

UNIVERSITY OF ALASKA SOUTHEAST INSTITUTIONAL REVIEW BOARD POLICY AND PROCEDURE MANUAL

TABLE OF CONTENTS

Human Research Subjects: Principles and Procedures Introduction

[General Principles and Institutional Review Board \(IRB\) Procedures](#)

[Glossary](#)

[Frequently Asked Questions](#)

Policies and Procedures

[Activities Subject to IRB Jurisdiction](#)

[Administrative Hold, Suspension, or Termination of IRB Approval](#)

Amendments to Previously Approved Applications or Claims of Exemption

[Approval and Expiration Dates on Informed Consent Documents \(ICDs\)](#)

[Assent/Dissent by Children or Cognitively Impaired Adults Lacking](#)

[Decision-Making Capability](#)

[Certificates of Confidentiality](#)

[Complaints Regarding Human Subjects' Research](#)

[Composition of the IRB and Quorum](#)

[Conflicts of Interest for Investigators and Key Study Personnel](#)

Engaged vs. Non-Engaged in Research

[\(Determinations Involving Performance Sites\)](#)

[General Responsibilities of Investigators](#)

[Human Subject vs. Non-Human Subject Research Determination](#)

[Institutional Research](#)

[Institutional Review Board Responsibilities](#)

[International Research](#)

[Internet Research](#)

[Investigation of Non-Compliance \(Serious or Continuing\)](#)

[Investigator Qualifications](#)

IRB Determinations/Motions

[Legally Effective and Prospectively Obtained Informed Consent](#)

[Payments to Research Participants](#)

[Procedure for Incorporating the Elements of Informed Consent](#)

[Publication of Research](#)

[Recruitment/Advertising](#)

[Recruitment of Students and Employees as Research Participants](#)

[Reporting of Adverse Events and Unanticipated Problems Involving Risk](#)

[Reporting to Appropriate Institutional Officials and The Department or Agency](#)

[Heads](#)

[Waiver of Informed Consent for Human Subjects' Research
or Exception of Informed Consent for Emergency Research](#)

Types of Human Subjects' Review by the IRB:

[Continuing Review](#)

[Exempt](#)

[Expedited](#)

[Full Board](#)

Vulnerable Populations: Special Categories of Research:

[Children](#)

[Cognitively Impaired](#)

[Prisoners](#)

[Pregnant Women, Human Fetuses, Neonates and Transplantation of
Fetal Tissue](#)

Forms:

Investigator Forms:

[IRB Proposal Cover Sheet \(Form 1A\)](#)

[Application Checksheet \(Form 1B\)](#)

[Dean's Assurance \(Form 2\)](#)

[Application for Human Research, Informed Consent Document,
And Assurances \(Form 3\)](#)

[Sample Short Form Written Informed Consent Document](#)

[Request for Exemption \(Form 4\)](#)

[Application for Continuing Review or Study Closure \(Form 5\)](#)

[Request for Amendment \(Form 6\)](#)

[Report of Adverse Events and Unanticipated Problems Involving](#)

[**Risk to Participants or Others \(Form 7\)**](#)

[**Request for Waiver or Alteration of Consent, Authorization, and/or Documentation of Consent \(Form 8\)**](#)

[**Assent Document for Children or Cognitively Impaired Adults \(Form 9\)**](#)

[**Request for Determination of Non-Human Subject or Non-Research \(Form 10\)**](#)

[**Vulnerable Populations: Children \(Form 11\)**](#)

[**Vulnerable Populations: Cognitively Impaired, Comatose or Traumatized Persons \(Form 12\)**](#)

[**Vulnerable Populations: Prisoners \(Form 13\)**](#)

[**Vulnerable Populations: Pregnant Women, Human Fetuses, Neonates, or Fetal Material \(Form 14\)**](#)

[**Complaint Form**](#)

Reviewer Forms:

[**IRB Decision Making Quadrant**](#)

[**Vulnerable Population Form: Children's Checklist**](#)

Appendix:

[**The Belmont Report**](#)

[**Code of Federal Regulation Title 45 \(The Common Rule\)**](#)

Human Research Subjects: Principles and Procedures

The University of Alaska Southeast (UAS), through the Office of the Provost, has established the Institutional Review Board (IRB) to develop and implement procedures for the protection of human subjects in research and has determined at this campus that the Chairperson will make decisions regarding the procedures for review of all protocols at UAS. The purpose of the IRB is to

- protect the rights, well-being, and personal privacy of individuals
- assure a favorable climate for the conduct of scientific inquiry
- protect the interests of UAS and its faculty, students, and staff.

The first section of the policy manual contains the following areas:

- **General Principles and Institutional Review Board**
- **Procedures**
- **Glossary**
- **Frequently Asked Questions**

General Principles and Institutional Review Board

The following general principles apply equally to all research involving human subjects or data related to human subjects, whether carried out solely with University resources or with the assistance of extramural funds. The University assumes responsibility for providing procedural guidelines; however, all faculty members, staff, and students who anticipate development, demonstration, or research projects involving human subjects are responsible for familiarizing themselves with the entire contents of the policy manual as it applies to the research conducted.

1. The University of Alaska Southeast and the individual members of its faculty, staff, and student body recognize their responsibility for protection of the rights and welfare of human subjects.
2. Appropriate professional attention and facilities shall be provided to insure safe conditions for and the well-being of human subjects. No subject in a research activity shall be exposed to an unreasonable risk to health or well-being.
3. No subject will be coerced in any way to participate in a research project, but will do so on a strictly voluntary basis.
4. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
5. In research involving more than minimal risk of substantial stress or discomfort, such risk, stress, or discomfort shall be carefully explained to the subject before his or her agreement to participate; the investigator shall be satisfied that the explanation has been understood by the subject; and the written consent of the subject, such consent containing the substance of the explanation, shall be obtained and kept as a matter of record. The elements of informed consent are established by the federal government and by the University (see federal regulations)
6. Research involving special subject populations (e.g., persons under the legal age of consent, legal incompetents, subjects of questionable competence, prisoners, pregnant women, persons under the care of a physician or psychiatrist) may be conducted as long as the investigator adheres to the guidelines outlined in the Federal Regulations.
7. A request by any subject for withdrawal from a research activity shall be honored promptly

without penalty or without loss of benefits to which the subject is otherwise entitled, within the reasonable limits of research.

Institutional Review Board (IRB): Functions and Responsibilities

1. An IRB composed of three research faculty members, one student member, and one community member (nonscientist) will be appointed as needed by the Provost and serve for a minimum of one academic year. The IRB will meet as needed to review proposed and ongoing research involving human subjects. The Chairperson of the IRB will serve a five year term renewable at the discretion of the Provost and Chair.
2. The IRB shall review on a continuing basis the University's policies and procedures with respect to the use of human subjects and recommend as may be appropriate through the Office of the Provost to the Chancellor.
3. The IRB shall review and have authority to approve, require modifications to secure approval, or disapprove all research activities involving human subjects or data related to human subjects.
4. Research activities shall be reviewed by the IRB for compliance with established federal regulations (i.e., U.S. Department of Health and Human Services and U.S. Food and Drug Administration) related to the protection of human subjects.
5. Research covered by these regulations that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Provost. However, the Provost may not approve the research if it has not been recommended for approval by the IRB. The Provost may delegate these duties to the Vice Provost for Research.
6. The IRB shall provide advice and guidance to investigators regarding the protection of the rights and welfare of human subjects.
7. Where necessary, the IRB shall serve as a referral board for complaints from subjects of research. The IRB will promptly investigate such complaints and make recommendations if necessary to the principal investigator of the study in question.
8. The IRB shall require that information given to subjects as part of informed consent is in accordance with federal regulations as indicated in federal regulation (see Section 3). The board may require that information, in addition to that specifically mentioned in federal regulation, be given to the subjects when in the Board's judgment, the information would meaningfully add to the protection of the rights and welfare of the subjects. Documentation of that process shall also be required.
9. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure Board approval. If the IRB disapproves a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
10. The IRB shall conduct a continuing review of research involving human subjects at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.
11. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and appropriate officials.
12. If a research subject registers a complaint, the investigator shall attempt to relieve the complaint by explanation or by a change of procedure. The investigator shall seek approval of such action

IRB Policy Manual

Introduction

from the source that granted original approval of the research activity. Written approval from the IRB is required for procedural changes.

Levels of Review and General Procedures

***(Specific Policies and Procedures for Types of Reviews are also Found Elsewhere in the Manual)**

The IRB authorizes three levels of review based on the type of research activity. These three levels are: (a) review by the IRB Chairperson, (b) review by an academic Dean, and (c) review by instructor. The following are general procedures to be utilized. It is the obligation of each investigator (faculty, staff, or thesis student) to bring any proposed research activity involving the use of human subjects or data related to human subjects to the attention of the University of Alaska Southeast IRB for review and approval, EXCEPT as indicated in sections 1 and 2 below.

1. Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the human subjects provisions of this chapter and need be submitted to the appropriate Dean only for approval prior to collection of data, provided that the Dean has forwarded or forwards an approved Assurance Statement to the IRB (see Form 2). Final determination of whether the research activities meet the EXEMPT criteria must be made by the IRB Chair. A faculty member, staff, or student cannot determine whether his/her research meets this category.

Such research includes the following:

- a. Research conducted in established or commonly accepted educational settings and involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - b. Research involving the use of educational tests (e.g., achievement, aptitude, cognitive, diagnostic), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or indirectly, through identifiers linked to the subjects.
 - c. Research involving (a) survey or interview procedures or (b) observation of public behavior (including observation by participants, except where ALL of the following conditions exist:
 - (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
 - (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and
 - (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt without exception when the respondents are elected or appointed public officials or candidates for public office.
 - d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if those sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
2. For all questionnaires (regardless of exempt or non-exempt status) the following statement or a reworded statement covering the same points must be prominently displayed on the front of the questionnaire or be explained to each subject:

“This survey is being conducted under guidelines established by the University of Alaska Southeast Institutional Review Board (IRB). By cooperating with this study, you will help the researchers find answers to important questions. However, your participation is strictly voluntary. You should omit answers to any questions that you feel unduly invade

your privacy or that are otherwise offensive to you. Confidentiality is guaranteed; your name will not be associated with your answers in any public or private report of the results.”

3. Student research activities (below the thesis level) that are undertaken as partial fulfillment of course requirements need be submitted for approval to the course instructor only prior to collection of data provided that the instructor has an approved certification statement for that course on file with the IRB. The end products of these research activities will not result in a publishable work or platform or poster presentation at a meeting forum.

Specific Review Procedures by Level

1. Review by University IRB Chair.
 - a. For all research that does not fall within the exempt categories as determined by the Chair or that is not part of a class project below the master’s thesis level, the investigator shall submit three copies of a full proposal to the Office of the Provost. The required contents of the application are described in the IRB proposal form (see Forms 1A and 1B). This application should be submitted through the appropriate Dean to the Office of the Provost no fewer than one month prior to the planned project start date.
 - b. The investigator is required to be available to answer all questions put forth by the Chair or any IRB member in order to clarify the proposal.
 - c. No research within the purview of the IRB shall be initiated until approval has been given.
 - d. Formal actions taken by the IRB will consist of:
 - (i) Approval—indicates the researcher may begin data collection and that the project meets the IRB standards for human subject research.
 - (ii) Approval Withheld Pending—indicates approval by the IRB has been withheld pending revision of specific points. Research may not be undertaken until the outlined revisions are submitted to and approved by the board.
 - (iii) Disapproval—indicates the proposed research does not meet the university and federal guidelines for the protection of human subjects. The research activity may not be undertaken and will not be afforded university endorsement. The investigator shall have the opportunity to respond in person or in writing to the IRB.
 - e. Approval of proposed research is usually granted for a period of twelve months commencing with the date approval is granted by the IRB. Based on the degree of risk to human subjects, the IRB may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Continuation of projects past the approval period requires resubmission of a proposal to the IRB. It is the responsibility of the investigator to reapply and obtain the approval of the IRB prior to expiration of the approved period.
 - f. Investigators, the appropriate Dean, and the Provost will be formally notified in writing of board action by the IRB Chair.
 - g. When the research activity involves an outside agency (e.g., clinic, hospital, public school), the investigator must secure written approval from the appropriate official within the agency prior to receipt of final approval from the IRB.
 - h. If the IRB gives the research proposal an Approval Withheld Pending status, the investigator must contact the IRB Chair regarding the required action within 60 days, or the proposal will be withdrawn from further board action.
2. Referral to IRB at University of Alaska Anchorage (UAA)
 - a. At the discretion of the Chair, if a study poses more than minimal risk, rather than convening

the UAS IRB, the study may be referred to the UAA IRB for action. In such cases, the UAS Chair will sit on the UAA IRB as a voting member for action on a UAS protocol.

3. Review by Instructor:

- a. Faculty who have approved Certification Statements on file (see Form 3) with the IRB may review and approve, within the limits of the Certification, student research activity (below the thesis level) that is required as partial fulfillment of course requirements. The procedures for filing a Certification Statement are outlined above, under Review by IRB).
- b. No research within this category shall be initiated until written approval has been obtained from the faculty member. Approval by the faculty member indicates that the research involves no more than minimal risk to the human research subjects (see definition in Section 4 below).
- c. If the research activity involves more than minimal risk to the subject(s), the faculty member must refer that project to the IRB, following procedures outlined above, under Review by IRB.
- d. All students (below the thesis level) wishing to conduct research activity as a project within a course, for which the faculty member does not have an approved Proposal on file with the IRB, must submit their project to the IRB for review and approval following the procedures outlined above under Review by IRB. This requirement applies to all investigators who are conducting research as students of the University of Alaska Southeast even if the activity is NOT being done for course credit.

GLOSSARY OF TERMS

Definitions:

1. **Administrative Hold**: An action initiated by the Investigator in response to an IRB request to place specific research activities on hold temporarily to allow for additional information to be obtained.
2. **Adverse Effect**: An adverse effect is a physiological, psychological, or social outcome of an investigation that is detrimental to a subject. An adverse effect may be anticipated or unanticipated. For the purpose of review, the Human Subjects IRB needs to know the following:
 - a. **New applications**: Information on adverse effects that most likely or only possibly may occur, based on the literature, previous studies, and other reliable sources. In addition to listing possible adverse effects, applications should indicate the probability that any adverse effect could occur.
 - b. **Renewal Applications**: The same information is required as for new applications, as well as information on adverse effects that have occurred during the study to date.
3. **Agent**: An individual employed by the University of Alaska Southeast who is authorized to act on its behalf.
4. **Amendment**: Any change to an IRB-approved study protocol regardless of the level of review it receives initially.
5. **Anonymity**: In the context of these guidelines, “anonymity” means that no one knows the identity of the subject. No identification of subjects should be possible by the procedure employed or by the information solicited. An example would be a mailed questionnaire with directions for subjects not to sign their names, where no code is used, where responses to questions will not reveal identities, and where the subject group is sufficiently large to avoid inadvertent identification.
6. **Assent**: An individual’s affirmative agreement to participate in research obtained in conjunction with permission from the individual’s parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
7. **Assurance**: A contract or agreement that establishes standards for human research as approved by the Office for Human Research Protections (OHRP).
8. **Certificate of Confidentiality**: A document that provides additional protection of data from legal subpoena. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research.
9. **Children/Minors**: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. According to Alaska State law, the legal age for consent is 18 years of age.
10. **Clinical Investigation**: Any experiment that involves a test article and one or more human subjects and is subject to requirements for submission to the Food and Drug Administration.
 - a. **Test article**: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.
11. **Coded Information**: For the purposes of this policy, identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Introduction

12. **Cognitively Impaired:** Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.
13. **Confidentiality:** Where the identity of subjects is known by name, by specific data, or by appearance, it is usually necessary to make provisions for confidentiality. Data should be stored in a locked file cabinet (or should be similarly protected) accessible only to the investigator and his or her authorized staff or representatives. No identifying information (e.g., documents, photographs, tapes) should be released except with the express permission of the subject.
 - Where confidentiality in reports of results or in reports of specific incidents of interest to the scientific community cannot be assured, this information must be included in the consent form. In those instances where unique information is received but was not anticipated at the time of consent, later consent for the release of identifying information should be obtained. Only personal information necessary to a research activity should be solicited from subjects.
 - To avoid an inadvertent breach of confidentiality, data should be coded, with the names of participants and other identifying information retained only on a master list to be securely stored separate from the data.
 - In double-blind studies, e.g., in drug studies, an appropriately designated individual should retain a copy of the key to the code and a listing of the drug and the dosage to be taken by each subject and should be available to break the code if necessary. In some circumstances, it may be necessary to break confidentiality. If this necessity is foreseen, the study subjects should be informed of this possibility on the consent form. An example would be subjects who engage in or have engaged in illegal activities. Because of legal interests, risk exists that the data or the investigators might be subpoenaed; prospective subjects must know of such possibilities prior to consenting.
14. **Continuing Non-compliance:** A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, UAS-IRB Policy, or determinations or requirements of the UAS-IRB.
15. **Continuing Review:** Periodic review of research activities necessary to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to participants or others, and whether any new information regarding the risks and benefits should be provided to participants.
16. **Dead Fetus:** A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).
17. **Deception:** Deception occurs whenever information about an activity is deliberately withheld from subjects. A dilemma may arise in some research when fully informed consent may itself have injurious effects on the subject, or it may invalidate the experiment, as in the use of placebos or double-blind studies.
18. **Delivery:** Complete separation of the fetus from the woman by expulsion or extraction or any other means.
19. **DHHS:** The Department of Health and Human Services.

Introduction

20. **Dissent:** An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.
21. **Emergency Applications:** Emergency applications are those that relate to emergencies where procedures must be initiated immediately or the opportunity lost.
22. **Emergency Research:** Research conducted in participants who are in a life-threatening or emergent situation, where available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
23. **Exempt Review:** Studies determined by the IRB to meet the exempt criteria as defined by the Federal regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.
24. **Expedited Review:** Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations.
25. **Expired Study:** When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the informed consent document. No activities can occur after the expiration date.
26. **Fetus:** The product of conception from implantation until delivery.
27. **Food and Drug Administration:** The office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with humans.
28. **Greater than Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
29. **Human Fetal Tissue:** Tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.
30. **Human Subject:** A living individual about whom an Investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual or with his/her identifiable private information or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.
 - a. **Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.
 - b. **Interaction:** Includes communication or interpersonal contact with a subject or their private identifiable information.
 - c. **Private Information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.
 - d. **Test article:** Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.
31. **Human Subjects Research:** Any research that involves humans as subjects and any clinical

Introduction

investigation.

32. **Incompetent:** In the context of the human subjects review process, an individual who is unqualified to give or is incapable of giving informed consent is considered to be incompetent. An incompetent may be a minor, an adult who has been declared legally incompetent, or an adult whose competency may be questioned because of an illness or an unusual circumstance.
33. **Immediate Family Member:** Spouse, domestic partner, or child.
34. **Independent Ethics Committee (IEC):** A specifically constituted review body whose responsibility is to ensure the protection of the rights, welfare and safety of research participants. An IEC shares the same composition, and operations as an Institutional Review Board.
35. **Individual Conflict of Interest:** A circumstance such that any action or decision in which an individual is substantially involved with the research may have direct or predictable effect on a financial interest of the individual, spouse, minor child, or organization in which the individual serves as an officer, trustee, partner or employee.
36. **Informed Consent:** An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.
37. **Institutional Review Board (IRB):** A specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.
38. **IRB of Record:** An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP. A Memorandum of Understanding is required, designating the relationship, for UAS to serve as the IRB of Record.
39. **Key Research Personnel:** The Principal Investigator and all individuals responsible for the design or conduct of the study.
40. **Legally Authorized Representative:** An individual, judicial, or other body authorized under applicable law to grant permission on behalf of a prospective participant for participation in research activities; a court appointed guardian or conservator, a Durable Power of Attorney for Health Care (DPAHC).
41. **Legal Guardian:** An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
42. **Major Amendment:** A proposed change in research related activities that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.
43. **Memorandum of Understanding (MOU):** A formal agreement between the University of Alaska Southeast and another institution that identifies the University of Alaska Southeast Institutional Review Board as the IRB of record for that institution.
44. **Minor Amendment:** A proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.
45. **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).
46. **Minimal Risk for Prisoners:** The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological

Introduction

examinations of healthy persons.

47. **Neonate**: A newborn.
48. **Non-compliance**: Failure to comply with Federal regulations, UAS-IRB Policy, or the determinations or requirements of the UAS-IRB.
49. **Non-Human Subject Research**: Any activity determined by the IRB to not represent “Human Subject Research.”
50. **Nonviable Neonate**: A neonate after delivery that, although living, is not viable.
51. **Not Less Than Once Per Year**: All research proposals, with the exception of exempt proposals, must receive IRB continuing review at a minimum of once every 365 days, per Federal regulations. There are no exceptions or grace periods allowed.
52. **Office for Human Research Protections (OHRP)**: The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.
53. **Parent**: A child's biological or adoptive parent.
54. **Performance Site**: A site where research is performed.
55. **Performance Site(s) Engaged in Research**: A performance site becomes "engaged" in human subjects research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human subjects' research when it receives a direct Federal award to support the research.
56. **Performance Sites Not Engaged in Research**: A performance site is "not engaged" in human subjects' research if its employees or agents do not 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. If a UAS Investigator or his/her staff, including site personnel contracted by UAS, performs all research related activities as well as screening, recruiting, or consenting at the performance site, the performance site would be considered "not engaged" in research, unless the non-UAS performance site releases identifiable private information to UAS researchers without first obtaining participants' permission.
57. **Permission**: The agreement of parents or legal guardians to the participation of their child or ward in research.
58. **Personal and Sensitive Information**: Examples of personal and sensitive information are: some demographic data, questionnaires, inventories, and scales that elicit subjective responses; opinions on sensitive issues or about other individuals or groups; and records, such as medical, academic, photographic, audio tapes, and videotapes.
59. **Pregnancy**: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.
60. **Principal Investigator**: The individual primarily responsible for submitting all research materials, writing of the grant, writing of the IRB protocol. The individual who is accountable for the conduct of the research.
61. **Prisoner**: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing. Probation and parole are treated the same and are usually NOT considered as incarceration. Ankle bracelets/in home restrictions are considered as incarceration. Mental and substance abuse facilities are considered incarceration if someone is mandated to attend in lieu of jail or prison; however, an individual in

Introduction

such a facility is NOT considered incarcerated if they voluntarily commit themselves.

62. **Related:** An event is “related” if it is likely to have been caused by the research procedures.
63. **Related Event:** An event is “related” if it is likely to have been caused by the research procedures.
64. **Research:** Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
65. **Research Misconduct:** Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
66. **Research Payments:** Cash and non-cash payments for reimbursement of time and expenses associated with participation in research activities.
67. **Right to Privacy:** The right to privacy is the right of individuals to decide for themselves how much they will share with others of their thoughts, their feelings, and the facts of their personal lives.
68. **Risks:** There are different types of risk to which human subjects may be exposed that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures that may induce a potentially harmful altered physical state or condition. Some examples are: the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercises; and subjection to deceit, public embarrassment, or humiliation. There is a wide range of medical, social and behavioral projects in which no immediate physical or psychological risk for the subject is involved, e.g., those involving the use of interviews, observations, personality inventories, photographs, questionnaires, records, stored data, and tapes. However, some of these procedures may involve varying degrees of discomfort or may be regarded as harassment or invasion of privacy, or constitute a threat to the subject’s dignity, all of which pose another type of risk.
69. **Risk-Potential Benefit Profile:** A summary of the risks and potential benefits that have occurred during the course of the study.
70. **Scientific Merit:** Scientific merit will not be considered by the IRB except in cases in which there would be moderate or high risk to subjects. In such cases the IRB must consider scientific merit (that is, the potential for contributing to knowledge) in order to help determine whether or not the potential benefits of the research to individuals or to society outweigh the risks. The IRB may utilize consultants in making this determination. The IRB will not approve research when the risk is significant and the project lacks, in the opinion of the IRB, appropriate merit. The IRB expects that the Department and School will ascertain the scientific merit of the study prior to submission.
71. **Secretary:** The Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
72. **Sensitive Information:** Includes, but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information, that if released, might be damaging to an individual’s financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information.
73. **Serious Adverse Event:** The FDA defines as any adverse event that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based

Introduction

upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

74. **Serious Event:** An event is “serious” if it involved a serious harm to one or more persons (who may or may not be participants), or required intervention to prevent one or more persons from experiencing serious harm.
75. **Serious Non-compliance:** An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant.
76. **Significant Financial Interest:** Any of the following financial interests of any key research personnel, or his or her immediate family, in aggregate. (The thresholds described below apply to the aggregate ownership of a key research personnel and his or her immediate family. For example, if an Investigator, his/her spouse, domestic partner and dependent children own together \$10,000 or 5% worth of equities in the sponsor). The thresholds do not apply to the combined ownership of all Investigators:
 - a. Compensation whose value could be affected by the study outcome.
 - b. A proprietary interest in the tested product included but not limited to, a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.
 - c. Any equity interest in the sponsor or product whose value cannot be readily determined through preference to public prices (e.g., ownership interest or stock options).
 - d. Any equity interest in the sponsor or product that exceeds \$10,000 or 5% ownership interest.
 - e. Significant payments or other sorts with a cumulative value of \$10,000 made directly by the sponsor as an unrestricted research or educational grant, equipment, consultation, or honoraria, or other payment.
77. **Sponsor-Imposed Suspension:** A determination from the sponsor of the study to place specific research activities on hold. This determination may be made for interim data analysis; inadequate drug availability; response to a data safety monitoring report/recommendation; or a pre-planned stopping point.
78. **Standard Review:** Studies reviewed by the full, convened IRB with a recorded vote and corresponding minutes to document the discussion.
79. **Subject:** A subject is a human being whose physical, intellectual, emotional, or behavioral condition is investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. If a person, such as a family member, employer, or teacher is asked to provide information about another individual, then both individuals are considered to be subjects. Donors of organs, tissues, body fluids, services and records, and informants are also considered to be subjects. The subject may be an adult, a minor, a student, a patient, military personnel, a resident of an institution for the mentally retarded, or a prison inmate. It is useful to distinguish between normal subjects and those who are of interest because of an illness or dysfunction. A subject is considered to be a normal subject if his or her participation in the activity is NOT determined by any illness or dysfunction that he or she exhibits.

Of particular concern are the following types of subjects:

- Persons of limited civil freedom such as prisoners and residents or clients of institutions for the mentally ill and the mentally retarded.
- Pregnant women, the viable fetus, the newborn, children, and the dead. The

- unborn and the dead are considered subjects to the extent that they have rights that may be exercised by their next-of-kin or legally authorized representative.
- The definition of “subject” excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals, in which the patient, student, or client is receiving aid or services intended only to meet his or her own personal needs or the overriding needs of society. The professional-client relationship has the welfare of the client as its primary objective whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. This difference may not be fully understood by the subject who is also a client and can result in the investigator’s gaining consent without free decision, in part due to a trust based on a presumed role that the investigator is not necessarily fulfilling at that time. If doubt exists as to whether the procedures to be employed are for the personal needs of the client, the activity should be considered to involve subject whose rights and welfare are to be protected in accord with these guidelines.
 - The normal employee-employer relationship in which legitimate services are tendered for salary, wages, or remuneration in keeping with customary written or oral contracts is also excluded from the definition of “subject.” Payment of volunteers, however, does not alter their status as subjects. If doubt exists as to whether the procedures are within the normal limits of the employees’ scope of work, the employees should be considered to be participating as human subjects, and their rights and welfare must be protected.
80. **Subject Advocate:** A subject advocate is an individual who participates in the consent process on behalf of an adult subject who has not been declared legally incompetent but whose ability to give informed consent is in question. The subject advocate should be a family member, a close friend, or someone who knows the subject well enough to attest to the subject’s probable agreement to participate.
81. **Suspension for Cause:** An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her study personnel.
82. **Termination for Cause:** An action initiated by the IRB to stop permanently some or all research procedures.
83. **Third-party:** Any person or vendor (external to the University) who receives payment for providing research-related services and/or products.
84. **Unanticipated:** An event is “unanticipated” when it was unforeseeable at the time of its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.
85. **Unanticipated Event:** An event is “unanticipated” when it was unforeseeable at the time of its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.
86. **Unanticipated Problem Involving Risks to Participants or Others:** Any event that was (1) unanticipated, (2) serious, and (3) related.
87. **Unexpected Adverse Event:** The FDA defines as any adverse event, the specificity or severity of which is not consistent with the current Investigator Brochure; or, if an Investigator Brochure is not required or available, the specificity or severity of which is not consistent with the risk

Introduction

information described in the general investigational plan or elsewhere in the current application, as amended. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the Investigator Brochure only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the Investigator Brochure only listed cerebral vascular accidents. “Unexpected,” as used in this definition, refers to an adverse event that has not been previously observed (e.g., included in the investigator brochure) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

88. **Unexpected Event:** An event is “unexpected” when its specificity, nature, severity or incidence are not accurately reflected in the information previously reviewed and approved by the IRB.
89. **Viable:** As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
90. **Whistle-blower:** An individual who reports sensitive information to the UAS- IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.

Frequently Asked Questions

1. What is an Institutional Review Board (IRB)? An Institutional Review Board is a committee formally designated by the Provost of the University of Alaska Southeast to review and approve the initiation and continuing review of research involving human subjects as required by the Department of Health and Human Services (Title 45 Public Welfare Part 46 Protection of Human Subjects). The purpose of IRB review is to assure that:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits for the subjects as well as for the importance of an anticipated gain in knowledge.
- Informed consent will be sought from each prospective subject, or the subject's legally authorized representative, and will be documented.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. Why do we need an IRB anyway? The Department of Health and Human Services in the federal government requires that any institution receiving DHHS funds must have a functional IRB to ensure that research complies with federal regulations for protection of human subjects (see Section 4 above). In the final analysis, however, an IRB serves as an established body that protects the rights of human subjects in research and provides information to researchers to help protect them from liability.

3. Who must apply for approval from IRB? Any member of the faculty, some students [student body not quite accurate – in some instances instructor approval under IRB certification is sufficient], or staff who proposes to use human subjects in a research activity sponsored by the university.

4. What kinds of activities require review? Any research projects involving human subjects, i.e., human beings whose physical condition, responses, tissues, fluids, or records are investigated or used for any purpose other than for the purpose of benefiting the subject as an individual. The use of interviews, tests, observations, inquiries, records, and tapes that provide non-public information about individuals or groups must be reviewed. In addition to research projects, demonstration activities, pilot projects, and course projects must also be reviewed if they involve human subjects. Research projects involving human subjects where the intent of the investigator is to publish or publicly disseminate the findings of the study in a forum such as a national meeting, poster session, or journal publication.

5. When must research involving human subjects be reviewed? Review must occur PRIOR to initiation of the research or pilot studies, PRIOR to implementation of any changes in procedures involving human subjects, and at least annually during the lifetime of the research activity. If the research is being proposed for external funding, WHENEVER POSSIBLE review should take place PRIOR to submission of the proposal to the funding agency. THERE IS NO RETROSPECTIVE REVIEW!

6. How does an investigator apply? An application is submitted through the appropriate Dean to the Office of the Provost, who decides whether a proposal requires IRB review or meets the criteria for exemption from review as confirmed by the IRB Chair.

7. Is any research exempt from review? Yes. Federal guidelines list research that is exempt from review. The Chair of the IRB will determine if a proposal meets the criteria for exemption.

8. How long does the IRB review process take? It is recommended that investigators allow at least one month. The following steps are typical in handling of applications:

- a. The application is submitted to appropriate Dean who reviews and forwards it to the Office of the Provost (OP).
- b. OP receives and logs in application.
- c. Application is screened for completeness.
- d. Application is assigned an IRB reviewer and possibly a meeting date.
- e. Application is reviewed by the IRB.
- f. Feedback, if any, from the IRB is forwarded to the investigator.
- g. Investigator's response, if necessary, is received by the IRB.
- h. Final action is taken on the application by the IRB.
- i. A copy of the approval letter is provided to the investigator and OP.

9. Who serves on the IRB? Five members serve on the IRB and Membership on this committee is drawn from the faculty and community. Appointments to the committee are made annually by the Office of the Provost.

10. May one appeal decisions of the Review Board? An investigator may respond in person or in writing to the IRB regarding any IRB action. There is, however, no authority outside the IRB that can grant approval to a project that has not received IRB approval, short of appealing to the Secretary of HHS.

11. Does an IRB or institution have to compensate subjects if injury occurs as a result of participation in a research project? No. The Food and Drug Administration (FDA) informed consent regulation (21 CFR 50.25(a)(6)) requires that for research involving more than minimal risk, the subject must be told whether any compensation and any medical treatment is available if injury occurs and, if so, what it consists of, or where further information may be obtained. Institutional policy, not FDA regulations, determines whether compensation and medical treatment will be offered and the conditions that might be placed on subject eligibility for compensation or treatment.

12. What is the University's compensation plan for adverse effects? None. Students, faculty, and staff have liability coverage, but there are no university compensation provisions.

13. Is the purpose of IRB review and of informed consent to protect the institution or the subject? The fundamental purpose of IRB review and of informed consent is to assure that the rights and welfare of subjects are protected. A signed informed consent form may be evidence that the information required by federal guidelines has been provided to a prospective subject. IRB approval of a proposal and review of the consent form are to ensure that the subject is given adequate information concerning the study and serve a dual function of protection of the subject and documentation that the institution complied with applicable regulations.

14. Is getting the subject to sign a consent form all that is required by the informed consent regulations? No. The consent form itself is merely an aid to ensuring that adequate information is provided to the subject. The signed consent form provides documentation of a subject's consent to participate in a study. The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject's questions, ensuring that the subject has comprehended this information, and, finally, obtaining the subject's voluntary consent to participate. To be effective, the process must provide an opportunity for the investigator and the subject to exchange information and ask questions. The consent form, therefore, is not an end point. It is one step in this communicative process.

15. How long must consent forms be kept? Three years after completion of the research study.

16. Can an institution's IRB review a study that will be conducted outside of that institution?

Yes. Although an IRB is not required to review studies conducted outside the jurisdiction of its institution, the IRB may choose to do so with that institution's approval.