Alliant International University
Systemwide Policies for the Protection of Human Participants in Research
Approved by Steering Committee October 13, 2011
Approved by Faculty Senate November 14, 2011

Table of Contents

Overview ........................................................................................................................................... 1
IRB Composition, Administration and Roles ......................................................................................... 1
Review of Research by the IRB ........................................................................................................... 2
  Collaborative/Cooperative Research ................................................................................................. 4
  Research Conducted by Students ....................................................................................................... 5
Risk Levels Associated with Research and Associated IRB Review Processes ................................. 5
  Research involving less than minimal risk ......................................................................................... 6
  Research that involves minimal risk ................................................................................................. 8
  Research that involves more than minimal risk .............................................................................. 10
Research that Involves Prisoners ....................................................................................................... 10
Pregnant Women and Neonates ......................................................................................................... 10
Research that Involves Children ....................................................................................................... 11
Research that Involves Alliant Students and Staff as Participants ................................ ................. 12
The IRB Review Process ................................................................................................................... 13
Minutes .............................................................................................................................................. 15
Appeals Procedure ............................................................................................................................. 16
Changes in Research Procedures ....................................................................................................... 17
Continuing Review of Research (Renewal of IRB Approval) ............................................................... 19
IRB Records ..................................................................................................................................... 20
Researcher Records ........................................................................................................................... 21
The Process of Informed Consent ..................................................................................................... 21
Information Needed for Informed Consent ......................................................................................... 21
Documenting Informed Consent ....................................................................................................... 26
Waivers and Modifications of the Consent or Assent Process .............................................................. 27
  Altering the information provided to participants ........................................................................... 28
  Deception and Incomplete Disclosure ............................................................................................ 29
  Waivers of the requirement for signatures on consent forms ....................................................... 30
Capacity to Consent .......................................................................................................................... 31
  Children .......................................................................................................................................... 31
  Individuals with cognitive impairments ......................................................................................... 31
Unanticipated Problems and Adverse Events .................................................................................... 32
Suspension or Termination of Research ............................................................................................ 34

Appendix 1: Ethical Standards for Research with Children ............................................................... 36
Appendix 2: Experimental Research Participant’s Bill of Rights ......................................................... 39
Alliant International University
Systemwide Policies for the Protection of Human Participants in Research
Approved by Steering Committee October 13, 2011
Approved by Faculty Senate November 14, 2011

Overview

Alliant International University is committed to ethical conduct in faculty, staff, and student research. Part of this conduct involves protection of the rights and well-being of human participants in research. The Institutional Review Boards for the Protection of Human Participants (IRBs) play an important role in this process. The purpose of Institutional Review Boards is to assure that the research is conducted in an ethical manner, that any risk or actual harm that might affect someone who volunteers for research emerging from Alliant International University will be minimized, and that volunteers are aware of any risks. IRB review is mandated by federal law, university policy, and ethical codes of many professions. Faculty, staff, and students at Alliant International University must comply with the Alliant IRB policy and procedures and receive IRB approval in writing prior to initiating any research conducted under the auspices of the university.

The major goal of the IRBs is the protection of human participants in research. Specifically, IRBs evaluate research according to the guidelines in this document, the Department of Health and Human Services Code of Federal Regulations (CFR), Part 46, "Protection of Human Subjects," and other relevant federal, state, international, and professional standards.

IRB Composition, Administration and Roles

In accord with the Department of Health and Human Services Code of Federal Regulations (CFR), Part 46, each IRB must consist of at least five persons. These must include: (a) at least one nonscientist, (b) at least one scientist, (c) members with relevant knowledge in discipline(s) represented in the research that it reviews; and (d) a member from the community at large who is knowledgeable about the community, not employed by the university or related to a university employee, and willing to discuss IRB issues from that perspective. Individuals are considered “scientists” if their training and occupation would lead them to view research using a behavioral or biomedical research perspective. “Nonscientists,” in contrast, have backgrounds that would lead them to view research from perspectives other than those involved in behavioral or biomedical research. When the IRB reviews research involving prisoners, at least one member should be designated as the “prison representative.” A prison representative is an individual with knowledge regarding issues related to incarcerated individuals, and who has the responsibility of providing special consultation on protocols involving prisoners.

Members of an IRB must represent more than one profession. All should be qualified to review protocols from the perspective of current literature and practice in research ethics. In addition, IRB members should be familiar with research issues pertinent to diverse populations. IRBs should be diverse in terms of the gender and the ethnic/racial composition of the IRB.
The Alliant IRBs operate independently under the direction of the Associate Provost for Research and Scholarship. The Associate Provost for Research and Scholarship, together with the University General Counsel, ensures that the Institutional Review Boards for the Protection of Human Participants at Alliant International University comply with Federal Regulations regarding IRBs. Each IRB is headed by a Chairperson. The Chairperson is responsible for overseeing the functioning of the committee. The Chair should be knowledgeable regarding research ethics, respected within the Alliant community, highly responsible, and capable of managing IRB issues with fairness and good judgment. The Associate Provost for Research and Scholarship solicits nominations from the Program Directors and faculty assemblies on the relevant campus for the IRB chairperson and appoints chairpersons for a 3-year term; renewals are permitted.

Specific responsibilities of the Chair include but may not be limited to: a) reviewing and keeping up to date with Alliant and Federal government IRB policies and procedures, b) convening, setting the agenda for, and facilitating IRB meetings, c) seeing that minutes are recorded appropriately; d) overseeing assignment of protocols to reviewers, e) maintaining a tracking system for protocols and other record-keeping, f) overseeing IRB staff members, g) providing lists of IRB members to the Associate Provost for Research and Scholarship; h) notifying the Associate Provost for Research and Scholarship when membership changes, i) communicating with investigators about the outcomes of protocol reviews, j) providing reviews of IRB protocols, k) providing or organizing outreach and education to faculty and students about the purpose and functioning of the IRB, as needed; l) representing their IRB in cross-campus IRB meetings; m) appointing members to the local IRB; n) overseeing protocol review and renewal processes to ensure compliance with university and Federal Regulations; o) providing yearly reports on activities to the Associate Provost for Research and Scholarship’s office; p) participating in summer IRB operations.

Faculty members on the IRB are appointed for the term of their 9-month academic contracts. Summer appointments for 9-month faculty members may occasionally be arranged. Specific responsibilities of IRB members include: a) becoming familiar with Alliant and Federal government IRB policies and procedures, b) preparing for and participating in IRB meetings, c) providing written reviews of protocols as requested by the IRB Chair or that person’s designate in a timely fashion, d) acting as liaison between the IRB and the member’s school or program, as needed; e) participating in outreach and education to faculty and students, as needed.

IRB staff members are responsible for: a) maintaining minutes of IRB meetings, b) receiving and distributing research protocols, c) logging in all IRB submissions and keeping data bases up to date; d) identifying research protocols that are due to expire and sending expiration notices, e) sending IRB reviews to investigators, f) communicating with investigators about the status of their protocols, upcoming meeting dates, etc., g) completing related administrative tasks as assigned by the IRB Chair.

**Review of Research by the IRB**

Faculty, students and staff conducting research under the auspices of Alliant International University are subject to these policies. Thus, any research involving human participants that
utilizes Alliant International University time, facilities, resources, and/or students must be reviewed and approved by the IRB before the research is undertaken.

The nature and type of IRB review depends upon the level of risk associated with the research. Federal regulations define “research” as “systematic investigation designed to develop or contribute to generalizable knowledge.” Equating research with “generalizable knowledge,” however, has led to considerable controversy across the US because this definition appears to exclude small scale or qualitative studies intended to yield more particularist or local rather than generalizable knowledge. These studies are nonetheless designed and intended to contribute to the professional knowledge base.

For the purposes of Alliant IRB policies, contributions to knowledge that involve systemic data collection from human participants, whether qualitative or quantitative, small scale or large-scale, are considered “research” if their purpose is to inform the professional knowledge base, regardless of their immediate generalizability. Activities where data from human participants will be published in any publicly available professional forum are considered “research” (e.g., professional journals, textbooks, doctoral dissertations or Psy.D. projects, organizational reports available to professionals outside the organization in which the data were collected). Dissertations, doctoral projects, or theses that involve qualitative or quantitative data collection or use of archival data are always considered research. Other examples of research include: survey studies with the intent to publish the data, observations of people’s behavior in public places with the goal of presenting the results at a conference, interviews with experts to provide information that will be summarized in a study to supplement additional data, collecting program evaluation data for presentation to a city or county group, and collecting pilot data when the data will be summarized in a way that will be publicly available. Pilot studies that meet the definition of research are treated just like any other research study and must be reviewed and approved by the IRB before they are initiated. Examples of prospective activities that do not fall under this definition of research include course evaluations collected to evaluate Alliant faculty, surveys for internal institutional evaluation and improvement, systematic assessments conducted as part of clinical or applied practice activities; classroom activities that involve observation or interviews as a class project, information collected to assess or improve the functioning of the internal working of an Alliant program, interviews collected as part of journalism, meta-analyses, and literature reviews. Members of the Alliant community should consult their IRB chairperson if they are not certain about whether a particular activity constitutes “research.”

Collecting data as part of research classes may or may not involve research as defined here. If the instructor anticipates that the projects will result in publication or presentation, the activity would constitute “research.” If the data are not intended for publication, the instructor, not the IRB, is responsible for ensuring appropriate oversight of the activities, and for appraising and limiting risks that may accrue as a result of student projects. When this is not clear, the instructor is advised to consult with the IRB chair about which course research projects would and would not require IRB approval.

Sometimes individuals collect information systematically with no intention of publishing or presenting the information to the professional community. At a later date, an Alliant student or faculty member may wish to present or publish the data in a professional forum. At this point
the researcher should apply to the IRB to examine the information as archival data. Examples of this sort of situation include: student class projects that yield interesting findings so the instructor encourages the student to write up the project for publication; a researcher who obtains access to clinic assessments and wishes to examine relationships between variables contained in the assessments; a consultant to a business who keeps systematic qualitative notes on the organization and later wishes to write these up as a case study for a journal.

**Collaborative/Cooperative Research**

An investigator should submit his or her protocol to the IRB that is designated as the official IRB for the campus at which the investigator resides. When faculty, staff, or students at different Alliant campuses collaborate on research, the research protocol should be submitted to the IRB at the principal investigator’s campus. Co-investigators at other Alliant campuses need not obtain approval from their campus IRBs.

When an Alliant investigator collaborates with someone affiliated with another institution, each institution will usually require approval from its own IRB in the interest of meeting its responsibilities to protect the rights and welfare of human participants in research. Ordinarily investigators will submit protocols to the IRBs of each institution. Approval by an outside IRB does not imply or guarantee that the Alliant IRB will approve the research.

To reduce investigator burden, Alliant investigators may apply to make use of collaborating institution’s IRB. In this case, the collaborating institution’s IRB takes full responsibility for overseeing the protection of human participants. The Alliant IRB Chairperson is responsible for evaluating the policies and procedures of a collaborator’s IRB prior to agreeing that the collaborator’s IRB shall oversee the project.

The investigator who wishes to pursue this option must submit a request in writing to the IRB Chairperson at his or her campus. If the investigator wishes for Alliant to oversee the project, the investigator must also submit a full Alliant IRB research protocol in addition to the request. If the investigator wishes for a different institution to approve the project, the researcher must submit the research protocol that has been approved by the collaborating institution’s IRB. Both participating IRBs must agree in writing that the collaborator’s IRB will oversee the project. Written approval of this arrangement for studies that involve minimal and moderate risk must be signed by the Alliant IRB Chairperson, and by the appropriate institutional official at the collaborator’s institution. For high risk (level 4) Research, the Associate Provost for Research and Scholarship at Alliant must also approve the request in writing. Faculty, staff and students involved in cooperative research are responsible for providing the IRB office with proper documentation demonstrating IRB approval from the collaborating institution.

Similarly, Alliant may agree to assume IRB responsibilities for the institution of someone who is collaborating with an Alliant investigator. This request must be approved in writing by the IRB Chairperson, the Associate Provost for Research and Scholarship, and by the appropriate institutional official at the collaborator’s institution. The Alliant IRBs do not review or take responsibility for research conducted by adjunct faculty members or Alliant alumni unless a current core faculty or staff member is a co-investigator on the project.
Occasionally an Alliant investigator may wish to collect data at another institution. For example, an Alliant researcher may intend to recruit participants from classes at a local college. In this instance, the Alliant investigator is responsible for investigating and complying with any IRB requirements of the institution where the data will be collected.

**Research Conducted by Students**

Students currently enrolled in an Alliant program who are the principal investigators on research studies involving human participants must have a core faculty or other qualified sponsor who oversees their IRB submission. Qualified sponsors for student research include core faculty, adjunct faculty operating in an official capacity regarding student research, and other individuals who hold the doctorate and serve at the university in administrative roles (e.g., Deans, Directors of Professional Services Centers). Sponsors of student research are responsible for ensuring that students’ IRB protocols are complete and for overseeing students’ compliance with IRB policies and procedures.

Faculty are also responsible for ensuring that students comply with any requirements of their academic program in terms of the timing of IRB submission (e.g., ensuring that a student’s dissertation proposal has been approved prior to submitting a protocol to the IRB [or vice versa], if this is a requirement of the academic program).

**Risk Levels Associated with Research and Associated IRB Review Processes**

The Alliant IRB recognizes four possible levels of risk associated with research: less than minimal risk (level 1 risk), minimal risk (level 2), moderate risk (level 3), and high risk (level 4). **Minimal risk** is defined as the degree of risk associated with routine medical, dental, or psychological examinations. Routine psychological examinations would include completing questionnaires about one’s attitudes and behaviors and responding to interview questions about one’s lifestyle and problems, but would not entail answering sensitive questions (e.g., about illegal behavior, drug or alcohol use, sexual behavior, or abuse). Routine physical examinations involve answering general questions about health, having heart rate and blood pressure assessed, and the like. **Moderate risk** means that the risk to participants is likely transient and beyond what would normally be experienced in routine mental, dental or psychological examinations. For example, the study may involve intrusive questions or procedures, or use vulnerable participants (e.g., infants, prisoners, etc.). **High risk** means that participants may be exposed to risk that may have lasting psychological, social or physical consequences.

Investigators should consider several types of risk to participants. These include, but are not limited to:

- Psychological risk, in which participation in the research may result in immediate and/or long term stress that would not otherwise be experienced by the individuals. Examples include procedures that might threaten participants’ self-esteem, expose participants to noxious events, request or demand behaviors which are discrepant with
individual's values, morals, and/or ethics; or require excess physical effort or discomfort.

- Social risk to the individual participant, where participating in the research may deprive or harm a participant’s relationships in formal and/or informal social groups. Examples include (but are not limited to) derogatory labeling, overt hostile reactions by others, negative effects on social standing or mobility, reduced opportunity for communication, lost or endangered membership in groups.

- Social risk to groups, in which research participation may pose a risk to the viability or vitality of a formal or informal group in which the participant is involved. Examples included (but are not limited to) derogatory labeling, overt hostile reactions from the social environment, reduced access to resources, diminished ability to recruit and retain members, negative effects on morale and other aspects of internal cohesion and organization, reduced opportunities for communication, distortion of group activities relative to established group purposes and functions.

- Legal risk: participation in the study may undercut individuals’ legal rights or lead to involvement of the legal system. Examples include violation of legally required procedures, request for information that will trigger mandated reporting to the government or legal systems.

- Physical risk: where participation in the research may result in physical injury, discomfort, or reductions in current physical functioning.

- Economic risk: participation in the study results in collection of data which, if it became known, could damage the participants’ financial standing or employability.

In evaluating risk, investigators and IRB members should consider whether certain subgroups of participants may be at elevated risk that other participants do not share. Relative risk may differ depending on the sample proposed for the study. For example, asking about discipline practices in families who attend therapy for child behavior problems will likely have a risk of eliciting information about ongoing abuse. Under most circumstances, this information must be reported to authorities. In identical investigations of community samples, this risk will be less, but it will still be present for community families with children with serious conduct problems. Investigators should consider this potential risk in both types of studies.

The burden of demonstrating the absence of risk lies with the investigator. Whenever data are available regarding risk associated with research procedures (particularly procedures that nonexperts might see as risky), investigators should summarize those data as part of their IRB application protocol. The absence of data on a procedure, however, does not guarantee the absence of risk from the procedure. At the same time, IRB members should be cautious about inferring risks that are extremely unlikely.

**Research involving less than minimal risk.** Research that involves less than minimal risk (level 1) falls into the “exempt” category. Although this means that the research is “exempt” from Federal Regulations, Alliant requires that the IRB review this research to verify its exempt (less than minimal risk) status. Ordinarily research involving less than minimal risk will be evaluated by the IRB Chair or a single member of the IRB.
The basic elements that must be met for a study to involve less than minimal risk are: (a) the absence of physical, psychological or social risk to participants; and (b) the inability, even of the researcher, to identify specific data with individual participants. The following categories of research entail less than minimal risk. These apply to both adults and children, except as noted:

1) Research conducted in established or commonly accepted educational settings involving normal educational practices such as (a) research on regular and special instruction 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) if information is recorded in such a manner that participants cannot be identified directly or through identifiers linked to them.

3) Research involving survey or interview procedures with adults except where the following conditions exist: (a) responses are recorded in such a manner that the human participants can be identified directly or through identifiers linked to the participants AND either b, c or d: (b) the participants’ responses, if they become known, could place them at risk of criminal or civil liability or be damaging to the participants’ financial standing or employability, OR (c) the research deals with sensitive aspects to the participants’ own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol, OR (d) the research is likely to entail stress for participants.

Examples that would entail less than minimal risk include: Open-ended, semi-structured interviews or surveys of employees about job aspirations where no personally identifying information is recorded; anonymous on-line surveys about personality or behavioral styles among adult community samples; ethnographic research with adults involving nonstressful interviews where no sensitive information will be collected.

Studies involving surveys and interviews with children, prisoners, and individuals with reduced cognitive capacity are always considered at least minimal risk studies (that is, must be reviewed via expedited or full-board review).

4) All research involving survey or interview procedures is exempt when the respondents are elected or appointed public officials or candidates for public office.

5) Research with adults involving the observation (including observation by outside observers or by the participants themselves) of public behavior except where the following conditions exist: (a) observations are recorded in such a manner that the human participants can be identified directly or through identifiers linked to them, AND either b or c: (b) the observations recorded about the individual, if they become known, could place the participant at risk of criminal or civil liability or be damaging to the participants’ financial standing or employability, OR (c) the research deals with sensitive aspects of the participants’ own behavior, such as illegal conduct, drug use, sexual behavior, or the use of alcohol.
This sort of research with children is considered less than minimal risk (exempt) only if the investigator does not participate in the activities being observed.

Examples of less-than-minimal risk observation include: participant observation in an organization or group in a public setting where the information being recorded is anonymous; observation of eating behavior of children at a restaurant where the investigator has no contact with the children or their caregivers; ethnographic observations of organizational communication in public meetings; observations of adults in university classroom interactions using a structured coding system.

6) Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens if these sources are publicly available OR if the information is recorded in such a manner that participants cannot be identified directly or through identifiers linked to them. In the latter case, the data must be anonymous EVEN to the investigator (e.g., names blacked out or redacted prior to the investigator receiving the data).

7) Data collection projects in courses that deal with established research methodology and include data collection from human participants as part of the course requirements which result in information that is used only in the instructional setting.

**Research that involves minimal risk.** Minimal risk is defined as the degree of risk associated with routine medical, dental, or psychological examinations. Research that entails minimal risk (level 2) will ordinarily be reviewed using expedited review processes. Expedited reviews may be completed by the Chair of the IRB or by one or more reviewers designated by the IRB Chair.

In some cases, investigators classify their research as “minimal risk” but an expedited reviewer believes the investigator may have underestimated the risks to participants. In these cases, the reviewer should refer the protocol to the IRB Chair and recommend that the protocol be reviewed by the full IRB.

Studies that may be evaluated via expedited review must fit into one of several categories. These are described below.¹ The categories in this list apply regardless of the age of participants, except as noted.

1) Collection of biological specimens for research purposes by noninvasive means. Examples include: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if extracted as part of routine dental care; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion

---

¹ These categories are heavily based on federal guidelines but on occasion are more restrictive. In addition, types of medical research unlikely to be conducted at Alliant are not covered here. Researchers with questions about IRB review of types of research not included in these guidelines should consult their IRB chairperson. The chairperson will consult federal guidelines and determine the type of review appropriate for the research.
or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

2) Collection of data through noninvasive procedures routinely employed in medical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved in the US for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy; (b) weighing or testing sensory acuity; (c) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

3) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis), but that does not meet the criteria for involving less than minimal risk (as described above).

4) Collection of data from voice, video, digital, or image recordings made for research purposes, where no other aspect of the investigation exposes the participant to greater than minimal risk.

5) Research on individual or group characteristics or behavior that meets the criteria for minimal risk as defined above. This includes but is not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Examples include: (a) surveys, interviews, or questionnaire studies that do not ask for sensitive information and in which the participant is not guaranteed anonymity, (b) nonexperimental evaluations of interventions, (c) social-psychological low-stress experiments with nonclinical populations; (d) studies in which live observers collect direct observations of children’s behavior in the schools; e) questionnaire or interview studies with clinical samples that ask about routine activities, everyday behavior, or attitudes and would be unlikely to be stressful for the clinical sample.

Any research where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability entails more than minimal risk and as such is not eligible for expedited review. Similarly, any research where identification of the participants or their responses could result in damage to the participants’ financial standing, employability, insurability, reputation, or might be stigmatizing is not eligible for expedited review. However, such studies may be reviewed by expedited procedures if reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and
breach of confidentiality are no greater than minimal. Should a reviewer or the IRB Chair be unsure about the adequacy of these protections, s/he should refer the protocol for full IRB review.

**Research that involves more than minimal risk.** Research involving moderate (level 3) or high (level 4) risk must be reviewed by the full IRB in a convened meeting. Procedures for full IRB convened meetings are described below. All research that does not meet the guidelines described above OR involves prisoners, pregnant women, or neonates (considered to be special populations) is considered to be more than minimal risk.

**Research that Involves Prisoners**

Prisoners are considered to be a vulnerable population because incarceration carries an enhanced risk for coerced participation in research. Research on incarcerated individuals that entails minimal risk is permitted only if it addresses the causes, effects, and processes of incarceration and criminal behavior, or prisons as institutions.

In addition, minimal risk and greater than minimal risk research on prisoners may be conducted under two conditions: 1) When the research addresses conditions or issues particularly relevant to prisoners (e.g., research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults), or 2) When the research examines practices which have the intent and reasonable probability of improving the health or well-being of the participant.

Several additional criteria must be met for the IRB to approve research involving prisoners, in addition to those described above. Specifically, the IRB should determine that (a) incentives or advantages to the prison participant are not so great that they override the individual’s ability to weigh the risks and benefits of participation. These analyses should take into consideration the generally limited circumstances and amenities to which prisoners have access. (b) Any risks involved in participating in the research are comparable to those that nonprisoner volunteers would experience; (c) Procedures for selecting participants in the prison are fair to all prisoners and not subject to arbitrary intervention by prison authorities or prisoners. (d) Participants are clearly informed that participation in the research will have no effect on decisions regarding parole, and that this assurance is accurate; (e) If prison participants are likely to need follow-up after participation, the researcher has a reasonable plan for doing this in light of different lengths of prison sentences.

**Pregnant Women and Neonates**

Pregnant women and neonates (newborn children) – particularly neonates of uncertain viability or who are not viable-- are considered to be vulnerable populations. A neonate is considered to be viable if the infant is able to maintain an independent heartbeat and respiration after delivery. Pregnancy includes the period of time from fertilization until delivery, miscarriage, or termination of the pregnancy. Research on pregnant women is considered to entail greater than minimal risk and may be approved if all of the following are met:

(a) Where scientifically relevant, studies provide data for assessing potential risks to pregnant women associated with participating in the research.
(b) Any risk to the fetus is caused solely by interventions or procedures that have the potential of direct benefit for the woman or the fetus; or, if there is no potential for benefit, the risk to the fetus is minimal or less, and the research will likely contribute important knowledge which cannot be obtained by any other means.
(c) Any risk is reduced to the least possible for achieving the objectives of the research.
(d) No incentives or persuasion, monetary or otherwise, will be offered to terminate a pregnancy;
(e) Individuals involved in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

Research on viable neonates is considered to entail greater than minimal risk. Research with neonates (newborns) who are not viable (either definitely or possibly) may only be conducted if it is permitted by Federal Regulations provided by the Office of Human Research Protections (TITLE 45 — PUBLIC WELFARE, Department of Health and Human Services, PART 46 PROTECTION OF HUMAN SUBJECTS).

Research that Involves Children

Individuals who have not reached the age required for consent to treatment or procedures involved in the research, as determined legally in the jurisdiction in which the research will be conducted, are considered to be children. In California, individuals are considered to be “children” until they become 18 or are emancipated. A person under 18 is emancipated if s/he meets any one of the following conditions: 1) The individual has been married, whether or not the marriage has been dissolved; OR 2) the individual is on active duty with the armed forces; OR 3) the individual has already been legally declared emancipated under the California Family Code.

Special conditions apply to children involved in research. Some of these involve parent or guardian consent and child assent and are discussed in the “consent” section of this document. Alliant has adopted the Ethical Standards for Research with Children, published by the Society for Research in Child Development, as guidelines for research involving children, and expects researchers to comply with these standards (see Appendix for these standards).

In addition, research that involves greater than minimal risk is evaluated in terms of whether it provides the potential for direct benefit to the child or not. Specifically:

1) Moderate or high-risk research that provides possible direct benefit to the child may be approved if: (a) the risk is justified by the anticipated benefit to the child, and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach.

2) Research that involves moderate risk with limited possibility of direct benefit to child may be approved if it is likely to produce generalizable knowledge about the participant’s disorder or condition. Research in this category must also meet the following conditions: (a) the risk represents a minor increase over minimal risk; (b) the research procedure presents experiences to children that are reasonably comparable to those they would likely experience in their actual or expected medical, dental, psychological, social, or
educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge that is extremely important in understanding or improving the disorder or condition.

Moderate or high-risk research that fails to meet the above criteria may also be approved but requires additional consultation and review. The IRB can only grant approval to this type of moderate or high-risk research after consultation with a panel of experts with expertise in relevant disciplines. The IRB must also find that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children. The panel of experts, composed of a minimum of three individuals from various academic disciplines relevant to the research focus, will be selected by the IRB chair after consultation with the researcher. This panel must also find that the research will be conducted in accordance with sound ethical principles. If the research is funded by the Department of Health and Human Services (DHHS), the study must also be approved by the Secretary of DHHS.

Special regulations come into play when children have been legally designated as wards. A ward is a person (usually a minor) who has a guardian appointed by the court to care for and take responsibility for that person. A governmental agency may take temporary custody of a minor for his/her protection and care if the child is suffering from parental neglect or abuse, or has been in trouble with the law. Such a child is a "ward of the court" (if the custody is court-ordered) or a "ward of the state."

Children who are wards of the state or any other agency or institution can be included in research only if such research is: (a) related to their status as wards; OR (b) conducted in settings in which the majority of children involved as participants are not wards (e.g., schools, camps).

When wards are involved in research, the IRB should appoint a participant advocate for each child who is a ward. The role of this advocate is to judge whether participating in the research is in the best interest of the individual participant for whom the advocate has responsibility. A single individual may serve as an advocate for more than one child. The advocate must have relevant expertise and experience, and agree to act in the best interest of the child. The researcher must secure the written informed consent of the advocate as well as the adult who has legal responsibility for the child (i.e., both the advocate and the adult with legal responsibility for the child should sign the consent forms for the participating ward). For example, some incarcerated children are likely to be wards of the state. An advocate would be required for these children. For those who are incarcerated and are not wards, an advocate would not be required but parental consent would need to be secured.

**Research that Involves Alliant Students and Staff as Participants**

Students and staff at Alliant have the same rights as any other potential participant to participate in a research project, irrespective of the degree of risk, provided all of the following conditions exist:

1. The research must not provide participating Alliant participants with any competitive academic or occupational advantage over other Alliant students or staff who do not
volunteer, and the researchers must not impose any academic or occupational penalty on those students or staff who do not volunteer.

2. Alliant students and staff must not be systematically treated differently from non-Alliant participants as part of the project.

3. Due to the potential for perceived or real coercion to participate, Alliant students and staff who wish to participate in the research should not be under the direct supervision of the principal investigator of the project. The IRB may waive this requirement if the investigator describes explicit procedures that will ensure that s/he is not aware of whether a particular student or staff member chooses or declines to participate.

The IRB Review Process

Investigators initiate the IRB review process for a particular study when they submit a complete protocol for IRB review to the IRB office. Complete protocols include the IRB application protocol, consent and assent forms as needed, measures, and any other stimulus materials. IRB staff screen proposal submissions for completeness and will return protocols to the investigator requesting revision prior to review if they are incomplete, unclear, or contain insufficient detail. The IRB Chairperson oversees how IRB staff assign minimal risk protocols for review. At least one member of the IRB will review these protocols, and may: 1) approve the research, 2) request more information prior to making a determination, or 3) request specific changes to the protocol before the protocol can be approved; or 4) refer the research to the Chair or the full IRB for review if the reviewer determines that the research may pose more than minimal risk to participants. The IRB member’s review must be in writing and should be sent to the IRB office. IRB members should not directly communicate with investigators about their studies without the express approval of the IRB Chairperson.

IRB members may not review their own research or research conducted by students under their supervision, or research conducted by family members. They also should not review research in other circumstances where a conflict of interest could reasonably be inferred or suspected.

The full IRB will evaluate research involving moderate or high risk at regularly convened meetings where the committee meets for simultaneous discussion in person or via videoconference or teleconference. IRB chairs will announce dates of these meetings in advance. Votes on proposals may occur only if a quorum has been established and the meeting includes at least one non-scientific member. Thus, for example, if the IRB roster has nine members, at least five members must be present and vote on the protocol, and at least one voting member must be a nonscientific member. To be approved, a protocol must receive a majority of votes of members present at the meeting. Proposals involving prisoners may only be approved if the prisoner representative is present for the discussion and voting.

Investigators may request to be available during the meeting to answer questions (if needed), but may not attend formal deliberations or votes on their protocol. In addition, the IRB may occasionally request consultation from an ad hoc consultant when no IRB member has the
required expertise to evaluate the risks and benefits of the research adequately. Consultants are independent of the IRB, have scholarly and/or scientific expertise relevant to the research in question, and do not have conflicts of interest with regard to the research. Consultants may be called upon to evaluate the risk-benefit ratio of a particular study, review the cultural appropriateness of the informed consent process, and/or offer other unique expert advice, as requested by the IRB chair. However, consultants may not vote with the IRB; they may only provide counsel.

When meeting as a committee to review proposals, the full IRB may take one of the following actions: Approve the research; request specific changes or conditions, request additional information to evaluate the protocol, or disapprove the research. Protocols that require specific changes may be re-reviewed by a subset of IRB members if changes are relatively minor and do not provide new information that would materially alter the risks or benefits to participants. The IRB will communicate decisions in writing to investigators. IRB approval will last for one year, unless the IRB specifically designates the need for re-review at an earlier date (e.g., with high-risk research where close monitoring is needed).

The IRB approves research only if the research plan meets all of the following requirements:

1) The study procedures minimize risks to participants:
   (a) By using procedures that are consistent with sound research and that do not unnecessarily expose participants to risk, and
   (b) Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

2) The IRB judges that (a) risks to participants that may result from the research are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably be expected to result, AND (b) that the researcher has a reasonable plan in place to deal with foreseeable injuries that could directly result from participating in the research.

   If only minimal risks are involved, IRBs do not need to protect competent adult participants from participating in research considered unlikely to yield any benefit.

3) Selection of participants is equitable in light of the purposes of the research, the setting in which the research will be conducted, and special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4) Informed consent procedures are appropriate (see section on Informed Consent).

5) Informed consent will be appropriately documented.

6) When appropriate, the research includes a reasonable plan for monitoring the data collected to ensure the safety of participants.
7) When appropriate, the research procedures protect the privacy of participants and maintain the confidentiality of data.

8) When some or all of the participants 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, the research plan includes additional safeguards to protect the rights and welfare of these participants, as required by these guidelines and Federal regulations.

9) The research procedures comply with relevant legal requirements of the state and/or country in which the research is conducted (e.g., HIPAA regulations, laws requiring disclosure of confidential information collected during the research, legal age at which minors become emancipated).

10) If the study is conducted with prisoners, pregnant women or neonates, or children, it meets the additional requirements described above and in the “consent” section of this document.

IRB members should be cognizant of differences in methodologies used by different disciplines to approach research questions. Quantitative and qualitative research projects often entail different procedures, and the review process should take these procedural norms and traditions into account. For example, in qualitative research, researchers often require a certain amount of latitude in determining lines of questioning to pursue. These investigators will submit protocols that describe their general approach and methods for protecting participant privacy, confidentiality, etc. In quantitative research, most methods require greater elaborations of specific procedures, questionnaires, stimuli, etc., in advance, and protocols should reflect this greater specificity.

It is not the charge of the IRB to evaluate the scientific merit of proposals submitted for review, other than where it impacts the risk-benefit ratio. When the research involves more than minimal risk, the IRB should evaluate the potential for the research to contribute important knowledge as a benefit that might offset risk. This involves evaluating (based expertise provided by IRB members or a consultant) whether the risks to participants are justified given the proposed research and its potential yields.

Minutes

Minutes of each IRB convened meeting should be recorded in writing, reviewed by the IRB Chair for accuracy and completeness, and distributed to IRB members with opportunities for corrections. Minutes should include the following information:

1) Attendance at the meeting for each action (designating any advocates for vulnerable populations that are present, and alternate members replacing primary members);
   a. “Members present” documents the names of IRB members present at any time during the meeting.
b. “Members absent” documents the names of IRB members who never attended the meeting at any time.

2) A list of all studies considered during the meeting, with the following information for each

a. Actions taken and decisions made by the Committee:
   i. Approved.
   ii. Tabled (more information requested).
   iii. Approved if the investigator makes specific changes (include explicit conditions required for approval in the minutes).
   iv. Disapproved.

b. Votes will record the number of members voting for, against, and abstaining, and the names of IRB members listed under “Members Present” who were absent from the vote. If a member was absent due to a conflicting interest, the notation “absent due to a conflicting interest,” should be noted next to the name.

c. Reasons for requiring modifications to the research proposal or consent forms or for disapproving the research protocol that will be communicated to the researcher.

d. A summary of the discussion of controversial issues, if any, and their resolution.

e. A summary of the discussion of issues pertinent to the protocol.

f. For studies that are tabled or approved with explicit conditions, the process for and individuals involved in re-reviewing the research after the investigator responds to IRB requests or requirements.

3) A summary of other issues discussed or decisions made.

Appeals Procedure

On occasion the IRB will disapprove an investigator’s application protocol. Disapproval indicates that in the opinion of the IRB, the research cannot be conducted as planned. Ordinarily research will be disapproved when the IRB judges that the risks outweigh the benefits and that reasonable changes to the procedures will not improve the risk/benefit ratio. Note that “disapproval” of research differs from withholding IRB approval until changes are made, particular ethical issues are addressed, or additional information is provided. Investigators may file an appeal when the research has been disapproved, but not when they disagree with the changes to the procedures or consent form required by the IRB.

Investigators may appeal disapproval of research. The affected researcher(s) must show cause in writing as to why the IRB decisions should be reversed within 14 working days after the negative decision. This appeal should be addressed in writing to the Associate Provost for
Research and Scholarship. The Associate Provost will appoint an appeals committee of three (or more) IRB members, including a majority from IRBs other than the campus IRB where the proposal was disapproved, to conduct a special appeals review.

The appeals committee may: (a) return the review to the total IRB at the investigator’s home campus for reconsideration; (b) affirm the original decision of the IRB denying approval to the appealing researcher and/or department, or (c) grant approval conditional upon modification of objectionable items with the research to conform to the IRB and DHHS guidelines. The appeals committee will communicate its decision in writing to the investigator, the Associate Provost for Research and Scholarship, and the Chairperson of the investigator’s home campus IRB.

As noted above, researchers may only appeal disapproval of research. Investigators who disagree with changes required by the IRB should discuss their concerns with the IRB Chairperson or the full IRB. IRB chairpersons are encouraged to seek peer consultation from other IRBs as appropriate in these circumstances.

Changes in Research Procedures

It is not uncommon for investigators to want to change their procedures or consent wording after IRB approval has been granted. Examples of changes to procedures include adding a new measure or substituting one measure for another, changing the recruitment procedures, expanding the inclusion criteria, changing the wording of the consent form at the request of a participating research site, etc. The IRB must approve these changes before the investigator puts them into practice.

IRB approval covers the research procedures and consent/assent forms AS SPECIFIED IN THE original approved IRB PROTOCOL. Investigators may not implement any changes to approved research UNTIL THEY HAVE RECEIVED FORMAL IRB APPROVAL OF THE AMENDED PROCEDURES in writing. In other words, if any of the research procedures change, the original IRB approval ceases and is no longer valid. Investigators must apply for approval of the procedures or documents they wish to revise. Investigators may continue to collect data using their original procedures while the amendment is under review.

Changes to research procedures may require changes to consent or assent forms. If this is the case, revised consent and assent forms must be approved prior to continuing the research.

Changes to the study may or may not change the risk level of the research. Minor changes to the study that do not increase the risk level of the research may be reviewed by a single member of the IRB (i.e., using expedited review procedures). Changes that increase the risk level of a minimal risk study to a moderate or high risk study must be approved by the full IRB. Major changes to a protocol that originally required review by the full IRB are likely to require review by the full IRB as well.

Examples of changes that are ordinarily considered “minor” would be increases in $N$, small changes in instructions to participants, minor changes in recruitment methods that do not
substantively alter the likely sample characteristics or risk, changes in the type (but not value) of research incentives, adding a measure that does not ask for sensitive information, and substituting one measure for another or changing questions in an interview protocol where the level of sensitive information or risk is the same. Examples of changes likely to be considered major include: significant alterations in study procedures, additional measures that ask for information of increased sensitivity, changes in consent forms and/or procedures based on requirements of a research site that requires its own IRB approval, altering ethnographic procedures in ways that may compromise participants’ privacy, and substantive changes in the participant sample characteristics or method of collecting data.

To request approval of an amendment to previously-approved research, the investigator must submit an IRB Changes in Research Procedures Form. This form requests a brief description of the changes and their rationale, an indication of whether these changes alter the risk level of the original research, and an indication of whether the original research was reviewed via expedited procedures or was reviewed by the full IRB. Also include a) a copy of any altered or new material (e.g., recruitment flyers, measures, specimen collection protocols) and b) a copy of consent and assent forms to be used, even if these are unchanged from the original protocol.

If the requested changes constitute major alterations in design, participant recruitment, procedures, or measures, the investigator should submit a complete revised protocol in addition to the above form. This is because extensive changes likely require a new look at all aspects of the study. The revised protocol should follow the guidelines and format used for submission of a new research project. The investigator submitting a revised protocol should a) complete Changes in Research Procedures Form, and indicate where in the revised protocol and appendices the changes may be found, and b) highlight (e.g., using yellow highlighting) the sections of the revised protocol and appendices that have changed. This material will likely be reviewed using the procedures used to review the initial protocol. For example, if the initial IRB approval was based on full IRB review, then the protocol will likely require full IRB review as well. If the changes increase the risk level of the study above minimal risk, full IRB review will be required. If the changes reduce the initial level of risk from moderate or high to minimal risk, expedited review is likely.

Alterations in student research must be approved in writing by the faculty sponsor before they can be submitted to the IRB for review. Students and their faculty sponsors are responsible for ensuring that the student also follows any additional program-specific requirements pertaining to alterations in research (e.g., that the entire dissertation committee must approve changes to dissertation research).

Approval of amended procedures does not change the expiration date for the research, which is one year after the original approval date. Procedures for applying for renewal of approved research are covered in the next section of this manual.

Investigators are permitted to change procedures without prior IRB approval only if these changes are required to eliminate an apparent immediate hazard to a research participant. If an investigator alters the research under these conditions, the researcher must report the changes promptly to the IRB and seek approval for continuing the alteration in the future.
alteration is in response to an adverse event, the researcher should report the adverse event as well.

**Continuing Review of Research (Renewal of IRB Approval)**

Federal regulations require continuing review of approved research, with the frequency of this review to be determined by the level of risk involved in the research. IRB approval is ordinarily valid for one year from the date of approval of the original protocol. Occasionally approval will be for briefer periods of time (e.g., if the research entails high-risk or highly experimental procedures). Investigators conducting minimum, moderate, and high risk research must apply for continuing review of their research and an extension of their approval if the PI wishes to continue collecting data beyond the initial approval date. If data collection is complete, the PI does not need continued IRB approval, even if the analyses and write ups of the project remain to be done.

IRB approval is no longer valid after its expiration date. Investigators may not continue to collect data without valid IRB approval in writing. The PI is responsible for retaining copies of IRB approval documents and must produce these upon request if needed to verify compliance with IRB procedures.

The **Principal Investigator is responsible for tracking the date when IRB approval will expire, and for submitting the relevant the IRB form for continuing approval.** To do this, the PI should submit a completed renewal application in writing for continuing review a minimum of one month prior to the date that IRB approval will expire. As a courtesy, the IRB will attempt to notify the PI of record via e-mail two months before the IRB approval is due to expire. If the PI is a student, the IRB will also attempt to notify the faculty sponsor. Nonetheless, the responsibility for tracking expiration deadlines lies with the PI.

To apply for continuing review and an extension of IRB approval, the investigator must submit: a) the Continuing Review of Research form; b) a copy of the original IRB protocol and any amendments (copies of measures and other appendices need not be included, c) a copy of currently-used consent and assent forms, d) a narrative containing any additional information the IRB requested that the PI report in its initial review of the protocol. The Continuing Review of Research asks the PI to report: 1) the number of participants who have been recruited to date, 2) a summary of unanticipated problems, adverse events, or complaints about the research that have occurred since the last IRB approval, if any; 3) a description and explanation of participant withdrawals from the project, if any; 4) a summary of any recent literature or other information relevant to the risks or benefits of the research since the last IRB review, including any qualitative or quantitative data that may have been collected during the course of the PI’s own research that is relevant to the risk level of the study.

Under rare circumstances, the IRB may also require that sources other than the investigator verify the status of the project and provide information about problems encountered with the study. This could occur, for example, when a student is the PI, when the PI has a history of noncompliance with the IRB or other ethical problems, or when the PI is not a core faculty member at Alliant International University. IRB Committees will make this
determination on a case-by-case basis and communicate special requirements to the investigator in writing.

The IRB will conduct continuing review of the research in accord with the guidelines followed to determine the initial review of the protocol. Thus, full IRB committee review is required for continued approval of moderate and high risk research and research involving prisoners. Expedited review may be used for protocols involving minimal risk research, unless adverse events or other significant problems involving research participants have occurred during the conduct of the research. Investigators should expect that expedited reviews will be conducted within two weeks of receipt of a complete renewal protocol. Continuing review by the full IRB review may take up to a month. Investigators who conduct moderate to high risk research should carefully consider how far in advance to apply for renewal, to avoid lapse in IRB approval.

Investigators who fail to renew their protocol by the renewal deadline and who wish to continuing collecting data must reapply for IRB approval using the submission process required for new submissions. They may not continue to collect data. The IRB will treat the application as a new submission. Investigators with expired IRB approvals must immediately cease data collection until the IRB has approved the new protocol in writing.

IRB Records

The campus IRB office will maintain the following records:

1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, reports of injuries to participants, and statements of significant new findings provided to participants.

2) Copies of documents related to amendments to approved proposals.

3) Minutes of IRB meetings.

4) Records of continuing reviews of research projects.

5) Copies of all correspondence between the IRB and the investigators.

6) A list of IRB members.

7) Detailed written procedures for the IRB.

IRB minutes shall be retained for at least 5 years. Similarly, the IRB shall retain records relating to research which is conducted (e.g., written approval documents, protocols and protocol amendments) for at least 5 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the university at reasonable times and in a reasonable manner.
Researcher Records

The investigator must keep written records of IRB approval of the research project and make these available upon request of an authorized university administrator (e.g., the IRB Chairperson). Similarly, the investigator must obtain and keep documentary evidence of informed consent of the participants or their legally authorized representative. The investigator must retain these forms on file for a minimum of 5 years after the conclusion of the project.

Investigators are responsible for destroying or de-identifying any original forms, surveys, code books, code sheets, and other documents that link participant’s identity with their data. This should be done as during a time frame consistent with the consent or assent forms (if used) or after a period not to exceed five (5) years subsequent to the completion of the study. This policy does not apply to databases, questionnaires marked with numbers rather than names, aggregate data or data compiled in such a manner that does not in any way disclose the identity of participants in a study. Such data do not have to be destroyed.

The Process of Informed Consent

The informed consent process is a crucial component of research with human participants. Obtaining research participants’ voluntary consent to participate in research involves more than providing a prospective participant with a consent form and obtaining the person’s signature. Instead, it is an educational process that in most cases involves interaction between the researcher and the potential participant. This process has four components: (a) providing sufficient information to participants for them to determine whether they wish to participate in the study; (b) documenting that a participant (or the person’s legal representative) has received the information; (c) documenting that the participant freely agrees to participate; and (c) determining that the potential participant is capable or competent (legally and ethically) to consent. Consent therefore must be informed (i.e., based on participants’ understanding of what participation will entail and likely risks and benefits) and voluntary (i.e., free from overt or implied coercion), and can only be given by an individual deemed competent to consent.

Investigators conducting Level 1 (less than minimal risk) research are not required to provide written evidence of volunteers’ informed consent to participate in the study, although many will choose to do so. However, for research involving minimal and greater than minimal risk (Levels 2-4), Federal regulations require that informed consent be obtained and documented with research involving human participants. Under a few circumstances, as described below, the consent process may be waived or altered if the IRB grants permission in advance. Providing

Information Needed for Informed Consent

Informed consent requires that the researcher give participants the information they need to make an informed choice about whether to participate in a study. An informed consent process is required (unless waived; see below) for all research, regardless of methodology (e.g., electronic data collection, qualitative methods, survey research). This information should be provided in language that is easily understood by the participants, considering the possible range
of ages, educational levels, (English or other primary) language proficiency, and socioeconomic status of any given group of potential participants. Consent forms should be written in language which is aimed directly at the participants and should avoid professional, technical and research language that impairs comprehension by the intended consumers, that is, the potential research participants. If participants cannot read well enough to understand the material, this information should be read to them. In the case of research being conducted with persons whose primary language is not English, the researcher must arrange to have all needed material available in the primary language of the participants.

A second major component of the consent process is ensuring voluntary participation. In order for persons to volunteer their participation in research, the consent process must be free of overt or implied coercive elements. The researcher should build in opportunities for prospective participants to ask questions or gain additional information about the research should they wish to do so before consenting or declining to participate. This process should permit the potential participant to ask questions or seek info about the study from an individual who is capable of understanding and responding to questions in a language in which the participant is fluent. Assistance of a translator fluent in both the researcher’s and the participant’s primary languages is permissible, as is some equivalent process.

Participants should be provided with the following information as part of the consent process. Ordinarily this will also be included in a written consent form:

(1) A statement that the study involves research. Students who are primary investigators (e.g., with dissertation research) should indicate that they are students and are completing the research under supervision of a faculty member;

(2) An explanation of the purposes of the research.

(3) A description of the procedures to be followed, and how much time participation in the study will entail. If the research involves treatment, describe any components of the research that are untested, for example, those procedures for which the benefits/risks are unknown. If participants will be audiorecorded or videorecorded, the investigator should explicitly describe this part of the procedure.

(4) A description of any possible risks participants might reasonably expect to experience as a result of their participation. If minimal risk is involved, this should be described in clear, non-technical language.

(5) A description of any benefits to the participant or to others which may reasonably be expected from the research. Note that compensation to participants for participation is not considered a benefit, although it should be described as part of the consent process.
(6) An opportunity to obtain a summary of the overall results of the study (where data are usually aggregated), if appropriate. Note that it is not customary for the investigator to provide results to participants about their own individual performance.

(7) If relevant to the study, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

(8) A description of how the records (written, audio, video, etc.) identifying the participant will be used, stored, and disposed of; and who will have access to these materials and under what conditions. With videorecordings and audiorecordings, participants must be told when the original data (i.e., the recordings) will be destroyed.

(9) A description of the relevant limits to confidentiality, if any, should also be described. When the researcher has a reasonable likelihood of obtaining sensitive information from identifiable participants that would require disclosure (e.g., danger to self or others, or child, elder, and dependent adult abuse), the researcher should provide information about circumstances under which the researcher must disclose information collected during the research.

Many researchers at Alliant have legal mandates to report child abuse and/or elder and dependent adult abuse and/or credible threats of to third parties (e.g., clinical psychologists and MFTs, students studying to enter these professions, teachers of pre-secondary students). These researchers should include the requirements of legal mandates in consent forms if abuse or related information may be elicited by the research procedures. Even those researchers who are not legally mandated to report have ethical obligations to consider how to handle this type of disclosure. When applicable, consent forms should indicate any steps the researcher will take to address potential threats to the lives and welfare of their participants and third parties, child or elder abuse, or other information that may lead the researcher to break confidentiality (e.g., imminent suicidality).

Studies in which this information cannot be elicited (e.g., internet questionnaire studies or mail-in surveys which do not ask questions regarding these issues), or studies in which the participant’s identity is completely anonymous need not include this information in consent forms.

(10) For research involving more than minimal risk, an explanation of how foreseeable research-related injuries, physical or psychological, will be addressed, should they occur. The explanation should include (a) whether compensation will be provided should injury occur that directly results from the research, and (b) whether any medical or psychological treatments are available if research-related injury occurs, and who will be responsible for the cost of treatment. The consent form must indicate the nature and scope of available treatment. Plans for how to deal with negative reactions caused by participation in the research should be
appropriate to the nature of the risks and the types of participants involved in the study.

Note that neither the investigator nor Alliant is required by law to provide care or payment for research injuries. However, the consent form should clearly indicate who will be responsible for research-related injuries and who will bear the cost.

(11) Information about who to contact (a) for answers to pertinent questions about the study itself (usually the researcher), (b) for answers about research participants' rights (usually the IRB Chairperson or the individual who staffs the IRB office), and (c) in the event of a research-related injury to the participant (usually the researcher, or – if the researcher is a student—the student’s faculty sponsor).

(12) Clear information stating that (a) participation is voluntary, (b) participants are under no obligation to participate, and (c) participants may stop participating at any time or may refuse to answer specific questions without negative repercussions or penalties.

The IRB does not require that data already collected be destroyed if a person withdraws from the study after completing some portion of data collection. Depending on the sensitivity of the data, however, the researcher or the IRB may require the researcher to inquire whether the participant wishes to withdraw data already collected (i.e., the data will be destroyed, erased, etc.). When the option of data withdrawal is a part of the procedures, this information should be included in the consent form in addition to the material described above.

(13) If the study involves a medical experiment, California Health and Safety Code Sections 21172 and 21173 require researchers to offer participants a copy of the "Experimental Participant's Bill of Rights." A "medical experiment" is defined in the bill as: "The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device as defined in section 26009 of 26010 (of the Health and Safety Code), electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefitting such subject . . . ." For these types of studies, the Experimental Participant's Bill of Rights (see Appendix 2 for copies in English and Spanish) must be given to participants along with a copy of the consent form for the study. The consent form should contain one or more sentences indicating that the participant acknowledges having received the Experimental Participant's Bill of Rights.

Examples of studies that would require this include but are not limited to: studies that collect blood or tissue samples from living participants, FMRI studies, and studies evaluating drug treatments.
(14) Other relevant information required by federal, state, or local laws or regulations.

Investigators should also include the following if relevant to the particular study:

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

(2) Anticipated circumstances in which the investigator may terminate the participant's participation without regard to the participant's consent.

(3) Any additional costs to the participant that may result from participation in the research.

(4) How a participant should terminate participation in the research and a description of possible consequences of a decision to withdraw from the research.

(5) A statement that the researcher will tell the participant about any significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation.

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

In addition to providing information described above, consent forms must meet the following requirements unless the IRB permits a waiver or modification (see below for exceptions that may be granted):

(1) The consent form may not contain exculpatory language in which a participant waives, or appears to waive, any legal rights, or to release the researcher or the institution from liability for negligence.

(2) Studies that involve monetary or other compensation should clearly specify the amount and type of compensation and the requirements to earn the compensation (e.g., telling participants details of compensation when the amount of compensation depends on how much of the study they complete; indicating the minimum participation needed to obtain compensation; giving participants the odds of winning if a raffle for completers is involved).

(3) The participant or the participant’s legal representative must sign the consent form (see later section on modifications of consent processes for how this may be handled with electronic consents).

(4) Participants must receive a copy of the consent form.
(5) Researchers must provide contact information. Students who are conducting research under the supervision of faculty members must provide both their own and the faculty member’s contact information (e.g., telephone number, e-mail addresses).

(6) Consent forms should state that the researcher is a student, staff, or faculty member at Alliant International University.

(7) Consent forms should be formatted to be professional in appearance and be free of typographical, grammatical, or spelling errors.

The campus IRBs will maintain copies of example consent and assent forms and make these available to researchers.

The consent process should be planned in ways that permit participants sufficient time to review written information and ask questions. The person obtaining the consent should be sufficiently knowledgeable to answer questions about the research and research procedures. If consent forms are distributed in ways that do not involve interaction with the researcher (e.g., parental permission forms in classrooms, internet consent), the participant must be provided with some way to contact the researcher for additional information if needed.

The researcher should also take steps to ensure that those who consent do so freely, in the absence of coercion. Occasionally, the institutional setting in which the consent is sought will pose the possibility of coercion or undue influence. Conducting research at institutions that provide services to participants may be perceived as implying that continued service is dependent upon participation in the research. Students in educational settings may be concerned that refusal to participate will affect their grades; prisoners may believe that refusal to participate may jeopardize parole opportunities. Researchers should address these concerns in the research protocol and as part of the consent process and consent form to ensure that participants have the right to refuse participation freely.

**Documenting Informed Consent**

All level 2, 3, and 4 research projects must contain provisions for obtaining and documenting written consent from participating human participants, unless these provisions are specifically waived by the IRB. Ordinarily, the participant or the participant’s legally authorized representative should sign a written consent form approved by the IRB. With electronic consents, the equivalent of a signature must be obtained (see later section).

Documenting informed consent may be done in one of two ways, unless the IRB approves specific modifications to consent procedure. The first is the more customary procedure. The researcher provides a written consent form embodying all of the required elements of informed consent described above under “Providing information needed for informed consent.” Participants or their legally authorized representatives may read this to themselves, or the researcher may read the document aloud. The participant or his/her legally authorized representative indicates agreement to participate by signing a consent form. With
electronic consents (e.g., studies conducted over the Internet), the person indicates agreement in some other acceptable way that is considered the equivalent of a signature.

The second way to document informed consent involves asking participants to sign a "short form" written consent form indicating that the basic elements of informed consent have been presented orally to the participant or his/her legally authorized representative. The IRB must approve a written script of what the researcher will say to the participant. This script should include the same required elements that would be required in a written consent form. The researcher who uses a “short form” consent must arrange for a witness to be present for the consent process. The participant or his/her legally authorized representative, the researcher, and the witness should sign the consent form. In addition, the person obtaining the consent and the witness must also sign a copy of the approved script, annotated to show any additions or alterations. The “short form” method is not applicable with research conducted over the Internet when participants and researchers do not interact in person (although it could be used, for example, with research conducted using Skype or comparable interactive technology).

Investigators sometimes intend to ask for information about the participants from outside sources, such as therapists’ files or institutional, occupational, or educational records. Investigators should check with the outside sources about what sort of permission is required to access the sources’ records, and ensure that participants complete any release-of-information forms required by other organizations as part of the consent process.

Investigators are responsible for understanding and complying with other federal laws relevant to their research and for ensuring that their consent process and forms comply with these additional regulations. These issues most often come into play when researchers collect information ABOUT individual participants from outside sources rather than from participants themselves. For example, studies that collect information ABOUT someone from an educational setting need to consider relevant Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) regulations; studies collecting health information about participants (e.g., from medical or therapist records) should comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (P.L.104-191) laws.

Waivers and Modifications of the Consent or Assent Process

The IRB may permit the investigator to modify or omit either: a) information the researcher gives to participants as part of the consent process, or b) the process by which the researcher documents consent. The requirements for altering the information provided to participants differ from the requirements for waiving documentation that the information has been received (i.e., the participant’s signature). Thus, investigators who waive the requirement that participants sign a consent form are still required to provide information to participants about what participation in the study will entail, unless waiver is granted for that element of consent as well.

Examples of studies when researchers may wish to request waivers of signatures include studies where consent forms will be signed electronically, studies of illiterate samples who
cannot write, and action or ethnographic research where the researcher may not know who the research participants may be in advance.

**Altering the information provided to participants.** As noted above, consent requires that the participant be given a number of pieces of information about participation. The IRB may permit the investigator to omit some or all information that is ordinarily required as part of the consent or assent process under either of two conditions:

1. The research is conducted or approved by state or local government officials AND meets both of the following criteria:
   - (a) The research examines (i) public benefit or service programs; or (ii) procedures for obtaining benefits or services under those programs; or (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; AND
   - (b) The research could not practicably be carried out without the waiver.

**OR**

2. The research:
   - (a) involves no more than minimal risk to participants, AND
   - (b) The waiver will not adversely affect the rights and well-being of the participants; AND
   - (c) the research could not practicably be carried out without the waiver or alteration; AND
   - (d) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Granting permission either to use modified consent procedures or to waive consent entirely requires the researcher to establish that the above conditions exist. These conditions also apply to waiving assent requirements for children and others not deemed legally capable of consent.

Examples of studies in which investigators sometimes wish to alter information to participants in the consent process include: studies conducted outside the US where different cultural norms require presenting information in different ways in order to be culturally appropriate; ethnographic investigations where it may not be possible to anticipate fully all of the procedures that may be involved; action research or critical inquiry research where the investigator may not know in advance who participants will be; and studies that involve intentionally misleading or deceiving participants.

Examples where the IRB might consider requests to waive consent entirely include ethnographic research, which involves observation of and interaction with the persons or groups being studied in the group's own environment, often for long periods of time; observations of individuals who will not be identified by name but who are observed in circumstances in which they would ordinarily have a reasonable expectation of privacy; or
epidemiological studies in which the researcher reviews records to determine eligibility for a particular study prior to obtaining consent to administer interview or questionnaire procedures.

Note that altering or waiving the consent process because it is easier for the researcher is not sufficient to meet the above requirements. Instead, the conduct of the research must be seriously compromised if usual procedures are followed. This occurs in studies involving deception (see next section for detailed discussion). Other examples when this might occur include studies of illiterate samples where procedures must be provided orally and research done in cultures where the concept of experimentation itself is unfamiliar or where written signed statements are mistrusted. Investigators and IRBs considering international research should be particularly sensitive to devising the best ways to honor the spirit and requirements of informed consent in culturally-appropriate ways.

The researcher requesting alteration or waiver of consent should clearly indicate how the research plan meets the above requirements for waived or altered consent. Investigators who wish to modify the consent process should, as much as is possible, propose alternative procedures that ensure that participants: (a) are given relevant information about the study, as described earlier; (b) have the opportunity to consent or decline in the absence of coercion, (c) are legally capable of consent.

The IRB should fully document reasons for permitting the use of modified procedures for the individual study in the reviewer’s comment (for expedited review) and in the minutes of IRB meeting (for full board reviews). When an IRB member conducts an expedited review of a study requesting a waiver of consent and is uncertain about whether the above conditions apply, that IRB member should refer the study to the IRB chairperson for consultation or for full IRB review.

Deception and Incomplete Disclosure. Investigators rarely disclose every detail of a study. For example, researchers usually do not disclose their research hypotheses, because (a) it is not possible to explain the purpose and the procedures of the study without disclosing what the investigator expects to find, (b) disclosure of hypotheses may lead to biased data, weakening the benefits of conducting the study, and (c) in most cases, participants do not need information about the hypotheses under investigation to make an informed choice about whether to participate or not.

Disclosure is considered “incomplete” when the researcher withholds relevant, important information during the consent process (i.e., information that a participant would reasonably be expected to use in determining whether or not to participate in the study). In the example above, knowledge of hypotheses is irrelevant to participants’ decision about whether to participate. In other cases, information that is withheld may be important. For example, as part of the research, the researcher may plan to stage an unexpected event in order to observe participants’ reactions; telling the participant about this in advance would invalidate the experimental manipulation. However, if this event is clearly stressful or aversive, knowledge of the event would likely be important piece of information in a participant’s decision to be in the study. Thus, withholding this information is a problem.
In other cases, the researcher may wish to actively deceive participants. For example, the researcher may tell participants that an experimental confederate is a participant in the study. Many past research studies that are now deemed ethically problematic were characterized by incomplete information about likely aversive events and by deception. Therefore, deception and incomplete disclosure should be used with extreme caution in research, when the investigator believes the deception or incomplete disclosure to be necessary and where the risk can be shown to be both small and manageable in terms of potential harm.

Incomplete disclosure and deception entail incomplete informed consent. Therefore, studies involving deception and incomplete disclosure require modifications of the consent process, and must meet the regulations described above. Specifically, the investigator should be able to demonstrate that: (a) deception is necessary to conduct the study; (b) the participants will not be exposed to more than minimal risk in the study procedures (other than the risk of negative reactions to the debriefing regarding deception); and (c) whenever appropriate, participants are debriefed following completion of the procedures. In addition, although not Federally mandated, Alliant adopts the following requirement for all studies involving deception, as recommended by the ethics code of the American Psychological Association: (d) When researchers debrief participants, they permit participants to withdraw their data if participants choose to do so after learning about the deception.

**Waivers of the requirement for signatures on consent forms.** The IRB may waive the requirement that the investigator obtain the participant’s signature to document the consent process for some or all participants under the following conditions:

1. The only record linking the participant with the research would be the consent form, and the principal risk of the research would be potential harm resulting from a breach of confidentiality. In this case, the researcher must provide each participant with a choice about whether they would like to link their identity to participation, and their choice will prevail.

   OR

2. The research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside of the research context.

Examples of situations in which signatures may be waived include: a) studies where only individuals with stigmatizing characteristics are included and retention of names of individuals poses a risk of breach of confidentiality (#1, above) (e.g., a study of HIV-positive individuals, a study of stressors associated with illegal immigration where retention of names poses a risk to confidentiality (#1); b) Internet research with adults where signatures are impossible but where participants are able to indicate their understanding of the research and agreement to participate in other ways (#2; e.g., by checking a box to indicate that they have received and read relevant information and agree to participate); c) mail-in survey research that asks adults for sensitive information and is anonymous, where returning the completed survey materials indicates consent to participate. (#2).
IRBs may approve electronic/Internet administered consent procedures that do not obtain written signatures indicating consent if the above conditions apply.

**Capacity to Consent**

Only individuals deemed capable of consent may agree to participate in research. Adults should be presumed competent to consent unless there is evidence of serious mental disability or condition that would impair reasoning or judgment during the consent process (e.g., inebriation, drug use, dementia). Mental disability alone does not disqualify a person from consenting to participate in research. Adults should only be deemed unable to consent if specific evidence indicates they are unable to understand consent-related information and to make an informed choice about whether to participate. When this is the case, legal guardians may consent for these individuals.

**Children.** Children are not considered legally capable of providing consent. Their parents or legal guardians must provide consent for the child’s participation. Children themselves must also agree (assent) to participate if they are capable of assenting. The IRB shall take into account the ages, maturity, and psychological state of the children involved in determining whether some or all of the children are capable of assenting. In general, normally developing children are capable of giving basic verbal agreement for participation from the age of 3, responding to more detailed verbal assent at age 5, and giving written assent from age 7 on. Written assent forms should summarize the elements of informed consent using language and concepts appropriate to the children’s developmental level. Children who are literate (usually age 7 and above) should sign the assent form.

Consent of one parent is required a) for minimal risk research (level 2), and b) for level 3 or 4 research where the child may directly benefit from involvement in the study. Consent of both parents is required for level 3 or 4 research where the child is exposed to risk and unlikely to directly benefit from participating in the study. The IRB may waive the requirement that both parents consent if 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.

Children’s wishes to dissent from participation or to stop participating during a study should be respected. There is one exception. In unusual circumstances, the research will have the potential to benefit the child’s health or well-being directly and in important ways, and these benefits will only be available if the child participates in the research, as when an investigator examines a new experimental treatment for a child disorder or condition. In these cases, the IRB may determine that the assent of the child is not necessary or permit a child’s parents’ wishes to overrule the child's dissent. Investigators must request and obtain explicit IRB approval should they wish to disregard children’s wishes to dissent from participation under these circumstances.

**Individuals with cognitive impairments.** Potential research participants whose decision-making capacity is diminished or absent during their participation in the consent process and the research itself are considered to be cognitively impaired. Participants unable to consent must have consent of their guardian or legally-authorized representative. The IRB will evaluate
whether participants unable to consent should be required to assent to participate; assent should be required unless the individual is deemed incapable of participating in the assent process.

Unanticipated Problems and Adverse Events

Investigators must report any unanticipated problem or unanticipated adverse event that occurs during the research to the IRB as soon as possible. An unanticipated problem is defined as a difficulty that is unexpected (in terms of nature, severity, or frequency) in light of the research procedures described in the research protocol and informed consent forms approved by the IRB; and the characteristics of the participant populations being studied. In addition, to warrant reporting, the unanticipated problem must (a) possibly or clearly relate to participation in the research; and (b) place participants at greater risk of harm than was previously known or recognized.

An unanticipated adverse event is defined as any untoward or unfavorable medical or psychological occurrence in a human participant that is unanticipated in terms of its nature, severity, or frequency, and associated with the subject’s participation in the research. It must also: a) possibly or clearly relate to participation in the research, and b) place the research participant at greater risk of harm than was previously recognized or known.

Not all adverse events and problems are unanticipated. Studies that involve more than minimal risk, for example, will likely have detailed procedures for dealing with problems that may occur. When these problems occur, they are “anticipated.” The investigator must deal with these in an ethical manner and in accord with their approved protocols. Ordinarily, these events need not be reported to the IRB.

With some high-risk studies, however, the IRB may request that the investigator report any adverse events, whether anticipated or not. This request may be made at the time of initial approval as a condition of approval, or during ongoing review of the research. In those cases, the investigator should follow the procedures described here for reporting all adverse events.

Problems and adverse events are considered “unanticipated” when they are unforeseeable or not consistent with the known or anticipated risks associated with the research. Examples of unanticipated problems that should be reported are: a) theft of a computer containing sensitive data that can be linked to individual participants given the files contained on the computer (this is unexpected, related to the research, and places participants at increased risk due to possible breaches of confidentiality); b) A participant who should have been screened out of a treatment study is accidentally enrolled because a screening measure was mis-scored (this participant is exposed to risk that s/he should not have been allowed to experience). Examples of problems that would not be reported are: a) an investigator finds that a research procedure takes much longer than planned (this does not put participants at increased risk), and b) de-identified data on sensitive or illegal behavior are misplaced or stolen (no increased risk because the data cannot be linked to individual participants); c) a computer with encrypted data is lost or stolen (because data cannot be traced to individuals).
Examples of adverse events that should be reported are: a) a participant calls a week after completing an interview that was considered “minimal risk” to complain of nightmares about the material s/he discussed in the interview; b) a participant has an allergic reaction to a snack served during a break in the study procedures. Examples of adverse reactions that would not require reporting (unless otherwise required as a condition of IRB approval) include: a) a participant is told during the consent process that s/he may experience some temporary discomfort with the research procedures and the participant appears distressed when answering some of the questions, although s/he reports feeling fine during the debriefing; b) a participant in a treatment study experiences a negative side-effect that can occur as part of the treatment (neither “a” nor “b” is unexpected, and do not elevate the participant’s risk over those known to exist when the protocol was approved. Note, however, that if a reaction or side-effect is more intense or frequent than anticipated, it would be considered an “adverse event”).

When in doubt, investigators are encouraged to consult the IRB Chairperson for guidance.

Investigators must report the following to the IRB in writing:

1. the title of the study and the investigator’s name. If the investigator is a student, the investigator should also provide the name of the faculty sponsor.

2. a detailed description of the adverse event, incident, experience, or outcome, and any effects the event has had on research participants.

3. an explanation why the investigator believes that the adverse event is an unanticipated problem.

4. a description of corrective actions that have been taken or are proposed in response to the unanticipated problem. Examples of changes include: methods of reducing harm to a particular participant or set of participants, changes to the protocol to reduce the likelihood of similar incidents occurring in the future, and suspension or discontinuation of the research.

If the event results in participant death, imminent danger of death, disability, hospitalization, or requires extensive intervention to prevent any of these conditions, the investigator a) should notify the IRB Chairperson as soon as possible about the adverse event, and b) must file the written documentation of an adverse event with the IRB within one week of becoming aware of the problem. The IRB Chairperson should report such events to the Associate Provost for Research and Scholarship immediately upon receipt of this information. If the adverse event or unanticipated problem does not meet any of these criteria, the investigator must file the written documentation of an adverse event within two weeks of becoming aware of the problem.

If the investigator plans to change any of the research procedures or the consent form as a result of the event or problem, these changes must be submitted following the procedures for obtaining IRB approval of an amendment of an approved proposal. If immediate changes are
required to protect individuals already enrolled in the study from similar adverse events or unanticipated problems, the IRB Chair may grant temporary approval pending a full review of the amendment to the study. Such approval must be granted in writing and documented in the IRB files for the study in question.

The investigator should submit the written report describing the unanticipated adverse event or problem to the Chairperson of the IRB. The Chairperson will make an initial review of the report and will then take one of the following actions: a) determine that the event or problem is was foreseeable, not connected to the research, or did not elevate participant risk, and take no further action on the report; b) determine that the investigator took appropriate action to remedy a relatively minor situation and that further review by the IRB is not warranted at this time; c) ask the investigator to provide further information about the event, d) ask the full IRB or a committee of the IRB to review the event and designate a course of action, or e) temporarily suspend the research pending further IRB review. The IRB Chairperson will notify the investigator in writing about his or her course of action following this initial review.

The IRB has the authority to require additional changes to the research protocol and consent process in response to adverse events or problems. The IRB may also temporarily or permanently discontinue the research, in accord with procedures described in another section of this document.

If the research is funded by the Department of Health and Human Services, additional procedures must be followed. The IRB Chairperson must report the event, actions taken, and other information relevant to HHS reporting requirements to the Associate Provost for Research and Scholarship at Alliant International University. The Associate Provost for Research and Scholarship must report this event to the supporting agency head (or designee) and to the Office of Human Research Protections (OHRP) within one month of the time the investigator provides written documentation to the IRB Chairperson. See http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html for guidance about what must be reported and how. If the research is supported by another source of extramural funding, the Associate Provost for Research and Scholarship will report the noncompliance following the procedures of the funding agency.

Suspension or Termination of Research

All individuals (students, faculty and staff) conducting research at Alliant are responsible for ensuring that human participants are adequately protected and that this protection is documented according to IRB policies and procedures. Faculty members overseeing student research share this responsibility with their students and are responsible for overseeing student compliance with IRB policies, procedures, and requirement in the conduct of their research. Individuals beginning a research project should ensure they are following up-to-date IRB policies and procedures.

The IRB may suspend or terminate approval of research: (a) that is not being conducted in accordance with the IRB's requirements, policies, or procedures, or (b) that has been associated with serious harm to one or more participants. The IRB Chair may temporarily
suspend research upon receipt of credible information that an investigator is not complying with IRB policies or that serious harm has occurred. The IRB Chair must communicate that s/he is suspending the research to the investigator in writing and should inform the Associate Provost for Research and Scholarship that the research has been suspended.

    Serious harm should be documented using the procedures described in the separate “Adverse Events” section of these guidelines.

    Failure to follow IRB policies and procedures in data collection is an ethical violation that can result in serious penalties for those involved. When the IRB receives credible information that a student, faculty member, staff member, or other individual associated with Alliant has failed to comply with IRB regulations or requirements, the IRB should investigate possible noncompliance with IRB procedures. Investigatory steps may include (but are not limited to): interviewing the investigator (and, if a student is the investigator, the student’s faculty sponsor), interviewing individuals involved in data collection (e.g., research assistants), and inspecting documents relevant to the research (e.g., consent forms, research proposal, completed data packets, etc.). Following this investigation, the IRB should determine whether noncompliance has occurred, along with any corrective and/or disciplinary steps to be taken. Depending on the nature and severity of the noncompliance, these steps could range from corrective education to termination of the research. In the case of a student project, the IRB may prohibit the student from using the data to fulfill thesis or dissertation requirements if those data were collected in violation of IRB policies or procedures.

    Research may be terminated only after review by the full IRB. In determining whether to terminate research, the IRB will investigate the relevant dimensions of the concerns brought before it, the seriousness of these concerns, and the likelihood of recurrence. If the IRB permits the research to continue, the IRB may require changes to research procedures or other corrective actions.

    The IRB Chair will report the results of any IRB investigation undertaken in response to serious harm or allegations of noncompliance to the investigator and to the Associate Provost for Research and Scholarship. The report should be in writing and should describe the reasons for the IRB's findings and action(s). If the investigator is a faculty member, the IRB will provide the faculty member’s Program Director and Dean with a copy of the report. If the investigator is a student, the IRB will provide a copy of the report to the faculty sponsor of the research as well as faculty member’s Program Director and Dean.

    If the research is funded by the Department of Health and Human Services, the IRB Chairperson must report the noncompliance, actions taken, and other information relevant to HHS reporting requirements to the Associate Provost for Research and Scholarship at Alliant International University. The Associate Provost for Research and Scholarship must report this event to the supporting agency head (or designee) and to the Office of Human Research Protections (OHRP) within one month of the time the IRB chairperson provides written documentation to the Associate Provost. If the research is supported by a different (non HHS) source of extramural funding, the Associate Provost for Research and Scholarship will report the noncompliance following the procedures of the funding agency.
APPENDIX 1


PRINCIPLE 1 - NON-HARMFUL PROCEDURES: - The investigator should use no research operation that may harm the child either physically or psychologically. The investigator is also obligated at all times to use the least stressful research operation whenever possible. Psychological harm in particular instances may be difficult to define; nevertheless its definition and means for reducing or eliminating it remain the responsibility of the investigator. When the investigator is in doubt about the possible harmful effects of the research operation, consultation should be sought from the Human Participants Protection Committee. When harm seems inevitable, the investigator is obligated to find other means of obtaining the information or to abandon the research. Instances may, nevertheless, rise in which exposing the child to stressful conditions may be necessary, if diagnostic or therapeutic benefits to the child are associated with the research. In such instances careful deliberation by the Human Participants Protection Committee should be sought before instituting such procedures.

PRINCIPLE 2 - INFORMED CONSENT: - Before seeking consent or assent (i.e. agreement) from the child, the investigator should inform the child of all features of the study that may affect his or her willingness to participate and should answer the child’s questions in terms appropriate to the child’s level of comprehension. The investigator should respect the child’s freedom to choose to participate in the research or not by giving the child the opportunity to give or not give assent to participation as well as to choose to discontinue participation at any time. Assent means that the child shows some form of agreement to participate without necessarily comprehending the full significance of the research necessary to give informed consent. Investigators working with infants should take special effort to explain the research procedures to parents and be especially sensitive to any indicators of discomfort in the infant. In spite of the paramount importance of obtaining consent, instances can arise in which consent or any kind of contact with the participant would make the research impossible to carry out. Non-intrusive filed research is a common example. Conceivably, such research can be carried out ethically if it is conducted in public places, participants’ anonymity is totally protected, and there are no foreseeable negative consequences to the participant. However, judgments on whether such research is ethical in particular circumstances should be made in consultation with the Human Participants Protection Committee.

PRINCIPLE 3 - PARENTAL CONSENT: - The informed consent of parents, legal guardians or those who act in loco parentis (e.g. teachers, superintendents of institutions) similarly should be obtained, preferably in writing. Informed consent requires that parents or other responsible adults be informed of all the features of the research that may affect their willingness to allow the children to participate. This information should include the profession and institution affiliation of the investigator. Not only should the right for the responsible adult to refuse consent be respected, but they should be informed that they may refuse to participate without incurring any penalty to them or to the child.
PRINCIPLE 4 - ADDITIONAL CONSENT: - The informed consent of any persons, such as school teachers for example, whose interaction with the child is the subject of the study should also be obtained. As with the child and parents or guardians informed consent requires that the persons interacting with the child during the study be informed of all features of the research which may affect their willingness to participate. All questions posed by such persons should be answered and the persons should be free to choose to participate or not, and to discontinue participation at any time.

PRINCIPLE 5 - INCENTIVES: - Incentives to participate in a research project must be fair and must not unduly exceed the range of incentives that the child normally experiences. Whatever incentives are used, the investigator should always keep in mind that the greater the possible effects of the investigation on the child, the greater is the obligation to protect the child’s welfare and freedom.

PRINCIPLE 6 - DECEPTION: - Although full disclosure of information during the procedure of obtaining consent is the ethical ideal, a particular study may necessitate withholding certain information or deception. Whenever withholding information or deception is judged to be essential to the conduct of a study, the investigator should satisfy the Human Participants Protection Committee that such judgment is correct. If withholding information or deception is practiced, and there is reason to believe that the research participants will be negatively affected by it, adequate measures should be taken after the study to ensure the participant’s understanding of the reasons for the deception. Investigators whose research is dependent upon deception should make an effort to employ deception methods that have no known negative effects on the child or the child’s family.

PRINCIPLE 7 - ANONYMITY: - To gain access to institutional records, the investigator should obtain permission from responsible authorities in charge of records. Anonymity of the information should be preserved and no information used other than that for which permission was obtained. It is the investigator’s responsibility to ensure that responsible authorities do, in fact, have the confidence of the participant and that they bear some degree of responsibility in giving such permission.

PRINCIPLE 8 - MUTUAL RESPONSIBILITY: - From the beginning of each research investigation, there should be some clear agreement between the investigator and the parents, guardians or those who act in loco parentis, and the child, when appropriate, that defines the responsibilities of each. The investigator has an obligation to honor all promises and commitments of the agreement.

PRINCIPLE 9 - JEOPARDY: - When, in the course of research, information comes to the investigator’s attention that may jeopardize the child’s well-being, the investigator has a responsibility to discuss the information with the parents or guardians and with those expert in the field in order that they may arrange the necessary assistance for the child.

PRINCIPLE 10 - UNFORSEEN CONSEQUENCES: - When research procedures result in undesirable consequences for the participant that were previously unforeseen, the investigator
should immediately employ appropriate measures to correct these consequences, and should redesign the procedures if they are to be included in subsequent studies.

**PRINCIPLE 11 - CONFIDENTIALITY:** - The investigator should keep in confidence all information obtained about research participants. The participants’ identity should be concealed in written and verbal reports of the results, as well as in informal discussion with students and colleagues. When a possibility exists that others may gain access to such information, this possibility, together with the plans for protecting confidentiality, should be explained to the participant as part of the procedure of obtaining informed consent.

**PRINCIPLE 12 - INFORMING PARTICIPANTS:** - Immediately after the data are collected, the investigator should clarify for the research participant any misconceptions that may have arisen. The investigator also recognizes a duty to report general findings to participants in terms appropriate to their understanding. Where scientific or humane values justify withholding information, every effort should be made so that withholding the information has no damaging consequences for the participant.

**PRINCIPLE 13 - REPORTING RESULTS:** - Because the investigator’s words may carry unintended weight with parents and children, caution should be exercised in reporting results, making evaluative statements or giving advice.

**PRINCIPLE 14 - IMPLICATIONS OF FINDINGS:** - Investigators should be mindful of the social, political, and human implications of their research and should be especially careful in the presentation of findings from their research. This principle, however, in no way denies investigators the right to pursue any area of research or the right to observe proper standards of scientific reporting.

**PRINCIPLE 15 - SCIENTIFIC MISCONDUCT:** - Misconduct is defined as the fabrication or falsification of data, plagiarism, misrepresentation, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, analyzing, or reporting research. It does not include unintentional errors or honest differences in the interpretation of data.
APPENDIX 2

Copied in entirety and verbatim with one exception: word “subject” changed to “participant.”

See also: [http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=24001-25000&file=24170-24179.5](http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=24001-25000&file=24170-24179.5)

Experimental Research Participant’s Bill of Rights

California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a participant in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject’s decision.
Los derechos de todo individuo que se somete a ensayos clínicos

Los derechos que se enumeran a continuación son los que tiene toda persona a quien se le solicita participar en un ensayo clínico. Como participante en un estudio médico de tipo experimental tengo los siguientes derechos:

1) Que se me informe sobre el propósito del ensayo clínico.

2) Que se me informe sobre que va a pasar conmigo y si alguno de los procedimientos, medicamentos o aparatos utilizados en el mismo son diferentes a los que se utilizan en la práctica habitual.

3) Que se me informe sobre los riesgos más serios y más frecuentes, efectos secundarios, malestares y todo lo que me puede ocurrir por someterme al ensayo clínico en cuestión.

4) Que se me informe si acaso puedo esperar algún beneficio por participar en el estudio y en caso afirmativo, cuál sería este beneficio.

5) Que se me informe sobre qué otras opciones de tratamiento tengo y si éstas son mejores o peores que la de participar en el ensayo clínico.

6) Saber que se me permitirá hacer todas las preguntas necesarias en relación al ensayo clínico, tanto antes de acceder a participar en el mismo como también durante su curso.

7) Que se me informe acerca de que otros tratamientos existen en caso de que surja alguna complicación.

8) Poder rehusarme a participar en el ensayo clínico. Ya sea antes de que éste comience o en cualquier momento durante el curso del mismo. También, saber que esta decisión no afectará en ningún modo al derecho a recibir el tratamiento que hubiera recibido si acaso no estuviera participando en este estudio.

9) Recibir una copia oficial, fechada y firmada, del documento de consentimiento.

10) No sentirme presionado en lo absoluto durante el proceso de tomar la decisión de participar o no en el ensayo clínico.

Spanish: Version 10-06