



INSTITUTIONAL REVIEW BOARD HANDBOOK
Guide for Research Involving Human Subjects

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0.0: Frequently Asked Questions (FAQ)

(1) Do I need special certification to conduct or approve research involving human subjects at Azusa Pacific University?

Yes. All those who conduct research, review the applications of researchers, or teach a course with a requirement for student research must complete training for the protection of human subjects in research. Please see Section 4.3 for instructions for certification.

(2) Is my project “research” with “human subjects” that must be reviewed by the IRB?

See Section 2.0 for the definitions of “research” and “human subjects”, and additional guidance.

(3) What level of IRB review is appropriate for my research project?

There are two categories of review, minimal risk and more than minimal risk. Within minimal risk, studies are reviewed as either expedited or as exempt. Studies with more than minimal risk are reviewed by the full board. Please note that the category labels are not descriptive. The difference between the review categories is the degree of scrutiny, which depends on the level of risk to human subjects.

- **Full Board Review** see Section 5.1
- **Expedited** – see Section 5.2
- **Exempt Status** – see Section 5.3
- **More than minimal risk** – see Section 5.1.1 and 6.1
- **Minimal risk** – see Section 6.2

(4) What does the IRB consider when reviewing a project for protection of human subjects?

See Section 3.4.

(5) When does the IRB meet?

The Full IRB Board meets monthly, twelve months a year, generally the third (3rd) Wednesday of each month. The deadline to submit an application for consideration by the full board is 10 working days before the meeting.

(6) Who are the members of the IRB?

The Research Integrity Officer (RIO) appoints members in accordance with federal guidelines. A majority of the members are faculty. For current members and alternates, contact the coordinator at irb@apu.edu.

(7) What needs to be submitted for an IRB application?

The IRBManager online application system will guide you through the process including required attachments such as Informed Consent form(s), participant recruitment, and survey instruments. You can access the application and attachment forms at <https://apu.my.irbmanager.com>.

(8) What are special considerations for persons planning to survey members of the APU community?

Persons planning to survey members of the APU community (whether electronic or paper surveys) must contact the Office of Institutional Research (OIRA) at oir@apu.edu or 626.387.5798 prior to submission to the IRB for assistance with the survey and for scheduling their data collection.

(9) Does a researcher from outside the APU community need to receive approval from APU's Institutional Review Board to conduct research using APU faculty, staff, or students?

Yes, IRB approval at APU is most often required, though this is determined on a case by case basis. Please contact the coordinator at irb@apu.edu

For any questions, send an email to irb@apu.edu.

1.0: Guidelines for Research Involving Human Subjects

1.1: Introduction

Azusa Pacific University (APU) encourages the conduct of research in and among its schools, and in collaboration with other educational institutions, agencies, and organizations. The University, while respecting the right of faculty and students to academic freedom in research, is firmly committed to adhering to the basic Christian ethical principles underlying the acceptable conduct of research involving human subjects.

All researchers affiliated with APU who are conducting research in which APU is engaged must obtain APU Institutional Review Board (IRB) approval for their research with human subjects before data collection begins. Engaging in research with human subjects without IRB approval has serious ethical implications and violates university and federal policies. Questions regarding whether APU's IRB approval is required may be directed to the coordinator at irb@apu.edu.

Adherence to the Common Rule: On June 18, 1991, seventeen federal departments and agencies adopted a common set of regulations known as the *Federal Policy for the Protection of Human Subjects* or "*Common Rule*." See <http://www.hhs.gov/ohrp/> (Regulations 45 CFR 46). These federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that research is reviewed and approved by the University's Institutional Review Board (IRB). The Common Rule was revised on January 19, 2017 and applies to federally funded or supported projects approved after the implementation date of January 21, 2019. The design of these regulations is based on established, internationally recognized ethical principles discussed in the Belmont Report (1979) as follows:

Respect for persons incorporates at least two ethical convictions: "first, that individuals should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection" (thus, the need to obtain informed consent).

Beneficence entails treating persons "in an ethical manner not only by respecting their decisions, but also by making efforts to secure their well-being. . . Two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated results and minimizing possible risks of harm."

Justice requires that the "benefits and burdens of research be distributed fairly" (thus, the principle of justice is applied in the selection of research subjects).

For more information, please refer to *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

1.2: Definitions for purposes of this Handbook

- (a) **Certification** means the official notification by the institution to the supporting federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.
- (b) **Clinical trial** means 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.
- (c) **Confidentiality** - Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. See page 25 for expanded information.
- (d) **Department or agency head** means the head of any federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.
- (e) **Federal department or agency** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates.
- (f) **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research:
 - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens; (§ 45 CFR 46.102[e] [1]).
 - (1) **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject's environment that are performed for research purposes.
 - (2) **Interactions** includes communication or interpersonal contact between investigator and subject.
 - (3) **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).
 - (4) **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.
 - (5) An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.
- (g) **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies)
- (h) **IRB** means an **institutional review board** established in accord with and for the purposes expressed in this policy.
- (i) **IRB approval** means the determination of the IRB that the research conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

- (j) **Legally authorized representative** (LAR) 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.
- (k) **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.
- (l) **Minor/Child** – Participant under the age of 18 except for emancipated minor.
- (m) **Privacy** - Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Please be attentive to threats to participants' privacy. An acceptable practice is to distribute invitations to a broad population and ask for persons to self-identify as meeting more narrow criteria. An option for some sensitive interview research is to offer the participant the opportunity to review publication drafts for unintended markers of identity.
- (n) A **project or study** is "research" in this context if it: a) is conducted with the intention of drawing conclusions that have some general applicability to populations or situations other than the one being studied ("generalizable knowledge"), and b) uses a commonly accepted qualitative or quantitative method. More specifically, generalizable knowledge is information based on results or findings that are expected 1) to be reproducible, and 2) to apply broadly with the expectation of predictable outcomes.
- (o) **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision or 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 employee 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.
- (p) **Research** is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (§ 45 CFR. 46.102 [I]). For the current Code of Federal Regulations, please see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.
The following studies are deemed **NOT** to be research:
 - (1) Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research and historical scholarship).
 - (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.
 - (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.
- (q) **Sensitive topics** are any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential is considered sensitive topic research. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive.
- (r) **Vulnerable populations** - Vulnerable populations are individuals or groups who, by reason of disability, illness, age, or other status exhibit diminished personal autonomy. Neither the federal regulations nor ethical codes proscribe inclusion of vulnerable persons as research subjects. However, the Department of Health and Human Services regulations mandate special justification for research involving fetuses, human in vitro fertilization, and children. Vulnerable populations could also include in some situations pregnant women, prisoners, those with

impaired decision-making capacity, and those who are economically or educationally disadvantaged.

- (s) **Written, or in writing**, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

2.0: Is it Human Subject Research?

A study may have the characteristics of human subject research but may not meet the regulatory definition requiring IRB review. If a study is submitted and does not qualify, the IRB will issue a communication stating that the project does not qualify as human subject research and does not require IRB review.

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (§ 45 CFR. 46.102 [I]). For the current Code of Federal Regulations, please see:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Human Subjects are living individuals about whom an investigator (whether professional or student) conducting research, obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens; (§ 45 CFR 46.102[e] [1]).

A project or study is “research” in this context if it:

- a) is conducted with the intention of drawing conclusions that have some general applicability to populations or situations other than the one being studied (“generalizable knowledge”), and
- b) uses a commonly accepted qualitative or quantitative method. More specifically, generalizable knowledge is information based on results or findings that are expected
 - 1) to be reproducible, and
 - 2) to apply broadly with the expectation of predictable outcomes.

2.1: Research involving Human Subject’s

The following types of studies that **are** considered human subject research include:

- Studies that utilize subjects for new devices, products, drugs, or materials;
- Studies that collect data through intervention or interaction with individuals;
- Studies using private information that can be readily identified with individuals;
- Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings;
- Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information;

2.2: Research NOT involving Human Subject’s

The following types of studies that **are not** human subject research include:

- Data collection for internal departmental, school, or other University administrative purposes, such as teaching evaluations, customer service surveys;

- Service Surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni;
- Information-gathering interviews with questions focused on things, products, or policies rather than people or their thoughts/personal opinions;
- Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, **but are not** intended for use outside of the classroom;
- Biography or oral history research involving a living individual that is not generalizable beyond that individual;
- Independent contract for procedures carried out for an external agency, such as cost-benefit analysis, customer satisfaction, IT usage, and software development;
- Quality improvement projects unless there is a clear intent to contribute to generalizable knowledge and use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice;
- Case histories of a single patient and do not contribute to generalizable knowledge which are published and/or presented at national or regional meetings;
- Publicly available data

Note: Although the general definition of a human subject includes only living individuals, thereby excluding decedents, there are cases in which the health information of the deceased and death data files may require IRB review. Check with the coordinator at irb@apu.edu.

2.3: Research Examples

If your project meets the criteria of both “research” and with “human subjects” as noted above, it must have some level of review from the IRB. In addition, the need for IRB review is not determined by whether the researcher intends to present or publish the study outcomes, since publishing the results of a project does not by itself classify the study as one that is generalizable. However, in some cases, the intent to publish can be used as one criteria for determining whether the project meets the above definition of “research.”

Opportunity samples, pilot studies, and preliminary studies designed to help the investigator refine data collection procedures, instruments, or research design, require the same scrutiny as full-scale research projects. They are therefore subject to IRB review.

Research involving the secondary analysis of existing data (e.g., public de-identified data) does not require review when it does not meet the definition of research with human subjects noted above. However, the secondary use of data may qualify for Exempt Status under the federal regulations if the initial dataset is identifiable and if it would not be possible for the researcher to identify the subjects. In some cases, secondary use of data may warrant expedited or full board review (e.g., research involving prisoners, research using data collected for a previous study where additional informed consent may be warranted). For additional discussion on research involving the secondary use of existing data, please refer to University of California, Berkeley’s guidelines on this topic which can be found at: <http://cphs.berkeley.edu/secondarydata.pdf>.

Studies initiated with the primary intent of improving institutional practice (sometimes labeled outcome studies or program assessment) are considered “quality improvement” activities and are typically not classified as research. However, some program evaluation projects may fall into the definition of research based on design and intent to generalize outside of the local area.

Studies conducted by faculty with their own students would not typically lead to generalizable outcomes and would not normally fall under the category of research to be reviewed by the IRB. Professors that choose to do research with their own university students should be aware that they will need to mitigate the inherent potential for bias built into that methodology.

Please note that, if human subjects are involved in a study which does not meet the definition of “research,” they must be protected using the same level of care as if IRB review had taken place. For example, the researcher must always obtain permission from participants and disclose any risks to them before collecting data. Please consult with the coordinator or the IRB chair for additional guidance.

See Decision Tree at: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>, Chart 1.

3.0: Institutional Review Board (IRB)

3.1: Membership

APU follows federal guidelines effective January 19, 2018 (implemented January 21, 2019) that require the IRB to have at least five members who are of varying backgrounds and experience, including a diversity of race and gender. The IRB will also be comprised of at least:

- one scientist,
- one non-scientist, and
- “one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution” (45 CFR 46.107[c]).

In addition, at least two alternate faculty members will be appointed to assure adequate representation at scheduled monthly meetings. Members are appointed to one year terms by the Research Integrity Officer in collaboration with the dean of the faculty’s School or College. All members and alternate members must have completed the CITI instruction for the protection of human subjects and received the Completion Report in order to be appointed to the IRB.

3.2: Functions and Operations of the IRB

The IRB will review proposed research requiring Full Board Review at convened meetings (at least monthly) at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it will receive approval of a majority of those members present at the meeting (§ 45 CFR 46.108). IRB applications, meetings, documents, and minutes are confidential.

A board member who has a conflict of interest with a proposal that is being reviewed must recuse himself or herself from the Board’s discussion and the subsequent vote by the Board. The recused board member, however, may answer clarifying questions if requested by the IRB.

Individuals with competence in special areas beyond or in addition to that available on the board, may be invited at the discretion of the IRB to assist in the review of a study. These individuals may not vote.

3.3: Responsibilities of the IRB

In order to approve research, the IRB must ensure that the following requirements are satisfied:

- Risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from those participants would receive even if not participating.

- Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted and be particularly mindful of the special problems of research involving vulnerable populations. Participants should share equally in foreseeable benefits and risks.
- Informed consent is sought, and will be obtained, from each prospective participant or the participant's legally authorized representative (LAR) in accordance with, and to the extent required by 45 CFR 46.116.
- Informed consent is appropriately documented in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- Additionally, when some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, impaired decision making capacity, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the study to protect the rights and welfare of these participants.

The IRB has the authority to approve, require modifications (in order to secure approval), or not approve all research activities. The IRB will notify the investigators in writing through IRBManager of its decision to approve or not approve the proposed research, or of modifications required to secure IRB approval. If the proposed research is not approved, the IRB will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to reapply. When the convened IRB requests substantive clarifications or modifications of protocol or informed consent documents from the principal investigator, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB.

3.4: Factors Considered when Reviewing IRB Applications

Benefit - Federal regulations charge the IRB with determining that research benefits outweigh research risks. Benefit can be defined as value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge.

Risk - Risk can be defined as the magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring. For purposes of protecting human subjects in research projects, risk includes:

- a. Violation of privacy
- b. Violation of confidentiality
- c. Questions that the participant may consider sensitive
- d. Possible emotional distress or physical injury
- e. Invasive procedures

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.

Benefit vs. Risk - The Common Rule instructs Institutional Review Boards to ensure that “risks to subjects are minimized” and “risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be reasonably expected to result”.

Vulnerable populations - Vulnerable populations are individuals or groups who, by reason of disability, illness, age, or other status exhibit diminished personal autonomy. Neither the Federal regulations nor ethical codes proscribe inclusion of vulnerable persons as research subjects. However, the Department of Health and Human Services regulations mandate special justification for research involving fetuses, pregnant women, human in vitro fertilization, prisoners, and children.

Sensitive topics - Any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential is considered sensitive topic research. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive.

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Confidentiality - Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. See Section 15 for expanded information.

4.0: Responsibilities of the Investigator

The principal investigator (PI) is ultimately responsible for assuring compliance with applicable Azusa Pacific University IRB policies and procedures, DHHS Federal Policy Regulations, and FDA regulations, and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks to members of his/her research team, the PI retains the ultimate responsibility for the conduct of the study.

4.1: Who May Serve as a Principal Investigator for a Study Reviewed by the APU IRB?

Because PI responsibilities involve direct interaction and supervision of the research team, as applicable, the PI must be a current employee or student of the University who is operating within their University affiliated role to oversee the conduct of the study. PIs who leave employment of the University are responsible for notifying the IRB well in advance of their departure so that arrangements can be made to either close the study or name another appropriately qualified individual currently at the University to serve as the PI.

The following individuals may serve as PI:

- **Faculty members:** All faculty members may serve as PI if their department allows them to serve as principal investigator.
- **Staff:** Other University staff may serve as PI if they have appropriate qualifications to conduct research and if they have obtained approval to conduct the research from their immediate supervisor.
- **Students:** Students may serve as principal investigators for their own research projects and are responsible for submitting the IRB application. However, when a student is listed as the PI, a faculty advisor must be listed on the protocol submission. The faculty advisor of record is also responsible for safeguarding human subjects in research projects undertaken by graduate and undergraduate students in their courses and programs of study.

Note: *The IRB reviews and holds student research projects to the same standards as human subject research conducted by faculty or staff. IRB approval or exemption must be obtained prior to initiating any research activity under IRB oversight. "Retroactive" IRB approval or exemption is not permitted under federal regulations and University policy. Failure to obtain IRB approval for research with human subjects may preclude the use of the previously collected data and could result in other institutional sanctions.*

4.2: Conflict of Interest

The University's Policy for Conflicts of Interest is consistent with federal requirements for research and best practices in academia. The full policy can be found at <https://www.apu.edu/researchandgrants/training/policies/downloads/ConflictsOfInterestInResearchPolicy.pdf>. In order to prevent bias or the appearance of bias in research, everyone engaged in research (see definition of "covered individual") must complete a Potential Conflict of Interest (PCOI) disclosure form at the time of application for funded research or when applying for IRB approval (whichever comes

first), and within 30 days of changes to any response on the form. In the case of federally funded research, covered individuals must verify potential conflicts of interest at least annually. Potential conflicts of interest will be reviewed by an institutional Committee for Conflicts of Interest and a management plan may be established in order to manage, reduce, or eliminate known or likely conflicts of interest relating to research.

The University, its faculty, and other members of the University research community commit themselves to the pursuit of research at the University in accordance with the highest standards of integrity and in compliance with legal, professional, ethical and other requirements that promote objectivity and protect against financial conflicts of interest in research. The University will identify possible conflicts of interest in research, whether apparent or real, and provide mechanisms for their management, reduction or elimination in compliance with federal and state law as well as any relevant policies of entities funding research at the University.

The success of Azusa Pacific University's research program depends upon the integrity of the research and the researchers as well as the public's confidence in them. Conflicts of interest in research strike at the heart of a University's integrity. In pursuit of its mission as a private institution of higher education, the University seeks excellence in the quality of its research, in the teaching and education it provides to its students, and in the service it provides to the broader community. This knowledge transfer inevitably leads to increasingly close relationships between universities and those with financial capital in the private sector. The benefits that potentially accrue from this proximity are accompanied by real or apparent risks that economic interests might compromise academic research by influencing an investigator's judgment about the design, conduct, reporting, or management of research, and, in the case of research involving human subjects, imperil the safety of participants.

Faculty assuming the responsibility for the design, conduct or reporting of research have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Any possible conflict of interest must be formally disclosed to the institution. Questions about the policy or the form may be directed to Donald Isaak, Research Integrity Officer, at 626.815.6000, extension 3796 or disaak@apu.edu.

The Potential Conflict of Interest Disclosure form which is required for applications to the IRB can be found at <https://apu.my.irbmanager.com> along with the other forms required for application.

4.3: Certification for Protection of Human Subjects (CITI)

Certification for the protection of human subjects in research is required of the following groups prior to application to the IRB:

- Faculty, staff, and students who intend to conduct research involving human subjects. This includes those who conduct Informed Consent or have any other contact with participants
- All those who review the applications of researchers

In an effort to provide the most comprehensive training for researchers of human subjects, APU's IRB requires training and successful completion of the Collaborative Institutional Training Initiative (CITI) Human Subjects Research course. This on-line course is free to APU faculty, staff, and students, and is divided into a number of modules. Each module requires a passing score of 75 percent and may be repeated until passed. An overall passing score of 80 percent is required for the certificate. The site can be entered and exited at any time during the training.

To access the CITI site go to: <https://www.citiprogram.org>. There you will login and choose a password. Once you have submitted your member information and have affiliated with APU, you will be directed to the APU page. From there you can review the instruction page, and then proceed to "Add a Course or Update Learner Groups". On the Human Subjects Research (IRB) page you will choose the learner group that is most appropriate for you from the four groups listed there. The four learner groups are Human Subjects Research (IRB), Laboratory Animal Research (IACUC), Responsible Conduct of Research (RCR), and Good Clinical Practice (GCP) for Clinical Trials Course. Each learner group consists of different modules. You will note that some modules are required and some are optional. Optional modules may be required if your research involves a particular topic or population. The coordinator is responsible for assigning additional modules based on the research topic. Issues that may prompt additional modules include the following:

- Vulnerable populations
- International Research
- Internet Research
- Students
- Cultural considerations

Once the CITI training is completed, you will receive the CITI Certificate and Completion Report which is valid for three years. You will receive a reminder from CITI when you are due to take a refresher course. Current CITI Certification is required in order to conduct research. Investigators whose CITI Certification has expired will not be able to conduct research until they complete and pass CITI training.

The coordinator is available for any questions you might have. Please feel free to contact the coordinator at irb@apu.edu.

4.4: Research Integrity

Azusa Pacific University values honesty and integrity of research and is dedicated to ensuring the credibility and trustworthiness of the research conducted by our research community, to protecting this community from unsubstantiated allegations of research misconduct, and to upholding the university's high standards for research activity. Misconduct in research represents a breach of the policies of Azusa Pacific University, the standards expected by our sponsors, and the expectations of scholarly communities for accuracy, validity, and integrity in research. It is therefore the policy of Azusa Pacific University to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged research misconduct. Further, it is also the policy to comply in a timely manner with sponsor requirements for reporting cases of possible research misconduct when sponsored project funds are involved.

The primary responsibility for maintaining standards of integrity is held by individual scholars and the departments in which they work. Accordingly, it is incumbent upon all faculty, principal investigators, and others in positions of responsibility to exercise active leadership in their supervisory roles to ensure the integrity of the research being conducted. The institutional Policy on Integrity in Research sets forth procedures by which Azusa Pacific University seeks to maintain and enforce integrity in research through impartial fact-finding and fair adjudications of allegations of research misconduct. Each allegation of research misconduct will be responded to in a thorough, competent, objective, and fair manner. An *Annual Report on Possible Research Misconduct* is filed with the Office of Research Integrity (in the U.S. Department of Health and Human Services) by the Research Integrity Officer (RIO).

Research misconduct is fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices in the relevant scientific community for proposing, performing, or reviewing research, or in reporting research results. Any observed, suspected, or apparent research misconduct must be reported to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with the RIO to discuss the suspected research misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

For a more detailed description of research misconduct and the procedures for reviewing an allegation, please see the full copy of the Policy on Integrity in Research located on the Office of Research and Grants website or at the following link <https://www.apu.edu/researchandgrants/training/policies/downloads/IntegrityinResearchPolicyrev10-14-144.pdf>.

4.5: Researcher's Continuing Responsibilities

Once a project has been approved by the IRB, researchers must adhere to the approved protocol and follow any additional IRB instructions. The continuing responsibilities include:

- enrolling only those subjects that meet the IRB approved inclusion and exclusion criteria of the study;
- properly obtaining and documenting informed consent;
- obtaining prior approval for any deviation from the approved protocol;
- keeping accurate records;
- **promptly reporting to the IRB any adverse events or unanticipated problems involving risks to subjects or others, as well as protocol violations and deviations;**

Research approved by the IRB may be monitored for compliance.

4.5.1: Reporting Adverse Events, Unanticipated Problems, and Protocol Violations and Deviations

Principal investigators are required to report to the IRB all adverse events and unanticipated problems, as well as protocol violations and deviations. It is the expectation of the IRB that protocol procedures are followed as currently approved by the IRB.

4.5.1.1: Adverse events

An **adverse event** is defined as an untoward or unfavorable occurrence in a human subject which may or may not be related to the subject's participation in the research. A **serious adverse event** is one which results in death, is life-threatening, requires hospitalization, results in a significant disability/incapacity, or any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed (See Section 13 for reporting of adverse events).

4.5.1.2: Unanticipated Problems

Unanticipated problems involving risks to subjects or others refers to a problem, event, or information that is not expected, given the nature of the research procedures and the subject population being studied, and which suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research, than was anticipated at the time IRB approval was conferred. Specifically, "unanticipated problems" are those that meet all three of the following criteria:

1. **Unexpected** (in terms of nature, specificity, severity, or frequency) given the research procedures described in the protocol-related documents and the characteristics of the subject population being studied.
2. **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3. **Suggests that the research places subjects or others at a greater risk of harm** (including physical, psychological, economic, legal, or social harm) than was anticipated at the time IRB approval was conferred.

4.5.1.3: Protocol Violations and Deviations

Protocol violations are any accidental or unintentional changes to, or non-compliance with the research protocol that has not been previously approved by the sponsor or IRB. Violations generally:

- increase risk or decrease benefit
- affects the participant's rights, safety, or welfare
- affects the integrity of the data

Deviations may result from the action of the participant, principal Investigator, or research staff.

Examples of violations include:

- Failure to obtain valid informed consent (e.g., signatures or dates)

- Loss of laptop computer that contained identifiable, private information about participants
- Accidental distribution of incorrect study medication or incorrect treatment
- Not following inclusion/exclusion criteria
- Disclosure of confidential information

Protocol deviations are any accidental or unintentional changes to, or non-compliance with the research protocol that;

- does not increase risk or decrease benefit;
- does not have a significant effect on the participant's right, safety or welfare;
- does not affect the integrity of the data.

Deviations may result from the action of the participant, principal investigator, or research staff.

Examples of deviations include:

- A rescheduled study visit
- Participants failure or refusal to participate in protocol specific activities
- Failure to collect an ancillary self-report questionnaire

5.0: Review Categories for FEDERALLY FUNDED STUDIES

Studies receiving funding from any government source are considered federally funded. Federally funded studies are obligated to comply with the applicable regulation of the funding department or agency. The federal guideline found at 45 CFR 46 is the regulation that most funding sources follow and provide the definitions, exemptions, and procedures an institution receiving the funds must follow. Federally funded studies may be reviewed as full board, expedited, or exempt depending upon the study submitted.

5.1: Full Board Review

The criteria for full board review include research that involves (a) more than minimal risk, or (b) vulnerable populations, or (c) sensitive topics.

5.1.1: More than Minimal Risk -The probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46). Invasive procedures, possible emotional distress, and the potential for lack of confidentiality, for example, are considered greater than minimal risk. In order to be approved by the Board, such risks must be addressed.

5.1.2: Vulnerable Populations - Research that involves vulnerable populations must be provided full review (see §45 CFR).

5.1.2.1: Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research: §46.201-207;

5.1.2.2: Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects: §46.300 - 306, prisoners;

5.1.2.3: Subpart D – Additional Protections for Children involved as Subjects in Research: §46.401 - 409, children and minors (except as included under exempt and expedited categories);

5.1.2.4: individuals with impaired decision-making capacity or educationally disadvantaged may also be categorized as a vulnerable population as stated in §46.111(b).

5.1.3: Sensitive Topics - Any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive (See information box below for examples of some sensitive topics).

Examples of Sensitive Topics that May Require Full Board Review

1. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
2. Information that could damage an individual's financial standing, employability, or reputation

3. Information (usually in medical records) that could lead to social stigmatization or discrimination
4. Psychological well-being or mental health, including physical or mental abuse
5. Sexual orientation, attitudes, preferences, or practices
6. Incest, rape, date rape, or sexual molestation
7. Genetic information
8. Religious orientation or views – Religion is just one example of a sensitive topic. As with all sensitive topics, the broader principle is whether or not there is a potential for harm if the data were revealed. Identifying religious orientation on a research project would not typically be considered a sensitive topic at Azusa Pacific University. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.
9. Veteran or wartime experiences
10. Topics that may be perceived as sensitive or injurious by participants
11. Immigration status

Please note: The sensitive subjects listed above are examples and not an inclusive list.

To complete an application to the IRB for Full Board Review go to <https://apu.my.irbmanager.com>.

5.2: Expedited Review

Expedited review procedures refer to research that does not involve **vulnerable populations, sensitive topics and involves no more than minimal risk** to human subjects. Expedited research proposals are reviewed for protection of human subjects by the chair of the IRB or designee.

5.2.1: Criteria for IRB approval of expedited review

1. Risks to subjects are minimized:
 - by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to the anticipated benefits if any to subjects and the importance of the knowledge that may be reasonably expected to result.
3. Selection of the subjects is equitable (equal).
4. Informed consent (or its waiver, alteration, or exception) is received from each prospective subject.
5. Informed consent is appropriately documented.
6. The research plan makes adequate provision to ensure the safety of subjects.
7. Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data.

All of the items under Criteria (Section 5.2.1) must apply for an application to be considered for Expedited Review.

See Decision Trees at <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>, Charts 8 and 9.

To complete an application to the IRB for Review go to <https://apu.my.irbmanager.com>.

5.2.2: Research Categories for Expedited Review

The following categories generally require an expedited review. For further explanation, see <http://www.hhs.gov/ohrp> (see expedited review).

- (1) Clinical studies of drugs and medical devices when either an investigational new drug application or an investigational device exemption application is not required.
- (2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as per guidelines.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means, e.g., hair and nail clippings, excreta, skin swab, etc.
- (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.
- (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.
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- (8) Continuing review of research previously approved by the convened IRB:
 - (a) where
 - (i) the research is permanently closed to the enrollment of new subjects; and
 - (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;
 - (c) where the remaining research activities are limited to data analysis.

5.3: Exempt Review

Some federally funded studies on human subjects may be exempt from the need for full or expedited review by the Institutional Review Board. Exempt research proposals are submitted to the coordinator via IRBManager and then reviewed for protection of human subjects by a member of the Institutional Review Board.

What categories of research may be exempt from requirements of the Code of Federal Regulations?

Many educational, behavioral, and social science studies present little or no risk to subjects and can be exempt from IRB review. See Code of Federal Regulations (45 CFR 46.104(d)). Studies of medical charts are not typically eligible for exempt review unless such records are publicly available.

5.3.1: Exempt Categories

Exemption 1

*Research, conducted in established or commonly accepted **educational settings** that specifically involves normal educational practices not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.*

Note: Exemption 1 is limited to normal educational practices conducted in commonly accepted settings. An example is the evaluation of the effectiveness of an existing instructional program. A study that involves evaluation of a radical new strategy or random assignment is not exempt because the methods employed are not normal educational practices.

Exemption 2

*Research that only includes interaction involving **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures**, **interview procedures**, or **observations** of public behavior (including visual or auditory recording) if at least one of the following criteria is met:*

- (i) 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;*
- (j) 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, or reputation; or*
- (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the subjects, and the IRB conducts a limited review (see Section 5.3.3.) to make the determination.*

Note: This exemption reflects concern with protecting subjects' privacy and avoiding any risks associated with breach of confidentiality. The participants' responses to survey questions must be anonymous or de-identified before data analysis. Exempt survey research data must not be

linked to individual subjects. If research data contain personally identifying information and if disclosure of data to unauthorized persons could harm the subject in any way, the research is not exempt. Survey research that deals with sensitive and private aspects of the subject's behavior, such as sexual preferences and substance abuse, is not exempt if data can be linked to individuals. Even if the research has no subject identifiers, invasive questions that may cause emotional distress or discomfort negate exemption.

Exemption 3

*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:*

- (i) 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;*
- (ii) 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*
- (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects and the IRB conducts a limited review (see Section 5.3.3.) to make the determination.*

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

Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Exemption 4

***Secondary Research** for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:*

- (i) the identifiable private information or identifiable biospecimens are publicly available;*
- (ii) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator not contact the subjects, and the investigator will not re-identify subjects;*
- (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated for the purposes of "health care operations" or research or for "public health activities and purposes";*

- (iv) *the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance.*

Secondary Research (Collection or Study of Existing Data)

Research for which consent is not required involving the collection of the 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.

Note: The data must be “on-the-shelf” at the time the research begins. The research data must be recorded so that subjects cannot be identified. In most cases the data collection must have been previously approved by an IRB. This includes demographic information that could link the data to the subject. The existence of a key that could be used to identify a subject disqualifies the research from using this exemption.

Exemption 5

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

- (i) *public benefit or service programs;*
- (ii) *procedures for obtaining benefits or services under those programs;*
- (iii) *possible changes in or alternatives to those programs or procedures; and*
- (iv) *possible changes in methods or levels of payment for benefits or services under those programs.*

Exemption 6

Taste and food quality evaluation and consumer acceptance studies,

- (i) *if wholesome foods without additives are consumed or*
- (ii) *if a food is consumed that contains a food ingredient at or 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.*

Exemption 7

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 the IRB conducts a limited review (see Section 5.3.3.) and makes the determination required by §46.111(a).*

NOTE: The repository protocol must be IRB approved prior to the collection of biospecimens and other data. Participants must consent prior to their specimens or data being collected and stored for use in future research.

Exemption 8

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:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained;
- (iii) The IRB conducts a limited review (see Section 5.3.3.) and makes the determination that the research to be conducted is within the scope of the broad consent noted above; and
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan.

Note: Exempt categories 7 & 8 always require limited IRB review (see Section 5.3.3.) and are only available when broad consent will be (or has been) obtained.

5.3.2: What research cannot qualify for exempt status?

Research that cannot qualify for exempt status includes:

- Research involving interaction with children
- Research involving prisoners
- Research that involves deception or withholding of information from subjects
- Research that involves intense physical exercise
- Research that may cause emotional distress or discomfort greater than what would be expected in daily life

See Decision Trees at <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>, Charts 2-7.

To complete an application to the IRB requesting Exempt Status go to <https://apu.my.irbmanager.com>.

5.3.3: Limited Review

Limited IRB review must be performed by the IRB chair or by an experienced IRB member. The review does not require consideration by the convened board. The reviewer may require modifications to the study prior to approval. Disapprovals must be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories.

The revised federal regulations for human subjects research, effective January 19, 2018 (implemented January 21, 2019), added a new type of review called “limited IRB review” for certain low-risk studies. The purpose of this review type is specifically to ensure there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data or biospecimens in the proposed research as required by §46.111(a)(7) and makes the determination that the research to be conducted is within the

scope of the broad consent. The IRB will conduct limited review during the initial review of the submitted study. In general, studies approved under limited review do not require continuing review.

Limited IRB review is required in the following circumstances:

1. **Exempt 2(iii):** 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 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.
2. **Exempt 3(i):** 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 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.
3. **Exempt 7:** 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.
4. **Exempt 8:** 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:
 - (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the required elements of informed consent;
 - (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the requirements for documentation of consent; and
 - (iii) The IRB conducts a 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;
- The overall sensitivity of the data being collected;
- Persons or groups who will have access to study data;
- The process used to share the data;
- The likely retention period for identifiable data;
- The security controls in place (physical safeguards for paper records; safeguards for electronic records; secure sharing or transfer of data outside of the institution);
- The potential risk for harm that would occur if the security of the data was compromised.

6.0: Review for NON-FEDERALLY FUNDED STUDIES

Studies that do not receive funding from any governmental source are considered non-federally funded. PIs of non-federally funded studies are obligated to comply with the applicable regulations of the funding department or agency supporting the study. The Common Rule found at 45 CFR 46 is the regulation that most funding sources follow, and it provides definitions, exemptions and procedures an institution receiving funds must follow. Non-federally funded studies may be reviewed by the full board or by the IRB chair or designee, depending upon the risk of the study submitted.

6.1: More than Minimal Risk

Non-Federally funded studies that are more than minimal risk require review by the full board. The definition of minimal risk is the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46). Invasive procedures, possible emotional distress, and the potential for lack of confidentiality, for example, are considered more than minimal risk. In order to be approved by the board, such risks must be addressed. Additionally, studies that deal with vulnerable subjects (children, prisoners) and sensitive issues are classified more than minimal risk and must be reviewed by the full board.

6.2: Minimal Risk

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. Studies determined to be minimal risk will be reviewed by the IRB chair or designee. Minimal risk studies will fall into one of 17 categories listed below.

6.3: Minimal Risk Categories

1. Normal educational practices
2. Interactions involving educational tests, survey procedures, or observation of public behavior
3. Benign behavioral intervention
4. Secondary research (publically available)
5. Study, evaluate, improve or examine public benefit or service programs
6. Taste and food quality evaluation and consumer acceptance studies
7. Storage or maintenance for secondary research for which broad consent is required
8. Secondary research use for which broad consent is required
9. Studies of non-IND drugs & medical devices
10. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as per guidelines
11. Prospective collection of biological specimens for research purposes by noninvasive means, e.g., hair and nail clippings, etc.
12. Collection of data through non-invasive procedures (routine clinical practice)

13. Research involving materials collected or that will be collected for non-research purposes (data, documents, records, or specimens)
14. Collection of data from voice, video, digital, or image recordings for research
15. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
16. Quality Assessment/Quality Improvement
17. Action Research (although an action research project does not automatically imply less than minimal risk)

7.0: Action Research (Course-Related Research by APU Students)

The instructor of record is responsible for safeguarding human subjects in research projects undertaken by graduate and undergraduate students in their courses and programs of study. Course related research projects may include research practices and undergraduate thesis projects involving research methodology and course-assigned data collection. These activities generally do not meet the federal definition of research because their purpose is to provide training in research as part of the overall educational mission of a program and are not designed to contribute to new generalizable knowledge. If, as an exception, a project with human subjects is intended to contribute to generalizable knowledge or to possibly lead to publication, the faculty and student must submit an application to the IRB prior to the collection of data.

The instructor of record must have a certificate in protection of human subjects and is responsible for ensuring that student projects are low risk and do not involve children or other vulnerable populations. In general it is advisable that all students complete CITI training in protection of human subjects before beginning their projects. In addition, the instructor must determine that students conducting course-related projects have documented informed consent from all participants when required (see Section 9 or contact the coordinator or IRB chair). In addition, the instructor must ensure that student researchers take proper steps to maintain confidentiality of research data. It is essential to remove participant names from research data.

It occasionally happens that a student is involved in a course-related activity designed to teach research methodologies, and the instructor along with the student wish to conduct further investigation and analyses in order to contribute to scholarly knowledge. Collecting additional human subject data in such situations requires prior IRB approval. APU does not have a provision for retroactive IRB approval.

8.0: Quality Assurance (QA) / Quality Improvement (QI)

There are many projects involving Quality Assurance (QA) and Quality improvement (QI) that do not meet the definition of “research” stated in the Department of Health and Human Services Regulations for the Protection of Human Subjects (45 CFR 46, Subpart A). Some QA/QI require IRB review based upon the nature of what is being studied, the population, and interventions. Students conducting QA/QI must have a faculty adviser assigned to them, who, along with the student, is responsible for ensuring the project is low risk and does not involve children or other vulnerable populations. In general, it is advisable that all students complete CITI training in protection of human subjects before beginning their projects.

Quality Assurance (QA) is conducted in order to discover and correct errors by inspecting activities. It is measuring compliance against the National Standards and Targets. Quality Improvement (QI) is a continuous process to review, critique, and implement positive change to achieve quality improvement in public health policies, programs, or infrastructure. QI moves beyond QA to proactively improve safety. Typically QA and QI projects are done in a healthcare system.

9.0: Informed Consent

No investigator may involve a human being as a subject in research covered by these policies unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

9.1: General Requirements for Informed Consent

General requirements for informed consent, whether written or oral, include the following:

1. Investigator shall obtain the legally effective consent of the subject or the subject's legally authorized representative (LAR);
2. The subject shall have sufficient opportunity to discuss and consider whether or not to participate with minimal possibility of coercion or undue influence;
3. The information in the consent shall be in a language that is understandable to the subject or the LAR;
4. The subject or LAR must be provided with the information that a reasonable person would want to have in order to make a decision;
5. Informed consent must begin with a concise and focused presentation of the key information;
6. The informed consent as a whole must present information in sufficient detail, organized, and presented in a way that facilitates understanding; and
7. The informed consent may not include any exculpatory language through which the subject or LAR is made to waive or appear to waive any of the subject's legal rights or releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

9.2: Basic Elements of Informed Consent

Basic elements of informed consent are as follows:

1. A statement that the study involves research;
2. An explanation of the purpose of the research, an invitation to participate and explanation of why the participant was selected, and the expected duration of the participant's participation;
3. A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the participant in another setting. Use of research methods such as randomization and placebo controls should be explained;
4. A statement of any financial or other means of sponsorship for the research;
5. A description of any foreseeable risks or discomforts to the participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them; as well as acknowledgment of potentially unforeseeable risks;
6. A description of any benefits to the participant or to others that may reasonably be expected from the research, and an estimate of their likelihood;
7. A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant;
8. A statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, and drug sponsors;

9. An explanation and description of any compensation and any medical treatments that are available if participants are injured through participation; where further information can be obtained, and whom to contact in the event of research-related injury;
10. An explanation of whom to contact for answers to questions about the research and the research participant's rights including the name and phone number of the principal investigator (PI);
11. A statement informing the subject that inquiries regarding the nature of the research, his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Research Integrity Officer at Azusa Pacific University;
12. A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled;
13. A statement that if a participant declines to continue, any data gathered to that point may be part of data analysis;
14. A statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information presented;
15. A statement outlining the nature of subject remuneration (if any). Remuneration should be described as a "token of appreciation" for participating subjects. Care should be taken to ensure that remuneration is appropriate to the scope and context of the project. Excessive remuneration may be viewed as potentially coercive;
16. California Experimental Subject's Bill of Rights - if human subjects are involved in an experimental clinical procedure;
17. Authorization for Use of Private Health Information - if personal information considered "Protected Health Information" is used in the study; and
18. The signature of the researcher after explaining the research to the participant and when they are satisfied the participant fully understands. It is not appropriate for the researcher to sign in advance or to use a stamped signature.

Informed consent should be on APU letterhead.

9.3: Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus) if the subject is or may become pregnant which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study (§ 45 CFR 46.116);

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;
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

9.4: Elements of Broad Consent

Broad consent can be used in place of informed consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) as noted in Sections 21.2 and 21.3. If the subject or LAR is asked to provide broad consent, the following elements shall be provided:

1. A description of any foreseeable risks or discomfort to the subject;
2. A description of any benefits to the subject.

9.5: Documentation of Informed Consent

1. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - a. 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
 - b. 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.

See Decision Trees at <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>, Charts 10 and 11.

2. Except as provided in paragraph 1 above, informed consent shall be documented by the use of a written consent form approved by the IRB or by use of an electronic consent form for electronic surveys (see Informed Consent form templates at <https://apu.my.irbmanager.com>). The written consent forms must be signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
3. Except as provided in paragraph 1 of this section, the consent form may be either of the following:
 - a. A written consent document that embodies the elements of informed consent required by §45 CFR 46.116 above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

- b. A short written consent document stating that the elements of informed consent required by §45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. See §45 CFR 46.117 for additional related regulations.

Informed Consent templates for face-to-face and electronic survey research can be found along with other required application forms at <https://apu.my.irbmanager.com>.

9.6: Student Assent Form

The IRB shall determine that adequate provisions are made for soliciting the assent of children participating in research when, in the judgment of the IRB, the children are capable of providing assent. Children 12-17 years of age must give their written assent to participate in research. The IRB may determine that children younger than 12 years of age must give their assent for a particular research project.

The Student Assent form for research with minors can be found along with other required application forms at <https://apu.my.irbmanager.com>.

10.0: Renewals for Continuing Research

After the initial approval, full board, expedited, and some exempt studies require continuing review by the IRB to ensure that the risk-benefit relationship of the research remains acceptable, the informed consent process and documents are still appropriate, and the enrollment of subjects has been equitable. The maximum period between these IRB reviews is one year. The investigator is responsible for applying for continuing review in a timely manner to ensure IRB approval is continuous.

Therefore, **researchers must submit an annual renewal request for their continuing research with sufficient time to allow for sign-off from their department, IRB review, and approval prior to the anniversary date of the original approval.** Renewal reminders will be sent from IRBManager at 60, 45, 30, 15, and 5 days prior to the expiration of your approval. Depending on the degree of risk involved, more frequent reporting may be requested by the IRB (§ 46.109.e). For research that initially required a **full IRB review and continues to accrue participants**, the Request for Renewal of Continuing Research form must be submitted to and approved by the full IRB board. If the study is no longer accruing participants, the Request for Renewal of Continuing Research may be expedited. If the initial approval was an **expedited review** procedure, the IRB chair or designee receives the request form. Exempt categories 2, 3, 7, and 8 requiring “limited review” may or may not require continuing renewal. If a study is not re-approved before the study’s expiration date, the research study is automatically suspended and no further research may be done. To reopen a suspended study or access the data, a new study application must be submitted for IRB review and approval.

The form for requesting a renewal of an approved research can be found at <https://apu.my.irbmanager.com>. To access the renewal form, click on the IRBManager link. Once in IRBManager, enter into the study. On the left-hand-side of the study is the link “startXform.”

11.0: Request for Revisions/Modification to IRB-approved Research

11.1: Revisions

Researchers who will in any way modify their research protocol or personnel which has been previously submitted to and approved by the IRB must submit a Request for Revisions or Additions Review form. Approval must be received from the IRB prior to commencing with the requested change. Deviations from the approved protocol may prompt an investigation by the Research Integrity Officer and may result in termination of approval by the IRB. The form can be found at <https://apu.my.irbmanager.com>

A revision to a study may increase the risk to participants in that study. Studies initially approved as exempt may no longer qualify as exempt.

11.2: Change in personnel

When a Request for Revision or Addition to an approved protocol is received where the only addition requested is to add APU student research assistants to the research, the policy for approval is as follows: The coordinator will verify the required CITI course has been completed and the Potential Conflict of Interest Disclosure form has been included when necessary. The coordinator then can approve the Request for Revisions or Additions.

Change in personnel requests adding APU faculty or staff must be approved by the IRB chair or designee. The coordinator will verify the required CITI course has been completed and the PCOI Disclosure form has been included.

12.0: Closure of Research Study

12.1: All Research Activity Completed

The Closure Report must be submitted after all data collection and de-identification is complete, and PRIOR to the date that the approval ends. New IRB applications from researchers who are delinquent on closure reports from previous research will be delayed until closure reports are filed. The Closure Report form can be found at <https://apu.my.irbmanager.com>

12.2: Leaving Azusa Pacific University

Researchers must contact the IRB as soon as they are aware of an impending departure from APU. They must then either file a closure report before their departure or make arrangements to name another appropriately qualified individual currently at the institution to serve as the PI.

The APU IRB will no longer cover a principal investigator once he or she leaves the institution even if that person remains a member of the research team. In that situation, a study revision would be required indicating the researcher's new role. It would be up to the RIO in consultation with the IRB to determine whether the former APU employee can continue with the project under APU's IRB umbrella.

13.0: Reportable Events

Reportable events as outlined on the IRBManager form include the following:

1. **Adverse Events**
2. **Unanticipated Problems**
3. **Protocol Violations**
4. **Protocol Deviations**

Adverse events and unanticipated problems must be submitted on the Reportable Events form if they meet **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
2. Related or possibly related to participation in the research (in this guidance document, possible related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An **adverse event** is defined as an untoward or unfavorable occurrence in a human subject which may or may not be related to the subject's participation in the research. Suppose, for example, a participant in a study develops a rash for which the reason of its origin are not clear. A **serious adverse event** is one which results in death, is life-threatening, requires hospitalization, results in a significant disability/incapacity, or any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed. An **unanticipated problem** includes any incident, experience, or outcome (not related to an adverse event). Examples of unanticipated problems include identifiable data being stored on a laptop which is stolen, a dosing error, etc.

Timeframe for Reporting:

1. Serious adverse events must be reported to the IRB or to the RIO within 24 hours of the investigator becoming aware of the occurrence of the event.
2. Other unanticipated problems or protocol changes and deviations that meet the three criteria above must be reported to the IRB within five days of the investigator becoming aware of the occurrence of the event.
3. Reports of all other events or adverse events that do not meet these reporting criteria, including unanticipated protocol changes and deviations, must be submitted within one week of the investigator becoming aware of the problem.

If **adverse events** or **unanticipated problems** occur during research, the principal investigator must report the following to the chair of the APU Institutional Review Board:

- Research number as assigned by the IRB and title of approved research project;
- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and

- A description of any recommended changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

Complete the report in IRBManager and submit to the IRB. The Reportable Event form will promptly present the report to the IRB chair. If the IRB chair is the principal investigator making the report under this policy, the report shall be presented directly to the Research Integrity Officer who will present the report to the IRB.

The IRB, the chair or designee will review the report to consider whether the event impacts the risk/benefit ratio and whether that warrants a reconsideration of the approval of the study, modifications to the study, revisions to the continuing review timetable, suspension of the study, or other action required due to safety concerns. The IRB has the authority to require, as a condition of continued approval by the IRB, submission of more detailed information by the investigator, the sponsor, or a DSMB about any adverse event or unanticipated problem occurring in a research protocol. The chair will brief the executive director of the Office of Research and Grants, who is the Research Integrity Officer, concerning all reports.

For serious adverse events, the chair or designee has the authority and responsibility to make immediate changes to the study, as noted above, and will refer the issue to the full IRB as soon as is feasible for additional consideration. Only a full IRB can make a determination to take no action on a serious adverse event.

Protocol violations and **protocol deviations** must also be submitted on the Reportable Events form and reported to the Azusa Pacific University's Research Integrity Officer. **A protocol violation** is the deliberate or inadvertent violation, or failure to comply with, federal regulations or HSC requirements for the protection of human subjects in research. A **serious protocol violation** is an act or omission that resulted in increased risk to subjects or others that compromised the subjects' rights, safety, or welfare. Examples of this are deliberate or repeated failure to obtain prior review and approval before initiating human subject research; deliberate or repeated failure to obtain or document informed consent; and deliberate falsification of documents. **Continued protocol violation** is a pattern of repeated acts or omissions that indicate an inability or unwillingness to comply with federal regulations governing human subject research. Examples include consistently late submissions of continuing review protocols or other items that require prompt reporting; repeated failure to comply with education and training requirement; and failure to submit required documentation. Protocol **deviations** occur for a variety of reasons, such as an investigator's decision to deviate from the protocol, the subject's lack of adherence to the protocol, or external/environmental factors (e.g., severe weather or holidays) that change the performance of a protocol. Some protocol deviations are anticipated and/or intentional; others are not. Deviations that are anticipated and/or intentional should be submitted to the IRB for approval prior to the event if possible. There are three kinds of deviations: (a) deviations that occur because an investigator, research staff or other party involved in the conduct of research intentionally decides to deviate from the approved protocol; (b) deviations from the protocol that are identified before they occur, but cannot be prevented; and (c) deviations from the protocol that are discovered after they occur.

Azusa Pacific University's Research Integrity Officer must promptly report to the Office for Human Research Protections any of the following occurrences when required by law:

- Unanticipated problems involving risks to subjects and others
- Serious or continuing noncompliance with requirements or determinations of the IRB
- Suspension or termination of IRB approval of non-exempt human subject research.

For further guidance, the principal investigator is encouraged to review the Department of Health and Human Services *Guidance on Reviewing and Reporting Unanticipated Problems Involving Risk to Subject or Others and Adverse Events* at <http://www.hhs.gov/ohrp/policy/advevntguid.html>.

14.0: Suspension or Termination of IRB Approval

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported within two business days to the investigator, faculty supervisor (if a student is involved), department chair and dean, provost, and any pertinent governing institution (such as a funding agency or the Office of Human Research Protection).

As a response to complaints, pressing concerns, or evidence of harm to subjects, the RIO or IRB chair may suspend a study. If necessary, the RIO may, with one or more IRB members, initiate an investigation. Every investigator will be given the opportunity to respond to the concerns. The convened IRB must vote on any action of suspension or termination upon completion of an investigation.

15.0: Data Safety Monitoring Plans

If an external funding agency requires a Data Safety Monitoring Plan (DSMP), the researcher should include this document in the IRB application. A DSMP is a document that describes how the researcher plans to oversee the safety of human subjects and the safety of the data during the conduct of the study. It details protocol compliance and the review and reporting of unanticipated events. In some cases, the DSMP will include the existence of a Data Safety Monitoring Board (DSMB), a group of carefully selected experts who will meet periodically to oversee the collection and processing of the data. Where a DSMB is planned, the document should also include proposed membership of the board and the anticipated communication of the DSMB and the IRB. (e.g., regarding unanticipated events).

16.0: Privacy and Confidentiality

Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Researchers must be attentive to threats to participants' privacy. An acceptable practice is to distribute invitations to a broad population and ask for persons to self-identify as meeting more narrow criteria. An option for some sensitive interview research is to offer the participant the opportunity to review publication drafts for unintended markers of identity.

Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. In most research, ensuring confidentiality can occur by following these routine practices:

- Substituting codes for identifiers or encrypting identifiable data
- Informed consent documents and de-identified research data are stored in separate secure locations
- Use random numbers to identify research records (Social Security and student ID numbers are not acceptable)
- Removing face sheets (containing identifiers such as names and addresses) from survey instruments containing data
- Properly disposing of computer sheets and other papers
- Limiting access to identifiable data
- Educating the research staff on the importance of confidentiality
- Storing paper records in locked cabinets or assigning security codes to computerized records

17.0: Data

17.1: Data Collection

Data collection is the process of gathering and measuring information on targeted variables of interest, in an established systematic fashion that enables one to answer stated research questions, test hypotheses, and evaluate outcomes. The data collection component of research is common to all fields of study including physical and social sciences, humanities, business, etc. While methods vary by discipline, the emphasis on ensuring accurate and honest data collection remains the same. Regardless of the field of study or preference for defining data (quantitative or qualitative), accurate data collection is essential to maintaining the integrity of research. Both the selection of appropriate data collection instruments (existing, modified, or newly developed) and clearly delineated instruction for their correct use reduce the likelihood of errors occurring.

17.2: Recording Data

In recording data, researchers should keep two principles in mind to avoid problems later, should someone ask about or question their work:

- Hard-copy evidence should be entered into a numbered, bound notebook so that there is no question later about the date the experiment was run, the order in which the data were collected, or the results achieved. Researchers who use human subjects should not use loose-leaf notebooks or simply collect pages of evidence in a file. They should not change records in a bound notebook without noting the date and reasons for the change.
- Electronic evidence should be validated in some way to assure that it was actually recorded on a particular date and not changed at some later date. It is easy to change dates on computers and thereby alter the date a particular file seems to have been created. If data are collected electronically, the researcher must be able to demonstrate they are valid and have not been changed.

As researcher collect data, it may be helpful to think about them as the legal tender of research – the currency researcher's cash in when they apply for grants, publish, are considered for promotion, and enter into business ventures. To have and hold their value, research data must be properly recorded. (Steneck, 2004, pp. 92-93)

17.3: Retention and Storage of Data

Responsible handling of data begins with **proper storage and protection from accidental damage, loss or theft:**

- Lab notebooks should be stored in a safe place.
- Computer files should be backed up and the backup data saved in a secure place that is physically removed from the original data. Computer files should be password protected and/or encrypted.
- Samples should be appropriately saved so that they will not degrade over time..

Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes. There is, however, no common definition of a *reasonable period of time*. NIH generally requires that data be retained for three years following the submission of the closure report. Some government programs require retention for up to seven years. APU requires that data be kept for three years after the closure report unless a longer retention is required by a specific agency. Before discarding notebooks or files, or erasing computer memory, researchers should consider who might benefit from the data in the future.

18.0: Just-in-Time Review

“Just-in-Time” is a procedure used by the National Institutes of Health to facilitate the timely collection of information to support proposals that are deemed to be in the fundable range. Supplemental information for proposals with a likelihood of funding (including IRB approval) is requested just before NIH council review, or “just-in-time” for the awards decision. IRB approval is not required at the time of grant application, saving researchers and IRB personnel time and effort in light of the low funding odds for grant applications.

Upon notification of the “Just-in-Time” (JIT) request, the principle investigator (PI) should begin to prepare the IRB application forthright. The director of Sponsored Research in the Office of Research and Grants will coordinate the timing of the protocol submission with the PI and the coordinator. The normal deadline to submit the protocol which is 10 days before a full board review may be shortened in these cases. The IRB application should include a draft JIT response letter and/or an explanation of potential discrepancies between the grant application and the IRB application and how they will be reconciled, if appropriate. If at all possible, a full board review of a Just-in-Time protocol should be undertaken during a regularly scheduled monthly IRB meeting. If this is not feasible, the IRB will make every effort to convene at another time in order to facilitate the timely review of the protocol.

Please note that federally sponsored research applications involving human subjects are required by the U.S. Department of Health and Human Services to be appropriately matched to an approved IRB protocol. The grant application and the human subjects documents must be reviewed by an APU representative (typically an IRB member, a member of the Office of Research and Grants, or the Research Integrity Officer) and determined to be “entirely consistent” (per OHRP guidance of May 31, 2000). This process may take up to 10 business days. Any discrepancy between the protocol and the grant must be resolved or accounted for before the grant can be approved, and preferably before the IRB protocol is approved. The IRB may therefore request that the IRB application be revised to reconcile discrepancies, be re-submitted demonstrating it is in alignment, or be supplemented with clarification on the differences. Non-federally funded grants may also be similarly reconciled.

19.0: International and Cross Cultural Research

All human subject research conducted internationally or across cultures must adequately protect the rights and welfare of the research subjects. Researchers must provide evidence that research projects and translated documents are sensitive to participants' local research context, particularly culture and language. These protocols should be categorized (i.e., expedited, full board) using the same risk/benefit considerations applied to any other research project. In addition to obtaining APU IRB approval, the PI must provide evidence that research projects and translated documents are sensitive to participant context, inclusive of culture and language. The first choice for documenting sensitivity to participant context is IRB review in the participants' country of residence. As an alternative, PI's may seek written documentation of sensitivity to local research context from persons who meet all three criteria, namely (a) indigenous to the participant culture, (b) a resident of the research area for two of the last 10 years, and (c) presently serving as an official of a local government or local academic institution.

International and cross cultural research proposals requiring translated documents should include contact information/scripts and informed consent. The PI can demonstrate accuracy and sensitivity of translated documents through back translation by persons indigenous to the participant culture and fluent in participant language. **The PI can translate documents, but cannot serve as back translator of documents employed in his/her research.** Local consulates may have personnel that meet IRB criteria that can assist with verifying that the planned research is culturally sensitive and/or with translations.

The International Compilation of Human Research Standards provides a resource of laws, regulations, and guidelines that govern human subject research as well as the standards from a number of international and regional organizations. These are listed by country and can be found here: <http://www.hhs.gov/ohrp/international/index.html>. In addition the Compilation of Guidances on General Data Protection Regulation must also be taken into account when conducting research in a European country. The European General Data Protection Regulation (GDPR) took effect on May 25, 2018, and the guidance may be located at the same web site as above.

Principal investigators who conduct research in an international setting must complete the supplemental training module on international research in the CITI program.

20.0: Cooperative Research (IAA)

Cooperative research projects are those projects that involve more than one institutions. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for compliance with the policy. Any institution located in the United States that is engaged in cooperative research that is federally funded must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The following research is not subject to cooperative research:

1. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
2. Research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context; or
3. Research not carried out in the United States, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangement for avoiding duplication of effort.

An institutional authorization agreement (IAA) is a formal, written document that provides a mechanism for APU to accept responsibility and authority to review and approve research conducted elsewhere, or for APU to cede that responsibility and authority to another entity. An IAA is a joint review arrangement that facilitates collaboration on human subjects' research, enabling collaborating institutions to rely on a single IRB (an "IRB of Record") for review and for some or all aspects of continuing oversight of the research, in order avoid a duplication of efforts. In all cases, the Institutional RIO must approve the arrangement upon the recommendation of the IRB chair and the executive director of the Office of Research and Grants.

Some instances when an IAA may be appropriate include, but are not limited to:

- If another institution receives a grant and contracts out all human subjects research to investigators at APU, then APU may agree to serve as the IRB of record; APU could accept additional authority.
- If APU researchers collaborate with researchers from another federally-assured institution and the research is collected at a neutral site, APU may agree to serve as the IRB of record in certain circumstances; APU could accept additional authority.
- If an investigator at APU collaborates on a project with another institution and his/her involvement is limited to data analysis of research collected by collaborating investigators at the other institution, then the other institution may agree to serve as the IRB of record for the project; APU could cede authority.
- If investigators at APU and another institution are collaborating on a project and the IRB at the other institution is better-prepared to review the research, then that institution may agree to serve as the IRB of record for the project; APU could cede authority.

Investigators may request an IAA, but generally they are initiated by IRB administrators and require approval of the Institutional Official at each institution. The IRB chair and executive director of the Office of Research and Grants will consider using an IAA on a case-by-case basis including factors such as

- 1) ensuring quality and thoroughness of protocol review;
- 2) local context issues;
- 3) institutional liability;
- 4) complexity of shared control and accountability;
- 5) costs of delegating or accepting review; and
- 6) relationship to the outside organization.

Exempt research projects are not eligible for consideration. Also, APU will not normally provide IRB-of-record services for research in which the university is not engaged, or in which its investigators are not otherwise involved. It will also not review research over which the university cannot appropriately address the local context or otherwise exercise adequate oversight.

The IRB chair and executive director of the Office of Research and Grants, in consultation with the coordinator, will determine eligibility for an IAA and will recommend the terms of such an agreement to the RIO. For becoming the IRB-of-Record, considerations include, for example, the time and resources required to accept the review, APU's expertise for initial and continuing review, and the willingness of the other institution to monitor compliance, review adverse events and to handle complaints. For ceding authority to another institution, considerations include the impracticability of an APU IRB review, the appropriateness of the other IRB to review the protocol, and the proposed arrangements for that institution to monitor and oversee the research.

As part of the IAA or in a separate document, the parties must establish and clearly document roles and responsibilities, the IRB of record for a protocol, communication channels, etc. Research may not commence until the IAA is fully executed. Because establishing an IAA requires thorough review, it should not be considered as a time-saving effort; indeed, some agreements take several weeks to negotiate, rendering a full board review more expedient.

In some cases, the Federalwide Assurance (FWA) of the institution relying on another institution's IRB or independent IRB may need to be amended to list the reviewing institution's IRB or independent IRB. Copies of the signed agreement must be kept at both institutions and be made available to any Common Rule agency upon request.

21.0: External Research Review Process

All requests from researchers outside of APU to involve APU faculty, staff, and students for their research with human subjects should be sent to the coordinator who will assist the researcher in understanding the APU specific review process for such requests. The extent to which APU personnel are involved in the research is the first review criteria. If the proposal is deemed to be “non-engaged research,” the researcher should submit a copy of his/her IRB application from his/her home institution, if one exists. If the proposal is deemed to be “engaged research,” the researcher must submit a completed APU IRB application, even if the research was classified as “exempt” at another institution. The IRB application should, whenever possible, identify a sponsor at APU -- someone at the department chair or director level. The external researcher’s proposal and supporting materials are forwarded to APU’s Vice Provost/RIO or a designated alternative.

The Vice Provost or designated alternative will request a review of the proposal by APU’s External Research Review Committee which will consider factors including the timing of the project related to other planned research projects, whether such information has recently been collected at APU, and the purpose and potential benefit of the research project. Based upon the committee’s recommendation, the Vice Provost or designated alternative will determine whether the proposed research is approved. The Vice Provost, designated alternative or coordinator will notify the researcher of the approval or denial, noting any conditions in the case of approval, and will direct the external researcher to the Office of Institutional Research and Assessment or another identified APU contact person for next steps. In the case of “engaged” research with human subjects, the next step is IRB review and approval. The coordinator will then direct the researcher to the on-line application process.

22.0: Deception and Incomplete Disclosure

In certain circumstances, the use of deception or incomplete disclosure in research are acceptable and important techniques, though it places special responsibilities both on the researcher and on the IRB. In these cases, the IRB requests additional information from researchers and will review those proposals carefully. Whereas deception occurs when research subjects are deliberately given false information about some aspect of the research, incomplete disclosure results when the true nature or purpose of the research is withheld. It is therefore the provision of erroneous information (deception) or the omission of information (incomplete disclosure) which creates a circumstance warranting special consideration for the protection of those human subjects.

In all cases of deception or incomplete disclosure, the following guidelines apply:

- The research must involve no more than minimal risk to participants
- The waiver or alteration of the informed consent may not adversely affect the rights and welfare of the participants
- The research could not practicably be carried out without the alteration or waiver
- At the appropriate time, participants will be provided with additional pertinent information regarding participation
- Participants must be given the right to withdraw their participation once they are made fully aware of the study's purpose

IRB applications proposing to use deception or incomplete disclosure should include the following information:

- A clear explanation of why deception or incomplete disclosure is justified and whether alternative methods could achieve the same research goals
- An indication of whether deception or incomplete disclosure may affect a participant's willingness to participate in research
- Identify what elements of the Informed Consent the researcher is requesting to waive
- An explanation of the process to debrief participants including who will debrief them and at what point in the study (include a copy of the debriefing statement and the debriefing script). *The informed consent document must include the fact that the information provided to the subject is incomplete and that they will be debriefed after research procedures are completed.*
- An explanation of whether deception or incomplete disclosure is likely to cause the subject discomfort before or after debriefing and how that risk will be minimized

The debriefing of participants is required at an appropriate point in time. Such a debriefing must include a full explanation of the research question and hypothesis, the procedures used for the study, and why deception was necessary. In no case can the debriefing cause more harm than the deception or incomplete disclosure.

In its review, the IRB must consider factors in addition to the scientific value of the research and the efficacy of alternative procedures. They will also need to confirm that the deception does not extend to influence the participants' willingness to participate, and that any experimentally induced harm may be removed through debriefing. Further, the IRB will consider whether the researcher is equipped to manage emotional reactions that may occur during debriefing, and whether the proposed deception could facilitate unwanted and inappropriate invasions of privacy.

Deception or incomplete disclosure cannot be approved if non-deceptive alternatives are available, if human subjects would likely not participate if the true purpose of the study were known to them, and if it places participants at significant risk of any type.

For additional information, see guidance and procedures at:

UCLA at <http://ora.research.ucla.edu/OHRPP/Documents/Policy/8/Deception.pdf> and

Swarthmore College's IRB policy at <http://www.swarthmore.edu/institutional-review-board/deception-incomplete-disclosure-debriefing>.

23.0: References

Collaborative Institutional Training Initiative (CITI) protection of human subjects in research.

Programmed instruction for certification www.citiprogram.org

Steneck, N. H. (2004). *Introduction to the responsible conduct of research*. U. S. Health and Human Services Department. Office of Research Integrity.

U. S. Department of Health and Human Services. Office of Human Research Protections (OHRP)

Categories of research that may be reviewed by the Institutional Review Board (IRB) through an expedited review <http://www.hhs.gov/ohrp/policy/expedited98.html>

Continuing review policy

<http://www.hhs.gov/ohrp/policy/continuingreview2010.html>

Guidance on certificate of confidentiality

<http://www.hhs.gov/ohrp/policy/certconf.html>

Human subjects regulation decision charts.

<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

Code of Federal Regulations

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Reporting incidences

http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html

Human Subjects: Guidance

<http://www.hhs.gov/ohrp>

U. S. Department of Health and Human Services. Office of Research Integrity (ORI)

Policies/Regs/Statutes <http://ori.hhs.gov>

Misconduct Regulation, Office of Research Integrity

<http://ori.hhs.gov/policies/ori-policies>

U. S. Department of Health and Human Services. National Institutes of Health (NIH) Office of Human Subject Research

Belmont Report: Ethical principles and guidelines for the protection of human subjects

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>