RESEARCH WITH HUMAN SUBJECTS

INVESTIGATOR’S MANUAL

UNIVERSITY OF THE PACIFIC
Institutional Review Board
Office of Research & Sponsored Programs

Acknowledgement: The University of the Pacific IRB would like to thank the University of Oregon for allowing it to use their Investigator’s Manual on Research with Human Subjects for the initial development of this manual.

Revised September 2017
INTRODUCTION

Why do we review research using human subjects?

The broad answer is that researchers using human subjects must have their experiments reviewed by independent reviewers to make certain that they do not harm their subjects. Pacific’s Institutional Review Board (IRB) has an obligation to review all human subjects’ research by Pacific faculty, staff and students as a condition of receiving Federal funding. More importantly, all research projects, whether funded or unfunded, directed or co-directed by the University’s faculty, students, or staff in which human subjects participate, are subject to the federal regulations governing such research requiring IRB review.

Scientific research has produced extensive social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later regulations intended to assure that research involving human subjects would be carried out in an ethical manner following three basic principles.

Basic ethical principles refer to general judgments that serve as a basic justification for the many ethical treatments and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of Respect, Beneficence and Justice.

The first principle is Respect for Person - meaning we must respect the autonomy of our subjects. We must tell them precisely what they are consenting to, and refrain from pressuring subjects to participate in research with which they do not feel comfortable. The second principle is Beneficence – meaning we must care about the well-being of our subjects. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. The third principle is Justice – meaning we must be fair to our subjects. An injustice occurs when some benefit to which a person is entitled is denied without good reason. The principle of justice is that equals ought to be treated equally. Applying these principles effectively requires broader knowledge than any one individual has, so research using human subjects thus merits review by several people.

In the United States, the Federal Government took the lead in establishing a process and a set of guidelines to review research using human subjects, and a system of review has been set in place that we all agree – explicitly or implicitly – to abide by.

The Promise We Make

In the United States, we live in a complex legal environment. We are governed by laws and regulations at the Federal, State, County, City, and Institutional levels. Different professions and disciplines also have codes of conduct and ethical and epistemic standards that govern their practitioners.

As employees of the University of the Pacific, we are bound by the policies of the University. The University has made an agreement with the federal government to review all the research done with human subjects under its auspices to ensure that it meets the standards set out in 45 CFR 46. This agreement is called a Federal Wide Assurance (FWA).

The University’s FWA agrees to put into place an Institutional Review Board (IRB) and a set of policies and processes assuring the protection of human subjects’ autonomy and safety. In some cases,
the minimum standards required by the Federal regulations are not always enough. Therefore the IRB must tailor the requirements to the unique situation of our University. Thus, the University’s policies and standards are more detailed and specific than the Federal regulations. As faculty, students and staff of the University, we agree to abide by the rules set by the University. Pacific IRB aims to help researchers using human subjects meet their moral and legal obligations to protect human subjects as effectively and efficiently as possible.

**Why should investigators care about the IRB process?**

Investigators do not want to cause harm to their subjects. When following a protocol approved by the IRB – researchers can be confident that they have minimized the risks to their subjects. Conformity with an approved protocol limits liability of the University and a researcher for any unanticipated harms that might occur. Finally, review by the IRB can often help increase the quality of the research.

**The Investigator’s Manual**

This Manual is the codification of the IRB’s policies and procedures for reviewing research involving human subjects associated with Pacific. Investigators unfamiliar with IRB review who are looking for a quick introduction to the approval process would be best served by looking at the IRB resources on our website and consulting the education materials made available by the IRB staff. The process researchers go through to get IRB approval consists of giving the IRB the specific information they need to determine what kinds of risks a subject may incur by participating in the research, and devising a way of clearly communicating to the potential subjects what they are being asked to do. The Manual is the comprehensive statement of policies that the IRB implements.

This Manual applies to all research involving human subjects performed at any University of the Pacific academic site (including, but not limited to, the Stockton, San Francisco, and Sacramento campuses) by University faculty, students, or unaffiliated third parties, and also to research involving human subjects conducted off-campus by University faculty and/or students. All research involving human subjects must be submitted to the IRB before any research activities or information/biospecimen/data collection commences.

All citations in this IRB Manual to applicable law, including the federal regulations, are subject to legislative or regulatory amendment from time to time. Should any conflict between the statements in this IRB Manual and the applicable law arise, the applicable law will control.

If you have any questions about research involving human subjects or the IRB review/approval process, please contact IRB staff at IRB@pacific.edu or 209.946.7716.
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I. RESPONSIBILITIES OF INDIVIDUALS CONDUCTING RESEARCH INVOLVING HUMAN SUBJECTS

Individuals who conduct research involving human subjects, or who supervise researchers, must comply with various ethical, legal standards, and obtain prior approval through the University requirements described below. Funding source, location, duration and the population subject to research do not alter the Principal Investigator’s responsibility to obtain IRB approval.

A. Conduct of Research Involving Human Subjects.

➤ You must accept responsibility for the ethical conduct of research involving human subjects and protect the research participants in accordance with the Belmont Report, Declaration of Helsinki, the Nuremburg Code of Ethics, the Common Rule, and the ethical principles of your discipline.

➤ You will ensure the research is conducted according to:

  • Sound research design and methods;
  
  • The IRB approved protocol including the informed consent process;
  
  • The applicable terms of the grant, contract, and/or signed funding agreements, if any; and
  
  • Applicable laws and regulations, including those that protect the rights, safety, and welfare of human subjects.

➤ You certify that you are sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research involving human subjects.

➤ You will act in accordance with applicable professional standards and codes of conduct as generally accepted in the relevant academic and/or professional discipline.

➤ You will ensure that all members of the research team, including any staff and trainees, are appropriately qualified, trained and supervised.

➤ You will personally conduct and/or directly supervise the research involving human subjects and ensure that you have sufficient time and resources to properly conduct and/or supervise this research and the members of the research team.

B. Ensuring and Maintaining Compliance.

➤ You will comply with the applicable federal and state laws and regulations and University requirements, including those relating to conflicts of interest.

➤ You will obtain IRB approval prior to commencing human subject research activities as well as prior to amending any previously approved research protocols or procedures.
❯ You understand that it is your responsibility to ensure that any research personnel, including yourself, who are responsible for the design, conduct, and reporting of research declare any potential conflicts of interest related to the research and that you must maintain current records. You will ensure that changes in conflicts of interest are promptly disclosed to the IRB.

❯ You will ensure that IRB stamped informed consent is obtained as approved by the IRB and a copy is provided to all participants, unless the IRB waives or alters these requirements.

❯ You will ensure that data, specimens and/or information are collected in an appropriate and ethical manner and in accordance with the protocol approved by the IRB.

❯ You will conduct the human subject research within the approval period issued by the IRB and if you need to extend the research period, you will submit a request to the IRB in advance of the expiration date.

❯ You must submit a closure report form prior to protocol expiration or within 45 days of completion of all research activities involving human subjects or identifiable participant data.

❯ You will maintain approval, as applicable, with collaborative entities including approvals from other countries or jurisdictions.

❯ You will promptly report to the IRB any instances of noncompliance or any new information about risks or problems associated with the approved protocol or requirements of the IRB and any unanticipated problems.

❯ You will assist in the facilitation of any monitoring and/or auditing of research activities and/or records as required by the IRB, funding entities, sponsors, and any federal or state regulatory agencies.

C. Investigator Records, Reports and Documentation.

❯ You will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence) for at least three years after the research activities conclude, or for the length of time specified in applicable regulations or University or sponsor requirements, whichever is longer. You will take measures to prevent accidental or premature destruction of these records.

❯ You will submit the required written forms/reports to the IRB and permit inspection of the research records as required by the IRB or University.

❯ You will ensure the safe and secure storage of research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.
II. IRB RESEARCH APPLICATION TIMELINES AND OVERVIEW OF REVIEW CATEGORIES

All research involving human subjects must obtain IRB review and approval before research activities commence. All review categories can be submitted to the IRB at any time. Researchers should plan well in advance to allow time for the approval process. All submissions will be processed in as expeditious a manner as possible; however, a minimum of two weeks should be allowed before an initial response can be expected. It is the responsibility of the principal investigator to ensure that the submission is presented to the IRB in a timely manner.

<table>
<thead>
<tr>
<th>General Timelines</th>
<th>Review Category Explained</th>
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<tbody>
<tr>
<td><strong>Exempt Review</strong></td>
<td>“Exempt Review” refers to research activities that meet very specific criteria established by the U.S. Department of Health and Human Services (“DHHS”) as human subject research exempt from certain regulatory requirements. The Exempt Review categories can be found in Section X. (page 37) of this Manual. A principal investigator submitting an IRB Research Application that meets the criteria for Exempt Review must file all of the documents required for the IRB to review the proposal. The principal investigator must also submit the Exempt Review Form stating the applicable category to support the Exempt status. The IRB makes the determination of whether the proposal is eligible for Exempt Review and whether Limited Review is required as a condition of the exemption. Exempt Review does not mean that the investigator is exempt from filing the documentation necessary for the IRB to review the proposal.</td>
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<td>1-3 weeks</td>
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<tr>
<td><strong>Expedited Review</strong></td>
<td>“Expedited Review” refers to research activities that meet very specific criteria established by DHHS. Those criteria can be found in Section X. (page 41) of this Manual. A principal investigator submitting an IRB Research Application that meets the criteria for Expedited Review status must file all of the documentation required for the IRB to review the proposal. The IRB makes the determination of whether the proposal is eligible for Expedited Review and an IRB subcommittee reviews Expedited Review proposals and makes the determination of whether the proposal is approved or disapproved.</td>
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<td>3-4 weeks</td>
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<tr>
<td><strong>Full Review</strong></td>
<td>“Full Review” refers to research activities that do not meet the criteria for Exempt or Expedited Review as described in Section X of this Manual. A principal investigator submitting an IRB Research Application for Full Review must file all of the documentation required for the IRB to review the proposal. An IRB subcommittee will first review proposals and makes recommendations to the full IRB for action at the IRB’s regularly scheduled meeting.</td>
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<td>4+ weeks</td>
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Research conducted off-campus (including overseas) may be subject to additional institutional review in the foreign jurisdiction which may extend the IRB’s timeframe for review.
### III. ABBREVIATIONS and DEFINITIONS

As the terms relate to the Design and Review of Research Involving Human Subjects, and definitions provided by applicable law, including the Common Rule:

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<tr>
<th>Abbreviations</th>
<th>Definition</th>
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<tr>
<td>IRB</td>
<td>The University of the Pacific's Institutional Review Board, established in accordance with federal regulations governing the protection of human subjects in research for the purpose of review and approval of such research.</td>
</tr>
<tr>
<td>RSP</td>
<td>The University of the Pacific’s Office of Research &amp; Sponsored Programs. All IRB materials are maintained by this office, and Principal Investigators should contact this office for information regarding procedures.</td>
</tr>
<tr>
<td>DHHS</td>
<td>U.S. Department of Health and Human Services, the federal agency which enters into agreement with institutions through a signed assurance of compliance with the HHS regulations for the protection of human subjects in biomedical or behavioral research. This assurance is called a Federal-wide Assurance (“FWA”) and is approved by the DHHS' Office of Human Research Protections (“OHRP”). DHHS requires compliance with 45 CFR 46 implementing Public Law 93-348 establishing institutional review boards and an ethics guidance program.</td>
</tr>
<tr>
<td>OHRP</td>
<td>Office for Human Research Protections under the U.S. Department of Health and Human Services. The University’s FWA is only for human subject research activities under the purview of OHRP and not for Food and Drug Administration (“FDA”)-regulated research (e.g., clinical trials, medical devices).</td>
</tr>
<tr>
<td>Pacific</td>
<td>The University of the Pacific, including all campuses and academic sites.</td>
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</table>

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<tr>
<th>Terms</th>
<th>Definitions</th>
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<tr>
<td>Anonymous</td>
<td>Refers to data collected without any identifiable information or identifiers on project materials which could link the data with individual subjects.</td>
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<tr>
<td>Assent</td>
<td>A child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.</td>
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<tr>
<td>Benign Behavioral</td>
<td>Behavioral (not biomedical) interventions in conjunction with collecting information from an adult subject through oral or written responses</td>
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<td>Terms</td>
<td>Definitions</td>
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<tr>
<td>Intervention</td>
<td>(including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. This exemption is for research activities that pose little risk to subjects. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. (See Section X for more information.)</td>
</tr>
<tr>
<td>Broad Consent</td>
<td>An alternative form of informed consent for prospective consent for the storage, maintenance, and secondary research use of private information or identifiable biospecimens. Broad consent may only be obtained for the storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens.</td>
</tr>
<tr>
<td>Children</td>
<td>Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR § 46.402(a))</td>
</tr>
<tr>
<td>Clinical Trial</td>
<td>A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. (45 CFR § 102(b))</td>
</tr>
<tr>
<td>Coercion</td>
<td>An action is considered coercive if it entails an overt or implicit threat of harm or negative consequence which could compel an individual’s involuntary participation and/or compliance. For example, telling a prospective research subject he/she will lose access to needed services if he/she does not participate in the research is coercive and will not be permitted.</td>
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<tr>
<td>Confidentiality</td>
<td>A researcher’s agreement with the research subjects about how each individual’s identifiable private information will be handled, managed, protected and disseminated.</td>
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<tr>
<td>Debriefing</td>
<td>The process through which research subjects are given previously undisclosed information about the research project following completion of their participation.</td>
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<tr>
<td>Deceptive Research</td>
<td>A study in which research subjects know they are participating in research, but they are not informed of its true purpose. Authorized deception involves prospective agreement by the subject to participate in the research/study where the subject is informed that he/she will be unaware...</td>
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<tr>
<td>De-identified</td>
<td>Data that has been stripped of personally identifiable information.</td>
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<td>Generalizable Knowledge</td>
<td>A study contributes to generalizable knowledge if the findings of a study are intended to be applicable to a larger population beyond the site of data collection or the population studied, and/or if the intent is to present or publish anything about the study or otherwise make the findings of it available for the development of knowledge beyond the scope of the study.</td>
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<tr>
<td>Genetic Information</td>
<td>As defined by California Government Code § 12926, “genetic information” means, with respect to any individual, information about any of the following: (A) the individual’s genetic tests; (B) the genetic tests of family members of the individual, (C) the manifestation of a disease or disorder in family members of the individual. Genetic information also includes any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by an individual or any family member of the individual. Genetic information does not include information about the age or sex of the individual.</td>
</tr>
<tr>
<td>Genetic Services</td>
<td>A genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.</td>
</tr>
<tr>
<td>Genetic Test</td>
<td>An analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.</td>
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<tr>
<td>Guardian</td>
<td>An individual who is authorized under applicable State or local law to consent on behalf of a child for general medical care.</td>
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<tr>
<td>Human Subjects</td>
<td>Living individuals about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR § 102(d)(1))</td>
</tr>
<tr>
<td>Identifiable Private Information</td>
<td>Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. For example, legal names, email addresses, and even screen names can be used to identify individuals, as can personal information disclosed during research about a person’s identity and/or experience (e.g., their narrative</td>
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<td>(45 CFR § 102(d)(5))</td>
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<tr>
<td>Identifiable Biospecimen</td>
<td>A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.</td>
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<tr>
<td>Identifiers</td>
<td>Any information that permits the data to be linked to individual participants, such as names, numbers or codes.</td>
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<tr>
<td>Informed Consent</td>
<td>A process to ensure that a research participant is aware of all the reasonably foreseeable risks and costs involved in participating in the research project. The individual must be able to voluntarily decide whether or not to participate as a research subject. If the subjects are minors, or are not capable of giving consent, then parental, guardian or other legal representative consent is required (refer to Section XII). Use of a written consent form that includes all the basic elements of informed consent must be documented by a signature of the subject or legally authorized representative. “Key Information” (as further described in Section XII of this Manual must appear at the beginning of the consent form and be presented first in the consent discussion.</td>
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<tr>
<td>Institutional Review Board</td>
<td>An independent committee formally designated to review, approve and monitor biomedical and behavioral research involving human subjects.</td>
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<tr>
<td>Interaction</td>
<td>Communication or interpersonal contact between investigator and subject (e.g., surveys, interviews, and observations). (45 CFR § 102(d)(2))</td>
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<tr>
<td>Intervention</td>
<td>Both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. (45 CFR § 102(d)(3))</td>
</tr>
<tr>
<td>Legally Authorized Representative</td>
<td>An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research. (45 CFR § 102(i))</td>
</tr>
<tr>
<td>Limited IRB Review</td>
<td>Limited Review is a condition for exemption of research activities involving (1) identifiable and sensitive educational tests, survey</td>
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<td>Terms</td>
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<td>procedures, interview procedures or observation of public behavior; (2) identifiable and sensitive benign behavioral interventions; and (3) secondary research use. Limited Review is used to make and document the determination to ensure that adequate privacy safeguards are in place for identifiable private information and identifiable biospecimens.</td>
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<td>Minimal Risk</td>
<td>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. (45 CFR 46.102(j)). Minimal risk is to be determined with regard to the state of vulnerability of the particular subject or subjects, especially if special populations are used as subjects. Refer to Section XL (page 49) for additional guidance in determining minimal risk.</td>
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<tr>
<td>Public Health Authority</td>
<td>An agency or authority that is responsible for public health matters as part of its official mandate. (45 CFR § 102(k))</td>
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<tr>
<td>Principal Investigator</td>
<td>The primary person responsible for the design, conduct, execution, and/or reporting of the research. This person should submit the documentation to the IRB for review and approval.</td>
</tr>
<tr>
<td>Principal Investigator (or Lead Researcher)</td>
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<tr>
<td>Privacy</td>
<td>Refers to a person’s desire to control the access of others to themselves.</td>
</tr>
<tr>
<td>Private Information</td>
<td>Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information provided for a specific purposes by an individual which the individual expects will not be made public (e.g., a medical record). (45 CFR § 102(d)(4))</td>
</tr>
<tr>
<td>Protected Health Information (“PHI”)</td>
<td>Individually identifiable health information transmitted or maintained in any form or medium by a HIPAA covered entity.</td>
</tr>
<tr>
<td>Protocol</td>
<td>The official procedure or system in place by which research is conducted.</td>
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<tr>
<td>Research</td>
<td>A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The general rule is that if there is any element of research in an activity, that activity should undergo IRB review to ensure the protection of human subjects. For example, some demonstration and service programs may include research activities.</td>
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<td>Terms</td>
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<td></td>
<td>The following activities are deemed <em>not to be research</em> and do not require IRB approval:</td>
</tr>
<tr>
<td></td>
<td>(1) scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship) including the collection and use of information focusing directly on the specific individuals about whom the information is collected;</td>
</tr>
<tr>
<td></td>
<td>(2) public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority, with such activities being limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters);</td>
</tr>
<tr>
<td></td>
<td>(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes;</td>
</tr>
<tr>
<td></td>
<td>(4) authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. (45 CFR § 102(l))</td>
</tr>
<tr>
<td>Risk</td>
<td>The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participating in research. Refer to Section XI. (page 47) for additional information on Risk.</td>
</tr>
<tr>
<td>Single IRB (sIRB)</td>
<td>This term is synonymous with “reviewing IRB” and “IRB of record” and is used in the context of cooperative research, which is research occurring at multiple sites or involving more than one institution.</td>
</tr>
<tr>
<td>Secondary Research Use</td>
<td>Re-using for research purposes, identifiable and non-identifiable information and biospecimens that are collected for some other primary or initial activity, such as for research studies other than the proposed research study.</td>
</tr>
<tr>
<td>Student</td>
<td>A person studying at Pacific who is receiving academic credit for performing a research project. A student must have an academic advisor who is responsible for overseeing the research.</td>
</tr>
<tr>
<td>Terms</td>
<td>Definitions</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Systematic</td>
<td>Having or involving a system, method, or plan.</td>
</tr>
<tr>
<td>Undue Influence</td>
<td>An act that includes an excessive or inappropriate reward or other overture may constitute undue influence. For example, offering a large sum of money to participate in a research study where the amount entices the subjects to disclose certain information that they would not otherwise willfully disclose may be viewed as unduly influential.</td>
</tr>
<tr>
<td>Unit</td>
<td>This may be a school or department at Pacific, depending upon the needs of the individual groups on campus.</td>
</tr>
<tr>
<td>Vulnerable</td>
<td>People who are more likely to be susceptible to coercion or undue influence which could affect the ability to make an informed decision about participating in the research. Examples of populations that are potentially vulnerable include: children, prisoners, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons.</td>
</tr>
<tr>
<td>Voluntary</td>
<td>Free of coercion, duress, or undue inducement.</td>
</tr>
</tbody>
</table>

Other definitions may be found throughout the Manual in appropriate sections.
IV. PACIFIC’S INSTITUTIONAL REVIEW BOARD

A. IRB Charge and Authority.

Background of the IRB. In accordance with federal regulations, Pacific assumes the responsibility for the protection of the rights and welfare of human subjects who participate in research conducted by, or under the supervision of, Pacific faculty, staff or students at any of the campuses, other academic sites, or off-campus. In addition, Pacific is responsible for reviewing protocols for research projects conducted on any of the three campuses by individuals unaffiliated with Pacific. To conduct this responsibility effectively, Pacific upholds the IRB standards for all three campuses, which is the governance body authorized and competent to review research and research methods, training and other activity protocols involving human subjects and to evaluate both risk and protection against risk for those individuals. The IRB serves all Pacific faculty, staff and students, regardless of location.

Responsibilities of the IRB. The Pacific IRB is specifically responsible for ensuring all research projects involving human subjects comply with the standards set out in part 46 of title 45 of the Code of Federal Regulations (45 CFR 46). The IRB committee reviews, examines and evaluates proposals for research and experimentation using human subjects in accordance with the federal regulations and guidelines supplied by the Office for Human Research Protections (“OHRP”) of DHHS. The IRB is charged with determining and evaluating:

- risks to human subjects;
- benefits or value to subjects and/or society;
- specific nature of subject’s participation including:
  - recruitment of subjects,
  - voluntary nature of subject participation,
  - informed consent,
  - remuneration (if any) to subject, and
  - specific procedures to be followed.
- sound research methods.

The IRB also assists the principal investigator in complying with federal regulations in a way that permits accomplishment of the research activity. The IRB aims to provide a service to the University and the public by facilitating ethical treatment of research subjects, while at the same time supporting the investigator’s endeavor to advance knowledge. This Manual is intended to explain the role of the IRB, to protect the rights and welfare of human participants, and to assist researchers and principal investigators in their efforts to perform research.

B. IRB Committee Membership.

Number of Committee Members. The IRB committee must have at least five members with varying backgrounds and diversity to promote complete and adequate review of research activities commonly conducted by the institution. Appointment to the IRB committee shall be made by the Institutional Official upon recommendation from the Associate Provost for Research. By law, the IRB can have as many members as necessary for it to perform its duties effectively. At Pacific, the number of members, their constitution, appointment and declaration of Chairs, is the responsibility of the Institutional Official or their designee, pursuant to the Faculty Handbook IRB charter.
General Qualifications. To promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, the IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes. In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. The IRB may not consist entirely of members of one profession.

Specific Member Qualification Requirements. The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. The IRB committee must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

Adjunct Members with Specialized Expertise. The IRB may, in its discretion, invite individuals (adjunct members) with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. For example, the IRB may request the expertise of someone familiar with particular cultural practices or consent requirements of a local jurisdiction for research conducted overseas. These adjunct members may not vote. The nonaffiliated member(s) of the IRB will be drawn from the University and local community-at-large, including ministers, teachers, attorneys, businesspersons, or homemakers. The person(s) selected must be knowledgeable about the local population of the particular jurisdiction and be willing to discuss issues and research from that perspective. Consideration will be given to the type of community from which the institution may draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

Conflicts of Interest. Federal regulations require that no IRB member may participate in the initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. Except when requested by the IRB to be present to provide information, IRB members should absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such will be noted in the IRB minutes.

C. IRB Subcommittees.

The IRB may establish subcommittees as deemed practical to utilize a specific member's expertise or as described in this Manual for specific circumstances, and may consult with individuals outside the IRB having competence in special areas to assist in the evaluation of complex issues.

D. IRB Determinations.

As specified in the federal regulations and as delegated to the IRB by the University, the IRB (or a quorum of its officially appointed membership) are responsible to review and give final approval to all research projects involving human subjects. University officials may review IRB determinations but may not approve research activities that have been disapproved by the IRB.
V. HUMAN SUBJECTS RESEARCH

Compliance with, or exemption from, the federal regulations will not in and of itself constitute approval by the University for a principal investigator to conduct research activities. The Office of Research & Sponsored Programs and the IRB shall, therefore, review all planned research involving human subjects to determine whether the University shall support or sponsor such research. This Section V describes the process for determining whether a research activity involves human subjects.

A. Who Makes this Determination?

The IRB Administrator is the only Pacific staff member, other than the IRB, who may make a formal determination. Principal Investigators may self-determine whether a research activity involves human subjects by completing the Human Subjects Research Worksheet.

Principal Investigators may choose to request a formal determination by the IRB by submitting the Human Subjects Research Worksheet and noting the request. The IRB Administrator and IRB have the authority to over-rule an investigator's self-determination.

B. Research Must Not Commence Until Determination Made and Approvals Obtained.

Research may not commence until the determination has been made, and, if required, IRB approval obtained. When a principal investigator requests a formal determination, the research must not begin until the investigator receives the determination and/or approval letter. When the determination (whether from the IRB or IRB Administrator, or by self-determination on the Human Subjects Research Worksheet) indicates that the planned activity is human subjects research, appropriate IRB approval must be requested and granted before the research may commence.

C. Modifications.

A determination applies only to the activity as described. A new determination must be made before implementing any changes to the activity (such as changes in procedures, specimen, collaborators, populations affected, etc.).

D. Principal Investigator Responsibilities.

As described in Section I of this Manual, the principal investigator is responsible to:

- Comply with applicable federal and state laws and University policies. For example a materials Transfer Agreement or Data Use Agreement may be required even if the research does not involve human subjects;
- Ensure that data/biospecimens/information are collected in an appropriate and ethical manner;
- Act in accordance with relevant professional standards and codes of conduct as generally accepted in the relevant academic and/or professional discipline; and
- Promptly notify IRB of any new information about risks or relevant problems associated with the activity (or any other know activity) that might affect the human subjects research determination.

The principal investigator is still responsible for complying with these general rules even if the research does not involve human subjects.
E. Procedures.

**Investigator Self-Determination.** Principal Investigators may use the Human Subjects Research Worksheet to assess the planned activity. Effective **September 1, 2017**, all Human Subjects Research Worksheets must be submitted to the IRB@pacific.edu for review.

**Investigator Request for Determination by the IRB.** Principal Investigators may also request a formal determination by the IRB if the investigator is unsure where the research involves human subjects. In this case, the investigator must provide the following documentation to the IRB:

- A completed Human Subjects Research Worksheet;
- A complete copy of the relevant grant, agreement, and/or contract (if applicable);
- A copy of any other materials (e.g., protocol); and
- This same process should be followed when requesting a determination about a proposed change to the research activity.

**Determination by IRB.** The IRB makes human subjects research determinations as part of the routine pre-review process as well as in response to requests from investigators. The IRB reviews the Human Subjects Research Worksheet and may request additional information as needed to make the determination.

**Routine Assessment.** The IRB makes the determination for all of the following items as part of the pre-review process, whether or not the researcher has requested it:

- IRB Research Application
- Exempt Review Requests
- Specimen or Data Use (whether identifiable or non-identifiable)
- Status Reports

**Documentation.** Determinations are considered IRB records. When the determination is in response to a researcher's request, the IRB communicates the determination in writing to the investigator. When the determination is part of a routine pre-review, IRB documents the determination in the file and communicates any determination that research does not involve human subjects in writing to the investigator.

**Appeals.** Any disagreements about the IRB’s determination will be reviewed by IRB Chair, then forwarded to the Associate Provost of Research, who will recommend final adjudication to the Institutional Official.

F. Common Misconceptions.

**Consent Forms.** An individual may be considered a human subject before signing a consent form. This is likely to occur when the research involves screening and/or pre-screening activities.

**Third Party or Secondary Subjects.** This refers to situations when an investigator obtains information about one individual (“A”) through interaction with another individual (“B”). If the information is private and identifiable, then person “A” is a human subject.
## VI. OVERVIEW OF PROCESS

### A. Prepare to Submit the IRB Research Application

1. **Complete Required Training.** Investigators receive the training by completing the Collaborative Institutional Training. Refer to Section XXIII. (page 88).
2. **Design Research in Accordance with Federal Regulations** so that research provides reliable and valid data by using procedures consistent with sound research design, which do not unnecessarily expose subjects to risk.
3. **Determine if the Project Must Be Approved by the IRB.**

### B. Preliminary Review and Required Approvals

1. **Review and Signature of Faculty Advisor (Student Research Only)**
2. **Submit for Preliminary Review for Adequacy by IRB Staff**

### C. IRB Review & Determination

1. **IRB Review Process begins**
2. **If Approved, Research May Commence**
3. **If Conditionally Approved, Research May Not Commence Until Conditions Resolved**
4. **If Disapproved, Principal Investigator May Appeal IRB Decision**

### D. Continuing Review and Additional Approval

1. **IRB Conducts Continuing Review at Regular Intervals**
2. **Any Changes to Approved Protocol Procedures Must be Submitted to the IRB for Review and Approval**
3. **IRB Must be Notified When Research Concludes**

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**A. Prepare to Submit the IRB Research Application.**

**Complete Required Training.** Each individual conducting research (PI/ALL personnel involved), working in an on-campus laboratory, collecting human subject biospecimen or information, recruiting subjects, or serving on a thesis/dissertation committee involving human subjects research must successfully complete the required training in human subjects research history, ethical principles; federal, state and local regulations; and general institutional review board procedures. Principal Investigators must receive training prior to submitting an IRB Research Application, regardless of investigator status or the category of research. Proof of training must be submitted to the IRB Staff with the application submission. Individuals must re-certify IRB training every three years.

**Design Research in Accordance With Federal Regulations.** Although scientific concerns are important in the design of research involving human subjects, the rights of human subjects must be the IRB’s primary consideration. The principles, policies and procedures set forth in this Manual should be kept in mind throughout the design of any research project.

**Determine if the Project Must Be Approved by the IRB.**

*Research Involving Human Subjects Must Comply with Federal Regulations.* It is Pacific Policy that all research projects, whether funded or unfunded, directed or co-directed by Pacific
faculty, students or staff in which human subjects participate on-campus or off-campus, are subject to the federal regulations governing such research, and to the policies and procedures outlined in this Manual. Such projects include individual or collaborative research projects, as well as any programmatic projects, class surveys or projects, and student government activities with a research component.

**Human Subjects Research Worksheet.** If the principal investigator has any doubt as to whether or not the research is subject to IRB Approval or the federal regulations, please review Section V. (page 20) and complete the Human Subjects Research Worksheet. If the principal investigator still has questions after completing the Worksheet, please contact the IRB Staff.

**Off-Campus or Overseas Research.** Research performed by Pacific faculty, students or staff off-campus, elsewhere in California, in another state, or even overseas, is subject to Pacific IRB review and approval. Such projects may also be subject to review and approval by another institution’s IRB and it is the responsibility of the principal investigator to comply with the local jurisdiction’s requirements.

**On-Campus Research by Researchers From Other Institutions.** In addition, non-Pacific-affiliated individuals wishing to conduct human research studies on any of the Pacific campuses are subject to Pacific policies and applicable regulations. Such research projects may be subject to review by another institution’s institutional review board and also Pacific’s IRB. Please see Section XIX. (page 82) (Non-University Affiliated Researchers Conducting Research at a University Academic Site) for further instruction.

**Grant Proposals or Multiple Projects.** Grant proposals lacking definite plans for involvement of human subjects, such as institutional block grants, training grants, or those projects in which the human subjects’ involvement will depend upon completion of instruments, prior animal studies, etc., shall require the investigator to submit a protocol to the IRB once plans for activities involving human subjects are formulated. In the case of multiple projects, the investigator must agree to take the responsibility for ensuring that each individual project involving human subjects is submitted to the IRB for review before research commences.

**The IRB Research Application.** The IRB Research Application form provides the IRB with the information that it needs to review and approve the proposed research, and should be completed by the principal investigator of the research project. Instructions for completing the IRB Research Application (and the additional required documents) are found in Section VIII. (page 29) of this Manual.

**B. Preliminary Review and Required Approvals.**

**Review and Signature by Faculty Advisor (Student Research Only).**

**Faculty Supervision Required.** All student-initiated research involving human subjects, whether dissertation, thesis, or other research projects, must be supervised by a University faculty member to ensure protection of human subjects’ health and welfare and compliance with the federal regulations and this Manual. No less important is the

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1 Please note that research conducted for personal evaluation or program evaluation with the purpose of self-improvement or program improvement in which results will not be publicly disseminated does not need to be reviewed by the IRB.
opportunity for faculty to educate students about University policies and procedures related to research with human subjects.

**Signature of Faculty Advisor Required.**

- For thesis or dissertation research, the signature of the University faculty advisor is required unless there appears to be a conflict of interest (See Section VII of this Manual for more information on Conflicts of Interest). If the faculty advisor is unable to sign, another member of the student's committee may sign.

- For student research other than thesis or dissertation projects, a faculty supervisor's signature is required.

- The faculty signature on student research attests that the research procedures comply with federal regulations and Pacific policies with regard to the protection of human subjects' health and welfare. The faculty supervisor is expected to monitor the research to ensure that the approved protocol with human subjects is followed. When approved by the faculty reviewer, the faculty member signs the IRB Research Application in the appropriate place.

**Preliminary Review for Adequacy by IRB Staff.** The proposed research project is logged in by the IRB Staff and assigned an IRB Protocol Review Number. As needed, the IRB Staff will perform a Preliminary Review of the research protocol to determine:

- the appropriate Review Category (Exempt, Expedited or Full Review) (see Section X. (page 36) for a description of the Review Categories);
- if the protocol meets the general requirements for review under the federal regulations; and
- if the informed consent procedure and form contains the required elements and is in satisfactory form for IRB review.

IRB Staff will consult with the principal investigator (and/or faculty supervisor, if student research) by phone, e-mail and/or in person for any reason regarding the completeness of the IRB Research Application, including, when the proposal does not meet the general requirements, the informed consent procedure and form are missing required elements without justification, or additional information or clarification is needed to determine the review category.

**C. IRB Review & Determination.**

The IRB can approve, conditionally approve, or disapprove the application as further described below. If the protocol is approved, and the investigator is a student, the outcome of the IRB will be sent to the student and the faculty member supervising the research.

**IRB Review Process Generally.**

*IRB Administrator or IRB Program Specialists Transmits Application to the IRB Reviewers.* The IRB Staff will send the IRB Research Application to the IRB reviewers, along with all supporting documentation submitted by the principal investigator (including the proposed Informed Consent form). If the IRB Staff has requested revisions, the revised forms will be sent to the reviewers in place of the original documents.
IRB Reviewers for Exempt Review. If the protocol is determined to be Exempt under the federal regulations the protocol is reviewed by the IRB Staff or the IRB Co-chair. If Limited Review of exempt research activities is required, the Limited Review will be conducted through the Expedited Review process.

IRB Reviewers for Expedited Review. If the protocol is determined to require Expedited review, the IRB Research Application and supporting documents will be reviewed by two members of the IRB who will make a recommendation of approval or disapproval to the IRB Co-Chair. At the request of either IRB reviewer (instead of making an approval or disapproval recommendation) or the IRB Co-Chair, the protocol will be referred to the full IRB for consideration at the next meeting.

IRB Reviewers for Full Review. If the protocol is determined to require Full review, the IRB Research Application and supporting documents will be distributed to the entire IRB. It will be initially reviewed by two members of the IRB who will make recommendations to the full IRB. The full IRB will meet to consider all protocols requiring Full Review, as well as protocols in the Expedited category for which at least one of the reviewers determines that the procedures require Full Review. Minutes of the IRB meetings will include:

- Date, place and times (start, end) of the meeting.
- Attendees will be noted, as will absences.
- Approval of previous meeting minutes, old business, new business, as well as deliberations, actions, and votes for each protocol undergoing review by the convened IRB.
- If the IRB approves a procedure which does not include all of the required elements or varies from approved procedures, this protocol-specific approval will be noted and justified.
- Documentation of risk and approval period.
- Vote records will include the number of members voting for, against and abstaining in the following format: Total = #; Vote: For - #, Opposed - #, Abstained - #.

If Approved by IRB, Research May Commence. If the protocol is approved, the IRB chair completes a Co-Chair Review Form electronically approving the protocol. The IRB Administrator then sends an approval letter to the principal investigator, indicating that the research activities may commence. If the principal investigator is a student, the outcome of the IRB will be sent to the student and the faculty advisor supervising the research. It is the responsibility of the principal investigator (and faculty advisor if applicable) to monitor the research to ensure that the approved procedures are being followed. Any adverse effects or harm to subjects must be reported to the IRB immediately (via the Report of Noncompliance form).

If Conditionally Approved by IRB, Research May Not Commence Until Conditions Resolved. If there are correctable problems with the research protocol, the IRB Staff or the Co-chair of the IRB will consult with the principal investigator(s) by phone, e-mail and/or in person, to seek revisions in the protocol. This consultation may occur at several times in the review process (e.g., after review by the IRB staff, after review by two members of the IRB, and/or after a vote of the IRB). Conditional approval requires that problems with the protocol must be corrected before the research may commence. Typically, determination of whether the changes made by the principal investigator satisfy the conditions set forth by the IRB can be made by the IRB Administrator or the Co-chair, obviating further discussion of the protocol by the full IRB. When the conditions have been satisfied, the chair completes a Co-Chair
Review Form electronically approving the protocol. The IRB administrator then sends an approval letter to the principal investigator (and faculty advisor if applicable), indicating that the research may commence.

**If Disapproved, Principal Investigator May Appeal IRB Determination.** If the protocol is disapproved, the principal investigator may not conduct any such research activities, and the IRB will provide in writing the reasons for its decision. Copies of this report will be given to the principal investigator, faculty advisor (if applicable), and Associate Provost for Research. The researcher will have the right to appeal the decision. Refer to Section IX.E. (page 35) regarding the appeals process.

### D. Continuing Review and Additional Approvals.

**IRB Conducts Continuing Reviews at Regular Intervals.**

*What is Continuing Review?* At regular intervals, the IRB will conduct continuing reviews of research projects in progress. The interval for continuing review will be appropriate to the degree of risk, but not less than once per year. All research protocols are currently reviewed annually. If the project is of high-risk, or has a high risk to potential benefit ratio, the IRB may require review more frequently than once per year.

*Process for Continuing Review:* Approximately six weeks before the expiration date of the IRB-approved research, the IRB Staff will send an Annual Protocol Review Form to the principal investigator. If there are no problems, adverse effects on subjects, or changes in research activities reported by the principal investigator, the continuing review will be handled by the IRB Administrator unless the initial review of research required Full Review. If any of the conditions described above are present, review of the research project will be conducted by the IRB.

**IRB Observation of Research.** The IRB has the authority to observe or have a third party observe the informed consent process and the research activities.

**Verification by Third Parties.** The IRB may determine that a continuing project may need verification from sources other than investigators that no changes have occurred since the previous review. This determination may be based on location or timing of the research, or other factors including:

- randomly selected projects;
- high-risk projects;
- projects conducted by investigators who have previously failed to comply with IRB regulations;
- projects where concern has been raised during continuing review or by other sources.

**Any Changes to Approved Procedures Must Be Approved by IRB.**

**Termination or Suspension of Research.** The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements, or the previously-approved procedures, or that has been associated with unexpected serious harm to subjects. Any such suspension or termination will include a statement of the reason for action and shall be reported promptly to the principal investigator, to the faculty advisor if the principal investigator is a student, to the
appropriate University officials, and to the appropriate federal officials. See Section XVIII. (page 80) (Noncompliance Policy) for more information.

**Changes Must be Approved by IRB.** Any changes in previously approved research activities must be approved by the IRB. Minor or substantial protocol revisions may be submitted to the IRB with a Protocol Revision Form. Changed research activities may not be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subjects.

**IRB Process for Reviewing Protocol Revisions.** The number of IRB reviewers for changes in procedures will correspond with the Review Category the project received when it was initially submitted to the IRB (i.e., the Administrator and Co-Chair for Exempt research, two committee members and Co-Chair for Expedited research, and the entire IRB (quorum) for Full Review projects). IRB Staff will send the completed Protocol Revision Form and the original IRB Research Application, as well as any new supporting documentation, to the IRB reviewers.

**Audits by IRB.** To ensure that protocol revisions are not made without prior IRB review and approval (except when necessary to eliminate apparent immediate hazards to the subjects); the IRB may randomly audit research records and activities or observe research being conducted.

**E. IRB Must Be Notified When Research Concludes.**

When the research project concludes (i.e., research activities involving human subjects are completed), the principal investigator must complete the Active Protocol Status Form and IRB Final Report and send it to the IRB Administrator. The principal investigator must keep all research records, including completed informed consent forms, pursuant to the Records Retention policy, Section XVII. (page 77). Research records are subject to audit at any time during the retention period. Audits may be conducted by Pacific’s IRB, Pacific’s internal auditor or investigator, the Department of Health & Human Services, the National Science Foundation, external audit agencies, or other external entities.
VII. CONFLICTS OF INTEREST

A. What is Conflict of Interest for a Researcher or Faculty Advisor?

**Derive Personal Benefit.** A conflict of interest is a situation where a person is in a position to derive personal benefit from actions or decisions made in his/her official capacity. Conflicts of interest for researchers and faculty advisors may arise due to financial interests, business transactions, personal relationships, or outside professional activities that compromise their ability to properly discharge their official duties.

**Non-Financial Conflict.** A non-financial conflict of interest may arise in situations where a subject may experience undue pressure or coercion during recruitment efforts, or during the consent or information/biospecimen collection activities, either because he or she is the student, employee, or client of the researcher. Unless there is a compelling scientific reason, the IRB will not allow researchers to recruit subjects with whom they have a supervisory or evaluative relationship.

B. Procedures for Disclosing Conflicts of Interest.

**Researchers, Faculty Advisors, and University Personnel.** No research activities by Principal Investigators of the University shall be adversely affected by the financial interests of the researcher, faculty advisor, or other University personnel carrying out those activities. All research undertaken at Pacific shall be conducted in full compliance with all Pacific policies and all applicable federal and state laws pertaining to conflicts of interest. Prior to commencing any research activities, the researcher, faculty advisor, or other University personnel having a potential conflict of interest shall disclose the details of the conflict in the IRB Research Application or immediately after the conflict is discovered by the conflicted party, using the Conflict of Interest Disclosure form. The IRB reviews such disclosures and institutes a plan for the management of any potential financial conflicts of interest.

**IRB Committee Members.** Potential or actual conflicts of interest may also arise with IRB Committee Members (voting), if they have a financial or personal relationship with the researcher, faculty advisor, or an entity deriving a benefit from the proposed research. If an IRB Committee Member has a potential or actual conflict of interest relating to research activities, the IRB Committee Member must inform the IRB Administrator in writing, and recuse himself/herself from any IRB presentation, discussion, and vote related to such research activities. Notwithstanding, the IRB may request certain information from the conflicted IRB Committee Member regarding the research activities, and IRB Committee Member agrees to reasonably cooperate with the IRB on such a request.

C. Failure to Comply with Disclosure Requirements.

Persons failing to comply with this disclosure procedure shall be subject to the Noncompliance Policy as set forth in Section XVIII of this Manual and may be subject to other disciplinary actions pursuant to other applicable University policies and rules.
Chapter VIII. IRB FORMS

The available IRB forms pertaining to human subjects research are described below. Forms can be found on the Office of Sponsored Programs Policies and Forms webpage and are also attached as appendices to this Manual. Questions concerning the forms or procedures should be directed to IRB Staff at 209-946-7716, IRB@pacific.edu. Other forms or documentation may be required depending on the research and funding, if any.

The following IRB forms are discussed below:

- Human Subjects Research Worksheet
- Exempt Review Form
- IRB Research Application
- Informed Consent Templates
- HIPAA Questionnaire
- HIPAA Authorization Form
- Existing Information/Biospecimen Research Application Form
- Cooperative Agreement Form
- External IRB Authorization Agreement Form
- External Investigator Agreement
- Active Protocol Status Report
- Protocol Revision Form
- Adverse Event/Unanticipated Problem Reporting Form
- Noncompliance Report


Human Subjects Research Worksheet. This Worksheet assists principal investigators to determine whether the planned research activities constitute human subjects research. Effective September 1, 2017, all projects considered “research” on the Worksheet (whether or not the principal investigator believes human subjects are involved) must be submitted to the IRB Administrator to confirm whether human subjects research will be conducted.

Exempt Review Form. If the principal investigator believes the human subjects research is eligible for Exempt Review, as described in Section X of this Manual, complete this form and submit with the completed Research Application.

IRB Research Application. This form must be used for new research protocol submissions for any research involving human subjects as described in Section I in this Manual. This includes research activities such as surveys and questionnaires, interviews, focus groups, ethnographies, experiments, and observations. This form must be submitted and must be approved prior to commencing any research activities involving human subjects.

How to Fill Out the Form. The Research Application should be written in clear, jargon-free language, understandable to people outside the researcher’s field. The form must be typed.

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2 One exception to this requirement is classroom projects that are supervised by a faculty. The faculty member, though, may request that the students fill out this form as part of the instruction on responsible conduct of research.
(as opposed to handwritten), signed and scanned as PDF documents, and submitted by e-mail to IRB@pacific.edu. The material presented in the Research Application must be complete in and of itself (i.e., do not refer to other sections of the proposal to provide information to the IRB).

Other Attachments: The Informed Consent form, HIPAA Authorization Form, HIPAA Questionnaire, and other pertinent information such as samples of the survey instrument, questionnaire, or interview questions, and a copy of the thesis/dissertation or grant proposal, also must be included with the IRB Research Application.

All Signatures Are Required Prior to Submitting the Research Application to IRB for Review. The investigator and the faculty advisor (if applicable) must sign on the appropriate line prior to submission of the Research Application to the IRB. It is the principal investigator’s responsibility to track the IRB Research Application and obtain the signature of the faculty advisor (if applicable). By signing the Research Application, the principal investigator is indicating that s/he will comply with the federal regulations and University policies outlined in this Manual. The Research Application will then be reviewed by the IRB pursuant to the Exempt, Expedited, or Full Review process detailed in Section X of this Manual.

Informed Consent Templates. The proposed informed consent forms must be attached to the copy of the Research Application. The following templates are available for reference and are discussed in Section XII of this Manual:

- Sample Long Form Informed Consent Form (for Research Subjects over Age 18)
- Sample Short Form Informed Consent (for Research Subjects over Age 18)
- Sample Short Form Summary of Informed Consent (Oral) (for Research Subjects over Age 18 who are presented the required consent items orally)
- Sample Children’s Assent Form (for Research Subjects under Age 12)
- Sample Children’s Parent Consent Form (for Research Subjects under Age 12)
- Sample Consent for Non-sensitive Questionnaires (for Research Subjects over Age 18)
- Broad Consent Checklist and Sample Form
- Informed Consent Checklist (Required and Additional Elements) (for Research Subjects over Age 18)

HIPAA Authorization Form. If research activities include the collection or creation of PHI, the principal investigator must: obtain authorization that complies with HIPAA from each research subject or obtain a waiver of authorization granted by the IRB unless the PHI is de-identified or a limited data set (as discussed below). HIPAA Authorization is a research subject’s permission to allow the University to use or disclose the subject’s PHI for the purposes and to the recipients stated in the Authorization. A HIPAA Authorization may be combined with an informed consent document, or it can be obtained via a separate form. (See Section XIII of this Manual for more information regarding research involving PHI.)
HIPAA Questionnaire. If your study includes access to identifiable medical information, you must complete the HIPAA Questionnaire. The information requested will be used to determine whether your study requires a HIPAA Authorization Form or other legal agreements.

Existing Information/Biospecimen Research Application. This form is to be used for new protocol submissions when human subjects are not directly involved and it is used in lieu of the IRB Research Application if the research qualifies under Exempt Review Category 4, or Expedited Review Category 8 (Continuing Review). For example, data on human subjects already exists in a database and retrospective research is desired. This data may already exist because it was originally collected for research purposes or because this data is part of normal operations for a clinic or institution. See Section XIV for additional information.

How to Fill Out the Form. Just as with the IRB Research Application, the Existing Information/Biospecimen Research Application should be written in clear, jargon-free language, understandable to people outside the principal investigator’s field. The form must be typed (as opposed to handwritten), signed and scanned as PDF documents, and submitted by e-mail to IRB@pacific.edu. All signatures (of the principal investigator and faculty advisor (if applicable)) are required prior to submitting this form to the IRB.

Cooperative Agreement Form. This form is to be used by principal investigators whose research has already been approved by another institution or for collaborative research with multiple institutions in which Pacific is not the lead institution (meaning, Pacific is not the principal investigator’s “home institution”). If Pacific is the principal investigator’s “home institution”, the IRB Research Application must be submitted for IRB approval. See Cooperative Research Agreements, Section XXI. (page 84) for additional information.

IRB Authorization Agreement Form. This form is to be used by principal investigators whose research has been approved by Pacific IRB but is also engaged in research with additional institution(s). The authorization ensures that all institutions are in agreement with the review authority.

External Investigator Agreement. This form is to be completed by the external investigator to ensure that the individual is aware of Pacific’s human subjects research policies and procedures and to ensure compliance with applicable requirements.

B. Previously Approved Protocols.

Active Protocol Status Report. This form is to be completed for both study continuation and study closure. The form is sent by IRB Staff to the principal investigator via email and must be completed and returned by email. Failure to submit this form timely will prohibit future IRB protocols from being reviewed until the previous/overdue reports are submitted.

Continuing Review. At regular intervals, the IRB will conduct continuing reviews of projects in progress. The interval for continuing review will be appropriate to the degree of risk, but not less than once per year. All research protocols are currently reviewed annually. If the project is of high-risk, or has a high risk to potential benefit ratio, it may require review more frequently than once per year.

Timing of Continuing Review. Approximately six weeks before the current expiration date, the IRB Program Specialist will send an Active Protocol Status Report to the principal investigator. The completed form must be completed and returned within thirty days following the current expiration date. If there are no problems, adverse effects to subjects or changes in research activities by the principal investigator, the continuing review will be handled administratively unless the initial review of research underwent a Full Review.
If any of these above conditions are present, review of the project will be conducted by the IRB.

**Conclusion of Research; Closure Report.** When the research activities conclude (when the procedures involving human subjects are completed), the Active Protocol Status Report must be completed and submitted to IRB Staff at IRB@pacific.edu to document the study’s closure.

**Failure to Submit Required Active Protocol Status or Final (Closure) Report.** If the principal investigator fails to submit the Active Protocol Status or Final (Closure) Report the approval for the protocol will automatically expire and research activities must cease. The IRB will not approve any subsequent research activities by the principal investigator until any and all expired protocols are officially closed (through submission and approval of the required reports).

**Protocol Revision Form.** This form is for principal investigators who need to change the study design of an IRB-approved protocol. Any changes made to a study must first be approved by the IRB before implementing the change. Failure to notify the IRB of changes or implementing a change before the IRB grants approval is considered noncompliance and will be handled pursuant to Section XVIII (Noncompliance Policy).

C. To Report Incidents of Noncompliance or Other Incidents.

**Adverse Event/Unanticipated Problem Reporting Form.** This form is to be used when an adverse event or unanticipated problem occurs during IRB-approved research activities. An adverse event or unanticipated problem is one that is an unexpected result or a risk that was not disclosed to the IRB as a potential risk to consider as part of its review and approval of the research protocol.

**Noncompliance Report.** This form is to be used when noncompliance from an approved study is detected or if research activities involving human subject has been conducted without IRB approval (even if the research activities are eligible for Exempt Review). This form can be completed by the principal investigator, other study or research team personnel, a study participant, or anyone from the general public who feels noncompliance has occurred. For anonymous submissions it is suggested that the form be completed, printed, and sent by US mail without a return address to the Office Research and Sponsored Programs, Attn: IRB Administrator, 3601 Pacific Avenue, Stockton, CA 95211. See Section XVIII (Noncompliance Policy) for more information about the policy.
IX. IRB DETERMINATIONS

A. IRB Authority.

The IRB is authorized by 45 CFR § 109 to approve, require modification in (to secure approval) or disapprove all research activities covered by the federal regulations.

B. Criteria for IRB Approval of Research Applications.

Pursuant to 45 CFR § 46.111, the IRB may approve research when the following conditions are satisfied:

- Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purpose;

- Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects, and the importance of the knowledge that may reasonably be expected to result;

**Note:** In addition to evaluating the sound research design/methodology and benefits/value of the research, the IRB will consider only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

- Selection of subjects is equitable;

**Note:** The IRB will consider the purposes of the research and the setting in which the research will be conducted, with special consideration for research involving a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be appropriately documented, unless informed consent or documentation is appropriately waived by the IRB;

- The research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects where appropriate;

- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data where appropriate; *(DHHS will issue guidance to assist IRBs in determining what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.)*

- For purposes of conducting the Limited Review of Exempt Categories 2, 3 and 8 research activities (where the Limited Review is a condition of exemption), the IRB shall evaluate whether there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data where appropriate;

- For purposes of conducting the Limited Review of Exempt Category 7 research activities (where the Limited Review is a condition of exemption), the IRB does
not need to make the determinations of items 1-6 above, and shall instead make
the following determinations:

- Broad consent for storage, maintenance, and secondary research use
  of identifiable private information or identifiable biospecimens is
  obtained in accordance with the requirements set forth in Section
  XII, G of this Manual;
- Broad consent is appropriately documented or waiver of
documentation is appropriate, in accordance with 45 CFR § 46.117;
and
- If there is a change made for research purposes in the way the
  identifiable private information or identifiable biospecimens are
  stored or maintained, there are adequate provisions to protect the
  privacy of subjects and to maintain the confidentiality of the data;
  (DHHS will issue guidance to assist IRBs in determining what provisions are
  adequate to protect the privacy of subjects and to maintain the confidentiality of
data.)

Where some or all of the research subjects are likely to be vulnerable to coercion or undue influence, such
as children, individuals with impaired decision-making capacity, or economically or educationally
disadvantaged persons, appropriate safeguards must be included in the study to protect the rights and
welfare of these subjects.

C. Possible IRB Determinations.

Approved. The proposal is unconditionally approved. The investigator may proceed with
information/biospecimen collection without further communication with the IRB, aside from the annual
renewal. It is the responsibility of the principal investigator (and faculty advisor if applicable) to monitor
the research to ensure that the approved procedures are being followed. Any adverse effects or harm to
subjects must be reported to the IRB immediately (via the Report of Noncompliance).

Conditional Approval. The proposal is approved but with conditions that must be remedied
before any research activities commence. The basis for the conditional approval will be recorded in the
minutes of the IRB meeting (for Full Reviews) or via email correspondence (all other reviews) and
provided to the principal investigator (and faculty advisor if applicable) via email correspondence. The
principal investigator must respond to the required modifications requested by the IRB prior to beginning
research activities. Once the principal investigator has satisfied the IRB’s request for modifications, the
principal investigator will receive approval from the IRB. The investigator may proceed with research
activities without further communication with the IRB, aside from the annual renewal or protocol
revisions. It is the responsibility of the principal investigator (and faculty advisor if applicable) to monitor
the research to ensure that the approved procedures are being followed. Any adverse effects or harm to
subjects or must be reported to the IRB immediately (via the Report of Noncompliance).

Disapproved. The research activities are not approved as submitted. The basis for not
approving the protocol will be recorded in the minutes of the IRB meeting and provided to the principal
investigator (and faculty advisor if applicable). The principal investigator must respond to the concerns
and/or modifications requested by the IRB at which point the Research Application will be re-reviewed
and project will be approved, conditionally approved or disapproved. If the principal investigator does
not agree with the IRB's determination, the principal investigator has the right to appeal the
determination (see Section IX.E page 35, regarding the appeals process).
D. Approval Required Prior to Commencing Research Activities; Release of Funds.

The IRB must approve an IRB Research Application prior to the commencement of any research activities. No funding may be used on research activities prior to IRB approval of the Research Application. The Co-chair of the IRB has the responsibility and authority to notify the business office to withhold all funds until such time as the project is approved by the IRB. Such notification responsibility may be delegated to the Office of Research & Sponsored Programs at the direction of the Co-chair.

E. Appeals Process.

In the event that an IRB Research Application is not approved by the IRB, the appeals process is as follows:

- The investigator submits the grievance in writing to the IRB Administrator for forwarding to the Co-chairs of the IRB;
- The Co-chairs discuss the grievance with members of the full IRB in an attempt to provide resolution;
- If the grievance cannot be resolved internally by the IRB, the principal investigator may request a meeting with the IRB, and may be accompanied by counsel or other persons with expertise or knowledge of research related to the research activities in question;
- The IRB may invite a faculty member or University official who is not a member of the IRB to act as an observer to the process; and,
- Based on the findings of the IRB, a final decision regarding the grievance will be made by a majority vote of the IRB to either approve or disapprove the principal investigator's IRB Research Application.

F. Additional Review by University Officials.

Research activities approved by the IRB may be subject to further review, and approval or disapproval, by University officials. However, University officials may not approve any research that has been disapproved by the IRB.

G. Review of Clinical Trials and Investigational Drugs or Devices Pursuant to FDA Regulations.

The federal Food and Drug Administration (“FDA”) regulations govern clinical trials and the use of investigational drugs and devices in research with human subjects and require the approval of an institutional review board. The Pacific IRB is only permitted to review research subject to the DHHS regulations, thus, FDA-regulated research is not permitted at the University (or any academic sites). The Office of Research and Sponsored Programs can assist principal investigators with making the appropriate certification to funding agencies when a clinical trial or an investigational new drug or device is proposed in research activities, and additional informed consent posting requirements will apply for research involving clinical trials. Consult with the Office of Research Sponsored Programs or the IRB Administrator for further information.
### X. IRB REVIEW CATEGORIES

Depending on the level of risk and the research subject demographic, an IRB Research Application will fall into one of three categories: Exempt, Expedited or Full.

<table>
<thead>
<tr>
<th>Exempt Review</th>
<th>Expedited Review</th>
<th>Full Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Research Involves Minimal Risk to Human Subjects</td>
<td>• Research Involves Minimal Risk to Human Subjects</td>
<td>• Research Involves Greater than Minimal Risk to Human Subjects</td>
</tr>
<tr>
<td>• One of the Exemption Categories Applies</td>
<td>• One of the Expedited Categories Applies</td>
<td>• No Exemption Category Applies</td>
</tr>
<tr>
<td></td>
<td>• Includes Minor Changes to Previously Approved Protocols</td>
<td>• Research Not Eligible for Expedited Review</td>
</tr>
<tr>
<td></td>
<td>• Limited Review of Exempt Activities</td>
<td></td>
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</table>

#### Minimum Documents Required

<table>
<thead>
<tr>
<th>Exempt Review Status Form</th>
<th>Human Subjects Research Worksheet</th>
<th>Human Subjects Research Worksheet</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Human Subjects Research Worksheet</td>
<td>• IRB Research Application</td>
<td>• IRB Research Application</td>
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**Who Reviews the Documents and Makes the Determination for the IRB?**

<table>
<thead>
<tr>
<th>Exemption reviewed and determination made by IRB Administrator in Consultation with IRB Co-Chair as necessary</th>
<th>IRB Research Application reviewed by two IRB Committee members who may recommend approval of the protocol, request changes, or refer it to the full IRB depending on the issues.</th>
<th>IRB Research Application reviewed by two IRB Committee members who will make recommendations to the full IRB, which has the authority to approve, require revisions, or disapprove the protocol. Approval will be based on outcome of committee vote.</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Research Application reviewed by IRB Administrator and or one IRB Co-Chair</td>
<td>Unless Full Review is needed, Expedited applications will be approved by IRB Co-Chair.</td>
<td></td>
</tr>
<tr>
<td>Full Review of Exempted protocols occur on a random basis by the Full IRB or governmental agencies</td>
<td>IRB may not disapprove IRB Research Application without Full Review.</td>
<td></td>
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</table>

**On Selecting the Level of Review.** Principal Investigators should request the level of review they feel is appropriate for their research project on the IRB Research Application. The IRB Administrator, in consultation with the IRB Committee if necessary, will determine the correct level of review.

**Informed Consent Requirements.** The standard requirements for informed consent (or its waiver, alteration, or exception as authorized by the IRB) apply regardless of the type of review (Exempt, Expedited or Full) utilized by the IRB.
EXEMPT REVIEW

A. What is Exempt Review?

“Exempt Review” refers to research activities that meet very specific criteria established by DHHS as human subject research exempt from certain regulatory requirements. The research activities may be eligible for Exempt Review if there is minimal risk to research subjects and the only involvement of human subjects falls into one of the specific categories discussed below (pursuant to 45 CFR § 46.104). Exempt Review does not mean that the investigator is exempt from filing the documentation necessary for the IRB to review and document the research.

B. What Documents Must Be Submitted to the IRB?

For research activities that the principal investigator believes to qualify as Exempt, the principal investigator must submit a completed Exempt Review Form to provide the IRB the necessary information to determine if the research qualifies as Exempt. The principal investigator must also submit a completed IRB Research Application form.

C. Who Makes the Determination?

The principal investigator may request Exempt Review but the IRB Administrator, in consultation with the IRB Co-Chair as necessary, makes the determination of whether the research activities meet the criteria for Exempt status. In some instances, the IRB will perform a Limited Review of the research activities as a condition to exemption.

D. Exempt Review Categories.

These categories may be used if the subjects are eighteen years of age or older (including pregnant women) and in some instances if the subjects are children as noted below:

1. Educational Settings. (This is also a permissible exemption for subjects who are children). Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Use of Anonymous or No-Risk Tests, Surveys, Interviews or Observation of Public Behavior. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

   • information taken from these sources is recorded in such a manner that subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; *

   • any disclosure of subjects responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; * or

   • the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and
an IRB conducts a Limited Review to make the determination as set forth in Section IX.B of this Manual.

**Note:** *The research under these criteria involving educational tests or the observation of public behavior of children is eligible for this exemption when the investigator does not participate in the activities being observed. **Research activities under this criterion are not eligible for exemption for children.*

### 3. Benign Behavioral Interventions

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination as set forth in Section IX.B of this Manual.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Examples of benign behavioral interventions under this exemption include (on the assumption that all criteria are met): having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. If the research involves deception of the subjects (regarding the nature or purposes of the research), this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances where the subject is on notice that he/she will be unaware of, or misled, regarding the nature or purposes of the research.

### 4. Secondary Research for which Consent is Not Required

(This is also a permissible exemption for subjects who are children). Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects; the investigator does not contact the subjects; and the investigator will not re-identify subjects;
- The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E (the HIPAA Privacy Rule) for the purposes of “health care
operations” or “research” as those terms are defined at 45 CFR § 164.501 or for “public health activities and purposes” as described under 45 CFR § 164.512(b); or

• The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002 (44 U.S.C. 3501) if all of the identifiable private information collected, used, or generated as part of the research will be maintained in systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552(a)), and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.).

The biospecimens and information do not need to be pre-existing at the time the investigator begins the research; prospective collection is permitted. (Note: This category of research will be submitted to the IRB for review using the Existing Information/Biospecimen Research Application instead of the IRB Research Application.)

5. Research and Demonstration Projects Conducted or Supported by Federal Department or Agency Regarding Public Benefit or Service Programs. (This is also a permissible exemption for subjects who are children). Research designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Programs include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department/agency must establish on a publicly accessible Federal web site (or other means determined by the department/agency) a list of the research and demonstration projects that the Federal department/agency conducts or supports under this exemption. The research or demonstration project must be published before commencing the research involving human subjects.

6. Taste and Food Quality Evaluation and Consumer Acceptance Studies. (This is also a permissible exemption for subjects who are children). Taste and food quality evaluation and consumer acceptance studies:

• if wholesome foods without additives are consumed; or

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

7. Storage or Maintenance for Secondary Research for which Broad Consent is Required. (This is also a permissible exemption for subjects who are children). Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if the IRB conducts a Limited Review as follows:
• Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained as set forth in Section XII.G of this Manual;
• Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR § 46.117; and
• If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. Secondary Research for which Broad Consent is Required. (This is also a permissible exemption for subjects who are children). Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

• Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained as set forth in Section XII.G of this Manual;
• Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR § 46.117;
• The IRB conducts a Limited Review and makes the determination as set forth in Section IX.B of this Manual and makes the determination that the research to be conducted is within the scope of the broad consent described in Section XII.G of this Manual; and
• The investigator does not include returning individual research results to subjects as part of the study plan. An investigator is not prevented from abiding by any legal requirements to return individual research results.

E. Limited Review.

Limited Review is a condition for exemption for research activities falling under Exempt Categories 2, 3, 7 and 8, and the specific criteria to be considered by the IRB in its Limited Review is specified in the descriptions of each category above.

F. Forms.

Exempt Review Form
EXPEDITED REVIEW

A. What is Expedited Review?

Research projects not eligible for Exempt Review may be eligible for Expedited Review if the research involves minimal risk. DHHS has established a list of categories of research deemed to involve minimal risk that may be reviewed by the IRB through Expedited Review, unless the review determines the research involves more than minimal risk. The full list of categories of research that may be expedited are listed in 21 CFR § 56.110 and are described below. Unless determined otherwise by the reviewer, the IRB will use the Expedited Review process: (1) if some or all of the research falls into one or more of the categories below and involves no more than minimal risk to subjects; (2) for minor changes in previously-approved research during the period for which IRB approval is authorized; and (3) for Limited Review of exempt research activities.

B. What Documents Must Be Submitted to the IRB?

The same documentation is required for Full Review because the research must be evaluated against the approval criteria set forth in Section IX.B of this Manual. Therefore at a minimum, the Human Subjects Research Worksheet and the IRB Research Application must be submitted.

C. Who Makes the Determination?

The principal investigator may request Expedited Review but the IRB Administrator/Staff, in consultation with the IRB Co-Chair as necessary, makes the determination of whether the research activities meet the criteria for Expedited status. The IRB Research Application is reviewed by two IRB Committee members who may approve the protocol, request changes, or refer it to the full IRB for determination.

D. Preliminary Requirements.

Before requesting Expedited Review, the principal investigator must ensure that:

- Minimal Risk is posed to human subjects, and
- Involve only procedures listed in one or more of the categories described below.

Additionally, Expedited Review may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

E. Expedited Review Categories.

If the Preliminary Requirements are satisfied, and if one or more of the following research categories applies, the research activities are eligible for Expedited Review. The categories described below apply regardless of the age of subjects, except as noted. Categories one (1) through seven (7) require both initial and continuing IRB review.

- 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, or venipuncture as follows:

- From healthy, non-pregnant adults (18 or over) who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

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

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for Expedited Review, including studies of cleared medical devices for new indications.)

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

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

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

- 7. Research on individual or group behavior or characteristics (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. The listing refers only to research that is not exempt.)

- 8. Continuing review of research previously approved by the IRB during the period (of one year or less) for which IRB approval is authorized as follows:
  
  - Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  
  - Where no subjects have been enrolled and no additional risks have been identified; or
  
  - Where the remaining research activities are limited to data analysis.

- 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories E.2 through E.8, above do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
FULL REVIEW

A. What is Full Review?

Research which involves more than minimal risk to the human subjects is not eligible for Exempt or Expedited Review, and will require Full Review by the IRB. Any research which involves children, prisoners, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons or individuals who may be subject to high risk must be provided Full Review of the IRB at a regular IRB Committee Meeting. Any research involving more than minimal risk to children requires Full Review.

B. What Documents Must Be Submitted to the IRB?

At a minimum, the Human Subjects Research Worksheet and the IRB Research Application must be submitted.

C. Who Makes the Determination?

The principal investigator may request Full Review but the IRB Administrator, in consultation with the IRB Co-Chair as necessary, makes the determination of whether the research must be reviewed by the full IRB. The IRB Research Application is reviewed by two IRB Committee members who will make recommendations to the full IRB, which has the authority to approve, require revisions, or disapprove the protocol.

D. Types of Research Requiring Full Review.

- Research activities involving more than minimal risk as determined by the IRB.
- Research activities that involve the intentional deception of subjects where misleading or untruthful information will be provided to subjects.
- Research activities involving vulnerable populations (as discussed in Section XV of this Manual).
- Research activities involving procedures that are personally intrusive, stressful, or potentially traumatic (where “stress” can manifest in physical, psychological, social, financial, or legal respects).

E. Exceptions to Full Review Requirement.

In certain limited circumstances, the IRB may determine that Expedited Review is permitted for research involving a special or vulnerable population. Contact the IRB Office for more information. Examples include: observation of public behavior of children involving no interaction and surveys or interviews of children involving no risk to the subjects.
XI. DETERMINING RISKS TO RESEARCH SUBJECTS AND RECRUITMENT OF SUBJECTS

A. The University’s Obligations to Research Subjects.

The University and Principle Investigators have an ethical and moral obligation to safeguard the rights and welfare of all subjects involved in research, where subjects are exposed to a risk that could be detrimental to their health or well-being. In those cases where risk may exist, even with informed consent, approval of a research project will be made only if the potential risk to the individual is outweighed by potential benefits. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research and shall not consider the long-range effects of applying knowledge gained in the research as among those risks that fall within the IRB’s purview of responsibility.

B. Availability of Assistance or Medical Attention.

The University is responsible for physical or psychological injury to human subjects attributable to university-sponsored research, development, and related research activities, to the extent that the University may be found liable under federal and state laws. Therefore, the obligation of researchers to conduct activities in a manner and at such locations as will assure the proximity of adequate medical attention if warranted, and to provide appropriate referrals to subjects for adequate facilities and professional attention should subjects suffer physical, psychological or other injury, is of paramount importance when designing research involving human subjects.

C. Evaluating the Seriousness of a Risk.

The seriousness of a risk to subjects is a function of the magnitude of the harm and the probability of the harm. A risk may be serious or significant because it has a probability (even a low probability) of great harm (e.g., a low probability of death), or because it has a high probability of slight harm (e.g., a near certain probability of physical discomfort or psychological distress).

D. Risks as Part of Research Design or Consequences of Procedures.

The risks of participation in research may be part of the research design or may be a consequence of the research procedures, or both (e.g., the risks of an adverse reaction to an investigational drug are part of the research design, while the risk of hematoma from blood drawn in the research is not part of the design but a consequence of the research procedures). Risks may be a consequence of the methods of recording, maintaining, or reporting data, and they may be a consequence of methods of obtaining informed consent.

E. Recruitment of Research Participants.

Voluntariness. Voluntariness begins with recruitment. Potential subjects must not feel that they have been coerced into participating, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate (such as on-going support by a social agency). Special care must be taken if the person doing the recruiting is a person who is in a position of authority (such as a teacher recruiting his or her own students) or makes decisions about the provision of services (such as a director of a training clinic). It is the principal investigator’s responsibility to ensure that a person’s decision to participate or not, will have no other effect on an existing relationship.
Using University Classrooms to Recruit Participants. Students at Pacific may be asked to participate in research projects for some courses. In such cases, the researcher should ask the instructor to give her/his permission to use class time to conduct a study. Because students in classrooms comprise a captive audience, care should be taken to respect their rights as subjects and as students. It should not be a coercive requirement, and informed consent, if appropriate, must be obtained. Instructors should ensure that several project options are available to the students, or alternative means are available for receiving credit if a student chooses not to participate or chooses to withdraw during the course of the study. To assure that students feel free to refuse to participate without concern that the evaluation of their classroom performance will be affected, the instructor should not be present during any research activities. Furthermore, the instructor should not be informed nor be aware of who participates.

If participating students will be awarded academic or extra credit for participating in research activities, the amount and type of credit as well as any required conditions must be clearly stated in the consent documents. Alternate academic or extra credit options must be available for students who do not wish to participate in the research and students must be informed that they may complete alternatives to receive the same credit as part of the consent process. The amount and type of academic or extra credit for nonparticipating students must be of equal difficulty and effort as participation in the study. If a participating student withdraws before completion of the study, such student must also be provided the academic or extra credit option available to nonparticipating students. The academic or extra credit opportunities for nonparticipating students shall be described in the IRB Research Application.

The IRB recognizes that participating in research and receiving information about the research may be instructionally relevant, but because research involves time that would otherwise be used for instructional activities, departments may wish to promulgate policies with regard to classroom research. Studies for classroom purposes only (not for publication or presentation), and which meet the criteria for the “exemption” category is solely the responsibility of the instructor and their department chair. The instructor should advise the IRB at the beginning of the semester, by submitting a memo or email, that such research will take place. It is the responsibility of the instructor and IRB co-chair to ensure that the project meets the requirements for an Exempt proposal, that all procedures for informed consent are adhered to, and that copies of the protocol and forms along with justification for the exemption are kept on file in the department office for three years after the end of the semester’s activities.

When principal investigators wish to audio record or video record University classes, students have the right to refuse participation. At the same time, students should not be penalized by losing significant classroom instruction in the event they decide not to be recorded. The following procedures should be used: (i) the principal investigator must notify students in advance that the class session will be recorded; (ii) recording must be stopped long enough before the end of the class to allow students to ask questions without appearing on the recording; and (iii) students must be given a full explanation of the project after the recording and given the option to arrange for deletion of their participation on the recording.

Recruitment of Subjects Who Are Clients of Social Service or Other Types of Institutions. The researcher shall not ask institutions to directly identify potential subjects for a research study. Rather, the investigator shall ask an intermediary (doctor, case worker, school administrator) to first approach potential subjects (or their guardians, as appropriate) and inform them about the research. If a potential subject agrees to participate, the intermediary should provide her/him with the information necessary to contact the researcher, in such a way that the institution is unaware whether the subject chooses to participate in the research. The intermediary should not obtain consent from potential subjects.

The researcher shall not ask institutions to release records or anecdotal information either for the purposes of identifying subjects, or for examination by the investigator, unless this information is public. An investigator wishing to examine records must first obtain permission of the subject via an intermediary. If a potential subject agrees to release his or her records, the intermediary should provide the information necessary to contact the researcher.
Advertising for Participants. If advertising for participants, principal investigators must follow these guidelines:

- Information must not be misleading to subjects, especially when a study will involve vulnerable populations;
- Include the name of the principal investigator, the purpose of the research and eligibility criteria for participation as subjects, a clear description of any benefits and/or risks of participating, the affiliation of the researcher, the location of the research and whom to contact for further information;
- If a drug or device is to be used in the research, no claim should be made as to its superiority, safety or effectiveness;
- A copy of the advertisement must be included with the IRB Research Application.

Inclusion of Women and Minorities as Research Subjects. All research that is supported by the NIH must provide information on the age ranges, gender, racial/ethnic composition and health status of the subject population. If this information is not included in the IRB Research Application, the principal investigator must provide a clear rationale for exclusion of this information.

Compensation for Participation.

Financial Compensation. If financial compensation is offered for participation in research, a pro-rated payment system should be used whenever possible. For example, when subjects choose to withdraw from participation early, they should receive a portion of the payment relative to the time spent participating in the study. The use of a drawing is not permitted as a form of compensation.

Academic/Extra Credit. If participating students will be awarded academic or extra credit for participating in research activities, the amount and type of credit as well as any required conditions must be clearly stated in the consent documents. Alternate academic or extra credit options must be available for students who do not wish to participate in the research and students must be informed that they may complete alternatives to receive the same credit as part of the consent process. The amount and type of academic or extra credit for nonparticipating students must be of equal difficulty and effort as participation in the study. If a participating student withdraws before completion of the study, such student must also be provided the academic or extra credit option available to nonparticipating students. The academic or extra credit opportunities for nonparticipating students shall be described in the IRB Research Application.

A copy of the class syllabus describing the academic and research extra credit options should be provided as part of the IRB Research Application.

Transportation of Research Participants. Research subjects shall not be transported by research team personnel in a personal or private vehicle or reimbursed for travel expenses unless under special circumstances.

F. Types of Risks to Research Subjects.

The risks to subjects fall into five broad categories: (1) physical; (2) psychological; (3) sociological; (4) economic; (5) and legal. The IRB will weigh the potential risks of research against the potential benefits as part of the review process. Principal Investigators are expected to list the probability and severity of the potential risks in addition to describing how he/she will take steps to minimize potential risks.
Physical Risks. Physical risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. A physical risk may result from the involvement of physical stimuli such as noise, electric shock, heat, cold, electromagnetic or gravitational fields, etc. Engaging a subject in a social situation which could involve violence may also create a physical risk.

Psychological Risks. Psychological risks include the production of negative affective states such as anxiety, depression, guilt, shock and loss of self-esteem and altered behavior. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.

Sociological Risks. Sociological risks include alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect from others, labeling a subject in a way that will have negative consequences, or in some way diminishing those opportunities and powers a person has by virtue of relationships with others.

Economic Risks. Economic risks include payment by subjects for procedures not otherwise required, loss of wages or other income (including missed work or lost benefits) and any other financial costs, such as damage to a subject's employability, as a consequence of participation in the research. These risks need to be explained to the potential subjects, even if they are being compensated for their participation.

Legal Risks.

Loss of Confidentiality: In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Subjects have the right to be protected against injury, illegal invasions of privacy and preservation of their personal dignity. The more sensitive the research material the greater the care that must be exercised in obtaining, handling, and storing data. In order to minimize the risk of loss of confidentiality, principal investigators should:

- Only collect personal information that is absolutely essential to the research activity;
- Data should be coded as early in the activity as possible, and plans for the ultimate disposition of the data should be made;
- Data should be securely stored and accessible only to the principal investigator and authorized staff;
- Identities of individual subjects should not be released without express permission of the subject;
- Inquire about data which was originally obtained for different purposes that involve identifiable subjects (e.g., a code list for the data still exists), and understand if it requires examination of the risk involved. A determination must be made whether the new use is within the scope of the original consent or whether obtaining additional consent or IRB approval is necessary and feasible, and provision made for the preservation of anonymity of the subjects;
- If Protected Health Information (“PHI”) will be collected from subjects, see Section XIII for more information on de-identifying PHI and what information and attachments must be included with the Research Application;
• An identifier that links a subject to identifiers kept elsewhere can increase the risk for loss of confidentiality. If records are linked to a second set of records (e.g., test scores linked to school grades) and the second set of records is identifiable, then the first set would also be identifiable. The risk of loss of confidentiality or privacy may also be elevated by identifying subjects as a qualified participant for a study (e.g., membership in Alcoholics Anonymous). The investigator should decide whether the information or data could be traced back to an individual subject, and make appropriate safeguards to ensure that confidentiality will be maintained. Please also refer to Section XLE (regarding Recruitment) above for information on accessing subjects’ records.

**Criminal or Civil Liability.** Criminal or civil liability risks exist when the research methods are such that the subject or others may become liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which they may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.

**Additional Risks: Deception.** Occasionally, some degree of deception is involved in a research study. Minor deception, such as failing to tell the subject what the specific points of interest are in an attempt to prevent biasing the results, can be acceptable provided the subject is fully debriefed after participating. Risks stemming from major deceptions, such as leading a subject to believe that he/she has committed a crime or has a disease, must be clearly counterbalanced by the benefits of the research. Withholding information cannot be used as a means to secure the participation of subjects in research.

**Debriefing Required.** The use of deception imposes special responsibilities on the principal investigator. One of these responsibilities is to provide appropriate debriefing to the subjects. In each case, the IRB will require information as to why deception is needed, how the potential benefits justify its use, and how debriefing will be done. If information was temporarily withheld from the subject during the study, or if deception was employed, a separate debriefing statement should be presented to the subject at the end of the research activity. This statement should clearly indicate why information was withheld during the study, and/or the purpose of the deception. Such information must be provided as part of the IRB Research Application.

**Mitigating Risk in Deceptive Research.** If the research involves deception of the subjects (regarding the nature or purposes of the research), the risk may be minimized if the subject authorizes the deception through a prospective agreement to participate in research in circumstances where the subject is on notice that he/she will be unaware of, or misled, regarding the nature or purposes of the research.

**G. Evaluating “Minimal Risk.”**

Defining "minimal risk" in research involving human subjects is useful for both the investigator and the IRB, in that research involving more than minimal risk requires additional elements in the informed consent documents, including a liability clause, and may require Full Review by the IRB. Projects with minimal risk are generally eligible for Exempt or Expedited Review.

**Minimal Risk Defined.** The federal regulations governing research with human subjects define minimal risk as follows: “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.”
In broad terms, a project may involve minimal risk if:

- the subjects experience no pain or physical danger beyond the levels normally to be expected in their everyday lives;
- the subjects experience no emotional arousal or psychological stress beyond the levels normally to be expected in their everyday lives;
- the project neither induces nor attempts to induce long-term significant change in the subjects’ behaviors (including attitudes toward self and others);
- the data would not embarrass or socially disadvantage subjects, were confidentiality lost; or,
- any concealment on the part of, or misinformation provided by, the principal investigator with regard to the specific purpose of the project is such that there is no basis for believing the subject would choose not to participate in the research had the true state of affairs been made known to him or her.

Additional Considerations to Determine Risk Level. Additional considerations for determining if the risk to subjects is minimal include whether the project provides a novel environment for the subject, or whether the subject will be exposed to situations which would not be considered a risk for the general public but might be risky for a special population such as disabled, young or elderly subjects.

Who Determines if the Risk to Subjects is Minimal, or Greater than Minimal? The IRB will make the final determination as to the research activities’ level of risk to subjects and the safeguards required to minimize risks for subjects.
XII. INFORMED CONSENT

A. Definitions.

**Informed consent** means the knowing consent of an individual, or his/her legally authorized representative, which is obtained prior to participation without undue inducement or element of force, fraud, deceit, duress, or other forms of constraint or coercion.

A **consent form** confirms informed consent and is designed to protect the investigator and the institution against legal liability.

B. Principal Investigator's Responsibilities for Informed Consent.

- The principal investigator is responsible for obtaining proper informed consent for all research subjects and for ensuring that no human subjects will be involved in any research activities prior to obtaining their consent.

- In obtaining informed consent, the principal investigator must minimize the possibility of coercion or undue influence.

- The principal investigator must ensure that each person who signs or is provided a consent form is given a copy of the consent form.

- The principal investigator is responsible (a) for placing the signed consent documents in a repository approved by the Office of Research & Sponsored Programs, and (b) for retaining completed consent forms pursuant to the retention schedule (see Section XVII).

- Unless such requirements are modified or waived by authorization of the IRB, the principal investigator is responsible for ensuring that legally effective informed consent:
  
  - is obtained from each research subject or the subject's legally authorized representative, memorialized in a written consent form, approved by the IRB, signed by the subject or the subject's legally authorized representative;
  
  - is in a language understandable to the subject or the representative;
  
  - is obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate and ask questions; and
  
  - does not include exculpatory language through which the subject or representative must waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.
C. Drafting the Consent Form.

- **Key Information.** Information considered essential to the decision whether to participate must receive priority by appearing at the beginning of the consent form and must be presented first in the consent discussion. This Key Information is what is most likely to assist a prospective subject (or legally authorized representative) in understanding the reasons why one may or may not want to participate in the research. The information must be clearly presented and organized.

- **Clear and Precise Wording.** One of the most common reasons for delay of approval of a protocol is an inadequate consent form. The consent form should be a statement addressed to the subject. Ordinarily, consent forms are worded in the second person (e.g., “you” or “your”). Consent forms must be in language the subject can understand (avoid or define technical terminology, adjust for educational background and ages, provide translations in other languages when subjects do not understand English). Informed consent must present information in sufficient detail and must be organized and presented in a way that does not merely provide lists of isolated facts. The consent form must facilitate the prospective subject’s (or the legally authorized representative’s) understanding of the reasons why one may or may not want to participate.

- **Children as Subjects.** Separate forms and addendums may be required for different subject groups (parents, children, University of the Pacific students, etc.). If subjects are children, assent forms must be used for the children in addition to obtaining signed consent forms from the children’s parents or guardians.

- **Research in Other Jurisdictions.** If research will be conducted overseas or in another jurisdiction, local laws or customs may require alternate or additional assent or consent requirements.

D. Delegating Informed Consent.

Investigators may not delegate the responsibility of obtaining informed consent to another person without IRB approval. If an investigator intends to delegate the responsibility, s/he should provide the name of the specific individual(s) that this duty is delegated to in the IRB Research Application. Those individuals must also be trained on human subject research, but ultimately the principal investigator must ensure that informed consent is properly obtained.

E. Required Elements of an Informed Consent Form.

Pursuant to 45 CFR § 46.116, a written consent form must include the following elements. In addition, special provisions are required when subjects are from vulnerable or special populations (refer to Section XV. (page 68).

- **Key Information Must be Presented First:**
  - **Research Involved.** Consent is being sought for research;
  - **Voluntary participation.** A statement that the subject’s participation is voluntary;
• **Purpose of Research.** An explanation of the purposes of the research;

• **Duration of Participation.** The expected duration of the subjects' participation;

• **Research Procedures.** A description of the research procedures to be followed;

• **Foreseeable Risks.** A description of any reasonably foreseeable risks or discomforts to the subject;

• **Benefits.** A description of any benefits to the subject or to others which may reasonably be expected from the research;

• **Alternative Procedures.** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

➢ **Disclosure of Experimental Procedures.** Identification of any procedures which are experimental;

➢ **Confidentiality.** A statement describing how confidentiality of records identifying the subject will be maintained (HIPAA regulations must be followed to protect identifiable medical information, if applicable);

➢ **More than Minimal Risk.** For research involving more than minimal risk (as described in Section XI of this Manual), the consent form must include an explanation of compensation, available medical treatments (if necessary), who is responsible for payment of medical expenses incurred as a result of participation in the study, and where further information may be obtained. The following language is suggested where the subject is responsible for medical expenses:

> You or your own insurer is responsible for any medical expenses resulting from injuries to you caused by your participation in this research project. If you are a University student or employee covered by a University medical plan, the terms of that plan may apply to such an injury.

➢ **Contact Information.** An explanation of:

- who the principal investigator is, his/her business phone number, (include faculty advisor name and phone number if appropriate) and what institution he/she represents.

- whom to contact regarding research subjects' rights (in the Office of Research and Sponsored Program or IRB Administrator); and

- whom to contact or where to go in the event of a research-related injury to the subject.

➢ **No Penalty or Loss of Benefits for Not Participating.** A statement that a subject's refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled;
Discontinuance of Participation at Option of Subject. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

If Collecting Identifiable Private Information or Identifiable Biospecimens. Include one of the following statements:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Acknowledgement. A statement that the subject has been informed about the research study and had an opportunity to ask, and have answered, any questions he/she has regarding participation in the study;

Copy of Consent Form. A statement that the subject may keep a copy of the consent form;

IRB Approval. A place for approval signature and date by a representative of the IRB (with such IRB approval included on consent forms used in the study); and

Subject’s/Representative’s Signature. A place for the research subject’s signature, date, and for the name, signature, and description of authority of the subject’s legally authorized representative, if applicable. The signature may be waived if the subjects are members of a cultural group or community in which signing forms is not the norm.

F. Additional Elements to Include in Informed Consent Forms if Appropriate.

Unforeseeable Risks. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.

Dismissal of Subject. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

Additional Costs to Subject. Any additional costs to the subject that may result from participation in the study.

Consequences of Withdrawal from Study. The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation.

Notification of New Findings Affecting Willingness to Participate. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue will be provided to the subject.
Number of Subjects. The approximate number of subjects involved in the study.

Compensation to Subjects. If subjects will be paid, include all information concerning payment, including amount and schedule of payment. If compensation is funded by Pacific, a statement regarding release of contact information to University Finance for tax purposes must also be disclosed in consent form.

Disclosure of Conflicts of Interest. A disclosure of any conflict of interest that may be present.

Commercial Profit. A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

Research Results. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

Genome Sequencing. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a somatic specimen with the intent to generate the genome or exome sequence of that specimen).

G. Broad Consent.

A principal investigator may obtain informed consent through the broad consent process; or, instead of obtaining broad consent, a principal investigator may: (i) conduct the research on non-identified information and non-identified biospecimen and request that the IRB waive the informed consent requirement; or (ii) obtain informed consent (as set forth in Sections XII.E-F, above). Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements set forth in Section XII.E (and F) above. If the subject (or legally authorized representative) is asked to provide broad consent, the following shall be provided to the subject (or legally authorized representative):

- **Foreseeable Risks.** A description of any reasonably foreseeable risks or discomforts to the subject;
- **Benefits.** A description of any benefits to the subject or to others which may reasonably be expected from the research;
- **Confidentiality.** A statement describing how confidentiality of records identifying the subject will be maintained (HIPAA regulations must be followed to protect identifiable medical information, if applicable);
- **Voluntary participation.** A statement that the subject’s participation is voluntary;
- **No Penalty or Loss of Benefits for Not Participating.** A statement that a subject’s refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled;
- **Discontinuance of Participation at Option of Subject.** A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- **Commercial Profit.** A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

- **Genome Sequencing.** For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a gum germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);

- **Description of Research.** A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

- **Description of Identifiable Information/Biospecimens.** A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

- **Duration of Storage, Maintenance, Use.** A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

- **Whether Research Details to be Provided.** Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject’s identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

- **Research Results.** Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject;

- **Contact Information.** An explanation of who to contact for answers to questions about the subject’s rights and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm; and

- **Documentation.** Broad consent must be appropriately documented or the documentation requirement may be waived, if appropriate.

**H. Acceptable Forms of Consent Documentation.**

The informed consent procedure may allow for written or oral consent as approved by the IRB:
Written. A written document that contains the required elements of informed consent as outlined in Section XII.E-G, above, to be read and signed (including in an electronic format with a written copy provided the subject) by the subject or the subject's legally authorized representative; or

Oral Presentation Documented in Writing. A written short form stating that the basic elements of informed consent, including the Key Information being presented first, were presented orally to the subject or legally authorized representative with the short form signed by the subject. The short form and summary of the oral presentation will be provided to the IRB. (See Section J below for more information on oral consent).

I. IRB Waiver of Documentation of Informed Consent.

Informed Consent is a process, not a document. Under certain conditions, the IRB may waive the requirement that the subject sign the written consent form. However, waiver of documentation of informed consent does not constitute waiver of the requirement to obtain informed consent. The IRB may waive the requirement for a principal investigator to obtain a signed informed consent form for some or all of the subjects if one of the following conditions exists:

- The consent document is the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality. Subjects (or legally authorized representatives) will be asked whether or not they want documentation linking them to the research, and the subject’s wishes will prevail;

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

For projects of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter attached to the questionnaire, which includes a statement that completion and return of the questionnaire will constitute consent to participate (a sample letter may be found in the appendix).

In cases where the IRB waives the informed consent documentation requirement, the IRB may still require the investigator to provide subjects with a written statement regarding the research. Requests to waive the informed consent documentation requirements must be included in the IRB Research Application.

J. Oral Consent.

Only in special and/or unusual circumstances can the consent of the subjects be obtained orally. Requests to obtain oral consent to waive the prior written informed consent requirement must be included in the IRB Research Application and approved by the IRB. The IRB may waive prior written informed consent and allow oral consent where:
The risk to the subject is minimal;

Use of primary procedures for obtaining written consent would invalidate important research objectives; or

Alternative means would be less advantageous to the subjects.

Oral presentation of the elements of informed consent should be used only when it is the most appropriate means of conveying required information to the subject, thus adapting the presentation to the subject's capacities. The oral presentation may be made in either of two ways:

- a written consent document that sets forth the required basic components of informed consent may be read to the subject or the subject's representative and the investigator will allow the subject or representative ample time to read and consider the document before it is signed; or

- the IRB may approve a short written form describing the particulars of required informed consent that are to be presented orally to the subject or representative.

Where oral consent (with use of the short form) is approved by the IRB, investigators shall ensure that:

- The oral presentation follows the written summary approved by the IRB regarding what is to be said to the subject or the representative;

- The Key Information is presented first;

- A witness is present at the oral presentation;

- The IRB approved short form is signed by the subject or the legally authorized representative;

- The witness signs both the short form and a copy of the written summary of the oral presentation;

- The person obtaining consent signs a copy of the summary; and

- A copy of the summary and short form are given to the subject or legally authorized representative.

**K. Waiver or Alteration of Informed Consent.**

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided one of the following sets of conditions exists and is documented in the IRB Research Application. The elements of Key Information set forth in Section XII.E may be waived if the informed consent procedure is completely waived, but Key Information may not be altered or omitted.

**Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs Conducted By or Subject to the Approval of State or Local Officials.** The IRB may waive the requirement to obtain informed consent, or approve a consent procedure that alters some of the elements of informed consent set forth in Section XII.E-F (except for Key Information), provided the IRB satisfies the following:
The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternative to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs; or,

The research could not be practically carried out without the waiver or alteration.

General Waiver or Alteration of Informed Consent. The IRB may waive the requirement to obtain informed consent, or approve a consent procedure that alters some of the elements of informed consent set forth in Section XII.E-F (except for Key Information), provided the IRB satisfies the following:

- The research involves no more than minimal risk to the subjects;
- The research could not practically be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practically be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Limits on Waiver and Alteration of Broad Consent. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements set forth in Section XII.G above, and refused to consent, the IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. The IRB may not omit or alter any of the elements required for broad consent set forth in Section XII.G above.

L. Exception to Informed Consent for Activities Involving Screening, Recruiting, or Determining Eligibility.

The IRB may approve a research proposal where the principal investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative if either of the following conditions is met:

- The principal investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; or
- The principal investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
M. Confidentiality/Anonymity.

In the informed consent procedure, subjects are often given reasonable assurances of protection against loss of confidentiality. Despite these assurances and subsequent efforts to preserve confidentiality, subjects may still be identifiable. For this reason, the principal investigator (and any member of the research team) should not promise anonymity.

Despite the University's attempts to protect confidentiality of subjects, the loss of confidentiality can occur in a legal proceeding when a court requires that research files must be submitted as evidence in a legal matter. The court may decide who has access to the files and whose identity must be revealed. In addition, loss of confidentiality can occur under the federal Freedom of Information Act (hereinafter, “FOIA”) or the California Public Records Act (“Cal. PRA”) if research records are provided to federal, state, or local agencies. Under FOIA or Cal. PRA, citizens can gain access to files of government agencies, unless an exception applies.

The University is obligated to protect subjects' identities when the promise of protection is made in obtaining their consent to participate. This obligation can be fulfilled in the following ways:

- Research files may utilize a coding system to identify subjects. Where the identity of subjects is not necessary for research purposes, no master code should be created.
- Confidentiality may not be preserved by locating the master code lists outside the University or the jurisdiction of the court, i.e., on a personal computer or in another country.
- Anonymity may be assured when there are no identifiers whatsoever on project materials which could link the data with individual subjects.
- Identifying records may be destroyed pursuant to the applicable IRB records retention policy. Participants should be informed if identifying information will be sent to a governmental agency, due to the potential for disclosure under FOIA or Cal. PRA.

N. Assessing Legal Age.

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person aged 18 years old or older to have attained the legal age for consent.

O. Forms.

Templates for informed consent forms for adults and assent forms for children can be found in the Appendix or at the Human Subjects Research website. Researchers need not copy the form language verbatim, but all required elements must be included in the informed consent form. If required, the IRB or IRB Staff will affix to the approved Informed Consent document an approval and expiration date for research that must be conducted during specific timeframes.

- Sample Long Form Informed Consent Form (for Research Subjects over Age 18)
- Sample Short Form Informed Consent (for Research Subjects over Age 18)
- Sample Short Form Summary of Informed Consent (Oral) (for Research Subjects over Age 18 who are presented the required consent items orally)
- Sample Children’s Assent Form (for Research Subjects under Age 12)
- Sample Children’s Parent Consent Form (for Research Subjects under Age 12)
- Sample Consent for Non-sensitive Questionnaires (for Research Subjects over Age 18)
- Broad Consent Checklist and Sample Form
- Informed Consent Checklist (Required and Additional Elements) (for Research Subjects over Age 18)
XIII. RESEARCH INVOLVING PROTECTED HEALTH INFORMATION (PURSUANT TO HIPAA)

A. Applicable Law and Policies.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) has three components: the Privacy Rule which protects the privacy of individually identifiable health information; the Security Rule which sets standards for the security of electronic protected health information (“ePHI”); and the Breach Notification Rule which requires covered entities and business associates to provide notification following a breach of unsecured protected health information. In the event of any data security incident involving a breach, or suspected breach, of unsecured protected health information, the principal investigator, researcher, or faculty advisor (if any) shall immediately report such incident to the IRB Administrator who, along with the IRB, the Office of Research & Sponsored Programs and other University offices, will assist in coordinating the applicable notifications pursuant to the University’s data breach procedures. The IRB Administrator will ensure that the IRB Co-Chairs are promptly informed of the incident.

B. Covered Entity.

The term used for the holder/transmitter of PHI. Specifically, it means: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with transactions for which the Secretary of the Federal Department of Health and Human Services has adopted standards under HIPAA. The University is a hybrid covered entity, meaning that some, but not all, components of the University provide health care and are therefore subject to HIPAA.

C. Protected Health Information.

Protected Health Information (“PHI”) is individually identifiable health information held or transmitted by a covered entity or its business associates, in any form or media, whether electronic, paper or orally.

D. HIPAA Authorization.

If research activities include the collection or creation of PHI, the principal investigator must: obtain authorization that complies with HIPAA from each research subject or obtain a waiver of authorization granted by the IRB unless the PHI is de-identified or a limited data set (as discussed below). Further, the principal investigator must safeguard the research data that includes PHI with appropriate physical, technical and administrative controls. HIPAA Authorization is a research subject’s permission to allow the University to use or disclose the subject’s PHI for the purposes and to the recipients stated in the Authorization. Informed consent, on the other hand, is a research subject’s agreement to participate in the research study, among other things. A HIPAA Authorization may be combined with an informed consent document, or it can be obtained via a separate form.

General HIPAA Authorization Requirements.

- Must be written in plain language.
- A copy of the signed Authorization must be provided to the individual signing it if the University is seeking the Authorization.
Federal law does not specify who must draft the Authorization but the IRB has provided a sample form, HIPAA Authorization Form, for general research purposes.

The Core Elements and Required Statements (described below) must be included.

**HIPAA Authorization: Core Elements.**

- Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).
- The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.
- The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the University may make the requested disclosure.
- Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, and not for future unspecified research.
- Authorization expiration date or event that relates to the research subject or to the purpose of the use or disclosure (the terms “end of the research study” or “none” may be used for research, including for the creation and maintenance of a research database or repository).
- Signature of the research subject and date. If the Authorization is signed by a research subject’s personal representative, include a description of the representative’s authority to act for the research subject.

**HIPAA Authorization: Required Statements.**

- The research subject’s right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the research subject may revoke Authorization, or (2) reference to the corresponding section(s) of the University’s Notice of Privacy Practices.
- Notice of the University’s ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.
- The potential for the PHI to be re-disclosed by the recipient and no longer protected by HIPAA. This statement does not require an analysis of risk for re-disclosure but may be a general statement that HIPAA may no longer protect health information.
Effect of Revoking Authorization. A research subject may revoke his/her Authorization at any time. However, the University may continue to use and disclose PHI that was obtained before the individual revoked Authorization to the extent that the University has taken action in reliance on the Authorization. In cases where the research is conducted by the University, this would permit the University to continue using or disclosing the PHI as necessary to maintain the integrity of the research, as, for example, to account for a subject’s withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.

E. Individually Identifiable Health Information.

Information, including demographic data, that:

- Identifies the individual, or for which there is a reasonable basis to believe can be used to identify the individual; AND

- Relates to:
  - The individual’s past, present or future physical or mental health or condition,
  - The provision of health care to the individual, OR
  - The past, present, or future payment for health care to the individual.

F. De-Identified PHI.

If PHI is “de-identified” pursuant to HIPAA requirements, the data is not considered PHI because it does not fall under the definition of PHI. To be considered “de-identified” pursuant to HIPAA requirements, the University must not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information and the following 18 data elements must be removed from the research data (as described in CFR §164.514(b)(2):

- Names (individual, employer, relatives, etc.)
- Address (street, city, county, zip code – initial 3 digits if geographic unit contains less than 20K people, or any other geographical codes)
- Telephone Numbers
- Fax Numbers
- Social Security Numbers
- Dates (except for years) including:
  - Birth Date
  - Admission Date
  - Discharge Date
  - Date of Death
- Ages >89 and all elements of dates indicative of such age (except that such age and elements may be aggregated into a category “Age>90”

- E-mail Addresses
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) Addresses
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints)
- Full-face photographs and any comparable images
- Any other unique identifying number, characteristic, or code

Or, alternatively, a person (otherwise considered an “expert”) with appropriate knowledge and experience applying generally accepted statistical and scientific methods for rendering information not individually identifiable applies such principles/methods, determines the risk is very small that the information could be used alone or in combination with other available information to identify an individual, and documents the methods/results that justify the determination.

G. Limited Data Set.

PHI from which 16 specific individual identifiers have been removed. The research use of a Limited Data Set may or may not be considered human subjects research, depending on whether the information is individually identifiable as defined by human subjects regulations. If the information is not individually identifiable, then the use of the Limited Data Set does not require IRB review.

How to Determine Research Using Limited Data Set is Subject to IRB Review:
Researchers may use the Human Subjects Research Worksheet or the Existing Data/Specimen Research Application to self-determine whether the research is human subjects research subject to IRB review. Researchers may request the IRB formally determine whether IRB review is needed by submitting the Existing Data/Specimen Research Application.

How to Obtain a Limited Data Set: HIPAA regulations require the principal investigator to enter into a Data Use Agreement (“DUA”) with the covered entity providing the data. The DUA promises specified safeguards and specific uses for the data.
H. IRB Waiver of HIPAA Authorization.

HIPAA allows an IRB to approve a waiver or alter the HIPAA Authorization process for any covered entity. However, covered entities may have institutional policies that additionally require other processes, groups or offices to approve such a waiver. The IRB expects principal investigators to request a waiver by providing the necessary information in the IRB Research Application. However, principal investigators may have omitted this information or be unaware that their research was eligible for a waiver. The IRB is authorized to grant a waiver without an explicit request if the IRB determines it is appropriate and if the IRB Research Application provides sufficient information to evaluate the waiver criteria.

I. Forms.

HIPAA Authorization Form.

HIPAA Privacy Rule Questionnaire
XIV. RESEARCH INVOLVING EXISTING INFORMATION AND BIOSPECIMENS IN RETROSPECTIVE RESEARCH AND SECONDARY RESEARCH

A. Research Involving Existing Information or Biospecimen.

If a principal investigator intends to use non-identifiable existing information or biospecimens which is eligible for Exempt Review Category 4 or Expedited Review Category 8 (Continuing Review), the principal investigator may use the Existing Information/Biospecimen Research Application to obtain the IRB’s review and approval of such research activities. If the research activities do not fall under Exempt Category 4 or Expedited Category 8, the principal investigator must use the IRB Research Application and obtain the IRB’s review and approval.

B. Secondary Research.

“Secondary Research” is a new concept added to the Common Rule commencing in 2018, which involves re-using identifiable information and identifiable biospecimens that were collected for some other “primary” or “initial” activity. Three types of secondary research may be eligible for Exempt Review (Exempt Categories 4, 7 and 8). (See Section X for more information about the various categories eligible for Exempt Review.)

C. Forms.

Existing Information/Biospecimen Research Application

Data Use Agreement
XV. VULNERABLE AND SPECIAL SUBJECT POPULATIONS

A. IRB Considerations Regarding Research Subjects Generally.

When considering approval of research, the IRB considers issues such as the selection of participants, privacy and confidentiality, coercion and undue influence, and performs a risk-benefit analysis. Decisions are guided by the ethical principles underlying human research as set forth in the Belmont Report. The IRB is cognizant of the vulnerable nature of many research subjects.

B. Types of Vulnerable Populations Given Special Consideration.

Special consideration is given to protecting the welfare of vulnerable participants, such as children, prisoners, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons (which does not include physical disabilities or impairments). If the principal investigator believes that the subject population of the research is vulnerable, but is not included in the foregoing categories, contact IRB Staff to discuss appropriate safeguards to include in the IRB Research Application. Please contact the IRB Administrator to discuss appropriate safeguards if the subject population includes or is directed at veterans.

C. Federal Regulatory Requirements for Vulnerable Populations.

There are specific federal regulatory requirements for research involving vulnerable populations. In order to approve research involving vulnerable populations, the IRB must determine, where appropriate, that sufficient additional safeguards are included to protect the rights and welfare of participants who are likely to be vulnerable to coercion or undue influence. Additionally, the IRB will evaluate whether appropriate additional safeguards are necessary if the IRB has reason to believe that the subject population may be vulnerable for any other reason not otherwise covered by the federal regulations.

D. Full Board Review Generally Required for Vulnerable Populations But Expedited Review May Be Appropriate In Limited Circumstances.

In certain limited circumstances, the IRB Chair may determine that Expedited Review is permitted for research involving special or vulnerable subject population(s). Contact IRB Staff for details. Examples of research that may qualify for expedited review are: observation of public behavior of children involving no interaction, and surveys or interviews of children involving no risk.

E. Who to Contact if the Principal Investigator Believes Research May Involve a Vulnerable Population.

The IRB strives to include among its members persons who are knowledgeable about and experienced in working with populations considered vulnerable. If the principal investigator believes that the research subject population may be vulnerable, the principal investigator should contact IRB Staff for guidance in advance of submitting the IRB Research Application.

F. IRB Considerations in Reviewing Research Applications Involving Vulnerable Participants.

The IRB considers the following elements of the research protocols when reviewing research involving vulnerable subject populations:
Strategic issues that involve inclusion and exclusion criteria for selecting and recruiting participants; informed consent and willingness to volunteer; coercion and undue influence; and confidentiality of data.

Group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates sufficient additional safeguards for vulnerable participants.

Participant selection to prevent over-selection or exclusion of certain participants based on perceived limitations or complexities associated with those participants. For example, it is not appropriate to target prisoners as research participants merely because they are a readily available “captive” population.

Application of state or local laws that bear on the decision-making abilities of potentially vulnerable populations. State statutes often address issues related to competency to consent for research, emancipated minors, legally authorized representatives, the age of majority for research consent, and the waiver of parental permission for research. (Compliance with federal, state, and local laws is the responsibility of the principal investigator.)

Procedures for assessing and ensuring participants’ capacity, understanding, and informed consent or assent. When weighing the decision whether to approve or disapprove research involving vulnerable subject populations, the IRB will verify that such procedures are a part of the research plan. In certain instances, additional safeguards may be required to ensure understanding of potentially vulnerable subjects. Examples include requiring someone not involved in the research to obtain the consent, the inclusion of a consent monitor, a participant advocate, interpreter for hearing-impaired participants, translation of informed consent forms into languages the participants understand, and reading the consent form to participants slowly and ensuring their understanding paragraph by paragraph.

Need for additional safeguards to protect potentially vulnerable populations. For example, the IRB may require that the principal investigator submit each signed informed consent form to the IRB, that someone from the IRB oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time for family discussion and questions.

G. Vulnerable Populations Under Federal Regulations.

Four types of populations are considered “vulnerable” or “special” under federal regulations: (1) Adults with Impaired Decision-Making Ability; (2) Pregnant Women; (3) Children (Minors); and (4) Prisoners.

Adults with Impaired Decision-Making Ability. The IRB has and follows written policies and procedures requiring additional safeguards for prospective participants who cannot give consent or whose decision-making capacity is in question. Individuals with impaired decision-making ability are those with diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals may be considered to have impaired decision-making ability because they are under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill,
or have severely disabling physical handicaps. The IRB must determine whether such participants should be recruited or whether support mechanisms, such as surrogate consent (where a legally authorized representative consents on behalf of the subject), are appropriate.

**Preliminary Considerations Include:**

- Can the potential subject or his/her legally authorized representative understand the information?
- Can the potential subject or his/her legally authorized representative retain enough of the information to think the question through?
- Is the potential subject legally able (considered capable) to give consent?
- If not, should the potential subject be involved in the discussion anyway?
- What are the alternatives to participation for the potential subject? Does the potential subject believe that those alternatives are real?
- What are the pressures on the potential subject to consent or refuse? If surrogate permission is necessary, what are the pressures on the legally authorized representative to consent or refuse?
- Is the selection of potential subjects equitable, particularly given the special considerations raised by research involving vulnerable populations?

**Criteria for Inclusion of Adults with Impaired Decision-Making Ability in Research.** The IRB considers and evaluates the following criteria before approving research involving adult participants with impaired decision-making ability:

- Adequate provisions are made for obtaining consent from the subject or the subject’s legally authorized representative;
- The research protocol must include appropriate procedures for respecting subjects’ dissent;
- The protocol must have an adequate plan for the assessment of the capacity to consent;
- The research protocol must consider whether or not to include procedures for obtaining assent;
- Whether any additional safeguards need to be used (e.g., consent monitoring);
- No greater than minimal risk to the subject as determined by the IRB; or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the subject; or, if greater than minimal risk and no prospect of direct benefit to individual subjects, the research is likely to yield generalizable knowledge about the subject’s disorder or condition that is of vital
importance for the understanding or amelioration of the subject’s disorder or condition;

• The research must relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants (See CA Health & Safety Code 24178(b)), for example:
  o The disorder (e.g., Alzheimer’s) leading to the individual’s lack of decision-making capacity is being studied, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke), but only if the study cannot be performed with only persons who have decision-making capability; and
  o The subject of the study is not directly related to the individual’s lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the study (e.g., transmission of methicillin-resistant Staphylococcus aureus (MRSA) infections in a nursing home where both individuals with, and those without, decision-making capacity are affected).

Assessment and Evaluation of Competency. Competency should be evaluated on an individual basis to avoid incorrect assumptions as to an individual’s ability to make decisions. Criteria for determining competence might vary according to the degree of risk or discomfort presented by the research procedures and the extent to which therapeutic gain can be anticipated. Some approaches to this assessment include:

• Post-Consent Quiz. A post-consent quiz documenting the participants’ knowledge of critical elements in the informed consent document (e.g., subject/nature of the research being studied, voluntary nature of participation, ability to withdraw at any time, consequences of withdrawing, possible risks and benefits of participation, procedures involved, time required, confidentiality, and whom to call with any questions. See Sample Post-Consent Quiz at the end of this subsection for sample questions.

• Third Party (Physician) Evaluation. The principal investigator may ask a physician/psychologist in or outside the research team to evaluate the potential subject’s decisional capacity. A determination of competency shall be made after an appropriate medical evaluation that concludes there is little or no likelihood that the subject will regain competency in a reasonable period of time, or as established by legal determination. This definition of competency is not limited to the legal definition but also may be a clinical judgment that a person lacks the capacity to understand the circumstances of participating in research and to make an autonomous decision to take part in the research activities.
**Additional IRB Safeguards.** The IRB may also consider additional safeguards to protect vulnerable subject populations, such as:

- Requiring the involvement of participant advocates;
- Requiring independent monitoring;
- Requiring waiting periods; and,
- Appointing a monitor to supervise the informed consent process.

Such decisions to include additional safeguards may be based on the amount of risk involved in the research and the likelihood that participants will derive health benefits from their participation.

**Obtaining Consent from a Legally Authorized Representative.** The IRB, consistent with state and federal regulations, requires that consent for research be obtained from the participant’s legally authorized representative if the subject lacks the capacity to consent (e.g., Cal. Health & Safety Code § 24178). Section 24178 of the California Health and Safety Code specifies the legally authorized representative of the subject in most (but not all) research situations in California, and its requirements must be met before a surrogate may be used under its provisions. Pursuant to Section 24178 and if consistent with state and local law, legally authorized representatives may be:

- Persons appointed as health care agents under Durable Powers of Attorney for Health Care (DPAHC);
- Court appointed guardians; or,
- Next of kin in the following order of priority: spouse, adult child, parent, adult sibling, grandparent or adult grandchild.

**Participants in Psychiatric Units or Mental Health Facilities. Special Rules.** Surrogates for an inpatient of a psychiatric unit or a mental health facility or a patient on a psychiatric hold may not be able to consent for research under California laws, particularly if the research participant has been adjudicated to lack the capacity to consent and a conservator has been appointed. A principal investigator who intends to include subjects such as these patients with the possible need for surrogate decision makers should discuss the situation with the IRB Administrator in advance of submitting the IRB Research Application.

**Sample Post-Consent Quiz.** Below are sample questions to use if there is any doubt as to the subject’s ability to understand and consent to participate in the research:

- What are you doing here today? (Alternative: Are we doing a research study?)
- What is the purpose of the study? (Alternative: Is the purpose of the study to learn more about [subject of study]?)
- How long is your role expected to take? (Alternative: How long are we going to talk for?)
What do you have to do to be a part of the study? (Alternative: Are you going to answer some questions for us?)

Are there any risks to your helping us? (Alternative: Are you in any danger? Will there be any discomfort? Will the questions hurt you?)

Is what you tell us confidential? (Alternative: Will we keep what you say a secret?)

Do you want to help us with our research?

Is anyone making you help us?

Do you have the right to end your participation at any time?

Will anything bad happen to you if you don’t help us?

Will anything good happen to you if you help us?

If you have questions, who should you call?

Children and Assenting Minors. Federal regulations impose additional protections on research involving children.

Children. By regulatory definition, “children” are 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. In California, a person under 18 years old is considered a “child,” and may not legally give consent, although there are certain exceptions for emancipated and self-sufficient minors.

Parental Permission. Since children cannot legally give consent, informed consent must be obtained from parents via parental permission, or the legally appointed guardian. The IRB requires the principal investigator to obtain the permission of a child's parent(s) or guardian before enrolling the child in a study.

Assent. When, in the judgment of the IRB, the children are capable of providing assent, the IRB may determine that assent is required - that adequate provisions are made for soliciting the assent of the children - and whether and how assent must be documented. Federal regulations do not specify the required age range for assent, and the IRB will evaluate this requirement on a case-by-case basis as part of the review of the IRB Research Application. Generally, children aged 7-18 may be asked to give their assent to participation.

Prisoners.

Additional Protections. Federal regulations consider prisoners to be a vulnerable population because both their incarceration and the constraints imposed on them during their incarceration may render them unable to make a truly informed and voluntary decision regarding whether to participate in research. Therefore, the IRB imposes additional protections pertaining to biomedical and behavioral research involving prisoners, limits the types of research that can be approved,
and requires special consent information. The principal investigator who intends to propose a research project involving prisoners should contact IRB Staff prior to submission of the IRB Research Application.

**California Law.** As required by California law, the IRB evaluates the consent process and the consent document to ensure that the information disclosed to the participant covers the requirements of California Penal Code §§ 3521-3522. These California consent requirements are identical to the federal regulations, except California law requires that the prisoner participant be informed of the expected recovery time after completion of the experiment.

**H. Other Potentially Vulnerable Populations.**

In addition to the populations deemed considered vulnerable under federal regulations, the following populations may also require special considerations and additional safeguards:

- **Pregnant Women.** Contact IRB Staff if the research may involve pregnant women, or human fetuses or neonates because federal regulations include specific requirements. Investigators must document specific findings to minimize the potential for risk or harm to the fetus, and additional attention must be given to the conditions for obtaining informed consent. In general, research involving pregnant women, human fetuses, and neonates should involve the least possible risk.

- **Illiterate Participants.** The IRB allows individuals who speak and understand English, but who cannot read the consent materials due to illiteracy, to enroll in a study by “making their mark” (e.g., signing or marking an “X”) on the consent document, after going through the informed consent process.

- **Additional Protections.** If a potential subject, or his/her legally authorized representative, is illiterate: (i) Information in the consent materials should be presented orally, including the California Experimental Subject’s Bill of Rights (as appropriate, and for clinical investigations); and (ii) Sufficient time should be allowed for questions to be asked and answered, both by the potential subject, and by the person obtaining consent to ensure the potential subject comprehends the consent information.

- **Documenting Consent for Illiterate Participants.** Additionally, the IRB suggests the following for documenting the consent process when a participant is competent and understands and comprehends spoken English, but is physically unable to talk or write, but can indicate approval or disapproval by other means:
  - Involve an impartial witness, present during the entire informed consent discussion, who signs and dates the consent document,
  - Consider audio or video recording the consent discussion,
  - The person obtaining consent (“POC”) might document on the consent form the method used for communication with the
prospective subject and the specific means by which the prospective subject communicated agreement to participate.

- **Copy of Signed Consent.** Participants (or their legally authorized representative) must be given a copy of the signed consent document(s), and any other written information provided to participants.

  ➢ **Non-English Speaking Participants.** Principal investigators are encouraged to recruit and include all segments of the community in research, including individuals whose primary language is not English. Participants who do not speak English should be presented with a consent document written in a language understandable to them, and which embody all the elements necessary for legally effective informed consent.

  - **Translated Full Consent Form.** The IRB strongly encourages the use of a long-form consent form translated into the potential subject’s language whenever possible. When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is required and must be included in the IRB Research Application, including an English version, prior to the commencement of any research activities.

  - **Translators and Interpreters.** Principal investigators may use language translators or interpreter services to obtain consent in a language understandable to the participant or the participant's legally authorized representative. The qualifications of the translators/interpreters, and the use of any such services, must be disclosed in the IRB Research Application.

  - **Potential Expedited Review of Forms Translated After Initial IRB Approval or Conditional Approval.** The IRB may utilize Expedited Review procedures in approving such translated informed consent documents if the English language consent document has already been approved.
XVI. ADDITIONAL GUIDANCE ON CERTAIN TYPES OF RESEARCH

A. Ionizing Radiation.

Principal Investigators who wish to enroll human subjects in research that results in the absorption of ionizing radiation (e.g., x-rays, DEXA scanner, etc.) are required to obtain written approvals from the IRB and may involve governmental oversight before the research is initiated.

B. Genetic Research.

Any researcher who proposes to conduct genetic research, including anonymous research, must submit the research to an IRB for a determination that the research is anonymous or for approval if the research is not exempt.
XVII. RETENTION OF RECORDS

A. IRB Records.

Although the IRB will maintain copies of the documents submitted to it for review as part of its review of the IRB Research Application (as described below), the principal investigator is responsible for maintaining records related to the research activities. For illustrative purposes, the IRB will maintain a copy of the informed consent templates submitted as part of the IRB Research Application, but it is the responsibility of the principal investigator to maintain copies of the informed consent forms signed by research subjects or their authorized representatives for at least three years.

➢ **IRB Records Defined.** The IRB shall maintain the following documents in accordance with 45 C.F.R. § 46.115 in printed form or electronically:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators and reports of injuries to subjects;
- Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB, the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion or controverted issues and their resolution;
- Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in 45 CFR § 46.109(f)(1);
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members in the same detail as described in 45 CFR § 46.108(a)(2);
- Written procedures of the IRB in the same detail as described in 45 CFR § 46.108(a)(3);
- Statements of significant new findings provided to subjects, as required by 45 CFR § 46.116(c)(5).
- The rationale for an expedited reviewer's determination under 45 CFR § 46.110(b)(1)(i) that research appearing on the expedited review list described in 45 CFR § 46.110(a) involves more than minimal risk;
- Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of the DHHS regulations, as described in 45 CFR § 46.103(e).
- The principal investigator shall also provide the IRB with a copy of the final research publication.
B. Principal Investigator’s Records

➢ **Research Data Defined.** The principal investigator is responsible for the collection, management and retention of research data (including, without limitation, informed consent forms, questionnaires, and other documentation created or collected as part of the research activities).

➢ **Retention for At Least Three Years.** Research data must be archived by the principal investigator for a minimum of three years after the conclusion of the research, with the original data retained wherever possible. It may be necessary to retain research data for longer periods of time, for example to protect any intellectual property resulting from the work, until allegations of research misconduct are resolved, or until a degree is awarded to the student involved in the research.

➢ **Location of Research Data.** Research data shall be stored in a repository approved by the Office of Research & Sponsored Programs for a minimum of three years after the conclusion of the research. The Office of Research and Sponsored Programs may also provide data storage guidance or requirements depending on the nature of the records (e.g., when the research involves “protected health information” as defined by HIPAA).

➢ **Destruction of Research Data.** Beyond the period of retention specified here, the destruction of the research records is at the discretion of the principal investigator and his/her department or school. Upon conclusion of the retention period, the PI will destroy all copies of the IRB’s records, unless there are extenuating circumstances that require the records to be retained for a longer period of time. Destruction of the data shall include: shredding of paper documents, erasure of computer files, and snipping and disposal of audio and/or visual tapes used in recording subject responses.

➢ **University Access to Research Data.** Where necessary, the University may access and/or take custody of the research data and researchers agree to cooperate with any such effort.
XVIII. REPORTING INCIDENTS & NONCOMPLIANCE POLICY

A. Reporting Adverse Events or Unanticipated Problems.

Adverse events or unanticipated problems (e.g., events or incidents that occur that were not disclosed as potential risks to the IRB to consider as part of its review and approval of the research) must be promptly (within 30 days of occurrence) reported to the IRB by submitting the Adverse Event/Unanticipated Problem Reporting Form. The IRB Administrator and IRB Co-Chair will review the submission, and the IRB Co-Chair or full IRB committee will determine the course of action necessary, if any. The full IRB committee may determine that research activities must be suspended or terminated depending on the severity of the incident. The IRB Chair will promptly inform the designated Institutional Official of the submission, and further respond and inform on the decision and rationale which led to it.

B. Issues of Noncompliance.

Investigators conducting research involving human subjects must have received IRB approval of their research activities via an approved IRB Research Application, Existing Information/Biospecimen Research Application, or Cooperative Research Agreement Form. Principal investigators must adhere to the IRB procedures detailed in this Manual, federal and state laws and regulations and University policies such as the University’s Policy on Integrity and Responsible Conduct in Research and Scholarship. The IRB, on behalf of the University, is responsible for ensuring that human subjects research complies with federal regulations.

Noncompliance Defined. Noncompliance is the failure to comply with or a deviation from an approved IRB Research Application or other approved IRB protocols, institutional policies, laws and federal regulations regarding the protection of human subjects found in Title 45 Code of Federal Regulation Part 46.

Minor or Major Noncompliance. Noncompliance issues can be minor, such as forgetting to annually renew an exempt protocol which poses no risk to subjects, or major (serious), such as modifying an IRB protocol without IRB approval that initially went through a full IRB review, research activities that increase the risk to subjects, a history of repeated noncompliance incidents or failure to obtain IRB approval before conducting human subjects research activities.

C. Report of Potential or Actual Noncompliance.

How to Report Potential or Actual Noncompliance. It is expected that any incidents of actual or potential noncompliance will be promptly reported to the IRB Administrator by anyone who suspects or knows of such noncompliance. The IRB relies on principal investigators, researchers, staff, faculty and students, and even the general public, to report potential issues of noncompliance. Individuals who know or suspect issues of noncompliance should promptly fill out a Report of Noncompliance Form and submit it to the IRB Administrator.

IRB Review and Investigation. Any potential issues of noncompliance should first be brought to the attention of the IRB Administrator. The IRB Administrator will then route the noncompliance form (or report however submitted) and originally approved protocol (and any other relevant IRB research records) to an IRB subcommittee who will investigate. The IRB subcommittee is charged with determining whether the incident constitutes actual noncompliance, and, if so, whether the noncompliance is major or minor. This IRB subcommittee will be a rotation of one Co-Chair and two IRB members. During this time, the principal investigator will be asked to suspend all research activities until the matter is resolved. The principal investigator and any other individuals involved agree to cooperate fully with any IRB or University investigation of the incident.
D. IRB Responses to Minor Issues of Noncompliance.

Minor issues of noncompliance will be dealt with by the IRB Chair(s) in conjunction with the IRB Administrator. Examples of IRB responses to minor issues of noncompliance include but are not limited to the following:

- Retaking the Collaborative Institutional Training Initiative (CITI) tutorial regarding research with human subjects, or such other training as identified by the IRB; and/or
- Early renewal of an IRB Research Application.

E. IRB Responses to Major Issues of Noncompliance.

Major issues of noncompliance will be discussed at a full IRB committee meeting and the IRB Responses will be determined by the committee members. Additionally, major issues of noncompliance will be disclosed to the appropriate University officials and/or the Office of Human Research Protections of DHHS if necessary. Examples of IRB Responses of major issues of noncompliance include one or any combination of the following:

- IRB Responses discussed under minor issues of noncompliance;
- IRB auditing of research protocol/data collection;
- IRB monitoring of research activities;
- IRB oversight of future research planning and protocol development (including, but not limited to, oversight in preparing subsequent IRB Research Applications);
- Prohibition of using any data collected out of compliance including the possibility of retraction of published data to the extent such published data includes inaccurate, misleading or falsified research findings or data (pursuant to the University’s Policy on Integrity and Responsible Conduct in Research and Scholarship);
- Notification to past/current subjects (in the case of inadequate informed consent) or obtaining new, legally effective informed consent of current subjects;
- Modification to the IRB Research Application; and/or
- Suspension or termination of such research activities.

IRB Responses to major issues of noncompliance will be submitted to the Provost for consideration as such noncompliance may implicate processes under other University policies including, but not limited to, the University’s Policy on Integrity and Responsible Conduct in Research and Scholarship. As a result, the researcher may be subject to the disciplinary proceedings and sanctions contained in such policies, subject to the oversight and approval of other University officials.

F. Questions?

For any questions please contact the IRB Administrator at: 209.946.7716 or vandeola@pacific.edu or the IRB Program Specialist at: 209.946.3903 or IRB@pacific.edu.
G. Forms.

Adverse Event/Unanticipated Problem Reporting Form

Report of Noncompliance Form.
XIX. NON-UNIVERSITY AFFILIATED RESEARCHERS CONDUCTING RESEARCH AT A UNIVERSITY ACADEMIC SITE

A. Non-University Affiliated Researchers Generally.

In the case of researchers from other institutions who would like to conduct research activities on University premises or with assistance from University personnel, determining whether the University is engaged in human subject research activities will determine whether IRB review is needed. If Pacific is not engaged in the research activities, IRB approval is not needed. If Pacific will be engaging in research activities, IRB approval is needed before commencing any research activities.

B. When the University is Not “Engaged” in Human Subjects Research.

Limited Purposes for University Staff/Agent Interaction. The University is not engaged in research involving human subjects if University staff or agents only do the following:

- inform prospective subjects about the availability of the research performed at or by another institution;
- provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other institutional review board approved materials) but do not do so to obtain the subject’s consent for the research or act as representatives of the researchers;
- provide prospective subjects with information about contacting the researchers for information or enrollment; and/or
- seek or obtain the prospective subjects’ permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient’s name and telephone number to researchers. If University personnel or agents will be engaged in research activities more so than what is described in this Section B above, IRB review and approval is required.

Limited Use of University Facilities/Premises. The University is not engaged in research involving human subjects if the University only permits use of its facilities or premises for intervention or interaction with subjects by researchers from another institution without any other involvement in the research activities.

Examples would be a school that permits researchers from another institution to conduct or distribute a research survey in the classroom; or a business that permits researchers from another institution to recruit research subjects or to draw a blood sample at the work site for research purposes.

Questions? For any questions about whether IRB review/approval is needed, please contact the IRB Administrator.
XX. RESEARCH PERFORMED AT LOCATIONS OTHER THAN UNIVERSITY ACADEMIC SITES (INCLUDING OUT-OF-STATE AND OVERSEAS LOCATIONS)

A. Will Any Research Activities be Performed at Locations Other Than University Academic Sites?

If any research activities are conducted in another state or another country, the principal investigator may need approval of the local government or other institution before commencing any research activities. For any questions about out-of-state or international research, please contact IRB Staff.

B. Application of the Federal Regulations.

Conducting research in other jurisdictions may subject the principal investigator to laws or regulations of the local jurisdiction. Generally, the federal regulations do not affect any state or local laws or regulations which may be otherwise applicable and which provide additional protections for human subjects of research (including local laws or regulations related to informed consent). Federal regulations also do not affect any foreign laws or regulations that may otherwise be applicable and which provide additional protections to human subjects of research.

C. International Human Research Laws and Standards.

OHRP publishes the International Compilation of Human Research Standards online (at the following link: http://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html). If any research activities will be conducted overseas, principal investigators should refer to this resource to become familiar with other legal requirements.

D. Equivalent Protections.

When research activities covered by the federal regulations take place in foreign countries, procedures normally followed in the foreign countries may differ from those followed in this IRB Manual and the federal regulations. In these circumstances, DHHS may determine that the procedures prescribed by the foreign institution affords protections that are at least equivalent to those provided in the federal regulations, and in that case, DHHS may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the federal regulations. Notices of such actions are published in the Federal Register as they occur or are otherwise published pursuant to DHHS procedures. To date, no foreign procedures have been accepted as equivalent by DHHS.
XXI. COOPERATIVE RESEARCH AGREEMENTS

A. Cooperative Research Generally.

In order to avoid duplication of effort, cooperative research between Pacific and other universities or institutions will be reviewed by the lead institution’s authorized institutional review board. The lead institution is normally the primary grantee or contractor for funded projects and/or home institution of the principal investigator. Pacific will accept documented review and approval by another institution’s IRB when appropriate. Each institution is responsible for safeguarding the rights and welfare of human subjects.

B. Cooperative Research Application Process.

If Pacific Researcher is the Principal Investigator. The principal investigator must submit the IRB Research Application and any other pertinent forms or documentation to the IRB for review and approval before commencing any research activities.

If Pacific Researcher is Not the Principal Investigator. Instead of the IRB Research Application, the participating investigator from Pacific must complete the Cooperative Research Agreement for any research that has been approved by another institutional review board prior to commencing any research activities. This form should be submitted with the lead institution’s approval letter and approved research application and any other relevant forms or documentation. A copy of the signed Cooperative Research Agreement will be kept on file.

C. Final Common Rule Requirements for Cooperative Research (Effective 1/20/2020)

Regulations regarding cooperative research are the only part of the Final Common Rule with a delayed effective date. By January 20, 2020, any US institutions engaged in federal cooperative research must rely upon approval of a single IRB for the research conducted within the United States. The reviewing IRB must be identified by the Federal department/agency supporting or conducting the research, and may be proposed by the lead institution (but is subject to acceptance by the Federal department/agency). Studies that must comply with the National Institutes of Health (NIH) policy on single IRB review have an effective date of January 25, 2018, with some exceptions.

If relying on another IRB for research performed at Pacific, the investigator must document the specific responsibilities of each participating institution.

The following research is not subject to this requirement:

- Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

- Research for which any Federal department/agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

For research not subject to the single IRB requirement, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangement to avoid duplication of effort.
Other types of reviews mandated by other regulations or Pacific policy are not included in the single IRB review (for example, reporting and management of conflicts of interest, etc.).
XXII. CLASSROOM RESEARCH

A. Projects Not Requiring IRB Approval.

The IRB provides flexibility in the level of review for classroom research/student research projects when all of the following conditions are met. Classroom Research/student research projects that meet all of these conditions described in this Section A may be conducted under the supervision of the faculty member who has received CITI training without submitting a protocol to the IRB for approval. Research projects that do not meet all of these conditions must be approved by the IRB before commencing any research activities.

Classroom Research/Student Research Defined. The project must meet the definition of classroom research/student research. This is defined as a project that:

- is a normal part of the student researcher’s coursework;
- is supervised by a faculty member who has successfully completed CITI training for human subjects research;
- has as its primary purpose the development of the student’s research skills;
- does not present more than minimal risk to participants or to the student researcher;
- does not include any persons as research subjects who are under age 18;
- does not include any persons as research subjects who are classified as protected populations or sensitive subjects according to Federal regulations; and
- is not genuine research that is expected to result in publication or some other form of public dissemination.

Must Meet Exempt or Expedited Review Criteria. Student research projects falling under this category must meet all the criteria for an Exempt or Expedited Review as defined in Section X of this Manual. If the faculty member has concerns or doubts about whether the research may require IRB approval, the faculty member should consult with the IRB Administrator or an IRB Co-Chair. The faculty member or student researcher may also request a formal review by the IRB of any student research project prior to beginning the research project.

B. Research That Does Not Meet All Criteria Above.

If any of the classroom research/student research projects do not meet all of the criteria described above or if the research fits into the Full Review category, the student researcher will need to submit an IRB Research Application and obtain IRB approval prior to commencing any research activities.

C. Faculty Responsibilities and Training Requirements.

Faculty teaching research methods and overseeing student research projects are expected to understand the philosophy, ethics, and practice of protecting human subjects in research; to adhere to these principles during the conduct and supervision of classroom research/student research projects; and to teach these research practices and principles to students. Faculty will be responsible for ensuring that all classroom research/student research projects are also conducted in accordance with applicable federal regulations.
and University policies regarding protection of human subjects in research. Faculty who want to supervise classroom research projects must complete the CITI Computer-Based Training modules. Please contact IRB Staff for access and instructions.
XXIII. TRAINING

A. Training Generally.

It is Pacific policy that each individual conducting research, collecting information/biospecimens/data, working in research labs, recruiting subjects, or serving on a thesis/dissertation committee with human subjects be trained in human subjects research history, ethical principles, federal, state and local regulations, and general institutional review board procedures. This means any individual working as an assistant on a project who will be handling information/biospecimens/data or working in a research lab must also be trained as well as any faculty serving as a thesis/dissertation committee member when the student is doing research involving human subjects. It is preferred that all faculty who teach research methods courses involving human subjects also keep current with training and incorporate Pacific’s IRB procedures and review timeline in class discussions.

B. Principal Investigators’ Training.

Principal investigators must receive training before beginning any research activities involving human subjects, regardless of investigator status or the category of research. Proof of training must be submitted to the IRB Administrator before commencing any research activities involving human subjects. IRB Research Applications will not be reviewed by the IRB until proof of the principal investigator’s training is confirmed.

C. CITI Training.

Investigators receive the training by completing the Collaborative Institutional Training Initiative (“CITI”) online tutorials found at: https://www.citiprogram.org/. Training is to be completed every three years according to the following formula:

- Year 1 – Full course
- Year 3 – Refresher course
- Year 6 – Refresher course
- Year 9 – Full course.

To register, follow the above link and claim University of the Pacific as your institution. From there you will have the option of completing the biomedical courses or the behavioral and social sciences courses. Choose your researcher status accordingly. Completion of all required modules in the full course will take several hours, but can be completed over time in intervals.

D. University IRB Procedures Training.

One-on-one training is conducted as requested.

E. OHRP Training.

OHRP offers online education tools to support IRB members and administrators, investigators, institutional officials, and others to better understand the HHS regulations for the protection of human subjects in research and their responsibilities in protecting human subjects. Available online education tools include e-learning modules, videos, and webinars.
XXIV. ELECTRONIC SIGNATURE POLICY

A. Policy.

IRB forms and correspondence do not require wet signatures and may be submitted electronically.

B. Correspondence To/From the IRB.

IRB members and the IRB Staff do not provide a wet signature on IRB correspondence to principal investigators or other researchers. All communications sent from the IRB to principal investigators will be in electronic format and considered official Pacific IRB business. Likewise, all correspondence received by the IRB from principal investigators (or other researchers) regarding IRB matters are considered official Pacific IRB business.

C. Forms Requiring Wet Signatures; Electronic Submission.

The IRB does not require any forms to be submitted with original wet signatures. All forms requiring a signature must be scanned and provided via PDF to the IRB Staff.
XXV. REFERENCES

(Available at: https://history.nih.gov/research/downloads/nuremberg.pdf).


DHHS Regulations and Policies

XXVI. APPENDIX