International University of Leadership

Human Subjects Research Review

Institutional Review Board Committee Policy

As adopter Ver. 4.2, August, 2019

This document was drafted by the Board of Directors for use in the IRB, to whom acknowledgement is given. Many policies herein might not seem applicable at the time of adoption and deployment, but nevertheless have been included to offer guidance for future circumstances. As such, it is a 'living' document and may be further modified or updated as needed.

The IRB expresses its appreciation to the research community associated with IUL in complying with these policies and procedures designed to assure the protection of humans. It is they who contribute to the advancement of scientific understanding and derive benefit from this document

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Introduction

The International University of Leadership, Institutional Review Board (IRB), was created for the purpose of protecting the rights and welfare of people involved in research and reviewing all proposals for research conducted online and onsite.
This manual, Policies and Procedures for Human Research Protection, details the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the University IRB Board. These policies and procedures apply to all research involving human subjects, regardless of sponsorship and performance site, where any IUL faculty, staff, students, or facilities are involved. These Policies and Procedures present the most current information for reference by potential investigators and their staff. Since the field of human research protection is constantly evolving, sections of this manual may be subject to change.

The National Research Act, passed by Congress in 1974, directed all institutions receiving federal support for research and evaluation studies including universities, public schools, hospitals, and nonprofit organizations to establish IRBs.
Federal regulations define "research" as: "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
Each proposal for research 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, 2018. 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 1974 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) for the International University of Leadership(IUL) is: **IORG0010147**, expires 04/24/2022, 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 University 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.

Ethical Principles

The Belmont Report

It is the duty of the University IRB Board to review and make decisions on all protocols for research involving human subjects. The primary responsibility of the IRB is the protection of research subjects from undue risk and from deprivation of personal rights and dignity. All research should abide by the three basic ethical principles outlined in the Belmont Report: *respect for persons, beneficence, and justice*. The principle of respect for persons would entail securing informed consent from research subjects.

This protection is best assured by consideration of three principles, which are the touchstones of ethical research:

(1) That voluntary participation by the subjects, indicated by free and informed consent, is assured,
(2) That an appropriate balance exists between the potential benefits of the research to the subject or to society and the risks assumed by the subject, and
(3) That there be fair procedures and outcomes in the selection of research subjects.

These principles are summarized as respect for persons, beneficence, and justice.

Voluntary Participation and Informed Consent

One of the most important elements in any research involving human research subjects is the assurance of voluntary informed consent. Any person, who is to be a research subject, whether designed for their own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what the potential risks and benefits are. The person must give their consent freely, without pressure or inappropriate inducement.

The Risk-Benefit Ratio

The IRB is charged with deciding, for any proposed activity which falls under its jurisdiction, whether "the risks to the subject are so outweighed by the sum of the benefit to the subject and the

importance of the knowledge to be gained as to warrant a decision to allow the subject to accept (those) risks" (Federal Register, May 30, 1974).

The Fair Selection of Research Subjects

Both the risks and the potential benefits of research should be spread fairly among potential individual research subjects and research subject groups. Study design and selection of subjects should avoid bias for or against particular social, racial, sexual, or ethnic groups.

Sharing Research Risks

The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups simply because they are easily accessible or can be persuaded to participate.

1. Definitions

Human Subjects Research – For the purposes of this policy "human subject research" is defined in 45 CFR 46.102(f). In addition, student research, if it involves human subjects as defined in 45 CFR 46.102(f) is included, even if the activity does not meet the definition of research in the same section.

> 45 CFR 46.102(f)
> *Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.*

IRB - An Institutional Review Board established in accord with and for the purposes expressed in this policy.

IRB approval - The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

DRDP- Director for Research and Doctoral Programs.

IO – Institutional Official. The IO has oversight of the University's human research protections program, including appointment of members to the IRB, signature authority for documents provided to DHHS (Assurance Signatory Official), and resource allocations to the IRB.

HRPP -- Human Research Protections Program.

DHHS - Department of Health and Human Services within the federal government.

Minimal risk - That the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Certification - The official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Investigator - (Doctoral Candidate sometimes referred to as a "Principal Investigator" or PI) is any individual who actually conducts the research project and who, typically, submits a human subject protocol to the IRB. In the event of an investigation conducted by a team of individuals, the investigator is the leader and person directly accountable for supervising the research at IUL. Additionally, an investigator may be at the University or partnering institution faculty member, including lecturers, emeriti, staff member, and administrators.

Student - The term is inclusive of all Doctoral Candidates in conjunction with IUL and other partnering institutions. Students may submit protocols for research or initiating a dissertation, and must be supervised or mentored by a faculty member, who 1) is their Chair/Mentor, 2) is their supporting advisor, and 3) the responsible faculty member.

Compliance Associate - the staff position at IUL responsible for administrative support to the IRB. Duties include the receipt of protocols, communications with PIs, coordinating meetings of the IRB, assisting with the training program, and keeping records associated with the human studies research program. The compliance associate is a non-voting and ex officio member of the IRB.

President – Refers to the president of IUL.

CAO – Refers to the Chief Academic Officer of IUL.

Protocol – Is the document completed by the PI(s) that describes the how, what, when, where, who, and why of the proposed study. It is submitted as an application of the proposed research study to the IRB for review. It includes, but is not limited to: background of the research; who will conduct it and their training; who the subjects are and how they will be recruited; how the data will be collected, for example the survey instruments; measures to provide protection against any risks; potential conflicts of interest; consent, assent, and permission forms; etc.

Full review – The process by which a study involving human subjects, either at a high level of risk or involving vulnerable subjects, must be evaluated. The IRB conducts the review "full," meaning at

a convened face-to-face meeting with quorum. What constitutes a full review is defined by federal regulation.

Expedited review - The process of reviewing a protocol by one or two members of the IRB because the study has potentially minimal risk to the human subjects. Expedited does not necessarily mean a rapid review, though it usually requires less time to complete than a full review. What constitutes expedited review is extensively defined by federal regulation.

Exempt review - The process of determining, by the IRB, that a protocol is not subject to either expedited review or full review, as defined in regulations and further in this document. Protocol applications with surveys that collect data in an anonymous fashion are often reviewed by the exempt method.

2. Purpose and Scope of Activities

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 Board). Members are charged with reviewing this manual on all human subjects' research, participate in regular training as defined by federal guidelines, which are conducted under the auspices of IUL to ensure adequate protections are in place.

2.1 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 Board 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.

2.2 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.

2.3 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.

3. Designation of Institutional Review Board Committee

The International University of Leadership has established (1) one IRB Board 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 faculty members of graduate studies. The employee reports to the President and Director for Research and Doctoral Programs. This review includes examination of attendance, expertise, affiliation and diversity.

3.1 Membership of the IRB

The IRB Board may be composed of faculty members, research staff, doctoral students and community members. The IRB Board 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 Board will have at least one member unaffiliated with the University (business community member),
- At least one member on the IRB Board 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 Board may also include a doctoral 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 Chief Academic Officer, Campus Director, Partnering institution members, and the President of the University, will annually review existing IRB membership and provide recommendations to the Director for Research and Doctoral Programs regarding recruitment, retention or dismissal of IRB members,
- Thus the membership and composition of the IRB Board is periodically reviewed and adjusted to meet regulatory and or organizational requirements,
- The IRB Board 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, an outside review by an individual with competence to review these activities would be sought.

IRB Board members will be nominated through the University's procedure for committee assignments. All new or continuing members and Chairperson are appointed by the Director for

Research and Doctoral Programs. 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 Board member will complete an on-line Human Subjects Training program before participating in any protocol review. They will also be provided a book of training materials and provided a mentor, as appropriate.

4. Roles and Responsibilities of the IRB

To be eligible to serve as Chair, the individual must have served for at least one year on the IUL IRB or other partnering institutions. Whenever possible, the Chair will be a tenured IUL faculty member. All newly appointed IRB Chairs and Vice Chairs, who were not currently members of the IRB, are required to undergo the initial orientation as outlined in the section entitled Education and Training of all IRB Board Members.
Newly appointed IRB Chairs and Vice Chairs receive training and support respective to the duties and functions of the position. This training and support will be provided by the IRB Chair, the other current IRB Vice Chairs, Director, Associate Director, and the HRPO staff.
The Chair manages the IRB and any matters brought before it. The Chair is responsible for conducting the meetings and is a signatory for correspondence generated by the IRB.
The Chair may designate other IRB members to perform duties, as appropriate, such as for review, signature authority, and other IRB functions. The Chair advises the IUL CAO-DRDS and the Compliance Associate about IRB member performance and competence. The Chair is a voting member of the IRB and contributes to establishing quorum.

4.1 Management of the IRB

The IRB Board meetings are presided over by the Chairperson. The Chairperson will confer with the Office of Research and Doctoral Studies regarding the agenda for meetings and consult on meeting minutes and documentation sent to investigators. The Chair is empowered to review and approve renewals of protocols in which there are no or no substantial changes to methods or subject handling.
The Chair is empowered to review and approve amendments to protocols in which there is no or no substantial change to risks posed to the subject. The Chair may designate an acting Chair in anticipation of absence. The IO may also designate an acting Chair when the Chair is unable to do so. The Chair may create a subcommittee to perform duties, as appropriate, for protocol review, signature authority, and other IRB functions. When appropriate, individuals outside of the IRB membership may be included in subcommittees.
Duties of a subcommittee may include the following:

- Serve as designees to the IRB Chair for the expedited review,
- Review and approve the revisions,
- Ensure fairness and expertise of an inquiry process.

Each IRB Board 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.

IRB Meetings are scheduled the second Wednesday each month, deferral to the meeting dates are scheduled for the second Friday of the month.

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 Board.

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

4.2 Functions of the IRB Board

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

Applications will be submitted to the Director for Research and Doctoral Programs and reviewed by the IRB staff for completeness and to determine if the proposed project constitutes research involving human subjects. The IRB Board 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 by the first of each month or least three 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 for Research and Doctoral Programs. A full committee must review and approve the decision to suspend or terminate an IRB Board approval.

4.3 Quorum of the IRB Board Members

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 Board cannot make a determination about an application.

IRB Board meetings are scheduled on a monthly basis per semester. The meeting is cancelled at the joint discretion of the IRB Chair and Director for Research and Doctoral Programs when there is no IRB research related business.

IRB Board 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.

4.4. IRB Roster

- An IRB membership roster is 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,
- IRB Administration identifies new replacement members for existing members who rotate off the IRB Boards, and submits the names of the members comprising the IRB Boards to the University Board of Directors for review and approval,
- IRB Administration is responsible for maintaining a current roster of all members serving on the IRBs. Current rosters are accessible on the IRB's IUL intranet website. Upon request, copies may be provided to external study sponsoring organizations, regulatory agencies, and/or representatives of each.

  The IRB roster shall include, at a minimum, the following:

  a. Name of members,
  b. Gender,
  c. Earned degree(s),
  d. Representative capacities,
  e. Scientific or nonscientific status,
  f. Primary area of expertise or specialty,
  g. Affiliation status with the institution,
  h. Employment or other relationship between university partners.

IRB Meeting schedule for 2019		
Month	**International University of Leadership IRB Board** **Chair ----------** **Vice Chair ----------**	**IRB Board alternate dates** **Chair ----------** **Vice Chair ----------**
January	Wednesday, January 16, 2019	Friday, January 18, 2019
February	Wednesday, February 13, 2019	Friday, February 15, 2019
March	Wednesday, March 13, 2019	Friday, March 15, 2019
April	Wednesday, April 17, 2019	Friday, April 19, 2019
May	Wednesday, May 15, 2019	Friday, May 17, 2019
June	Wednesday, June 12, 2019	Friday, June 14, 2019
July	Wednesday, July 17, 2019	Friday, July 19, 2019
August	Wednesday, August 14, 2019	Friday, August 16, 2019
September	Wednesday, September 11, 2019	Friday, September 13, 2019
October	Wednesday, October 16, 2019	Friday, October 18, 2019
November	Wednesday, November 13, 2019	Friday, November 15, 2019
December	Wednesday, December 11, 2019	Friday, December 13, 2019
	Location: Main Campus in Orlando, partnering institutions, participation of independent faculty members online and phone connect. **Time**: 11:00 EST, Florida campus and online participants.	

4.5. IRB Composition

Appointments of voting IRB Board members are made by the Institutional Official of the University. Recommendations for board members can be made to the IO by either the IRB Chair or Campus Director based on the specific needs of the IRB Board.

Committee members are initially appointed to a term of three years. Committee members may be requested to accept reappointment to the IRB for an additional term of three years at the discretion of the Chair. At the end of the six year term, a determination will be made about an additional reappointment period. If a member declines full membership, s/he may be asked to become an alternate member. Reappointed members will be asked for an updated CV and demographic sheet.

Affiliated IRB Board members do not receive any direct monetary compensation for participation on the board. Unaffiliated IRB Board members will be reimbursed at an amount not to exceed $50 per month. Reimbursement payments will be issued quarterly.

1. Each IRB Board will be comprised of at least five members, with varying background and expertise to provide complete and thorough review of research activities commonly conducted by the Institution,
2. The membership of the IRB will be sufficiently qualified through the experience and expertise of its members and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research subjects,

3. The IRB Board shall include persons able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice,
4. The IRB Board shall include members of more than one profession,
5. The IRB Board shall include at least one member who represents the perspective of research participants,
6. The IRB Board shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas,
7. The IRB Board shall include at least one member who is not otherwise affiliated with the University who is not part of the immediate family of a person with such affiliation.

4.5.1 Alternates

The University maintains a roster of trained alternates who may vote in place of an absent voting member. In addition, all active members listed on the rosters may be utilized as alternates for other active members as long as all applicable regulatory requirements and IRB policies are met through correspondence sent on October 11th, 2018.

1. The alternate member will have similar expertise as the regular committee member for whom they are serving as a replacement (physician, scientific/non-scientific),
2. The alternate member will assume all of the responsibilities of the committee member for whom they are serving as a replacement,
3. Alternate members may attend IRB meetings without serving as a replacement for a regular committee member; however, in this capacity, the alternate member may not participate in any of the final approval decisions of the committee,
4. IRB minutes will document if a member present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.

4.5.2 Consultants

During initial review (at the time of meeting assignment, DRGS review, vice chair review, or primary reviewer review) of a proposed research study, an IRB Board member or a HRPO staff member may determine that the current membership of the IRB does not include appropriate expertise to conduct an adequate study evaluation and may defer to another IRB Board or may invite individuals with competence in special areas to assist in the review.

1. Consultants may be chosen from past IRB members or by contacting the department chair or division chief (or their designee) of the area from which the research is being submitted,
2. Consultants will be provided with a copy of the IRB protocol and consent document as well as any attachments (investigator brochures, multicenter protocols, etc.) prior to the IRB meeting,
3. Consultants are held to the same standards as regular members of the IRB Board,
4. Consultants may attend the meeting to participate in the review and discussion of the research study; however, they may not vote or count towards quorum,

5. If the consultant is unable to attend the meeting, their written comments will be taken into consideration by the Committee during its review of the respective research protocol and will be documented in the IRB meeting minutes,
6. During the review of a proposed research study, an IRB Board member may obtain consultations by directly contacting colleagues for information related to a research study. Before obtaining advice from a consultant in this manner, the IRB Board member should ensure that the university does not have a conflict of interest with the research study.

4.6 Evaluation of IRB Board Members

The IRB Chair, Vice Chairs and HRPO Leadership meet monthly to discuss the conduct of IRB Board meetings and the performance of IRB membership.

- New IRB members will meet with the Vice Chair within two months of their first IRB Board meeting. The Vice Chair will identify any areas for improvement, including, but not limited to understanding of IRB responsibility and function, proficiency with the electronic submission platform, meeting participation and overall performance of IRB reviews,
- Committee member performance is discussed monthly with respect to awareness and understanding of relevant ethical issues, regulations, and institutional policies. The performance of the members will also be assessed by evaluating quality of performed reviews to ensure they are timely, comprehensive, and well-informed. If concerns are identified, the IRB Vice Chair or Chair will address these with the individual committee member and then provide necessary guidance materials or educational sessions,
- Committee coordinators will interact with the Vice Chair to provide feedback on member performances. If concerns are identified, the IRB Vice Chair and IRB Chair, if necessary, will address these with the individual committee member and then provide necessary guidance materials or educational sessions,
- Attendance of the members will be monitored by the Associate Director or designee. Any issues that arise related to non-attendance will be discussed with the IRB Chair to determine whether action is necessary. Attendance reports will be sent to the members' responsible department chairs or center/institute director at their request,
- Each member will be given an annual letter that describes performance as satisfactory or requiring attention. The letter will include metrics on attendance and volume of IRB assignments for the member. Self-evaluations will be distributed annually to members and members will have the opportunity to meet informally with the Vice Chair and/or IRB Chair.

4.7 Resignation and Termination of IRB Members

Resignation of IRB membership status, based on the wishes of the IRB member, will be submitted, in writing, to the Institutional Official and copied to the IRB Chair and, where applicable, the member's department chair or director.

IRB Membership status may be terminated by the IRB Chair due to failure to attend and/or otherwise actively participate in IRB functions. Termination of any individual from IRB membership will be reported to the Institutional Official to include a written justification for the termination.

4.8 IRB Records of sessions

The IRB must prepare and maintain adequate documentation of the IRB's activities including: copies of all items reviewed, including but not limited to research proposals, recruitment materials; scientific evaluations (if any) that accompany the proposals; approved consent documents; approved Authorization document, if separate from the informed consent, any proposed amendments and the IRB action on each amendment; progress reports submitted by investigators; reports of injuries to subjects and serious and unexpected adverse events; documentation of protocol violations; and documentation of non-compliance with applicable regulations.

IRB records must also include continuing review activities; copies of all correspondence between the IRB and investigators; and statements of significant new findings provided to subjects must be maintained with the related research proposal and, when reviewed at an IRB meeting, must be documented in the minutes.

4.9. Minutes of IRB Meetings

Proceedings of a convened meeting of the IRB are written and made available for review by the next regularly scheduled IRB meeting date. They can be approved electronically, whereby the minutes are circulated to all members (both full and alternates) via e-mail. Two-thirds (2/3) of those actually in attendance at the meeting must approve the minutes, allowing for minor changes (typographical errors, grammar, etc.). If less than two-thirds approve or there is a matter of significance, then the minutes are to be placed on the next agenda for further discussion. Once approved by the members, the minutes must not be altered by anyone, including a higher authority.

5. Roles and Responsibilities of Investigators, Research Staff and PI

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable University IRB policies and procedures, DHHS Federal Policy Regulations, and FDA regulations and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks to members of their research team, they retain the ultimate responsibility for the conduct of the study.

Because PI responsibilities involve direct interaction and supervision of the research team, the PI must be a current employee or doctoral student of the University and/or partnering institution who is operating within their University or oversee the conduct of the study. PIs leaving the institution are responsible for notifying the IRB well in advance of their departure so that they can make

arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

The following individuals may serve as PI:

- **Faculty members:** All categories of compensated faculty members may serve as PI if their School allows them to serve as Principal Investigator on applications for sponsored funding administered through the University. Adjunct faculty of the University, including lecturers and instructors, are not permitted to serve as a PI or Faculty Mentor but may serve as co-investigator. Faculty with a "visiting" title cannot serve as PI unless it is temporarily assigned during transition from another institution.
- **Students:** Doctoral Candidates/Students may serve as principal investigators for their own research projects and are responsible for submitting the IRB application. However, when a student is listed as the PI, a faculty mentor must be listed on the protocol submission. If a student from another partnering institution is also a staff member at the University, a faculty mentor is not required.
- **Staff:** Other University staff may serve in this role if they have appropriate qualifications to conduct the research and if they have obtained approval to conduct the research from their immediate supervisor.

5.1. General Responsibilities of Principal Investigators

As a general condition for the approval of a research study, the IRB holds the principal investigator of the study responsible for ensuring that:

- Risks to research subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes,
- Risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result;
- Selection of human subjects and patients for research participation is equitable,
- Individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each prospective human research subject, or their legally authorized representative, in accordance with, and to the extent required, by University policies and federal regulations,
- Informed consent of human research subjects will be obtained in advance of research participation and appropriately documented in accordance with, and to the extent required, by University policies and federal regulations,
- Where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects;
- The privacy of human research subjects is protected and the confidentiality of data is maintained;

- Appropriate additional safeguards are included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).

6. Educating IRB Board members and Principal Investigators

IRB Board members and Principal Investigators need training and education in research ethics and current research regulations if they are going to be conduct research and apply for federal funds. The opportunity for doctoral students to conduct research is a high-impact educational practice that is correlated with student success. Protection of human participants during research is of the utmost importance for practical and ethical reasons.

All systematic research undertaken by IUL doctoral candidates and faculty is subject to review under the Institutional Review Board (IRB) policies and procedures for protection of human subjects in research. The federal definition for research is "a systematic investigation, including research development, testing and evaluation, designed to develop and contribute to generalizable knowledge (Federal Regulations 45 CFR 46)." This definition includes any surveys, tests, observations of people, or experiments which involve systematic data collection that could result in knowledge reported in dissertations, publications and professional meetings. The Institutional Review Board operates under federal policies and procedures mandated by the U.S. Department of Health and Human Services and the Office for Human Research Protections.

Doctoral candidates must undergo training in excess of 12 hours on ways to protect human subjects during research, development of Waivers and implementation of (Federal Regulations 45 CFR 46).

The key information that needs to be delivered includes:

- The basic ethical principles underlying research with human participants as elucidated in the Belmont Report,
- The federal regulations for the protection of research participants, and
- The history and ethics of research with human participants.

Completion of training requirements for doctoral students and research faculty should be documented and kept on file so that the institution can demonstrate that IRB members and PIs have been provided the relevant information. Although, appropriate training may be provided free of charge by the University's IRB Board, researchers and doctoral students may choose to take IRB courses training from CitiPrograms and complete 16 modules receive a certificate of completion. In-house training to IUL IRB board members by the certified IRB members and thus provide certificate documentation for successful program completion.

7. Exempt Undergraduate Research

All other undergraduate research involving human subjects, including research done in courses, should be submitted to IRB Board for review. Research undertaken by undergraduate student at IUL is restricted to the "Exempt" category of research only. The term "Exempt" does not affect the requirements for Informed Consent and protection of human subjects.

The definition of "Exempt," as it applies to IUL undergraduate student research with human subjects, means that:

- Undergraduate student researcher must not cause harm to research participants: "harm" may apply to one's physical, psychological or emotional well-being, reputation, and/or employability.
- The research is anonymous; and
- The proposed research must fall under at least one of the following six categories in order for the IUL IRB Board to authorize the research project:

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(a) Research on regular and special education instructional strategies, or

(b) 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:

(a) information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and

(b)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 #2 (above) if:

(a) the human subjects are elected or appointed public officials or candidates for public office, or

(b)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 or records if these sources are publicly available or the information is recorded by the investigator in such a manner that the 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 (federal) department or agency heads and which are designed to study, evaluate or otherwise examine:

(a) public benefit or service programs,

(b) procedures for obtaining benefits or services under those programs,
(c) possible changes in or alternatives to those programs or procedures, or
(d) possible changes in methods or levels of payment for benefits or services under those programs.

6) Taste and food quality and consumer acceptance studies, if:
(a) wholesome foods without additives are consumed or
(b) 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.

8. 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 Board. 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.

8.1. Application process

A new study must be submitted three weeks before the IRB scheduled meeting. If the study is approved exactly as submitted, a memo documenting approval is sent out approximately one week later. It takes about five weeks from the time of submission of the study to the IRB to notice of approval. If the IRB defers the study for more information, it usually is not considered again until the next meeting, increasing the time from submission to approval to eight weeks.
The IRB does one of the following based on its review:

- Approves the study as it has been submitted,
- Approves the study contingent on minor stipulations in the study protocol or for the protection of subjects,

- Defers the study to obtain further information and/or clarification of the protocol and/or procedures for protecting subjects,
- Disapproves the project for conduct because the balance of risks and benefits is not appropriate, because subjects are not adequately protected, or because of concerns about conflicts of interest.

8.2 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 Board 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.

8.2.1 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.

Under the 2018 Requirements version of the Common Rule, some exempt research requires a limited IRB review (administrative review). In two of the exempt categories, limited IRB review is required to ensure there are adequate confidentiality and privacy safeguards. In the other two categories, limited IRB review is required for broad consent in studies involving identifiable private information.

8.3 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 provided in the review. The expedited review process can be applied to new doctoral dissertation 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 Board 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.

8.4 Review Not Required

Researchers, including doctoral candidates/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."

8.5. Dissertations, Independent Study, and Senior Scholars

These research activities are considered to meet the federal definition of Human Subjects Research and must be independently submitted to the IRB by the student-researcher, who is deemed the investigator. However, when students conduct research as part of a course of study, a faculty member ultimately is responsible for the protection of the subjects, becoming the responsible investigator (RI), even if the student is the primary researcher and actually directs the project.

These provisions apply when students are not formally enrolled in independent study for credit, but are engaged in research to gain experience as preparation for application to graduate-doctoral study. They apply to former students and volunteers who are not currently enrolled as students, working under the supervision of a faculty member.

Class projects are expected to fall within the exempt or expedited categories of minimal risk research. This will enhance the likelihood that the review can be completed in time for the students to complete their projects.

Students who are learning scientific methods in the classroom by conducting projects for pedagogical/andrologogical reasons and who do not intend to publish or otherwise disseminate their results do not meet the federal definition of research and thus these projects do not need to be reviewed by the IRB. Because such activities occur within the context of a course, they are de facto educational and, thus, do not need to be deemed educational by any additional review.

8.6. Consent Procedure for Surveys and Questionnaires

The requirement for consent of people who participate in telephone surveys or fill out questionnaires can usually be satisfied by providing the subject with the information about the study in the form of a "script" that is read to them when they are contacted, in a cover letter sent with the questionnaire, or in a printed box at the top of the questionnaire. The following information must be provided so that the person who is being asked to be in the study can make an informed decision about whether or not s/he wants to be a participant:

- A statement that the study is research,
- A description of the purpose of the study,
- The name of the person doing the study,
- The reason why the person is being asked to participate,
- What they are being asked to do,
- A description of the risks and benefits of participating, if there are any,
- A statement that they do not have to participate in the survey.

8.7 Informed Consent

There is general consensus on the importance of informed consent in research. Most people have the expectation that they will be treated with respect and as autonomous individuals. They also expect that they have the right to make decisions about what will and will not be done to them and about what personal information they will share with others. However, researchers also are aware that there are circumstances in which obtaining and documenting consent in social and behavioral research may be a complex, and often challenging, process.

The federal regulations (at 45 CFR 46, Subpart A) provide sufficient flexibility to address some of these concerns, particularly for research posing no more than minimal risk of harm. For example, the regulations allow waivers of and alterations in the requirements for the consent and documentation processes.

Consent should begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding the research, what is expected of them, and the potential risks of harm and benefits. Informed consent is a process that begins with the recruitment and screening of a subject and continues throughout the subject's involvement in the research.

9. Criteria for Approval (Quoted from §45 CFR 46.111)

In order to approve research covered by this policy the IRB Board 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.

10. 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 Board'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 for Research and Doctoral Programs. No other University official has the authority to override or disapprove an IRB Board decision.

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

11. Information required in an application protocol

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 Board 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.

11.1 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 Board staff will determine if the Continuing Review Report will be reviewed in full committee or if it can be reviewed through an expedited process.

11.2 Amendments to an approved protocol

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.

11.3 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 Board Authorization Agreement can be used between IUL and the other partnering 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.

11.4 Concept Approval

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

11.5 Approval of 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.

12. Reporting of Unanticipated Problems

The principal investigator is responsible for reporting all unanticipated problems or adverse events to the Director of Research and Doctoral 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 Doctoral 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 Doctoral 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 Doctoral 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.

13. IRB Application Forms – Protocol

Doctoral candidates and Research fellows may download Protocol files (multipage application form) from the IUL website. It should be completed in its entirety with a mentor of the doctoral program or a Committee/Jury member/s assigned to the doctoral dissertation phase of the research. Failure to complete the application phase will delay any completion of the doctoral program.

14. Doctoral Program 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/candidates 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.

14.1 Classroom Research and online Courses

Classroom research including certain online research courses does not need IRB Board 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 research 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.

15. 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 Board 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 Board 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 Board 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 Board, 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.

16. 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 Board 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.

16.1 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.