# Pepperdine University
# *Protection of Human Subjects in Research:*
# *Policies and Procedures Manual*

Pepperdine University Institutional Review Boards

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## I. Introduction

It is the policy of Pepperdine University that all research involving human subjects must be conducted in accordance with accepted ethical, federal, and professional standards and that all such research must be approved by one of the university's Institutional Review Boards (IRB). Both, the Seaver College and College of Health Science (CHS) IRB, and the Graduate and Professional Schools (GSP) IRB (Pepperdine's IRBs) are charged with monitoring the ethical propriety of all research involving human participants/subjects conducted under the auspices of Pepperdine University. It is the policy of Pepperdine University that its IRBs have the authority to approve, require modifications of, or disapprove any research involving human subjects conducted under Pepperdine's auspices.

The primary objective of the Pepperdine University IRB is to protect the welfare and dignity of human subjects. However, by addressing the human subjects concerns in an applicant's proposed research, the IRB also works to protect investigators from engaging in potentially unethical research practices. These guidelines describe the policies and procedures of the Pepperdine IRB.

In the review and conduct of research, Pepperdine University is guided by the ethical principles set forth in the Belmont Report (i.e., respect for persons, beneficence, and justice) (see section I.D. below). In addition, all human subjects research conducted by or under the auspices of Pepperdine University will be performed in accordance with the U.S. Code of Federal Regulations, Department of Health and Human Services (DHHS) (CFR), Title 45 Part 46 (45 CFR 46), entitled *Protection of Human Subjects***,** and Parts 160 and 164, entitled *Standards for Privacy of Individually Identifiable Health Information* and the California Protection of Human Subjects in Medical Experimentation Act (Code Sections 24170 24179.5). All research conducted will be reviewed under the new Revised Common Rule (NRCR), which was published by the U.S. Department of Health and Human Services on January 19, 2017 and provides several revisions that offer clarification and reduce administrative burden. Where applicable, FDA regulations on human subjects research will be followed (CFR Title 21 Parts 50, 56, *Protection of Human Subjects* and *Institutional Review Boards*). The actions of Pepperdine University will also conform to all other applicable federal, state and local laws and regulations, including tribal law passed by the official governing body of an American Indian or Alaska Native tribe.

Pepperdine University has assured the Office of Human Research Protections (OHRP) of the DHHS that all human subjects research will be conducted in accordance with 45 CFR 46 and has been issued Federal Wide Assurance (FWA00006872) by the OHRP.

**Prior to initiating any research project that seeks to obtain data from human subjects, the investigator must complete an online application using the online eProtocol system.**

### *A. How to Use this Manual*

Pepperdine University's Protection of Human Subjects in Research: Policies and Procedures Manual is a reference book for investigators that outlines the policies, regulations, and procedures governing research with human subjects, and the requirements for submitting research proposals for review by the Pepperdine University Institutional Review Boards (IRBs). This manual describes the application and review process, as well as applicable regulatory requirements. It is important for investigators to thoroughly familiarize themselves with the contents of this manual, and complete the required educational components before submitting proposals to the IRB. Although this manual contains the most current information for potential investigators, sections of the manual are subject to change as new or amended policies and procedures are developed. The Pepperdine IRB support staff will keep the Pepperdine University research community informed of such developments/changes. Chairpersons and committee members of Pepperdine IRBs are also available to consult with investigators who have questions about the application process. The members of the IRB committees can be located on the following website: community.pepperdine.edu/irb/.

### *B. Organization of the Pepperdine University Institutional Review Boards (IRBs)*

It is the policy of Pepperdine University that all research involving human subjects must be conducted in accordance with accepted ethical and professional standards for research and that all such research (except as provided in **Section II.B.)** must be reviewed and approved by the appropriate Pepperdine IRB.

- **Graduate and Professional Schools IRB**: Responsible for reviewing research applications of investigators from the Graduate School of Education and Psychology, the Graziadio Business School, the School of Law, and the School of Public Policy.

- **Seaver College and College of Health Science (CHS) IRB**: Responsible for reviewing research applications of investigators from any division/department within Seaver College and the College of Health Science (CHS). Additionally, staff members or employees of Pepperdine who do not have a faculty appointment, but who are conducting research investigations also should submit IRB applications to the Seaver College and CHS IRB.

The Authorized Institutional Official (AIO) and Signatory Official (SO) for Pepperdine University is the Vice Provost. At Pepperdine University, the Provost appoints the AIO and SO. The Authorized Institutional Official (AIO) is the person responsible for the oversight of research and IRB functions within Pepperdine University. The AIO has the legal authority to act and speak for the institution, and ensures that the institution can effectively fulfill its research oversight function.

The Human Protections Administrator (HPA) for Pepperdine University is the Associate Provost. At Pepperdine University, the Vice Provost appoints the HPA. The HPA is the primary contact for human subjects protection issues at Pepperdine. The HPA has operational responsibility for Pepperdine's human subjects protection programs.

The Research Integrity Officer (RIO) for Pepperdine University, appointed by the Provost, is responsible for assessing allegations of scientific misconduct, determining when such allegations warrants inquiries, and overseeing inquiries and investigations. For more information about the University Policy for Responding to Allegations of Scientific Misconduct, see https://www.pepperdine.edu/about/administration/provost/policies/.

The AIO, SO, HPA and RIO are identified on the Pepperdine University Human Protections website: https://community.pepperdine.edu/irb/

### 1. Composition of Pepperdine IRBs

In accordance with federal regulations governing the composition of Institutional Review Boards for research utilizing human subjects (45 CFR 46.107) each Pepperdine IRB is composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at each school of Pepperdine University. It is made up of persons of diverse gender, racial, and ethnic backgrounds, and includes at least one member whose primary concerns are in the nonscientific areas, as well as at least one member who is not otherwise affiliated with Pepperdine University (nor part of the immediate family of a person affiliated with Pepperdine University). Members possess expertise on vulnerable populations, or will seek the assistance of an outside consultant if this expertise is not present in an IRB reviewing an application regarding a vulnerable population.

Each year, a chairperson is selected for each IRB by the HPA. A co-chairperson may also be selected on an as-needed basis. The service of the co-chairperson will be required in cases in which there is a conflict of interest (e.g., when the IRB chairperson is also the chairperson or faculty advisor of a student's research project; when the IRB chairperson is submitting an application for his/her own research). In such cases, the IRB co-chairperson will preside over the review of the student's/chairperson's work, will be responsible for notifying the student/chairperson of the outcome, and will be listed on the informed consent form as the agent representing the IRB.

Pepperdine IRB includes a staff position(s) who oversees the operation of the IRB process. While applications are submitted online, IRB inquiries can be directed to this person (see **Section II.D.** *"Contacting Pepperdine's IRBs"*).

**2. Conflicts of Interest**

No member of the IRB may participate in an initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. According to the federal regulations, members with a conflict of interest should be absent during discussion and voting. Should the quorum fail during a meeting, no further votes can be taken unless the quorum can be restored. A quorum is the minimum number and type of IRB member that must be present at a convened meeting for the IRB to conduct business. In order to review proposed research at a convened meeting, a majority of the members of the IRB must be present (a minimum of three voting members), including at least one member whose primary concerns are in nonscientific areas (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met.

### *C. Key Definitions*

Most federally funded research with human subjects is governed by federal regulations embodied in Title 45 Code of Federal Regulations Part 46 (45 CFR 46) (See **Appendix A**). It should be noted that Pepperdine's Institutional Review Boards (IRBs) follow federal and state regulations to review all University affiliated human subject research, ***regardless of funding***, to ensure the rights, welfare, and protection of all participants and subjects. Thus, investigators should understand the federal definitions of "research" and "human subjects" in order to help determine whether their proposed research requires an IRB review.

- **RESEARCH:** *"a systematic investigation, including research 46.102(l) development, testing and evaluation, designed to develop or contribute to generalizable knowledge."*
  *For purposes of this part, the following activities are deemed not to be research:*
  *(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, that focus directly on the specific individuals about whom the information is collected.*
  *(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. Such activities are 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).*

*(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.***

*(4)* ***Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions****.*

- **HUMAN SUBJECTS:** *"a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."* Human subjects may also be referred to as human participants by Pepperdine IRBs in order to recognize the active relationship of persons in our research endeavors. 46.102(e)

- **LEGALLY AUTHORIZED REPRESENTATIVE**: *" means 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." 45CFR.46.102( c) and 21CFR50.3(l)*

- **INTERVENTION:** *"includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes." 46.102(e)*

- **INTERACTION:** *"includes communication or interpersonal contact between the investigator and subject." 46.102(e)*

- **PRIVATE INFORMATION:** *"includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record)." 46.102(e)*

- **IDENTIFIABLE PRIVATE INFORMATION:** *"private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information." 46.102 (e)*

- **IDENTIFIABLE BIOSPECIMEN:** *"a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen."*

- ***CLINICAL TRIAL***: *"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." 46.102(b)*

- ***PUBLIC HEALTH AUTHORITY***: *" an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate." 46.102(k)*

- ***WRITTEN OR IN WRITING***: *"refers to writing on a tangible medium (e.g., paper) or in an electronic format." 46.102(m)*
- **CARVE-OUT**: *"refers to the individualization of Exempt category two; and, the discussion among researcher(s) and IRB chairperson to minimize risk prior to approval of exempt research".*

- **LIMITED IRB REVIEW**: *" refers to the revised federal regulations governing human subjects research, effective January 19, 2019, requiring a new type of review called "limited IRB review" for certain exempt and expedited protocols*".

  The new provision for limited IRB review allows certain research to be categorized as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for exemption, the study must meet the standards of the limited IRB review. If the information is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review may allow an exemption determination to be made.

***Limited IRB review is required in the following circumstances:***

1. **Exempt category 2** (educational tests, surveys, interview or observations of public behavior) When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation. 46.104(d)2(iii)

2. **Exempt category 3** (benign behavioral interventions)

When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation. 46.104(d)(3)(i)(c)

3. **Exempt categories 7 and 8** (secondary research use; broad consent)
When investigators plan to store, maintain or use identifiable private information or identifiable specimens collected for non-research purposes and the information/specimens are obtained with a broad consent process. 46.104(d)(8) and (7)

> At this time, the Pepperdine IRBs will not mandate nor implement the institutional use of Broad Consent, as tracking requirements may be burdensome. *Exemption categories 7 and 8, which rely on Broad Consent will not be available in the Pepperdine eProtocol system.*

***Purpose of Limited IRB Review***
When reviewing the exempt categories 2 and 3, the limited IRB review assures adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data.

***Reviews Related to Privacy and Confidentiality under Limited IRB review***
In order to assure appropriate protections, the limited IRB review may consider the following topics:

• The nature of the identifiers associated with the data
• The justification for needing identifiers in order to conduct the research
• Characteristics of the study population
• The proposed use of the information

Certain research projects may also need to comply with California law regarding "medical experiments" (See also **Appendix F**).

- **MEDICAL EXPERIMENT**: *"includes: (a) the severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject; (b) the investigational use of a drug or device; or (c) withholding medical treatment*

*from a human subject for any purpose other than maintenance or improvement of the health of such subject."*

- **VULNERABLE SUBJECT/POPULATIONS**: There are a number of research populations described in the Federal regulations as "vulnerable" or that require additional consideration or protection. "Vulnerable" or "special" classes of subjects include: human fetuses and neonates, prisoners, children, individuals with impaired decision-making ability, students and employees, minorities economically and/or educationally disadvantaged, AIDS/HIV+ subjects, and terminally ill subjects. 45 CFR 46.107

- **DECEPTION:** *"authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research"*. 45 CFR 46.104(d)(3)(iii).

All research should ensure that risks to human subjects be minimized in accordance with basic ethical principles (see **Section I.D.** "*The Belmont Report*" below). Minimal Risk, defined by HHS policy for the Protection of Human Research Subjects at 45 CFR 46.102i, is defined as follows:

- **MINIMAL RISK:** ***"****means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

### *D. The Belmont Report*

On July 12, 1974, the National Research Act (Public Law 93-348) was signed into law and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. In fulfillment of their charge to identify basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human participants, the Commission created the Belmont Report. The Belmont Report forms the basis for 45 CFR 46 and defines three important principles considered basic to the protection of human subjects: 1) respect, 2) beneficence, and 3) justice. Available at: https://community.pepperdine.edu/irb/policies/

The Pepperdine IRBs are guided by the ethical principles set forth in the Belmont Report. Investigators need to be familiar with these principles in designing and implementing their research projects.

**1. Respect**

Respect for persons subsumes two ethical beliefs: (1) that individuals should be treated as autonomous agents, and (2) that persons with diminished autonomy are entitled to protection. It is imperative that an individual's decision to voluntarily participate in a research study is based on his/her ability to make a knowledgeable and informed assessment of the risks and benefits of the research. Investigators can help ensure that this principle is upheld by seeking voluntary, written informed consent with potential participants (See **Section VIII.**). The informed consent process should provide adequate information about the study and emphasize the voluntary nature of study participation so that potential participants can intelligently decide whether they wish to be involved in the research. This information should be provided in language that is easy for potential participants to understand.

Respect for persons also means honoring the privacy of individuals and maintaining their confidentiality. Individuals' privacy rights must also be protected in research conducted at certain health and mental health organizations involving personally identifiable health information by the new federal law, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA or the Privacy Rule (See **Sections X. and XI**.).

When individuals have diminished autonomy (e.g., minors, mentally disabled persons) investigators must take special care to protect them in research studies. In some cases this may mean excluding immature or incapacitated individuals from research activities that may harm them. The extent of protection depends on the risk of harm and the likelihood of benefit. Judgments that any individual lacks autonomy should be periodically re-evaluated and will vary in different situations.

**2. Beneficence**

The principle of beneficence embodies the idea that research investigators should seek to secure the well being of their study participants by trying to maximize the potential benefits to the participants and minimize the potential risks of harm. If there are risks resulting from participation in a research study, then there must be benefits. These may be direct benefits to the subjects, benefits to humanity, or the larger society in general.

**3. Justice**

The principle of justice means that the selection of research participants is fair and that the risks and benefits of research are equitably distributed. Investigators should not select research participants simply because of their ease of availability, their compromised position, their manipulability, or because of social, racial, sexual, economic, or cultural biases institutionalized in society. The selection of research participants should be based on factors that will most effectively address the research problem.

### *E. Education Regarding Research with Human Subjects*

**All Pepperdine faculty, students, and staff involved with research activities must complete training on the federal guidelines for the protection of human subjects.** IRB Committee members/reviewers may also need to complete additional training and should consult with the appropriate IRB chairperson. Investigators, students, and staff must complete such online education **before** submitting an IRB application through eProtocol, and before working on a research project in any capacity.

If a research project is covered under federal law, HIPAA, then HIPAA training is also required (see Sections X. and XI.). HIPAA applicability, policies, forms, and other information is available at **What Is HIPAA Security? | Pepperdine Community.**

Investigators are responsible for maintaining record of their human research protections training and the documentation of the completion of training of all members of a research project (e.g. PI, research assistants) must be submitted within each eProtocol IRB application in order to demonstrate investigators' basic knowledge of human subjects protection policies. If new members join the project after approval is granted, the investigator must confirm that the required training certificates are added to the eProtocol IRB application via a protocol modification (amendment).

**Pepperdine investigators should complete their human subjects protection training online via CITI Program.** Additional educational programs may be available to fulfill this requirement and investigators should contact their IRB chairpersons for more information. **Note that human subjects training must be updated every three years.**

As noted above, IRB members, including the AIO, HPA, and IRB chairpersons, also must complete the CITI training found at community.pepperdine.edu/irb/seaver/.

## II. Submitting an Application to the IRB

### *A. Who Needs to Apply*

#### 1. Pepperdine Faculty, Students, Staff

In accordance with federal regulations (45 CFR 46.112), Pepperdine University requires that all research involving human subjects conducted under Pepperdine University's auspices must be ***prospectively*** reviewed and approved by the designated IRB. Pepperdine IRBs are charged with protecting the rights and welfare of all research subjects, not just those subjects who participate in federally funded projects. Pepperdine University pledges that *all research irrespective of funding:* (1) involving human

subjects; (2) using records gathered on human subjects; or, (3) involving human tissue, will receive IRB review prior to initiation. See section 1.C. for key definitions.

For this reason, all proposed research in which a faculty member, student, or employee of Pepperdine University is the principal or co-principal investigator and that involves either direct or indirect contact with human subjects must submit an application to one of the Pepperdine University IRBs. Investigators are welcomed and encouraged to contact IRB chairpersons and committee members with any questions.

**2. Collaborators**

Pepperdine investigators who are working with researchers from another institution must also ensure that IRB approval is obtained from the other institution before the research project can commence.

According to the federal regulations (§46.114), cooperative research projects are projects that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. In some circumstances, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. A completed IRB Cooperative Authorization Agreement and other documentation must be attached to the eProtocol application.

**3. Non-Pepperdine Affiliated Investigators**

Investigators not affiliated with Pepperdine University and who are not collaborating with investigators affiliated with Pepperdine University, but would like to use Pepperdine University resources for research purposes should adhere to the following procedures.

**a. Outside Investigator With Home Institution's IRB Approval**

- Outside investigators are required to submit an Unaffiliated Investigator Agreement, along with their home institution's IRB approval and a copy of the approved protocol documents to the Pepperdine IRB. **A separate application submission to the Pepperdine IRB is not required.** The chairperson of the IRB will review the proposal and will make a recommendation to the HPA. Approval from the HPA and relevant departmental approvals must be obtained and submitted to the Pepperdine IRB prior to study commencement.

b. **Outside Investigator Without Home Institution's IRB approval**

- Outside investigators who wish to use Pepperdine University resources for research purposes but do not have an IRB approval from their home institution are required to submit their request to the HPA. The HPA will consult with the appropriate IRB chairperson. If approved to move forward, the outside investigator will submit an eProtocol IRB application to the relevant Pepperdine IRB committee. The application will then follow Pepperdine IRB review procedures as determined by the protocol category (see **Section III.B.**).

#### 4. Student Research Projects Continuing Post-Graduation

If a student starts a research project as a Pepperdine student and then graduates, but wishes to continue the research study post-graduation, the alumnus must notify the IRB chairperson. If the student's faculty advisor is still actively working with the student as a collaborator on the study, the IRB protocol can be modified, see **Section VII.D.**, so that the principal investigator on record is the affiliated faculty member. The alum can be listed as a co-investigator on the protocol. However, if the faculty supervisor is no longer actively working with the student as a collaborator on the study, and the student is not affiliated with Pepperdine, Pepperdine's IRB is no longer responsible for continuing oversight of the student's research study and the IRB can close the student's study.

If an alumnus is affiliated with another institution and is collaborating with an investigator affiliated with Pepperdine, the alumnus must submit an application to their home institution's IRB for review and submit those approvals to Pepperdine's IRB chairperson.

If an alum's research study involves the use of Pepperdine University resources, and they are not collaborating with an affiliated Pepperdine investigator, the alumnus is considered an outside researcher and is required to follow the procedures outlined in **Section IIA3**.

### *B. What Types of Projects Require IRB Review?*

#### 1. Student Research Projects

Research projects conducted by any Pepperdine undergraduate or graduate student, such as theses, dissertations, and independent research projects, with the intent to contribute to generalizable knowledge must be supervised by a Pepperdine faculty member. Because such directed or independent research projects employ systematic data collection and plan the public dissemination of the research findings, they must also be submitted to the IRB for review.

It is the responsibility of the faculty member supervising the research to ensure that approval of the Pepperdine University IRB is obtained. By signing as a sponsor of a

student project, faculty advisors take the responsibility for ensuring that all research procedures comply with federal, state, and university policies pertaining to the protection of human subjects. Faculty members must advise students throughout the eProtocol IRB application process. Student IRB protocols can only be submitted after the Faculty Chair/Sponsor has approved the study by clicking the "obligations" box in the eProtocol IRB application.

In the event that a student begins a research project without consulting faculty or staff, the student will be contacted to determine if the research is plausible and can be supervised by a staff or faculty member. If the student initiated research is not able to be linked to a supervising staff or faculty member, then it will not be reviewed by the Pepperdine IRBs and the student will be notified and asked to cease the research activity.

**2. Classroom/Educational Research and Service Learning Projects**

**a. When IRB Review Is Not Required**

A number of schools and departments offer courses that may have a research component or constitute training in research methodology. Such classes require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these course projects is to train students and provide them with greater understanding of social, educational, psychological, or biomedical processes, and an opportunity to practice various research methods. Such projects are conducted primarily for instructional purposes within the context of a formal class, and are not designed to contribute to general knowledge (e.g., through conference presentations, journal publications). Therefore, the IRB does not consider them to be research. Thus, IRB review and approval are not required, provided the instructor is prepared to accept professional and ethical responsibility for all research projects conducted in conjunction with the class.

Under these conditions, it is the instructor's responsibility to monitor the ethical propriety of the projects. Experience has taught us that time spent with students discussing matters such as confidentiality and avoidance of unnecessary discomfort or invasion of privacy will be time well spent. Some responsibilities include: communicating to students the ethical principles for the protection of human subjects, reviewing student classroom research projects, and monitoring their activities and consent procedures. All adverse incidents must be reported to the IRB, and in some cases the RIO, for review (see **Section III.I**.).

Although IRBs do not review such class projects, instructors, and students are encouraged to follow federal guidelines and university policy when designing and conducting class projects with human subjects. The explicit recognition of the existence of IRBs at all educational institutions, and discussion of their goals and concerns, should be an integral part of introducing students to research methodologies.

If you think any data will be published, in any format, it is wise to have the project reviewed. The category of review (Exempt from Full Board review, Expedited

review, or Full IRB review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

**b. When IRB Review Is Required**

Classroom research projects that are intended to contribute to generalizable knowledge (e.g., through publication or presentation) are subject to the federal regulations and are required to undergo IRB review. The category of review (Exempt from Full IRB review, Expedited review, or Full IRB review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

Review may also be required if an instructor is not prepared to insure the ethical propriety of a student's project. If the instructor has concerns or questions concerning a particular project, review by the IRB is required.

Because some classroom research assignments could place subjects at risk, the IRB may require some or all classroom projects to be reviewed. Be sure to consult your IRB regarding its requirements. The following categories, which might trigger IRB review, are provided for your reference only:

- The project involves more than "minimal risk" ***(****the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*).
- The project is not limited to surveys/questionnaires/interview procedures, observation of public behavior, or standard educational exercises directly related to the topic(s) being studied in an official university course.
- Surveys/questionnaires/interviews, if used, contain sensitive personal questions (e.g., questions about alcohol/drug use, sexual behavior/attitudes/orientation, criminal activity, suicidality/self-injurious behavior, violent or aggressive behavior, medical history, grades/test scores). or other personal information that could "label" or "stigmatize" an individual.
- The participants are from a "vulnerable" population that requires extra protections (e.g., prisoners, children under age 18, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons).
- Information recorded with direct or indirect (code number) identifiers linking the participant to his/her data when the questions being asked could reasonably harm the participant's reputation, employability, financial standing, and/or place the participant at risk of criminal or civil liability.
- The project includes deception. Participants must be fully informed and given the opportunity to voluntarily consent to participation.
- The results of the classroom assignment leave the university. Or, if the project involves gathering data from or about a company, agency, or organization and

the data/results are shared with others *beyond that company, agency, or organization.*

### 3. Program Evaluations and Administrative Review Projects

Program evaluations and administrative review projects need not be reviewed by the IRB if they are not research, if the results will not be distributed outside the institutional setting, or if they are used solely to evaluate or review a program in order to build a better program. If, however, the results of the project will be published or otherwise distributed to an audience outside the institution, the project must be reviewed by the IRB. If in doubt, submit the study for IRB review. The category of review (Exempt from Full Board review, Expedited review, or Full Board review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

### 4. Pilot Studies and Focus Groups

A pilot study is a preliminary investigation of the feasibility of a study, usually done on a small scale (e.g. fewer than 10 subjects/participants) and exploratory in nature. A focus group is defined as a small, targeted group of consumers, led by a moderator, whose opinions and perceptions on a certain topic are elicited. Both procedures are typically designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. At the point of academic discussions, (e.g., "how could this survey question be misunderstood?") such studies would not contribute to generalizable knowledge and therefore are not considered research and do not require IRB review.

However, the IRB has encountered cases in which information derived from pilot studies and focus groups have been considered or used for research purposes (e.g., publication or presentation). The IRB urges investigators preparing pilot studies to weigh the likelihood that the pilot data will actually be used for research purposes. In those instances, IRB review and approval is required before pilot study data collection commences. Such studies often involve an application for expedited review, but may require full IRB review.

### 5. International Research

Investigators conducting studies internationally should be aware of the laws and regulations governing human research protections in those countries. The Office of Human Research Protections (OHRP) has compiled a list of national policies which can be found on OHRP's website at www.hhs.gov/ohrp/international/. Investigators are responsible for identifying and abiding by the laws, regulations, and human subjects research protections in those countries where the research will be conducted. It is the investigator's responsibility for providing the IRB with the necessary information to adequately review the study.

Investigators are required to obtain and submit IRB approval (or equivalent), if available, from the foreign institution and submit those approvals to Pepperdine's IRB for review. If the foreign institution does not have an IRB (or equivalent), documentation granting approval to conduct research at the foreign institution/research site from that institution/research site's official must be submitted to the IRB prior to approval and study commencement.

Investigators should check the U.S. Department of State's Travel Advisory Warnings at http://travel.state.gov/ when submitting an application to the IRB. Research studies conducted in a country(ies) listed on the travel advisory list may have to be reviewed by Pepperdine's Office of Insurance and Risk in advance of review at the full convened IRB meeting. The investigator should consult with the IRB chairperson(s) prior to submitting an application for review.

### *C. When to Apply*

Each IRB will set a calendar of application submission dates each year, which will be available to the Pepperdine University community online: https://community.pepperdine.edu/irb/. Submission deadlines apply to applications seeking full review of either archival and prospectively conducted research projects. Applications seeking confirmation of exempt status or expedited review of either archival or prospectively conducted research projects may be submitted at any time. Provided the research protocol is in order you can generally expect the following review timeline:

- *Exempt* Reviews:

Initial Review Results within 15 business days of submission

Subsequent Review of Revisions within 10 days of submission

- *Expedited* Reviews:

Initial Review Results within 20 business days of submission

Subsequent Review of Revisions within 14 days of submission

The IRBs make every attempt to review all applications submitted for a particular month. Applications will be reviewed in the order in which they are submitted via the eProtocol IRB system. Because IRB meetings not only include reviews of new applications, but also reviews of re-submitted applications, discussion of amendments to approved projects, adverse event reports, etc. it may not be possible for the IRB to review all applications submitted during a particular month. Because many funding agencies require proof of IRB approval prior to the award of grants, investigators should take care to submit their IRB applications concurrently with submissions for funding.

Investigators must document completion of the **required** human subject research education before submitting an eProtocol IRB application, as described in the "Investigator Education Regarding Research with Human Subjects" section above.

Student submissions to the IRBs may be subject to additional requirements by school/department within the University. It is the responsibility of all faculty members supervising student projects to review and co-sign their students' eProtocol IRB applications. For example, there may be timing requirements (e.g., GSEP psychology doctoral students completing the clinical dissertation are required to submit the IRB application **after** successful completion of the preliminary oral examination and **after** having made any methodological modifications to the proposal as stipulated by their clinical dissertation committee). Thus, students should check with their department/school to determine if there are any formal requirements that must be fulfilled prior to submitting an eProtocol IRB application.

### *D. Contacting Pepperdine IRBs*

Contact information for both the Graduate and Professional Schools IRB and the Seaver College and CHS IRB is available at https://community.pepperdine.edu/irb/.

## III. The IRB Review Process

Pepperdine IRBs are responsible for ensuring that all approved research complies with the principles embodied in the Belmont Report (e.g., respect for persons, beneficence, and justice) as well as with the letter and spirit of the human subject protections regulations. Federal regulations require that IRB membership reflect experience, expertise and diversity in academic, research and professional background, racial and cultural heritage, and possess sensitivity to community attitudes so that a fair and informed review of research proposals can be undertaken. When an IRB reviews research involving a vulnerable category of subjects, it is required to include one or more individuals qualified to represent that group, either through personal experience or experience working with that population.

The review process begins with the submission of the application and supporting materials via the eProtocol IRB system at irb.pepperdine.edu/. Communication between the IRB and investigators most often takes the form of correspondence that is generated from the committee's review of the investigator's eProtocol IRB application. Receiving correspondence from the IRB indicating that changes or modifications are required to a study protocol or associated documents (e.g., informed consent form) is common and should not be viewed as a negative statement about the content of the investigator's research.

Pepperdine University's IRBs have the authority to approve, require modifications in, and disapprove proposed human subject research. An IRB can also suspend or revoke its approval of ongoing research (e.g., research that has been associated with unexpected serious harm to subjects). Failure to comply with IRB requirements is considered serious misconduct and may lead to sanctions including:

- suspension or termination of research;
- re-consenting subjects;
- notifying subjects of non-compliance;
- training for investigators and staff;
- monitoring of ongoing activities;
- restriction of funds or other resources;
- correction to publication, or retraction of publication;
- prohibition on use of data collected as part of protocol noncompliance;
- barring investigators from future submissions to IRB/suspension of investigators;
- or required disclosures that data were collected unethically/outside protocol.

Suspension or termination of approval will be promptly reported to the investigator, Vice Provost, and appropriate institutional and agency officials and will include a statement of the reasons for the IRB's actions.

### *A. Issues Considered in an IRB Review*

In reviewing applications, the IRBs examine many elements of a proposed research project including 1) study design, 2) investigator qualifications, 3) selection of subjects and participant recruitment procedures; 4) *vulnerable subjects/populations; 5) risks and potential benefits to participants, 6) the informed consent process, and 7) confidentiality and privacy. Consideration of these factors helps to ensure that recruitment of participants will be done in an equitable, non-coercive manner, that participants will be fully informed about the risks and benefits involved in participation, and that participants will not be exposed to undue risks. If the proposed research seemingly poses a more than minimal risk, then the Pepperdine IRB Chairperson will proceed with a discussion with the researcher(s) to determine if the research design can be changed such that it brings the proposed research to no more than minimal risk.

#### 1. Study Design:

The IRB will review the design of a study with the aim of determining whether it adversely impacts the rights and welfare of the human subjects. It is considered unethical to subject human subjects to a study that is so methodologically flawed that little to no reliable information is likely to result. In some cases, it may be necessary for the IRB to consult with an outside expert to determine whether a study's design places participants at unnecessary risk. Information should also be included in the application about how the

study plans to address adverse events (e.g., what will happen if preliminary results show that the protocol is harmful or injurious?).

Study designs involving deception or withholding of information can be approved by the IRB under the federal regulations if such strategies are justified and the protocol provides for a post-study debriefing of the subjects. A waiver of the debriefing requirement may be granted by the IRB if the debriefing may be harmful to the subjects.

**2. Investigator Qualifications**:

The IRB will examine the qualifications of students, faculty, and/or staff investigators. Procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or experience in qualifying the investigator for the performance of the proposed procedures are reviewed by the IRB. In addition, the IRB will consider the facilities and equipment used to conduct the research and maintain the rights and welfare of the subjects.

**3. Selection of Subjects**:

It is important that selection of subjects be equitable and free of coercion. In order to evaluate this, the IRB will take into consideration where and for what purposes the research is being conducted, and will carefully review research involving vulnerable subject populations, including children, individuals with impaired decision-making capacity, educationally or economically disadvantaged subjects, and prisoners. Thus, it is important that investigators explain in their eProtocol IRB application how the appearance of coercion in the recruitment of subjects will be avoided, and what steps will be taken to safeguard the rights and welfare of subject populations.

**4. Vulnerable Subjects and Exempt Research**

Due to the vulnerable nature of the population the exemptions in 45 CFR 46.101(b) do not apply to certain types of research involving children and prisoners, Subparts C and D. Specifically, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. In addition, exemption from IRB review should be utilized conservatively when applied to research involving special classes of subjects who are not defined by regulation as vulnerable. In reviewing these research projects, the IRB determines if the inclusion of the vulnerable population is adequately justified and that safeguards are implemented to minimize risks unique to each population.

During its review the IRB must determine which of the following categories the research would involve:

- the research does not involve more than minimal risk to the subject;
- the research is likely to benefit the subject directly, even if the risks are considered to be more than minimal;

- the research involves greater than minimal risk with no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition; or
- research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the subject.

Requests for approval of any research that exposes vulnerable populations to risks that do not meet one of the above criteria must be submitted to the United States Secretary of Health and Human Services for review and approval. The mere presence of the appearance of vulnerability should not lead to a presumption that a person is incapable of making a decision regarding participation in research and of giving valid informed consent. Yet sometimes these conditions do impair the decision-making capacity required to give a valid informed consent, raising ethical concerns about the vulnerability of persons in such conditions in research.

**5. Risks and Benefits:**

IRB applications will be reviewed to determine if risks posed to subjects are reasonable in relation to any anticipated benefits to subjects. Consideration will also be given to the importance of the knowledge that may be expected to result from the research. Because the federal regulations do not allow the IRB to evaluate potential long-range effects of applying knowledge gained through research (e.g., possible effects of research on public policy), the IRB considers only those risks and benefits that may directly result from the research.

The IRB also reviews any possible benefits a subject may derive from participating in research, and considers benefits of new knowledge that may justify asking a person to undertake the risks of the study. Investigators should note that paying subjects for their participation in research is NOT considered a benefit.

**6. Informed Consent Process (45 CFR 46.116(a-c) and 46.117):**

The proposed informed consent process will be carefully reviewed by the IRB to determine that it is appropriately obtained and documented. See **Section VIII**. for elements that an informed consent procedure should include.

For the Informed Consent there are five elements at the beginning of the consent form and during the consent process that would encompass the required key information.

1. The fact that consent is being sought for research and that participation is voluntary.
2. The purposes of the research, expected duration of the prospective subject’s participation, and procedure to be followed in the research.
3. The reasonably foreseeable risks or discomforts to the prospective subject.
4. The benefits to the prospective subject or others but may reasonably be expected from the research.

5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

**Subsections of Informed Consent:**

46.116(a)(4). Requires that subjects be provided with the information that a "**reasonable person**" (undefined in the regulations) would want to have. It remains the investigator's responsibility to provide more information when requested by subjects, allow sufficient time and opportunity to discuss the research, and answer questions to improve a subject's understanding. For certain types of research (such as when there is reason to believe some subjects will find the research controversial or objectionable), the "reasonable person standard" may require a more complete description (more specific details) of the research.

46.116(a)(5) Investigators need to present informed consent information in sufficient detail and in ways that help with subject comprehension, not just running down a list of procedures and risks of harm.

### 7. Broad Consent.

Broad Consent is defined as "*seeking of prospective consent from subjects to unspecified future research for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens*". 46.116(d)(1-7), Revised Common Rule: Federal Register, Vol. 82 No. 12 (January 19, 2017)

Under the current regulations, secondary research use of identifiable data/biospecimens is permissible through study-specific consent, by obtaining an IRB waiver of consent, or by removal of identifiers. In the Revised Common Rule, Broad Consent is an (optional) alternative consent process for use only for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future, yet-to-be-specified research.

To utilize Broad Consent, the study team and/or the unit/biorepository responsible for the storage of the identifiable data/biospecimens are required to:

- identify the types of research that may be conducted with the data/biospecimens,
- record and track who has agreed to or refused consent, and
- to track the terms of consent to determine whether proposed future secondary research use falls within the scope of the identified types of research.

For full details about Broad Consent including the requirements, limitations, and considerations for use, see SACHRP's Recommendations for Broad Consent Guidance at www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html.

At this time, **the Pepperdine IRBs will not mandate nor implement the institutional use of Broad Consent**, as tracking requirements may be burdensome. Exemption categories 7 and 8, which rely on Broad Consent, will not be available in the Pepperdine eProtocol system. Pepperdine IRBs will continue to support study teams seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through the following processes:

- Study-specific consent and comprehensive IRB review.
- IRB waiver of consent (as eligible) and comprehensive IRB review.
- Exemption #4 - de-identification to remove the research activity from Common Rule purview and not require IRB review or consent.

**8. General waiver or alteration of consent.** 46.116 (f)

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in **Section VIII**. or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- the research involves no more than minimal risk to the participants;
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the participants will be provided with additional pertinent information after participation.
- if the research involves the collection of identifiable private information or identifiable biospecimens, a statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent.
- a statement that 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. 46.116(c)(7)
- a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions 46.116(c)(8)
- for research involving biospecimens, a statement about whether the research project might include whole genome sequencing (e.g., sequencing of a human germline or somatic specimen with the intent to generate the genome or, exome sequence of that specimen. 46.116(c)(9)
    - Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject.

- The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.

**9. Screening, recruiting, or determining eligibility.** 46.116 (g)

IRB may approve a research proposal in which an 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 are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; **or**
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

**10. Posting of clinical trial consent form.** 46.116 (h)

- 46.116(h)(1) The responsibility for posting is on the awardee or the federal department or agency component conducting the study. The posting can take place any time after the trial is closed to recruitment, so long as the posting is no later than 60 days after the last study visit by any subject (as required by the protocol).
- 46.116(h)(2) The redaction of proprietary or institutionally sensitive information of portions of consent forms is allowed.
- 46.116(h)(3) Only one version (not necessarily the final) of the consent form (absent any signatures) for each clinical trial must be posted on the federal website after the clinical trial is closed to recruitment. The posted consent must be IRB-approved consent that was used for enrollment purposes, but there is flexibility in that it does not have to be the "final version". In accord with the new Singer IRB (sIRB) review requirement, only one posting is required for each multi-institution study. There is no expectation that a version would need to be posted for each study site nor even for each class of subjects in the study (for example, posting both for adults and children).

**11. Secondary Research:**

Secondary research is "*re-using [for research purposes] identifiable and non-identifiable information and biospecimens that are collected for some other 'primary' or 'initial' activity*" (such as from research studies other than the proposed research study). The information or biospecimens that are used for secondary research would generally be found by the investigator in records, archives, information systems, databanks, or tissue repositories.

De-identified information or biospecimens would be considered for Exempt review.

**12. Confidentiality and Privacy:**

The IRB application will be reviewed to ensure that the research plan makes appropriate provision for protecting the privacy of subjects and maintaining the confidentiality of data in all stages of the research.

Applicants should understand the difference between anonymity and confidentiality. Anonymity can be defined as when a person is not named or identifiable in any manner. Confidentiality may be defined as when personally identifiable and private information is entrusted to an investigator to not disclose it. Thus, routine practices for assuring confidentiality include: substituting codes for identifying information; removing cover sheets (containing names and addresses); limiting access to identified data; and storing research records in locked cabinets. Even signed consent forms are records that contain confidential information. None of the above examples involve anonymous data because each involves some way of linking a person to the data.

The IRB will consider the following when discerning "confidentiality and privacy":

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified.
- The use of the information.
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released.
- The likely retention period or life of the information.
- The security controls that are in place to protect the confidentiality and integrity of the information.
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

## *B. IRB Review Procedures*

IRB review of proposals is conducted in strict compliance with federal regulations (45 CFR 46 and 45 CFR 50), which specify three broad categories of research involving human subjects:

1. Research which is **exempt** from federal regulation (see Appendix A and B);
2. Research which is appropriate for **expedited** review (see Appendix A and C); and
3. Research which requires **full** review by the IRB.

**1. Claim of Exempt Research Application**

Upon receiving a claim of exempt research application (see **Section VII.A**.), the chairperson and/or a designated IRB member will determine whether or not the proposed research is subject to federal regulation under 45 CFR 46.104(d)(1-8) (see Appendix A and B). The following criteria must be satisfied:

- It is clear that the nature of the proposed research fits one of the categories in 45 CFR 46.104(d)(1-8).
- No implications for criminal or civil liability, employability, or damage to the subject's financial standing or reputation would exist if data were known outside the study.
- The research does **not** use a protected group as subjects (e.g. fetuses, pregnant women, prisoners, mentally handicapped, minors in a survey or interview study, or minors in a participant observation study).
- The study does **not** present more than a minimal risk to subjects.
- The study does **not** involve deception.

If the proposal is determined to be exempt from federal regulation, the IRB will provide the investigator with appropriate documentation, and the study may proceed. If the proposal is not deemed exempt, the investigator will be contacted and advised regarding submitting an appropriate application or other course of action.

**It is important to underscore that even protocols that are ultimately deemed exempt need to be submitted via the eProtocol IRB system. It is the IRB that must make this determination, not the investigator or his/her collaborator or faculty advisor.**

**2. Application for Expedited Review**

Upon receiving an eProtocol IRB application requesting expedited review (See **Appendix A and C**), the chairperson and/or a designated IRB member will determine whether or not the proposed research meets the guidelines for expedited review under 45 CFR 46 (See **Appendix A and C**). If judged appropriate for expedited review, the at least designated IRB committee members will review the application and recommend which of the following actions should be taken regarding the proposal: (a) approved without stipulation; (b) contingent approval (list conditions); or (c) refer to Full IRB review. According to the federal regulations, IRB reviewers cannot deny an application submitted for expedited review; only the full IRB can exercise this authority.

**3. Applications Reviewed by Full IRB**

The IRB convenes meetings at regular intervals to review proposals which cannot be approved through procedures of expedited review and which require full board review (see **Section VII.C.)**. Convened meetings will be conducted in person or by video conferencing so that all members are gathered to discuss IRB issues and review

applications. Investigators may be invited to meetings to answer questions and/or offer clarification about the proposed research project, however the investigator must be absent during discussion and voting.

IRBs in operation at Pepperdine University may choose to utilize a primary reviewer system for applications reviewed by the full IRB. In the primary reviewer system, IRB members are designated as the primary reviewer(s) for an application and are given the task of conducting an in-depth review of the application, the project proposal (e.g., grant application, dissertation prospectus), and all the study-related appendices, including the informed consent form. The remaining committee members focus on the application and appendices (however, complete documentation is available for all members to review). Designation as a primary reviewer may be rotated among the committee members. IRB members may not serve as primary reviewers of any research with which they are directly affiliated (e.g., principal investigator, co-investigator, faculty advisor, dissertation committee member, etc) or otherwise have a conflict of interest.

Regardless of the decision of an institutional IRB to use either the full review or primary reviewer system during initial review of an IRB proposal, application materials will be made available via the eProtocol IRB system to committee members for review approximately 1-2 weeks prior to the convened IRB meeting.

No action may be taken by the IRB at convened meetings unless a quorum of its members are present, including at least one member whose primary concerns are in nonscientific areas. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting. In addition, the IRB may be required or may elect to invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond that available on the IRB.

According to the federal regulations, members with a conflict of interest will be absent during discussion and voting. Members can be available to answer questions before discussing and voting takes place. Should the quorum fail during a meeting, no further votes can be taken unless the quorum can be restored. Minutes of the meeting will document that a quorum was in place, and will list the number of individuals voting for full approval, provisional approval, or denial.

The full board review will result in an IRB determination that the application is: (a) approved without stipulation; (b) contingent approval[1]; (c) not approved as proposed.

[1] When the convened IRB requests *substantive* clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research will be deferred, pending subsequent review of the responsive material by the convened IRB. When the convened IRB stipulates specific revisions requiring simple concurrence by the investigator, the IRB Chairperson or another IRB member designated by the Chairperson will subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure.

Should the IRB provisionally approve an application, the investigator will be asked to incorporate the requested revisions into the written research protocol and any relevant accompanying documents (e.g., informed consent form). This practice ensures that there is only one complete protocol with the revision dates stored via the Pepperdine eProtocol IRB system. All revisions will be submitted via the eProtocol IRB system as well.

Findings will be documented in the IRB minutes and will be communicated to the investigator in writing via email and/or the eProtocol IRB system. A copy of all IRB minutes, which contains IRB findings and actions, will be sent to the HPA.

### *C. Single IRB (sIRB) Review*

When more than one institution is involved with a research study, the regulations define this as a cooperative research project (community.pepperdine.edu/irb/irbforms/). In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects; however, this creates a situation where there are multiple IRBs involved, asking for multiple things, and creating an environment of duplication of effort. In an effort to streamline the process and prevent duplication of effort, the use of one IRB for cooperative research will be required, also known as "Single IRB" (sIRB). The exceptions to sIRB include:

- Cooperative research for which more than sIRB 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 or agency supporting or conducting the research determines and documents that the use of a sIRB is not appropriate for the particular context.

It is the policy of Pepperdine University that for any "cooperative research project" involving human subjects to proceed, the PI must identify "primary" and "secondary" designations for the participating institutions. Both the "primary" and "secondary" institutions are guided by the ethical principles regarding research involving human subjects as set forth in the CFR 45, Part 46 and the Belmont Report. In conducting a review as the "primary" institution, it will:

(1) recognize that all human subjects research must be conducted in accordance with the United States Federal Policy for the Protection of Human Research Subjects.

(2) be responsible for the initial and continuing review of the project in accordance with the requirements of 45 CFR 46.

(3) report promptly to the other party to this agreement and to any sponsoring agency:

(i) any unanticipated problems or injuries involving risks to subjects or others,

(ii) any serious or continuing noncompliance with the federal rules or with the requirements or determinations of the "primary" institution,
(iii) any changes in a project which are reviewed and approved by the "primary" institution, and
(iv) any suspension or termination of IRB approval by the "primary" institution.

The designated "primary" institution shall keep the "secondary" institution informed and, at a minimum, shall provide copies of the submitted protocol, any revisions to the protocol, copies of continuing reviews, and any minutes of meetings of the "primary" institution that include actions or discussions regarding the referred protocol. IRB disapproval of any protocol referred under this cooperative agreement may not be administratively overruled by either cooperating institution.

If Pepperdine is designated as the "primary" institution, the PI should apply per standard IRB application processes, via the eProtocol IRB system.

If the PI decides that Pepperdine will be the "secondary" institution, then they should obtain approval from the "primary" institution's IRB and submit the following materials via email to the appropriate Pepperdine IRB chairperson.

- Signed "Cooperative Authorization Agreement" - found online at community.pepperdine.edu/irb/irb-forms/
- Copy of IRB approval letter from "primary" institution
- Copy of full IRB application reviewed by "primary" institution

### *D. Criteria for IRB Approval of Research*

It is the policy of Pepperdine University that in order for any research proposal to be approved, the IRB must determine that *all* of the following requirements are satisfied:

1. Risks to the subjects are minimized and are reasonable in relation to anticipated benefits of the research;
2. Selection of subjects is equitable given the purposes and the setting of the research;
3. Appropriate informed consent will be sought from each subject or the subject's legally authorized representative, and such consent will be appropriately documented;
4. The research plan makes appropriate provision for monitoring the data collected to insure the safety of subjects;
5. Appropriate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data;

6. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included to protect the rights and welfare of these subjects.

All research proposals are reviewed in accordance with California's Protection of Human Subjects in Medical Experimentation Act. See **Appendix F** for a detailed description of California's requirements.

If the proposed research constitutes a "medical experiment" the following additional requirements must be satisfied:

1. The subject must be provided with an *Experimental Subject's Bill of Rights;*

2. The subject must provide written, dated, informed consent in compliance with California Health and Safety Code §§ 24172-24175.

### *E. Investigator's Right of Appeal from Initial IRB Decision*

It is the policy of Pepperdine University that the final decision regarding approval or disapproval of all proposals rests with the IRB. No research involving human subjects may be conducted under Pepperdine University's auspices without the prior and continuing approval of the IRB. Any investigator who disagrees with a decision of the IRB may request a hearing of appeal at any duly convened meeting of the IRB, during which relevant arguments and/or witnesses may be presented on behalf of the investigator. The final decision, however, rests with the IRB.

### *F. Modifications and Amendments to Currently Approved Research*

Amendments to approved research may undergo expedited review if the modification does NOT constitute more than a minor change in the approved protocol.

If the amendment includes more than a minor change to an approved protocol, IRB review at a convened meeting is required. The amendment may be (a) approved as proposed; (b) approved provisionally; (c) denied as proposed. Findings will be documented in the IRB minutes and will be communicated to the investigator in writing via email and/or the eProtocol IRB system. The investigator must receive notification of the IRB approval before the modifications can be implemented, except when necessary to eliminate apparent immediate hazards to a research participant.

Investigators should submit modifications or amendments via the eProtocol IRB system (See **Section VII.D.**), including a revised research protocol and IRB application

that incorporates the requested protocol modifications. This practice ensures that there is only one complete protocol in the eProtocol IRB system with the revision dates recorded in the eProtocol IRB system.

### *G. Continuing IRB Review (Revised Common Rule)*

Under federal regulations, annual continuing review requests are **no** longer required in the following circumstances:

- Research eligible for expedited review.
- Research reviewed by the IRB in accordance with the limited IRB review.
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    (a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    (b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

It is the investigator's responsibility to initiate "Continuing Review" at least one month prior to the expiration date of IRB approval (see **Section VII.E.**). This submission via the eProtocol IRB system will notify the IRB that a study has been completed (e.g., no further recruitment or contact with human subjects is planned).

Individual IRBs will determine whether a project requires more than annual review. This could occur, for example, for high-risk protocols or protocols with a high risk: potential benefit ratio. In such cases, the investigator will be notified in the IRB approval notice of the length of approval granted and will be provided with an explanation as to why the study is deemed to require re-review in less than a one year period.

The IRB may also require an appropriate monitoring procedure that could include monitoring of the consent process (including requiring the use of a date stamped consent form), observation of the research procedures, and review of research-related records.

In some cases, the IRB may determine that a project requires verification from sources other than the investigator(s) that no material changes have occurred since the previous IRB review. Such projects may include, but are not limited to, complex projects involving unusual levels or types of risk to subjects, projects conducted by investigators who previously have failed to comply with the requirements of the federal regulations or the requirements or determinations of the IRB, and projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources. In such cases, the investigator will be informed in writing of the need for such additional verification and the person or entity that will be responsible for conducting the additional review (e.g., an independent Data Safety Monitoring committee).

Continuing review of research must be substantive and meaningful. In accordance with HHS regulations at 45 CFR 46.108(b) and at 46.115(a)(2), continuing review by the convened IRB, with recorded vote on each study, is required unless the research is otherwise appropriate for expedited review under Section 46.110. Furthermore, HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review. The procedures for continuing review by the convened IRB may include a primary reviewer system.

In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including:

- The number of subjects accrued;
- A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- Any relevant multi-center trial reports;
- Any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed consent document.

When reviewing the current informed consent document(s), the IRB should ensure the following:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b) (5).

Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

Furthermore, the minutes of IRB meetings should document separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB.

The IRB and investigators must plan ahead to meet required continuing review requirements. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

### *H. Adverse Event Reporting*

Investigators must report adverse events that occur during the course of their research with human subjects to the IRB in a timely fashion. An adverse event, as defined by the Department of Health and Human Services, is "an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy)." An adverse event in non-medical research can include an undesirable and unintended consequence of, or reaction to, procedures. An unanticipated adverse event can also be defined as any adverse experience whose nature, severity, and frequency of risk were not described in the information provided for IRB review or in the consent form.

Adverse events/experiences include, but are not limited to:

- problems related to the safety of subjects such as injury, life threatening events, or events that require or prolong hospitalization, produce a disability, result in a congenital anomaly/birth defect, or require medical evaluation (such as additional laboratory testing) and/or medical treatment.
- incidents or serious problems involving the conduct of the study or subject participation, such as, problems with recruitment and/or the consent process.
- issues of noncompliance.
- major unresolved disputes between a research investigator and a research subject or between research investigators (including research staff) involved in the conduct of the research study,

Only unanticipated adverse events that are associated with a research intervention must be reported to the IRB. An adverse event is considered to be associated with a research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (e.g., a causal relationship between the reaction and research intervention cannot be ruled out by the investigator(s)).

All adverse reactions and unexpected events should be reported as soon as possible to the IRB Chairperson and no later than 96 hours from the time the investigator became aware of the problem. All fatal or life-threatening events MUST be reported to the IRB within 48 hours after discovery. Investigators should file such reports in writing, using the "Adverse Event Reporting Form" found online. All relevant documents and

supporting material should be included with the Adverse Event Reporting Form. When attaching supporting material and consent forms, participants' personal identifiers (e.g., name, social security number) should not be included.

In some instances a serious or unexpected adverse event may necessitate an immediate change in protocol to relieve an apparent immediate hazard to research participants. In such situations, the principal investigator may implement a change in protocol in order to protect the welfare of the research participants. Investigators should be certain to describe such changes in protocol in the Adverse Event Reporting Form.

When the IRB receives an Adverse Event Reporting Form, the information will be reviewed to determine:

- whether the IRB requires additional information;
- whether further action (e.g., modification) is required regarding the protocol and/or consent form;
- if current participants need to be informed of adverse event;
- if the study is to be monitored for a specified period of time;
- whether the research activity should be temporarily suspended;
- if actions taken by the investigator adequately addressed the adverse event or whether further actions to be administered by the investigator are required; and/or
- if the study is to be permanently discontinued.

The investigator will be informed in writing of the findings of the IRB review. The IRB will also promptly report to appropriate institutional officials, any supporting Agency or Department heads, and OHRP any (i) unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval. If the adverse incident appears to constitute scientific misconduct it must be referred to the RIO. The Pepperdine University Policy for Responding to Allegations of Scientific Misconduct is available for review at www.pepperdine.edu/about/administration/provost/policies/.

### *I. Research Noncompliance*

All investigators are required to conduct their studies in compliance with the IRB-approved protocol as well as comply with Pepperdine's IRB and University policies, state and local laws, and federal regulations related to the rights and welfare of human subjects research. If any allegations of noncompliance are made to the Pepperdine IRB or the Vice Provost, those allegations must be investigated and it must be determined whether the allegation has a basis in fact or not. If the noncompliance appears to constitute scientific misconduct it must be referred to the RIO. The Pepperdine

University Policy for Responding to Allegations of Scientific Misconduct is available for review at pepperdine.edu/about/administration/provost/policies/.

Investigators are required to self-report to the IRB any instances of noncompliance that involves potential risk to subjects or involves significant failure to comply with federal regulations, state laws, University policies, and/or IRB requirements. Pepperdine personnel, including investigators, research team, faculty, staff, administration, or students are also responsible for reporting to the IRB suspected or actual noncompliance. Reports of suspected noncompliance may also be reported to the IRB or Associate Provost by research subjects, subject's family members and others external to the University, including regulatory agencies. These reports may be in the form of complaints and may also be made anonymously.

### *J. IRB Review in Emergency Situations*

Federal regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval (see 45 CFR 46.103[b] and 46.116[f]). For example, if an investigator provided emergency medical care to an individual without prior IRB review and approval, the individual may not be considered a research subject under 45 CFR Part 46. The federal guidelines make clear that an investigator (e.g., physician) can provide emergency medical care to an individual when such care is warranted without regard to IRB review and approval, but also clearly state that such emergency care may not be claimed as research. Furthermore, any data regarding such care cannot be included in any report of a prospectively conceived research activity. If the emergency care involves drugs, devices, or biologics that are considered to be investigational by the Food and Drug Administration (FDA), then it may be necessary to meet FDA requirements to use the investigational article for emergency purposes.

## IV. The IRB Application

Completing the eProtocol IRB application will be facilitated by a study that has been thoughtfully planned and carefully delineated.

An application to the IRB will most commonly include the following documents:

1) The Pepperdine University eProtocol IRB application found online at: irb.pepperdine.edu/. Student investigators will complete the same eProtocol IRB application and will require a sign-off by their faculty sponsor(s).

2) Any documents that will be presented (in written or oral form) to participants including, but not limited to, study flyers or

advertisements, the informed consent/assent form(s) (See **Section VIII.**), HIPAA forms (See **Section X**.), cover letters that will accompany materials given to/mailed to participants, scripts of in-person or telephone presentations about the study made to participants or organizations/individuals who will be recruiting participants, questionnaires, surveys, or other forms that the participants will read and/or complete as part of the study

3) A complete, detailed IRB protocol containing enough background material to properly assess the benefits of the research and the risks (physical, psychological, social or economic, as applicable) inherent in the proposed methodology. In some cases, a grant proposal or a dissertation or thesis prospectus may provide sufficient detail to achieve this purpose. However, investigators should make certain that the items discussed in **Sections III.A.1** and **III.A.3** of this manual, and in 45 CFR Part 46.111 are addressed in the scientific protocol. Furthermore, the complete scientific methodology to be used in the investigation should be included in the IRB protocol.

4) Depending on the nature of the research, other documents may be required as part of the submission. Investigators are encouraged to contact their IRB Chairperson prior to application submission if they feel other supporting documentation may be required for protocol review.

5) Documentation that the investigator has completed required education components (as described in **Section I.** above).

Information is provided below regarding each of the aforementioned documents. It is imperative that investigators (and student advisors in the case of student research) carefully and thoroughly review the materials submitted as part of the IRB application. Incomplete proposals will not be reviewed until they are complete and applications that are hastily put together are likely to result in further delays in the review and approval process. At their discretion, IRBs may institute a screening process to review proposals for completeness, and may return applications that are not complete to the investigator before review. Investigators are encouraged to consult their IRB before submitting an application.

## V. Records

### *A. Investigator Records*

Record retention requirements vary with the type of research conducted and the provisions of the investigator's funding source. Therefore investigators must understand

and follow any record retention requirements of their sponsor. In addition, Pepperdine University and OHRP guidelines require that investigators maintain research records for at least three years after completion of the research. HIPAA-related research records must be retained for at least six years. Furthermore, all records must be accessible for inspection and copying by authorized representatives of the IRB, department or agency supporting the research. Conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. These rules apply equally to research conducted by students and/or staff. Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations[2].

### *B. IRB Records*

Documentation of IRB activities is maintained for at least three years (or at least 6 years for HIPAA related protocols) following the completion of research and includes the following (§46.115):

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;

2. Documentation of actions taken through procedures of exempt and expedited review in the IRB minutes and in other appropriate files;

3. Minutes of IRB meetings in sufficient detail to show attendance; actions taken; vote on these actions including the number of members voting for, against, and abstaining; basis for requiring changes in or disapproving research; length of approval granted for projects; and a written summary of the discussion of controversial issues and their resolution[3];

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[2] Current FDA policy states that investigators are required to maintain records for the longest of either:

1. A period of at least two years following the date on which the results of the clinical investigation are submitted to the FDA in support of an application for a research Investigational New Drug Number or Investigational Device Exemption or marketing permit; or
2. A period of at least three years following the date on which an application for research or marketing permit (in support of which the results of the clinical investigation were submitted to the FDA) is approved by the FDA; or
3. Three years after the investigation is discontinued and FDA is notified.

[3] When approval is granted for a consent procedure which does not include, or which alters, some or all of the required elements of informed consent (as outlined in

4. Records of continuing review activities;

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

6. A roster of IRB members. IRBs may also keep on file a copy of each member's professional vitae; and

7. Written operating procedures for the IRB.

8. Statements of significant new findings provided to subjects.

All records shall be accessible for inspection and copying by authorized federal representatives at reasonable times and in a reasonable manner.

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Section VIII. of this manual) or when a waiver of the requirement to obtain informed consent is granted, the minutes will reflect (using protocol specific information) how the criteria specified at 45 CFR 46.116(d) justifying this type of approval have been met.

Similarly, where federal regulations require specific findings on the part of the IRB, such as (a) approving a procedure which waives the requirement for obtaining a signed consent form (see 45 CFR 46.117(c)); (b) approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207); (c) approving research involving prisoners (see 45 CFR 46.305-306); or (d) approving research involving children (see 45 CFR 46.404-407), the IRB minutes will document such findings in a protocol-specific manner.

## VI. Appendices

*APPENDIX A*

*Title 45 Code of Federal Regulations Part 46 (45 CFR 46)*

**CODE OF FEDERAL REGULATIONS**

**TITLE 45**
**PUBLIC WELFARE**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**NATIONAL INSTITUTES OF HEALTH**
**OFFICE FOR PROTECTION FROM RESEARCH RISKS**

**PART 46**
**PROTECTION OF HUMAN SUBJECTS**

**45 CFR 46 may be downloaded or reviewed at**

***http://www.nihtraining.com/ohsrsite/guidelines/45cfr46.html***

*APPENDIX B*

*Research Activities Exempted From Federal Regulation (CFR)*

**Investigators should note that these exemptions (45 CFR 46.104(d)(1-8) do not apply to research involving prisoners, human fetuses, neonates, pregnant women, or human in vitro fertilization (Subparts B and C).**

**The exemption at 45 CFR 46.104(d)(1-8), for research involving survey or interview procedures or observations of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.**

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

   A) Research on regular and special education instructional strategies, or

   B) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   C) Research cannot adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

2A) **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:**

   D) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

   E) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

   F) Data may involve visual or audio recording as well as a carve-out that allows for the collection of sensitive, identifiable data to be collected as long as a limited review is conducted.

2B) **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior** that is not exempt under paragraph (b)(2) of this section, if:

G) The human subjects are elected or appointed public officials or candidates for public office; or

H) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

3) **Benign behavioral interventions in conjunction with the collection of information from adult subjects.** Research, involving "benign interventions" involving adults that allows for deception under certain conditions. Data may be sensitive and identifiable as long as "limited review" is conducted by the IRB.

4) **Secondary research for which consent is not required.** Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This category includes all biospecimens, as well as special carve-outs for HIPAA-covered data, federally conducted research, and federally generated data.

5) **Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine**:

I) Public benefit or service programs;

J) Procedures for obtaining benefits or services under those programs;

K) Possible changes in or alternatives to those programs or procedures; *or*

L) Possible changes in methods or levels of payment for benefits or services under those programs.

This category provides further clarification about what are "research and demonstration projects that are conducted or supported by a Federal department or agency".

6) **Taste and food quality evaluation and consumer acceptance studies, if**

M) Wholesome foods without additives are consumed OR
N) 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 use for which broad consent is required.** Research using identifiable data and/or biospecimen repositories as long as a "limited review" is conducted.

8) **Secondary research for which broad consent is required.** Research pertaining to secondary use of identifiable data and/or biospecimens from a repository as long as certain conditions are met. Allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived.

*****At this time, **Pepperdine IRB will not mandate nor implement the institutional use of Broad Consent**, as tracking requirements may be burdensome. Exemption categories 7 and 8, which rely on Broad Consent, will not be available in the Pepperdine eProtocol system. Pepperdine IRB will continue to support study teams seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through the following processes:

- Study-specific consent and comprehensive IRB review.
- IRB waiver of consent (as eligible) and comprehensive IRB review.
- Exemption #4 - de-identification to remove the research activity from Common Rule purview and not require IRB review or consent.

## *APPENDIX C*

### *Research Activities Which May Be Reviewed Through Expedited Review Procedures*

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure 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 subjects' 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.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRB are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

**Research Categories for Expedited 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, ear stick, or venipuncture as follows:

(a) From healthy, nonpregnant adults 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; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 mL or 3 mL 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 a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection 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 noninvasive 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 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, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (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 HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)

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

(Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)

(7) Research on individual or group characteristics or behavior (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 HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) 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

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational device exemption where categories two (2) through eight (8) 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.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the DHHS regulations as "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).

***APPENDIX D***

**Update to Continuing Review Requirements**

Continuing review for research initially approved using expedited review procedures no longer needs to occur. Because the parenthetical comment defining the review period ("of one year or less") that was included in the pre-2018 rule was removed, there is now no requirement for review after initial approval.

However, the IRB can require continuing review for the research if the IRB reviewer "justifies why continuing review would enhance the protection of research subjects" (HHS 2017). The IRB must document this justification according to the new documentation requirement at 46.115(a)(3).

Ongoing research studies initially approved prior to the general compliance date are not required to comply with the revised Common Rule unless institutional policy requires it (and an IRB or institution dates and documents the change in which regulation the research is subject to [HHS 2018b]). This means that research approved via expedited review and governed by the pre-2018 rule still requires continuing review. Research approved via convened IRB review also still requires continuing review.

46.115(a)(8) Under the Final Rule, a study is presumed to be minimal risk if it meets one of the categories of the HHS Secretary's list. If the expedited reviewer determines that the study involves more than minimal risk, the reviewer can override that presumption, but must document the rationale for doing so.

***APPENDIX E***
***Limited IRB Review***

Limited IRB review is review by an IRB Chair or designated IRB member as a condition of exemption for categories 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), and (d)(8). Review these exempt categories.

1. Research that only includes interactions involving 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:
    a. 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;
    b. 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
    c. 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 IRB review to make the determination required by § __.111(a)(7) (HHS 2017).

2. 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***:***

    a. 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;

    b. 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

    c. 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

IRB review to make the determination required by § __.111(a)(7) (HHS 2017).

3. An IRB conducts a limited IRB review and makes the determination required by § __.111(a)(7) and makes the determination that the research to be conducted is within7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § __.111(a)(8) (HHS 2017).

4. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § __.116(a)(1) through (4), (a)(6), and (d);
    b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § __.117;
    c. the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
    d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results (HHS 2017).

Limited IRB review is used to ensure certain criteria are met, including the following::

- adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- ensure respect for subject's autonomy
- research conducted is within the scope of broad consent

***Difference between an Expedited Review and a Limited IRB Review***

Expedited review requires all approval criteria to be assessed by the IRB member conducting the review; whereas, limited IRB review requires only specified criteria to be assessed.

***Limited IRB Review as a Condition of Certain Exempt Research***

The Final Rule's new concept of limited IRB review as a condition of exemption is included for four of the exempt categories (2, 3, 7, and 8). Limited IRB review has different requirements based on the exemption categories.

***When is Limited IRB Review Required?***
For categories 2 and 3, a limited IRB review is only required if the research involves identifiable information (the Final Rule states "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" [HHS 2017]). Then, the IRB must conduct a limited IRB review to determine if there are adequate provisions in place to protect privacy and confidentiality as defined under 46.111(a)(8).

For categories 7 and 8, it is always required. These are the broad consent exempt categories.

***Limited IRB Review Applicability to Social, Behavioral, and Educational Research***
For research in social, behavioral, and educational areas, a limited review may be required when the research involves benign behavioral interventions in conjunction with the collection of information from adult subjects (category 3) and when it involves educational tests, surveys, interviews, or observations of public behavior (category 2) (HHS 2017).

A limited review must be conducted for exempt research in these categories when information is recorded in a manner in which the identity of the subjects can be readily ascertained, and a disclosure of the data could pose a risk of harm (limited review does not need to be conducted if the identifiable data would not reasonably place the subjects at risk of harm).

There is only one criterion for limited review for categories 2 and 3 (HHS 2017): When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data. 46.111(a)(7)

## *APPENDIX F*

## *Human Subject Research Policy For Medical Experiments: California Requirements*

Certain medical experiments are subject to California's Protection of Human Subjects in Medical Experimentation Act (California Health and Safety Code § 24170-24179.5).

This Act applies if the proposed experiment involves:

1. The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to

maintaining or improving the health of such subject or otherwise directly benefiting such subject;

2. The investigational use of a drug or device;

3. Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such subject.

If the experiment falls within one of these categories, the following additional requirements must be satisfied:

1. The subject must be provided with an *Experimental Subject's Bill of Rights* (see attached);

2. The subject (or appropriate conservator/guardian) must provide written, dated, informed consent:

- The consent form must be in a language in which the subject (or appropriate conservator/guardian) is fluent;

- The consent form pursuant to California Health & Safety Code §§ 24127-24175 is similar to the general consent form for research on human subjects. However, California statute requires that the following statement be included on the form:

  "I have received a copy of the *Experimental Subject's Bill of Rights* which I have read and understand."

- See attached draft consent form listing information which must be provided to all potential subjects.

- Who may give informed consent?

  1. The person to be subjected to the medical experiment may give informed consent.

  2. If the medical experiment is related to maintaining or improving the health of the human subject or related to obtaining information about a pathological condition of the human subject then the following may give informed consent:

     ***If a person is under a conservatorship of the person or of the person and estate, informed consent for a***

***medical experiment involving such person shall be obtained:***

1. As provided in § 2354 of the Probate Code if the person has not been adjudicated to lack the capacity to give informed consent for medical treatment.

2. As provided in § 2355 of the Probate Code if the person has been adjudicated to lack the capacity to give informed consent for medical treatment.

***If an adult person is gravely disabled and is under a conservatorship of the person or of the person and estate, informed consent for a medical experiment involving such person shall be obtained from such person, unless the conservator of such person has the right to consent to medical treatment on behalf of the conservatee.***

***If an adult person is developmentally disabled and has no conservators and is mentally incapable of giving informed consent, informed consent shall be obtained for a medical experiment involving such person, pursuant to subdivision (c) of § 4655 of the Welfare and Institutions Code.***

**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS**

[Pursuant to California Health and Safety Code § 24172]

Any subject of a medical experiment has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of the signed and dated written consent form.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

| | |
|---|---|
| Parent or legal guardian's signature on participant's behalf if participant is less than 18 years of age or not legally competent. | Participant's Signature |
| Date | Date |
| | Witness |
| | Date |

## VII. PEPPERDINE IRB APPLICATION AND FORMS

***All application categories can be accessed via the Pepperdine IRB eProtocol system at irb.pepperdine.edu. This includes:***

a. ***Claim of Exempt Research Application***

b. ***Secondary Analysis of Public-Access, Anonymous Data Sets***

c. ***Application Form for Exempt, Expedited, and Full Board Review***

d. ***Request for Modification to an Approved Human Subjects Research Protocol***

e. ***Continuing or Completion of Review Form for Human Subjects Research***

### *A. Adverse Events Reporting Form*

The Adverse Events Form may be obtained from the Pepperdine University IRB website at https://community.pepperdine.edu/irb/irb-forms/.

### *B. Non-Human Subjects Research Form*

The Non-Human Subjects Research Form may be obtained from the Pepperdine University IRB website at https://community.pepperdine.edu/irb/irb-forms/.

### *C. IRB Cooperative Agreement*

The IRB Cooperative Agreement Form may be obtained from the Pepperdine University IRB website at https://community.pepperdine.edu/irb/irb-forms/.

## VIII. INFORMED CONSENT

### *A. Documentation of Informed Consent*

Informed consent is one of the primary considerations underlying research with human subjects. It is too often forgotten that informed consent is an ongoing educational process that takes place between the investigator and prospective subject; it is not solely a piece of paper that must be signed. Nevertheless, in most cases the federal and California regulations require that informed consent be documented. For medical experiments, see **Section IX.A.** below for a suggested form pursuant to California Health & Safety Code §§ 24172-24175. It should be reiterated, however, that the consent document does not substitute for discussion.

If informed consent cannot be obtained, the investigator must apply for a waiver of informed consent. See **Section VIII.D**. below for more detailed information on this process.

According to the federal guidelines, the three necessary elements of the informed consent process are:

1. **Full disclosure of the nature of the research and the subject's participation**. This involves 8 basic elements: (1) description of the research (purpose, duration, procedures); (2) risks; (3) benefits; (4) alternatives; (5) confidentiality; (6) compensation for injury; (7) whom to contact; and (8) right to withdraw or refuse. Additional elements include: (1) risks related to pregnancy; (2) anticipated reasons for termination from the study; (3) costs; (4) consequences of withdrawal; (5) new findings; and (6) number of subjects; (7) 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; (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (e.g., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

2. **Adequate comprehension on the part of the potential subjects**. Informed consent is not valid unless the consenter understands the information that has been provided. The investigator must consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place in determining the appropriate way to present the information.

3. **The subject's voluntary choice to participate**. In order to be valid, consent must be freely given, without any form of coercion. In addition to overt forms of coercion, the investigator needs to be sensitive to more subtle forms of coercion, such as social pressure, requests from authority figures, and undue incentive for participation.

Documentation of "legally effective informed consent" usually involves the use of a written consent form signed by the subject or the subject's legal representative. Again, the consent form is merely the documentation of informed consent, and does not, in itself, constitute informed consent. The fact that a subject signed a consent form does not mean that s/he understood what was being agreed to or truly gave his/her voluntary consent.

Federal officials (OHRP) recommend that consent forms meet the following four criteria:

1. Be brief, but have complete basic information
2. Be readable and understandable to most people
3. Be in a format that helps people comprehend and remember the information
4. Serve as a script for the face to face discussions with the potential subjects/participants.

Note: Informed consent templates can be found online at https://community.pepperdine.edu/irb/.

Pepperdine IRBs may require that the approval and expiration dates be affixed to all approved informed consent documents and stipulate that copies of these dated documents must be used in obtaining consent. This procedure is recommended by federal officials because it helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuing review.

1. If the **RESEARCH INVOLVES THE PARTICIPATION OF MINORS (under 18 years of age)**, please read the *Description of Requirements for Research Involving Children* which is attached. Additional requirements concerning the parental consent forms and children assent forms are discussed.
2. If the **RESEARCH ACTIVITIES ARE DIRECTED TOWARD PREGNANT WOMEN**, please see subpart B of the federal guidelines for rules as to whether the mother and/or father must give consent after having been fully informed regarding the impact on the fetus. For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D.
3. Instructions for **Informed Consent Procedures for Human Participant/Subjects Who Do Not Speak English**

The federal regulations for the protection of human subjects require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117).

Where informed consent is documented in accordance with §46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. Federal officials (OHRP) strongly encourage the use of this procedure whenever possible.

Alternatively, §46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is

presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document (see sample attached) should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.

At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (e.g., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of §46.117(b) (2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

It is the responsibility of the IRB to determine which of the procedures at §46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

### *B. Research Involving Children*

Federal regulations (15 CFR 45, Subpart D) require additional protections for research involving children because they are considered a vulnerable research population as persons who have **not attained the legal age** for consent **in the jurisdiction in which the research will be conducted (45 CFR 46.402(d)** )

Note that whenever feasible, appropriate studies should be conducted on animals, adults, and older children before young children are involved as research subjects.

The IRB must find that **the activity represents one of four permissible categories** of research, and that adequate provisions are made for soliciting **the assent of the children and the permission of each child's parents or guardian. --- 45 CFR 46.404-408**

Children who are **wards of the State** or any other agency, institution, or entity can be included in research only under certain conditions. **--- 45 CFR 46.409**

The Institutional Review Board is required to consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children as well as the permission of parents or legal guardians. The IRB's policy with respect to obtaining consent from the parents or legal guardians and assent from minors is specified below:

1. In most cases, parental consent must be obtained if the research involves minors under the age of 18. A written consent form must be used to document informed consent. Both parents must sign the consent form unless this requirement is waived by the IRB. (The requirement for parental consent may be inappropriate in some cases such as research on child abuse.)

2. Minor subjects/participants 6 years of age or older should be involved in the decision to participate in a research project unless:

    A. The subject/participant is incapable, mentally or emotionally, of being reasonably consulted;

    B. The IRB specifically waives this requirement.

Unless the requirement is waived by the IRB, documentation of assent is required for subjects aged 7-17. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the IRB for review. The form should include a simplified version of the elements of informed consent which are described in the *Instructions for Documentation of Informed Consent.* Note that the child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

### *C. Research Involving Prisoners*

Subpart C of the HHS regulations requires additional protections for research involving prisoners as subjects:

- ***Prisoner*** means any individual **involuntarily confined or detained** in a penal institution, including individuals detained in other facilities which provide alternatives to criminal prosecution or incarceration, and individuals detained pending arraignment, trial, or sentencing.**--- 45 CFR 46.303(c)**
- At least **one** member of the Institutional Review Board (IRB) must be a **prisoner or a prisoner representative** with appropriate background and experience. **--- 45 CFR 46.304(b)**
- The IRB must find, and certify to OHRP where required, that **six additional protections** specific to prisoners have been satisfied. **--- 45 CFR 46.305**

(1) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(2) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(3) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(4) the information is presented in language which is understandable to the subject population;

(5) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(6) where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

- The IRB must find, and OHRP must determine in certain cases, that **the research represents one of four permissible categories of research.** Certain research may go forward only after OHRP has consulted with appropriate experts in penology, medicine, and ethics. **--- 45 CFR 46.306**

(1) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

*(Note that the definition of minimal risk for prisoner research at 45 CFR 46.303(d) differs from the definition of minimal risk for other research, contained in 45 CFR 46, subpart A, 45 CFR 46.102(i))*

(2) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(3) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(4) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.

**D. Waiver of Informed Consent**

Under the federal guidelines (§45CFR46.116), the IRB can approve study procedures that involve the waiver of informed consent in two situations. First, if the following conditions are satisfied:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

**OR**

1. 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 alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

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

There is no such process as "implied consent." If written informed consent is not possible, an investigator must apply to the IRB for a waiver of this requirement. Under CFR §46.117, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

> (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
>
> (2) That 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**The Pepperdine IRB Application for Waiver or Alteration of Informed Consent Procedures form should be used for both waivers of and alterations to the informed consent process. This form can be found online at https://community.pepperdine.edu/irb/forms.htm.**

## IX. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

### *A. What is HIPAA?*

The *Health Insurance Portability and Accountability Act of 1996* (HIPAA) is a new Federal law that provides safeguards to protect the health information of individuals obtaining healthcare in the USA, also known as the Privacy Rule. Since investigators may create, use or exchange individually identifiable health information when conducting research, Pepperdine University must assure compliance with HIPAA as it relates to research.

For more information on Pepperdine's HIPAA policies and procedures, see the HIPAA Policies, Procedures and Forms Manual at www.pepperdine.edu/provost/policies/ or contact the Pepperdine Privacy Official. The Pepperdine Privacy Official is identified on the Pepperdine University Human Protections website: https://community.pepperdine.edu/irb/. Pepperdine University's HIPAA Notice of Privacy Practices can also be found at www.pepperdine.edu/provost/policies/.

HIPAA contains provisions to protect the confidentiality and security of individually-identifiable health information. The Privacy rule does NOT replace or modify the Common Rule or FDA regulations. The Privacy rule is in ADDITION TO privacy protections of these regulations.

#### 1. What is Individually Identifiable Health Information?

*Individually-identifiable health information* is any information created, used, or received by a health or mental health care provider that relates to:

- the past, present, or future physical or mental health or condition of an individual,
- the provision of health care to an individual, or

the past, present or future payment for the provision of health care to an individual with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

The collection of individually-identifiable health information for research constitutes human subjects research. The HIPAA rule governs the use of individually-identifiable health information when it is ***Protected Health Information (PHI)***.

**2. What is PHI?**

***PHI*** is defined as any individually identifiable health information collected or created as a consequence of the provision of health care by a covered entity, in any form, including verbal communications.

All Pepperdine research related disclosures of PHI must obtain prospective approval by a Pepperdine University IRB. In general, except for treatment, investigators are restricted to the minimum PHI reasonably necessary to conduct the research.

**HIPAA Defined Personal Identifiers**

| | |
|---|---|
| 1. Names | 10. Account number |
| 2. Dates of birth, death, admission, and discharge (except year) | 11. Certificate/license number |
| 3. Postal address including city, state, & zip code | 12. Vehicle identifier |
| 4. Telephone number | 13. Device identifiers and serial number |
| 5. Fax number | 14. URLs |
| 6. E-mail address | 15. IP address |
| 7. Social Security number | 16. Biometric identifiers, including fingerprints |
| 8. Medical record number | 17. Full face photos and other comparable images |
| 9. Health Plan ID number | 18. Any other unique identifying number, characteristic or code |

Removal of these identifiers makes information de-identified and not subject to HIPAA. Coded data is de-identified as long as the code is not derived from an identifying source, and as long as the key to the code is secure (source: kutkatl@od.nih.gov).

**3. Am I A Covered Entity? Is My Data Source a Covered Entity?**

A Covered Entity is:

- a health care provider who transmits health information in electronic transactions for which the Secretary has adopted standards/for certain purposes. For example, a physician who electronically bills for services.
- A health plan
- A health care clearinghouse

Pepperdine University is a Hybrid Entity under HIPAA. A Hybrid Entity means a single legal entity that is a covered entity, performs business activities that include both covered and noncovered functions, and designates its health care components as provided in the Privacy Rule (45 C.F.R. § 164.504). Investigators conducting research should

determine whether they are planning to obtain data from part of Pepperdine that is a Covered Entity**,** which include:

- Student Health Center and/or Wellness Program;
- Athletic Training Center;
- Student Counseling and Testing Control;
- Pepperdine Psychology and Educational Clinic;
- Pepperdine Communications Counseling Center;
- Pepperdine Jerry B.H. Union Rescue Clinic; and
- Center for Human Resources, Benefits Department.

If you are seeking to obtain information for research purposes from a Pepperdine institutional unit not noted in the above list, your research does not fall under HIPAA.

Pepperdine faculty, staff or student researchers who are not planning to do research in/with one of the above Pepperdine Covered Entities, but who plan to collect data from a non-Pepperdine Covered Entity (e.g., most hospitals; some counseling centers) must follow the HIPAA procedures of that CE. Contact your supervisor, IRB Chairperson, and/or Pepperdine's Privacy Officer, if you have questions about your status or the status of your research project, and which procedures you need to follow.

**4. What Types of Research are Typically Covered by HIPAA?**

**Investigators should remember that PHI has three main components: (1) Covered Entity, (2) Health (and mental health) Information, (3) Identifier.** All 3 components need to be met for your research to be covered under HIPAA. The PHI can be transmitted or maintained in any form (paper, electronic, web-based, etc.). Decedents' information can be included. PHI does not include de-identified health information or biological tissue.

1. Research that includes the review of medical records (including some mental health records) or biological materials with attached identifying information from a covered entity,
OR
2. Research that results in the addition of new information to a medical record of a covered entity (e.g., research in which a health care service is performed, such as testing a new diagnostic method, or a new drug, biologic, or device, creating new information in a medical record).

**5. What is the IRB's Role?**

Each Pepperdine IRB will act as a Privacy Board (required by HIPAA) to review the research use or disclosure of PHI and determine whether:

a. subjects should sign a "HIPAA Authorization," in addition to or in combination with the informed consent form for participation in research, OR
b. a Waiver of Authorization (roughly analogous to a Waiver of Informed Consent under 45 CFR 46) may be granted, AND
c. Investigators and research staff should have HIPAA research certification.

**6. What Procedures Will Investigators Have To Follow?**

**If the study involves PHI, all members of the study team are required to complete a HIPAA research certification (like the Human Subjects Research education requirement) before the IRB will approve the protocol.**

**<u>Also, an investigator conducting research involving PHI must:</u>**

A. Obtain the "HIPAA Authorization" of the subject. Research subject authorization for release or inclusion of individually identifiable health information may only occur if the subject has signed both (1) a HIPAA Authorization for Release of Protected Health Information for Research Purposes form and (2) the IRB approved informed consent document for the research or a combined form.

If you will ask subjects to create or use their PHI, please use one of the following HIPAA Authorization forms, or the approved form of a covered entity from which you are obtaining the PHI.

*Existing Protocols:*

- **Subjects enrolled prior to April 14, 2003 are "grandfathered," meaning their existing signed research informed consent document is HIPAA compliant.**
- **New subjects must sign a "HIPAA Authorization" unless a waiver of informed consent and authorization have been granted by the IRB.**

***OR***

B. Obtain from the IRB permission for the use or disclosure of PHI without a Privacy Rule Authorization, through one of the following methods (as explained further in subsection C below):

1. a Waiver of HIPAA Authorization, or

2. use of a limited data set (LDS), or

3. use of a de-identified data set; or

4. the use of a de-identified data set ("Statistical Standard"); or

5. certification of use under Preparatory to Research provisions; or

6. certification of use of decedents' information.

***B. HIPAA Authorization***

**INFORMATION FOR COVERED ENTITIES AND RESEARCHERS ON AUTHORIZATIONS FOR RESEARCH USES OR DISCLOSURES OF PROTECTED HEALTH INFORMATION**

- Source: http://privacyruleandresearch.nih.gov/authorization.asp

A Privacy Rule Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. In contrast, an informed consent document is an individual's agreement to participate in the research study and includes a description of the study, anticipated risks and/or benefits, and how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research. If a covered entity obtains or receives a valid Authorization for its use or disclosure of PHI for research, it may use or disclose the PHI for the research, but the use or disclosure must be consistent with the Authorization.

The Authorization must be written in plain language. A copy of the signed Authorization must be provided to the individual signing it if the covered entity itself is seeking the Authorization. The Privacy Rule does not specify who must draft the Authorization, so a researcher could draft one. The Privacy Rule specifies core elements and required statements that must be included in an Authorization. An Authorization is not valid unless it contains all of the required elements and statements. An Authorization form may also, but is not required to, include additional, optional elements so long as they are not inconsistent with the required elements and statements and are not otherwise contrary to the Authorization requirements of the Privacy Rule.

*An Authorization, whether prepared by a covered entity or by a person requesting PHI from a covered entity, must include the following core elements and required statements:*

**Authorization Core Elements (see Privacy Rule, 45 C.F.R. §164.508(c)(1))**

- 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 covered entity 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, not for future unspecified research. Authorization may be used to create a repository or database.

- Authorization expiration date or event that relates to the individual 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 individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual.

**Authorization Required Statements (see Privacy Rule, 45 C.F.R. § 164.508(c)(2))**

- The individual'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 individual may revoke his/her Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.

- Notice of the covered entity'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 the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.*

A research subject may revoke his/her Authorization at any time. However, a covered entity may continue to use and disclose PHI that was obtained before the individual revoked his or her Authorization to the extent that the entity has taken action in reliance on the Authorization. In cases where the research is conducted by the covered entity, this would permit the covered entity 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.

* If an Authorization permits disclosure of PHI to a person or organization that is not a covered entity (such as a sponsor or funding source of the research), the Privacy Rule does not continue to protect the PHI disclosed to the noncovered entity. However, other applicable federal and state laws as well as agreements between the disclosing covered entity and the PHI recipient may establish continuing protections for the disclosed information.

### *C. Use or Disclosure of PHI WITHOUT Authorization*

Investigators who are covered entities, or who are proposing to obtain human subjects information from covered entities, do not always need to get Authorization for research-related activities. There are at least six ways that an investigator may use or disclose PHI without Authorization.

#### 1. IRB or Privacy Board Waiver of HIPAA Authorization

Similar to the process for a waiver of informed consent which requires that the research be no more than minimal risk, the waiver of authorization requires that the research be no more than minimal risk to privacy and the application needs to provide for an explicit plan to protect private information, a plan to destroy identifiers as soon as practicable, and written assurance the information will not be re-used or disclosed secondarily. The waiver of authorization also includes the provision that the research could not be practicably carried out without the waiver, but this is directed toward required access to PHI, which is slightly different that the consent waiver requirements regarding impracticability (§45CFR164.508 and 164.512(i)).

If this research results in information pertinent to the subjects whose records/specimens are used, then the investigator must submit a written plan for providing this information to the subjects. This plan must be approved by the IRB before research subjects are contacted.

In order to approve a waiver of HIPAA Authorization, therefore, the following components must be demonstrated:

a. Outline how the use and disclosure of PHI poses no greater than minimal risk[4] to the subjects.
b. Written assurance that the PHI will not be reused or disclosed to any other person or entity except as required by law, for study oversight, or for other research for which the use and disclosure of PHI would be permitted;

[4] 45 CFR 46.102(i): Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

c. An adequate plan to protect the identifiers from improper use or disclosure, except as required by law, or for other research as permitted by the HIPAA regulations; and
d. An adequate plan for the destruction of the identifiers at the earliest opportunity consistent with the conduct of the research, or a health or research justification for retaining the identifiers or provide the legal reference requiring retention of the data (Be specific, state a date or event, such as following data analysis, following publication).
e. The research could not practicably be conducted without the waiver or alteration; and
f. The research could not practicably be conducted without access to and use of the PHI.

**2. Limited Data Set (LDS)**

HIPAA allows investigators to use or disclose PHI if the IRB approves the use of a LDS:

a. Please provide a written assurance that the data set will only include the following PHI elements:

   i. Zip code
   ii. Date of birth or date of death
   iii. Date(s) of service
   iv. Geographic subdivision (city)

b. Provide the signed data use agreement between the investigator and the Covered Entity (CE) [the institution legally authorized to maintain and provide the information]. The data use agreement must include the following:

   i. List the permitted uses and disclosures of the LDS (recipient cannot use or disclose PHI in a way that the covered entity cannot)
   ii. Establish who is permitted to use or receive the LDS
   iii. Assurance that the recipient or investigator will:
      (1) not use or further disclose the information other than as specifically permitted in the agreement or as required by law,
      (2) Use appropriate safeguards to prevent use or disclosure of the information other than as provided in the agreement,
      (3) Report to the CE any known, unpermitted uses or disclosures,
      (4) Ensure that anyone to whom s/he provides the data (e.g., subcontractors) agrees to the same restrictions and conditions with respect to the information, and
      (5) Not re-identify the information or contact the individuals to whom the information belongs.

**3. De-Identification (Removal of Identifiers, a.k.a. "Safe Harbor Standard")**

HIPAA allows investigators to use or disclose PHI if the IRB approves the use or disclosure of de-identified data by removing the identifiers listed below. The investigator must provide an assurance that the following identifiers have been removed:

| | |
|---|---|
| 1. Name | 11. Health plan ID number |
| 2. Location smaller than State | 12. Account number |
| 3. Last 2 digits of zip code | 13. Certificate/license number |
| 4. All dates (year is acceptable) | 14. Vehicle identifier |
| 5. Ages over 89 | 15. Device identifiers and serial numbers |
| 6. Telephone number | 16. URLs |
| 7. Fax number | 17. IP address |
| 8. E-mail address | 18. Biometric identifiers, including fingerprints |
| 9. Social Security number | 19. Full face photos and other comparable images |
| 10. Medical record number | 20. Any other unique identifying number, characteristic, or code |

**4. De-Identification ("Statistical Standard")**

HIPAA allows investigators to use or disclose PHI if the IRB approves the use of de-identified data by using the following methodology:

a. The Statistical Standard requires documentation from a qualified statistician specializing in de-identification of data demonstrating that the proposed methods and analysis will effectively de-identify the data. Please provide appropriate information about the statistician certifying her/his expertise in de-identification methods and analysis.

b. Please provide documentation from the statistician that the proposed methods and analysis for the research will result in:

   i. The data being rendered de-identified and
   ii. The risk being very small that the information can be used to identify an individual.

**5. Activity preparatory to research**

The researcher must certify that:

a. PHI is to be used solely to prepare a protocol, or for a similar preparatory purpose, AND
b. PHI will not be removed from the CE, AND
c. PHI is necessary for research purposes.

For research recruitment purposes, researchers who are **not** covered entities themselves may use the Preparatory to Research provision to identify subjects (but not remove their PHI from the CE). However, they may not contact subjects without obtaining a Waiver of Authorization or becoming a Business Associate of the CE for the health care operation.

For research recruitment purposes, researchers who **are** covered entities themselves may use the Preparatory to Research provision to identify subjects (but not remove their PHI from the CE). They may be able to contact subjects without obtaining a Waiver of Authorization for research related treatment and for health care operations.

**6. Research that is on decedent's information**

The researcher must certify that:

a. Use or disclosure of PHI is solely for research on decedents, and
b. Individuals are decedents, and the investigator must provide documentation of this fact upon CE's request, AND
c. PHI is necessary for research purposes.

## X. HIPAA Forms

### *A. HIPAA Authorization forms*

If a Pepperdine investigator is seeking to conduct research at or with a Covered Entity (CE), the CE will probably have its own HIPAA Authorization forms for research purposes. Accordingly, the investigator should use such forms. If the CE does not have an Authorization form for research purposes, then the investigator should develop one using one of the two formats offered below.

This section provides sample language and issues to consider in developing a research Authorization. Two sample forms are provided for investigators to consider. In the first sample form (HIPAA Authorization Form One), language addressing the required elements is listed first, followed by a set of optional elements that may be useful in specific research situations. The second form (HIPAA Authorization Form Two) contains California state law requirements.

Copies of both sample HIPAA Authorization Forms, HIPAA Authorization Form One and HIPAA Authorization Form Two, may be obtained from the Pepperdine University Research Protections web site at https://community.pepperdine.edu/irb/hipaaforms/.

***B. Revocation of HIPAA Authorization form***

The Revocation of HIPAA Authorization form may be obtained from the Pepperdine University Research Protections web site at https://community.pepperdine.edu/irb/hipaaforms/.

***C. Application for Use or Disclosure of PHI Without HIPAA Authorization form***

The Application for Use or Disclosure of PHI Without Authorization form may be obtained from the Pepperdine University Research Protections web site at https://community.pepperdine.edu/irb/hipaaforms/.

## XI. PROCEDURES FOR AMENDING HUMAN PROTECTIONS POLICIES AND PROCEDURES

1. **Human Protections Administrative Council.** The administrative body responsible for maintaining and changing, as needed, human research protections policies and procedures is the Human Protections Administrative Council (HPAC). Within this document, human research protections policies and procedures relate to all Pepperdine University policies and procedures governing the protection of human research participants, including the content of the *Protection of Human Participants in Research: Policies and Procedures Manual*

   Members of the HPAC are the (i) Vice Provost; (ii) Human Protections Administrator; (iii) Chairperson of the Graduate and Professional Schools IRB; (iv) Chairperson of the Seaver College IRB; and (v) Provost (ex officio)

2. **Initiation of Changes.** Requests for changes in Pepperdine University human research protections policies or procedures shall be submitted in writing to a member of the HPAC. Upon receipt, the request shall be distributed to all members of the HPAC.

3. **HPAC Approval of Changes.** All requests for changes in Pepperdine University human research protections policies or procedures will be reviewed at annual meetings of the HPAC. At the discretion of any member of the HPAC, additional meetings may be requested to consider alterations or revisions in human research protections policies or procedures. The HPAC will determine whether a proposed

change is substantive or non-substantive, as defined below. **All changes in human research protections policies or procedures must be approved by no fewer than three members of HPAC, regardless of the number of members present at the meeting.**

4. **Substantive Changes.** Substantive changes in human research protections policies or procedures include changes that:
    A. Possess the potential to affect the health and safety of research participants;
    B. Are required to conform to requirements of, or alterations in, federal or state law; or
    C. Materially increase the demands on the Investigator during the preparation and submission of an IRB application.

5. **Non-substantive Changes.** Non-substantive changes in human research protections policies or procedures include changes that:
    A. Do not affect the health and safety of research participants;
    B. Do not materially increase the burden on the Investigator during the preparation and submission of an IRB application;
    C. Correct minor errors in published human research protections policies or procedures; or
    D. Improve the clarity in expression of published human research protections policies or procedures.

**6. Review and Approval Process.** Upon approval by the HPAC, *substantive* changes in human research protections policies or procedures will be reviewed by the University Academic Council (UAC). During the period of review by the UAC, the proposed change will be distributed to all Pepperdine University faculty members for no less than a 30 day period of review and comment.

If no comments are received during the period of review and comment, the change shall become effective within 90 days of the Provost's approval, in accordance with the guidelines stated in section 7. If substantive comments are received during the period of review and comment, the Provost may direct the HPAC to reconsider the change. Upon consideration of the comments, the HPAC will forward its recommendation regarding the change to the provost for approval.

In the event of urgent circumstances (such as a deadline imposed by a governmental or other external agency or institution), that make it impossible or impracticable for the HPAC to provide the period of comment and review before recommending a substantive change to the provost, the HPAC may provide the period of comment and review after the provisional adoption of the policy or take other steps to ensure that faculty have an opportunity to review the change.

7. **Effective Date for Substantive Changes.** Approved *substantive* changes in human research protections policies or procedures become effective within 90 days of the

Provost's approval as determined by HPAC. A formal announcement of all substantive changes will be distributed to Pepperdine University faculty and documented on the IRB website. A record of the changes shall be maintained in an appendix of the *Protection of Human Participants in Research: Policies and Procedures Manual*.

8. **Effective Date for Non-substantive Changes.** Approved *non-substantive* changes in human research protections policies or procedures will become effective at the discretion of the HPAC, but no later than twelve months following approval. Changes will be documented on the IRB website, and approved non-substantive changes also will be published in an appendix of the *Protection of Human Participants in Research: Policies and Procedures Manual* on August 15th annually.

## XII. Changes to the IRB Manual

**August, 2004**

1. Updated out-of-date URLs throughout the document.
2. Removed out-of-date hyperlinks in Section VIII. Informed Consent.
3. Named Dr. Lee Kats as the AIO and SO in Section I.
4. Included FWA information in Section I.
5. Modified Section II.D. regarding contacting GPS IRB.
6. Added material explaining the difference between confidentiality and anonymity in Section III.A.6 .
7. Removed text of 45 CFR 46 from Appendix A of the manual and provided a link to this material at http://www.nihtraining.com/ohsrsite/guidelines/45cfr46.html.
8. Experimental Bill of Rights updated to comply with California law.
9. Added material and forms for research utilizing only the Secondary Analysis of Public-Access, Anonymous Data Sets to Section VII.
10. Added category for "Faculty Research" to IRB forms in Section VII.
11. Added description of other vulnerable populations in IRB Application, Section VII. Appendix C.

12. Added Section XI, Procedures for Amending Human Protections Policies and Procedures.

13. Modified the exemplar informed consent for participation in medical research activities form in Section IX.

14. Modified the exemplar informed consent for participation in research activities form in Section IX.

15. Added Section XII. Miscellaneous Forms and Appendix A.

16. Added Section XIII, Changes to the IRB Manual.

**August, 2005**

1. Updated out-of date URLs throughout the document.

2. All application and authorization forms were removed from the manual and replaced with the appropriate link to the document.

3. Names of people holding positions within the IRB were deleted from the manual and can be found on the IRB website.

4. Added information about the Protocol Review Subcommittee to Section I.B.1.

5. Updated list of approved IRB & HIPAA training programs in Section I.E.

6. Edited second to last bullet point in Section II.B.2.b.

7. Deleted last bullet point in Section II.B.2.b.

8. Deleted the specific number of primary reviewers designated to review an application in Section III.B.3.

9. Templates were created for Sections IX.A., IX.B., and IX.D. The URL to the templates is given in the manual.

10. Modified application for a waiver or alteration of informed consent procedures in Section IX.E.

11. Inserted a link to see sample HIPAA authorization forms in Section X.A..

12. Corrected various formatting errors throughout the document.

13. Updated Section XIII, Changes to the IRB Manual.

**September, 2008**

1. Updated out-of date URLs throughout the document.

2. Updated office title "Corporations, Foundations, and Sponsored Programs" in Section I.B. (pg. 8)

3. Edited information regarding the Protocol Review Subcommittees to Section I.B.1.

4. Updated the application to Conduct Secondary Analysis of Public-Access, Anonymous Data Sets form in Section VII.B.

5. Updated Section XIII, Changes to the IRB Manual.

**November 2009**

1. Added the following sections:
    a. "**Non-Pepperdine Affiliated Investigators"** section added as #3 after "Collaborators" in section IIA
    b. "**Alumni and Adjunct Faculty Research"** section added as #4 in section IIA
    c. "**International Research"** section added as #5 in section IIB
    d. "**Research Noncompliance"** section added after "Adverse Event Reporting" in section III
2. Updated Section XIII, Changes to the IRB Manual.

**April - October 2018**

1. Updated out-of date URLs throughout the document.
2. Updated titles through the document, according to new reporting structure for Pepperdine IRB committees.
3. Updated grammar throughout the document.
4. Provisions, changes, and additions to comply with Revised Common Rule (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)
    a. New and revised definitions
    b. New exemption categories regarding secondary research
    c. Elimination of continuing review
    d. Revised informed consent requirements
    e. Harmonization with other agency guidance
    f. Guidance on application to clinical data registries
    g. Cooperative research studies (sIRB review)

5. Removed samples from Appendix IX. Informed Consent and referred readers to the Human Subjects Protections website at https://community.pepperdine.edu/irb/.
6. Updated Section XII, Changes to the IRB Manual.

September 20, 2021

1. Updated web link on page 15 E.(1) - https://about.citiprogramorg/en/homepage/.