the Research Integrity Coordinator for completeness and to determine if the proposed project constitutes research involving human subjects. The Research Integrity Coordinator will also determine whether the application will be waived (exempt), qualifies for expedited review or requires full committee review. Applications that require a full committee review will be placed on the agenda of the next IRB meeting. Applications must be received at least two weeks prior to a meeting date to be placed on that agenda.

The IRB can take one of four actions: approve, approve with modifications (conditional) or deny or return the application to the investigator for more information before making a decision (incomplete).

Investigators will receive written documentation regarding the decision made about their application. Any conditions or modifications required will be sent to investigators by email within 3-4 week after submission of the application. The time between submission to approval is typically 4-6 weeks. Approval letters will be sent by e-mail and in hard copy. Approval is for one year.

In order to continue a project, a Continuation Review Report is required at least annually, however, the IRB can require continuing review more frequently for high risk research.

The IRB may also review reports of unanticipated problems on the request of the Research Integrity Coordinator. A full committee must review and approve the decision to suspend or terminate an IRB approval.

3.2 Operations of the IRB

A majority of the regular membership who are in attendance in person or by phone constitute a quorum. If a quorum is not present, the IRB cannot make a determination about an application.

IRB meetings will typically be held every two weeks except during winter break and summer term. During those times, IRB meetings will be held at least once per month.

IRB members will be notified of the schedule of meetings at the beginning of the academic year. Time and place of meeting, as well as agenda and applications to be reviewed will be delivered to each member a week prior to the scheduled meeting.

4.0 Categories of Human Subjects Research

All research that involves human subjects conducted by faculty, other employees and students at PSU must have prior review and approval by the HSSRC. The Research Integrity Coordinator will determine the level of risk involved and the type of review needed: Waived (Exempt), Expedited or Full Committee review. The determination of the type of review is based on an assessment of the level of risk. Research of no greater than minimal risk can be reviewed at the waived (exempt) or expedited level, while research of greater than minimal risk will be reviewed at the full committee level.

Minimal risk is defined as the probability that the magnitude of harm or discomfort anticipated in the proposed research is no greater in and of itself than those ordinarily encountered in everyday life, or during the performance of routine physical or psychological examinations or tests.

All investigators must submit a complete IRB application, even if they believe that their research falls under one of the exemption categories.

4.1 Waived (Exempt)

Research that involves human subjects may be determined to meet one of the six categories for exemption. This determination is made by the Research Integrity Coordinator in consultation with the Chairperson of the IRB. **To be considered exempt, the PSU IRB must find the research to be both minimal risk and to fit into one of the following exemption categories.** PSU's IRB policy requires a consent process even if the research falls under one of the exemption categories and the IRB may require changes to a protocol even though it may fall under one of the exemption categories. Even if a research project appears to fit under an exemption category, the Research Integrity Coordinator may determine that the risk to subjects is too high to be waived.

Waived (Exempt) categories: *(Quoted from 45 CFR 46.101)*

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

below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4.2 Expedited

Research activity that involves no greater than minimal risk to subjects may be eligible for expedited review.

Expedited reviews are conducted by the IRB Chairperson or his/her designee and one or more members of the IRB who have knowledge in the area of research to be reviewed.

The expedited review process can be applied to new applications with minimal risk or minor changes in previously approved research (also called amendments).

Under the expedited review procedure, the Chairperson or his/her designee examines the expedited review reports and has the authority as the IRB to make a determination to approve or request modifications. However, research cannot be disapproved through the expedited process as a majority of members must vote to disapprove an application.

Upon evaluation of the application, the reviewers may request review by a full committee.

Expedited categories (*Quoted from 45 CFR 46.110*)

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) From other adults and children¹ considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in a week period and collection may not occur more frequently than 2 times per week.

¹ 1 Children are defined in the DHHS regulations as “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.” 45 CFR 46.402 (a). In Oregon, this is 18 years of age.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist ebullization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding 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: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing², body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

4.3 Full Committee Review

All research that does not meet either exempt or expedited criteria must be reviewed by the full committee. All research with more than minimal risk will be referred for full committee review. All research with prisoners must be reviewed by full committee. Typically research that

² Muscular strength/endurance testing

involves children, pregnant women and individuals with diminished cognitive capacity will be referred for full committee review.

4.4 Review Not Required

Researchers, including graduate students working on thesis, dissertations or master's projects, whose project **meets all four** of the following criteria need to complete the form titled "Review Not Required" (if the project involves secondary data but does not meet all four criteria, a complete application must be submitted):

- Data already exist
- Data were collected previously by another investigator
- All identifying information has been removed and data cannot be linked back to individuals
- No contact between subject and student is/was involved.

5.0 Criteria for Approval (*Quoted from 45 CFR 46.111*)

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable and when needed, precautions have been taken for vulnerable populations.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- Informed consent will be appropriately documented.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study.

6.0 Voting Requirements and Appeals

A majority of the regular membership who are in attendance in person or by phone constitute a quorum. A majority of persons present (in person or by phone) at the meeting is required to approve and/or disapprove an application.

Whenever a vulnerable population is involved in research, the Research Integrity Coordinator will assign the protocol to at least one reviewer with knowledge of the population. For example, any study that involves prisoners as research participants will be reviewed by at least one reviewer who has knowledge of the criminal justice system. (e.g. works for corrections, criminal justice investigator).

If an investigator disagrees with either the IRB's decision or the conditions placed on the protocol, they may request to meet with the Research Integrity Coordinator and the Chairperson of the IRB. The purpose of this meeting will be to review the decisions and discuss possible alternative resolution. If the investigator is not satisfied with the outcome of this meeting he or she can appeal to the Associate Vice Provost for Research and Sponsored Projects and subsequently to the Vice Provost for Research and Sponsored Projects. The Vice Provost for Research and Sponsored Projects has the final decision making authority regarding IRB actions. No other University official has the authority to override or disapprove an IRB decision.

7.0 Information required in an application

The initial application requires submitting information on each of the following:

- Study Title and Prospectus
- Exemption Category (if seeking a waived review)
- Description of the informed consent process and informed consent form to be used
- Description of subject recruitment
- First person scenario
- Description of any potential risks and safeguards
- Description of potential benefits
- Information on records storage and distribution
- All study instruments, consent forms and recruitment materials to be used (survey, interview questions, recruitment scripts, focus group outlines, etc)

For research that will be conducted with vulnerable populations, the Research Integrity Coordinator or the IRB may ask for verification of the investigator's qualifications to work with the population.

Graduate students must provide a description of the research support they will have available including the involvement of an advisor (e.g. Dissertation chair).

(HSRRC application - http://www.rsp.pdx.edu/forms/hsrrc_app.pdf)

7.1 Continuing review

Investigators are required to complete a continuing review report each year if they wish to continue the study past one year. The report must include a description of the status of the project including information on enrollment numbers, adverse events, changes to consent documentation, etc. The Research Integrity Coordinator will determine if the Continuing Review Report will be reviewed in full committee or if it can be reviewed through an expedited process.

(Continuing Review Report - http://www.rsp.pdx.edu/forms/cont_rev_report.pdf)

7.2 Amendments

Amendments to an approved protocol may be submitted at any time. Details of the proposed changes are to be sent to the Research Integrity Coordinator along with any revised forms. The Research Integrity Coordinator will determine whether the amendment needs full committee review or can be reviewed through an expedited process. If the amendment significantly changes the protocol or increases the risks to subjects, the Research Integrity Coordinator can require a new application. Amendments cannot be implemented until they are approved. If there is a need to avoid immediate risks to subjects, researchers should contact the Research Integrity Coordinator to discuss any immediate changes to a protocol.

7.3 Authorization Agreement

For investigators collaborating with other institutions, the Research Integrity Coordinator may determine if separate applications for each institution are needed or if an IRB Authorization Agreement can be used between Portland State University and the other institutions. An Authorization Agreement allows institutions with approved federal wide assurances to assign oversight of the research project to a collaborating institution who also has an approved federal wide assurance. Researchers should contact the Research Integrity Coordinator to discuss this option which is granted on a case-by-case basis.

7.4 Concept Approval

In rare cases, the IRB may grant concept approval for a low risk research project in which the design and methodology has not been fully developed. However, data collection from human subjects cannot be implemented until the complete details of the research activities have been provided to the IRB and reviewed and approved by the IRB. Please consult the Research Integrity Coordinator for information.

7.5 Pilot Studies

A pilot study is defined as 1) a study that tests the effectiveness or applicability of an already existing research instrument on a new population or 2) a study that tests the effectiveness or applicability of a new research protocol (i.e. interview schedule) on a new population. The researcher must consult the Research Integrity Coordinator to determine if the pilot study will

require IRB review. The decision will depend on 1) the type and number of subjects; 2) that data will not be used in any analysis other than the pilot test; 3) the pilot test results will not be published; 4) there is no greater than minimal risk to the subjects in the pilot test.

8.0 Reporting of Unanticipated Problems

The principal investigator is responsible for reporting all unanticipated problems or adverse events to the Research Integrity Coordinator as soon as possible but no later than five working days after the event. The event may be reported by telephone or e-mail but must be followed up by a formal report on the form provided at the ORSP web site.

(Unanticipated Problem form -
http://www.rsp.pdx.edu/forms/Unanticipated_problem_adverse_event.doc)

Unanticipated problems or adverse events are those which cause unanticipated harm or increased risk to subjects or others, specifically problems not explained in the consent form. An example of an unanticipated problem is loss of data files containing personal information about participants.

The Research Integrity Coordinator will review the report and determine if the event was (a) unforeseen (b) caused harm or placed a person at increased risk of harm and (c) was directly related to the research procedures. The Research Integrity Coordinator will take action which may include but is not limited to: requiring a modification of the research protocol, requiring additional information on the informed consent, requiring that all affected participants be notified of the increased risk. The Research Integrity Coordinator may also refer the report to a full committee for review and recommendation for action. The decision to suspend or terminate a research project because of an unanticipated problem or adverse event must be made by the full committee.

9.0 IRB Record Requirements

An IRB membership roster will be available on the ORSP website and updated at least annually.

Written procedures and guidelines will be available from ORSP and on the ORSP website. This document will be reviewed and updated every five years or as needed.

Written minutes of the IRB meetings are kept in the office of the Research Integrity Coordinator. The minutes will document members present, summary of discussion on debated issues, the record of IRB decisions and the record of voting. IRB meeting minutes are retained for three years.

Written or electronic records of study protocols, approved consent forms, written communication to and from the IRB, adverse reaction reports, and continuing review reports will be kept under the supervision of the Research Integrity Coordinator for three years.

10.0 Special considerations

10.1 Master's and Doctoral Student requirements

A thesis or dissertation is automatically considered to be adding to generalizable knowledge because the University intends to disseminate its contents for the use of others. Therefore, students completing a master's thesis or doctoral dissertation that involve the use of human subjects must submit an IRB application for review and approval. If a student's master's project includes human subjects and meets the definition of research described in this policy, a review is needed.

10.2 Capstone Courses and Classroom "Research"

Capstone course activities do not need IRB review if the following criteria are met:

- Projects are identified as "classroom-directed exercises" and supervised by a faculty member
- Projects will not place subjects at greater than minimal risk
- All data collected by students are recorded anonymously, i.e. without names, Social Security numbers or other identifiers

In a situation where a community partner of a capstone project may wish to disseminate data, please consult with the Research Integrity Coordinator to determine if the work is research in need of a review.

Similarly, research conducted as part of a classroom assignment will not routinely be reviewed by the IRB. Usually, this type of research is conducted under the purview of the classroom instructor who is responsible for assuring that human subjects are adequately protected. A research paper written as a class assignment only within the classroom setting is an example. The classroom instructor is responsible for determining the risks to subjects and may wish to consult with the Research Integrity Coordinator.

In the case of research conducted as coursework, faculty and students have an ethical responsibility to inform participants of the purpose of the project, the scope and duration of each activity in which they are expected to take part, and the expected outcomes—in essence, to obtain informed consent. The Research Integrity Coordinator is available for consultation in drawing up informed consents or cover letters. In addition, if any data collection of a sensitive nature is to take place, it is recommended that the investigator work with the Research Integrity Coordinator to incorporate appropriate protections for those involved in the project.

11.0 Special Populations

11.1 Children (Modified from 45 CFR 46, subpart D)

It is expected that children will be included in all research involving human subjects unless there is a scientific reason to exclude them, such as the following:

- research topic to be studied is irrelevant to children
- there are laws or regulations barring the inclusion of children in the research
- insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment)

The researcher should contact the Research Integrity Officer if assistance is needed in determining scientific inclusion and exclusion justifications.

The IRB will review projects in which no greater than minimal risk to children is presented, only if adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

The IRB will review projects in which 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 risk is justified by the anticipated benefit to the subjects;
- 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
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

The IRB will review projects in which 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 risk represents a minor increase over minimal risk;
- 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;
- 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
- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Research which is not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children will only be reviewed if the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Unless permission to forgo obtaining either assent by the child or permission from his or her parents or guardian is explicitly granted by the IRB, both are required in research that will involve children.

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, we may still waive the assent requirement under circumstances in which consent may be waived in accordance with general informed consent provisions. When the IRB determines that assent is required, it shall also determine how assent must be documented.

In addition, the IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For research involving greater risk and no prospect of direct benefit to subjects, permission is to be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects--for example, neglected or abused children--it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law.

11.2 Prisoners (Modified from 45 CFR 46, subpart C)

Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary decision regarding whether or not to participate as subjects in research.

The IRB shall review research only if it finds that:

- The research is in a permissible category (see below);
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

- The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentence, and for informing participants of this fact.

Permitted Research Involving Prisoners

Biomedical and behavioral research may involve prisoners as subjects only if the proposed research involves the following:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk or inconvenience to the subjects;
- Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk or inconvenience to the subjects;
- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only (when DHHS funding is sought) after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register of the intent to approve such research; or
- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners (in a manner consistent with protocols approved by the IRB) to control groups which may not benefit from the research, the study may proceed only (when DHHS funding is sought) after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.