Human Subjects Research Review

Institutional Review Board Committee Policy

The International University of Leadership Institutional Review Board (IRB) was created for the purpose of reviewing all proposals for research conducted online. Each proposal is reviewed using criteria described in the Office for Human Research Protections, Protection of Human Subjects, Title 45, Code of Federal Regulations (C.F.R.), Part 46, 1991. Research proposals are reviewed for safety, confidentiality (information about individuals is not released to anyone), degree of benefit, and the need for and quality of informed consent.

Much research has been done ethically and with great benefit to people before IRB's were mandated in 1981 in the USA. Some research has been unethical, that is, has harmed individual people or communities and/or has been less beneficial than it could have been. The purpose of all IRB's, is to help minimize harms to individuals and maximize benefits to society; insure that individuals are respected; and insure justice in research (The Belmont Report).

Federal Wide Assurance and the Federal Regulations

Federal Wide Assurance

Federal government agencies, such as the U.S. Department of Health and Human Services (HHS), require institutions and persons who apply for federal funding to conduct human subject research to sign an assurance that they will comply with federal human subject research regulations and requirements. The "Federal Wide Assurance" (FWA), which is approved by the Office for Human Research Protections (OHRP) at the Department of HHS, allows an IRB to approve federally funded research. In this assurance, IUL has agreed that it will apply these standards to all human subject research, whether or not it is federally funded.

Federal Regulations

Various federal regulations also contain requirements for the review and conduct of human subject research. Those regulations include 45 C.F.R. Part 46, entitled "Protection of Human Research

Subjects" (HHS regulation), 21 C.F.R. Part 50, entitled "Protection of Human Subjects" (FDA regulation), and 21 C.F.R. Part 56, entitled "Institutional Review Boards" (FDA regulation). Other applicable FDA regulations, which the Southwest Tribal IRB and the investigator must follow, depending on the study, include 21 C.F.R. Part 312, "Investigational Drugs" and 21 C.F.R. Part 812, "Investigational Devices." In addition, the NIH and FDA disseminate guidelines for the conduct of certain types of research from time to time

1. Purpose and scope

The International University of Leadership 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 IRB Committee). Members are charged with reviewing this manual on all human subjects' research, as defined by federal guidelines, which are conducted under the auspices of IUL to ensure adequate protections are in place.

1.1 Applicability

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

1.2 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.

1.3 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. Designation of Institutional Review Board Committee

The International University of Leadership has one IRB Committee that is 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 IRB are facilitated by the staff of graduate studies. The employee reports to the President and Director of Research and Graduate Studies. This review includes examination of attendance, expertise, affiliation and diversity.

2.1 Membership of the IRB

The IRB Committee may be composed of faculty members, research staff, graduate students and community members. The IRB Committee may use, as necessary, non-voting business advisory committee members and business consultant reviewers to provide specific expertise needed for the review of an application. The University and federal regulations require that there be a minimum of 5 regular voting members.

- The IRB Committee will have at least one member unaffiliated with the University (business community member),
- At least one member on the IRB Committee 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 this individual may also fulfill the role of community member,
- The IRB Committee may also include a graduate student member. The 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 Director of Research and Graduate Studies, Integrity and the Campus director, and the President of the University, will annually review existing IRB membership and provide recommendations to the Director of Research and Graduate Studies regarding recruitment, retention or dismissal of members.

- Thus the membership and composition of the IRB Committee is periodically reviewed and adjusted to meet regulatory and or organizational requirements.
- The IRB Committee will include an individual with competence in special areas to assist in the review of complex issues that require expertise beyond that available on the board.

If however, there is no such voting member available then this is another time when an outside review by an individual with competence to review these activities would be sought.

IRB Committee members will be nominated through the University's procedure for committee assignments. All new or continuing members and Chairperson are appointed by the Director of Research and Graduate Studies. Members are appointed for three years. Members may be asked to serve a longer term at the recommendation of the President of the University.

Each appointed IRB Committee member will complete an on-line Human Subjects Training program before participating in a review. They will also be provided a book of training materials and provided a mentor, as appropriate.

3. Management of the IRB

The IRB Committee meetings are presided over by the Chairperson. The Chairperson will confer with the Office of Research and graduate studies regarding the agenda for meetings and consult on meeting minutes and documentation sent to investigators.

Each IRB Committee member is expected to attend meetings regularly (online or onsite), 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 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 Committee.

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

3.1 Functions of the IRB Committee

The IRB will review all business research involving human subjects conducted by faculty, other employees and students of the university, or under IUL affiliation. The IRB Committee may also review applications from non IUL entities at the discretion of the Director of Research and Graduate Studies. A fee may be charged for these non-IUL reviews.

Applications will be submitted to the Director of Research and Graduate Studies and reviewed by the IRB Committee staff for completeness and to determine if the proposed project constitutes research involving human subjects. The IRB Committee staff will also determine whether the application can be certified as exempt, qualifies for expedited review or requires full board review. Applications that require a full board 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:

1. approve,
2. approve with modifications (conditional),
3. deny, or
4. return the application to the investigator for more information before making a decision.

Investigators will receive written documentation regarding the decision made about their application. Any conditions or modifications required will be sent to investigators by email typically within 10 working days after submission of the application. The time between submissions to approval is generally 2-4 weeks. Approval letters will be sent by e-mail. The IRB may also review reports of unanticipated problems at the request of the Director of Research and Graduate Studies. A full committee must review and approve the decision to suspend or terminate an IRB Committee approval.

3.2 Operations of the IRB Committee

Quorum is defined as a simple majority with one more than half of the voting members present either in person or on the phone at the time of the meeting. Quorum also requires that at least one voting member in attendance is a non-scientist member. If a quorum is not present, the IRB Committee cannot make a determination about an application.

IRB Committee meetings are scheduled once per semester. The meeting is cancelled at the joint discretion of the IRB Chair and Director of Research and Graduate Studies when there is no IRB research related business.

IRB Committee 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 typically be delivered to each member a week prior to the scheduled meeting.

4. Categories of Human Subjects Research

All research that involves human subjects conducted by faculty, other employees and students at IUL must have prior review and approval by the IRB Committee. The IRB Administrator will determine the level of risk involved in the doctoral research and the type of review needed:

- Exempt,
- Expedited, or
- Review Not Required.

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 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 Exempt

Research that involves human subjects may be determined to meet one of the six categories for exemption. This determination is made by the IRB staff in consultation with the Chairperson of the IRB as appropriate. To be considered exempt, the IUL IRB must find the research to be both minimal risk and to fit into one of the following exemption categories. The policy requires a consent process even if the research falls under one of the exemption categories and the IRB Committee 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 IRB staff may determine that the risk to subjects is too high to be 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 6 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 one or more voting IRB members who have knowledge in the area of research provide this review. The expedited review process can be applied to new doctoral applications with minimal risk or minor changes in previously approved research (also called amendments).

Under the expedited review procedure, the Chairperson examines the expedited review reports and has the authority as the IRB Committee 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.

4.3 Review Not Required

Researchers, including graduate students working on dissertations 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

The Review Not Required form is also used when an investigator believes a project does not require IRB review and approval because the activities do not meet the definition of "human subjects" or "research."

5. Criteria for Approval (Quoted from 45 CFR 46.111)

In order to approve research covered by this policy the IRB Committee 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. Voting Requirements and Appeals

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

Whenever a vulnerable population is involved in research, the IRB staff will assign the protocol to at least one reviewer with knowledge of the population.

If an investigator disagrees with either the IRB Committee's decision or the conditions placed on the protocol, they may request to meet with the IRB Chairperson. 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 President of the University or Director of Research and Graduate Studies. No other University official has the authority to override or disapprove an IRB Committee decision.

However, by regulation, while the President of the University and Director of Research and Graduate Studies cannot approve research that the IRB has disapproved.

7. Information required in an application

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

- Study Title,
- Exemption Category (if seeking a exempt review),
- Description of the informed consent process and informed consent form to be used,
- Description of subject population and recruitment,
- 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 IRB Administrator or the IRB Committee 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.

7.1 Continuing review

Investigators are required to complete a continuing review report annually 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 IRB Administrator or other IRB Committee staff will determine if the Continuing Review Report will be reviewed in full committee or if it can be reviewed through an expedited process.

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 IRB Administrator along with any revised forms. The IRB Administrator 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 IRB Administrator 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 IRB Administrator to discuss any immediate changes to a protocol.

7.3 Authorization of Agreement

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

7.4 Concept Approval

In rare cases, the IRB Committee 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 Committee and reviewed and approved.

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 IRB Administrator to determine if the pilot study will require additional 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. Reporting of Unanticipated Problems

The principal investigator is responsible for reporting all unanticipated problems or adverse events to the Director of Research and Graduate Programs 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 on the IUL web site.

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 Director of Research and Graduate Programs 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 Director of Research and Graduate Programs 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 Director of Research and Graduate Programs 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. IRB Committee Record Requirements

An IRB membership roster will be available on the IUL website and updated at least annually. Written procedures and guidelines will be available from website. This document will be reviewed and updated every five years or as needed.

Written minutes of the IRB meetings are kept by the IRB Administrator. The minutes will document all 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 IRB Administrator for three years if the study is unfunded, withdrawn, or denied. Records will be kept for a minimum of five years following completion if the study is funded.

10.1 Doctoral Student Requirements

A 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 doctoral dissertation that involve the use of human subjects must submit an IRB application for review and approval.

If a student's research project meets the federal definition of research and involves human subjects as defined by federal guidelines, a review is needed.

10.2 Capstone Courses and Classroom "Research"

Capstone course activities do not need IRB Committee 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 business community partner of a capstone project may wish to disseminate data, the IRB Administrator must 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. 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 IRB staff.

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 IRB Administrator 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 IRB Administrator to incorporate appropriate protections for those involved in the project.

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 or business related 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 IRB Committee Administrator 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 Committee 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 Committee 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 Committee, 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 Committee 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 non-prisoner 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.