Institutional Review Board Handbook

Guide for Research involving Human Subjects

2014-15

Institutional Review Board (IRB) Frequently Asked Questions

(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 subject in research. Please see page 2 for instructions for certification.

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

Here are the Federal definitions of "**research**" and "**human subjects**":

Research:

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 [d]). (For the current Code of Federal Regulations, please see: http://www.hhs.gov/ohrp/ A project or study is research if it: a) is conducted with the intention of drawing conclusions that have some general applicability, and b) uses a commonly accepted qualitative or quantitative method. (Opportunity samples are subject to IRB review.) For research involving human subjects, you must have IRB review regardless of whether you intend to present or publish (except low risk, non-publishable classroom research).

Human Subjects:

Human Subjects are "living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information" (§ 45 CFR 46.101[f]).

If an auditor could reasonably conclude that your project meets both of these criteria, your project must have some level of review from the IRB. If the project does not meet the Federal definition of "research" with "human subjects", you can proceed with data collection and publish findings. Research with public databases does not include identifiable private information and does not require review by the IRB. Studies initiated with the primary intent of improving institutional practice (sometimes labeled outcome studies or program assessment) are considered "quality improvement" activities and are not classified as research. See Decision Tree at: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, Chart 1.

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

There are three categories of review:

- **Exempt – see pages 8-10**
- **Expedited – see pages 5-7**
- **Full Board Review – see pages 3-4**

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.

a. Exempt Research

Exempt research proposals are submitted to the IRB Coordinator and then reviewed for protection of human subjects by a member of the Institutional Review Board. See IRB Handbook page 8 for exemption categories. The Exempt Status Request form is found in the

Appendix of this handbook on page 36. The Principal Investigator should submit a complete form with required signatures and attachments in one .pdf file to the IRB Coordinator.

b. Expedited Research

Expedited research proposals are reviewed for protection of human subjects by the Chair of the IRB or designee. Review IRB Handbook pages 5 and 6 for guidance in determining whether your project is eligible for expedited review.

c. Full Board Review

The Full Board in convened session reviews all projects that include any of the following:

1) Vulnerable populations
2) Sensitive topics
3) More than minimal risk
4) Invasive procedures

(4) What are some esoteric issues the IRB considers when reviewing a project for protection of human subjects?

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.

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.

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 18 for expanded information.

(5) When does the IRB meet?

The Full IRB Board meets monthly, twelve months a year, generally the 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 Vice Provost for Graduate Programs and Research/Research Integrity Officer appoints members in accordance with Federal guidelines. A majority of the members are faculty. For current members and alternates, contact Joanie Stude, IRB Coordinator.

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

This depends on the type of review your research requires. For a full board review, see page 4 for submission requirements, for expedited review, see page 7, for exempt review, see page 10. For any questions you may contact Joanie Stude, IRB Coordinator jstude@apu.edu or at 626.815.2036 (on campus at extension 2036).

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

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

(9) Are studies of medical charts eligible for exempt review?

No, unless records are publicly available.

(10) 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?

Persons from outside the APU community wishing to conduct research at APU should contact Joanie Stude, IRB Coordinator at jstude@apu.edu. See page 12 for further information.

2014-15 INSTITUTIONAL REVIEW BOARD HANDBOOK
For research involving human subjects

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Appendix

Guidelines for Research Involving Human Subjects

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 IRB approval for their research with human subjects. Questions regarding whether APU's IRB approval is required may be directed to the IRB coordinator at jstude@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 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

Certification for Protection of Human Subjects

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
- 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. The site can be entered and exited at any time during the training. All those who have taken the NIH course prior to January 1, 2014 will continue to have valid certification for two years from the date on their certificate.

To access the CITI site go to: 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. 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 IRB Coordinator is responsible to assign 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, the CITI Completion Report is valid for three years. You will receive a reminder from CITI when you are due to take a refresher course.

The IRB coordinator is available for any questions you might have. Please feel free to contact Joanie Stude at jstude@apu.edu.

Full Board Review

Criteria for a Full Board Review

Research that involves (a) more than minimal risk, or (b) involves vulnerable populations or (c) includes sensitive topics requires full board review. Examples of vulnerable populations and sensitive topics are listed below.

A. Vulnerable Populations - All research that involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk must be provided full review.

See §45 CFR 46.201 - 207, pregnant women;
46.300 - 306, prisoners;
46.401 - 409, children and minors (except as included under exempt and expedited categories)

B. 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).

C. 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 (45 CFR 46).

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.

Process for Requesting a Full Board Review

Principal Investigators making application to the Institutional Review Board and those reviewing applications must complete training for the protection of human subjects in research. See page 2 in this handbook for information regarding this required training. Include a copy of the certificate(s) or Completion Report(s) with the application.

For an IRB application to be considered by the Board, the following must be included:

a.) 2014-15 Institutional Review Board Application – Appendix, page 25.

b.) Potential Conflict of Interest Disclosure Form – Appendix, page 47.

c.) Informed Consent or the Informed Consent for Survey Questionnaires for studies that exclusively use electronic questionnaires or opinion surveys. A Student Assent form will be required for research involving minors. Informed Consent forms must be on APU letterhead. (In some cases the Informed Consent requirement may be waived by request. See page 15.)

d.) Copies of all research instruments that will be used (survey, questionnaire, etc.).

e.) Letter of agency approval if data collection involves working with a constituency of an agency/institution other than Azusa Pacific University. The letter should include a statement that the agency/institution official has read the proposal and approves the research being conducted at their facility.

f.) Participant recruitment information (email, poster, verbal invitation to participate).

g.) For research in an international setting, a credible host country perspective on research congruence with local cultural norms.

h.) California Experimental Subject's Bill of Rights for research involving clinical treatment, if needed - Appendix, page 51.

i.) Authorization for Use of Private Health Information if medical records are used, if needed - Appendix, page 52.

j.) A copy of the human subject research certification for all investigators and those reviewing the application. See page 2.

Procedure for submitting applications: Once the application is complete as detailed above, add a footer to the application which includes pagination and the last name of the applicant. This is required before an application can proceed for review. Submit the complete application as detailed above in ONE .pdf file to the IRB Coordinator ten working days before the scheduled meeting. The request will be reviewed at a regular monthly IRB meeting. The IRB coordinator routinely invites applicants to be available to the board at the monthly meeting to respond to questions.
Note: It is recommended that the primary researcher be as thorough as possible in completing the application. The most frequent reason that an IRB application is delayed is because there is not enough detail included to explain the exact nature, benefit and procedure of the study.

Expedited Review

Criteria for an 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.

Criteria for IRB approval of expedited review include:

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.

4. Informed consent 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 above 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.

Research Categories for an 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 employing survey, 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;
      OR
   (c) where the remaining research activities are limited to data analysis.

Process for Requesting an Expedited Review

Principal Investigators making application to the Institutional Review Board will need to complete training for the protection of human subjects in research. See page 2 for information regarding this required training. Include a copy of the Certificate or Completion Report with the application.

For an IRB application to be considered as Expedited, the primary researcher needs to include the following:

a.) 2014-15 Institutional Review Board Application – Appendix, page 25.

b.) Potential Conflict of Interest Disclosure Form – Appendix, page 47.

c.) Informed Consent or the Informed Consent for Survey Questionnaires for studies that exclusively use self-report questionnaires or opinion surveys. A Student Assent form will be required for research involving ages 12-17. Informed Consent forms must be on APU letterhead. (In some cases the Informed Consent requirement may be waived by request, see page 13).

d.) Copies of all research instruments that will be used (survey, questionnaire etc.).

e.) Letter of agency approval if data collection involves working with a constituency of an agency/institution other than Azusa Pacific University. The letter should include a statement that the agency/institution official has read the proposal and approves the research being conducted at their facility.

f.) Participant recruitment information (email, poster, verbal invitation to participate).

g.) California Experimental Subject's Bill of Rights if research involving clinical treatment - Appendix, page 51.

h.) Authorization for Use of Private Health Information if medical records are used - Appendix, page 52.

i.) A copy of the human subject research certification for all investigators and those reviewing the application. See page 2

Submit: Once the application is complete as detailed above, add a footer to the application which includes pagination and the last name of the applicant. Submit the complete application as detailed above in ONE .pdf file to the IRB Coordinator. The application will be forwarded to the IRB Chair for approval.

Note: It is recommended that the primary researcher be as thorough as possible in completing the application. The most frequent reason that an IRB application is delayed is because there is not enough detail included to explain the exact nature, benefit and procedure of the study.

Exempt Review

Some studies on human subjects may be exempt from the need for full or expedited review by the Institutional Review Board. The Exempt Status Request form is found on page 36.

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 46.101(b).

Exemption 1 - Normal Educational Practices and Settings

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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 (Ref IRB Mgmt. and Function, p 94).

Exemption 2 - Anonymous Educational Tests, Surveys, Interviews or Observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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 the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption 2 above, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) the federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4 - Collection or Study of Existing Data

Research 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 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.

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 that what would be expected in daily life

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

Process for Requesting an Exempt Review

Principal Investigators submitting an application to the IRB will need to complete training for the protection of human subjects in research prior to submitting the application. See page 2 in this handbook for information on this required training. Include a copy of the certificate or Completion Report with the application for all researchers.

Decisions about whether studies are **exempt** from the requirements of the Common Rule will be made by a member of the Institutional Review Board. **An exempt research project still requires that an application is filed with the Institutional Review Board. The following steps must be completed to be considered for exempt review:**

a.) The 2014-15 IRB Request for Exempt Status form - Appendix, page 36.

b.) Potential Conflict of Interest Disclosure Form – Appendix, page 47.

c.) Informed Consent or the Informed Consent for Survey Questionnaires for studies that exclusively use questionnaires or opinion surveys. Informed Consent forms must be on APU letterhead. (In some cases the Informed Consent requirement may be waived by request. See page 13.)

d.) Provide copies of all research instruments that will be used (survey, questionnaire, etc.).

e.) Letter of agency approval if data collection involves working with a constituency of an agency/institution other than Azusa Pacific University. The letter should include a statement that the agency/institution official has read the proposal and approves the research being conducted at their facility.

f.) Participant recruitment information (email, poster, verbal invitation to participate).

g.) Include a copy of the human subjects in research training certification or Completion Report for all investigators and those reviewing the application.

Procedure for submitting applications: Submit an electronic copy of the complete form including required signatures and attachments as detailed above to the IRB Coordinator. Please note that the electronic copy must be contained in ONE .pdf file. The application will be forwarded to an IRB member for review.

The applicant will receive a certificate of Exempt Status upon the reviewer's determination of qualification for Exempt status. This certificate must be received before the researcher commences with the research.

Classroom Research Projects

The instructor of record is responsible for safeguarding human subjects in classroom research projects. Classroom research projects may include research practica 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 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 human subject 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 would be required to complete CITI training in protection of human subjects before beginning their projects. In addition, the instructor must determine that students conducting classroom projects have documented informed consent from all participants and 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 class activity designed to teach research methodologies, and instructor along with student wish to conduct further investigation and analyses in order to contribute to scholarly knowledge. This suggests the need for fresh data collection conducted with IRB approval. APU does not have a provision for retroactive IRB approval.

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 ten 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

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 IRB 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. This is a necessary step, 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 for Graduate Programs and Research.

The Vice Provost 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 will determine whether the proposed research is approved. The Vice Provost or IRB 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.

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. **See Informed Consent templates in the Appendix: General Informed Consent, Informed Consent for Electronic Survey Questionnaires, and Student Assent Form, pages 42-46.**

The Informed Consent will contain:

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;

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.

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).

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

    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 in the Appendix). 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.

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.

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 www.apu.edu/grants/policies. 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), annually thereafter during the conduct of research, and within 30 days of changes to any response on the form. 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. Because federal regulations changed on August 24, 2012, IRB applicants are urged to read carefully the questions on the new form as well as the definitions of key terms which can be found accompanying the PCOI form and in the full policy. Excerpts from the policy are found below.

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.

The Potential Conflict of Interest Disclosure form can be found on page 47. Questions about the policy or the PCOI form may be directed to Dr. Diane Guido, Research Integrity Officer, at 626.812.3034 or dguido@apu.edu.

Integrity in Research

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 Policy on Integrity in Research sets forth the 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 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 (the Vice Provost for Graduate Programs) 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 at www.apu.edu/grants/policies.

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.

Researcher's Continuing Responsibilities

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 IRB approved inclusion and exclusion criteria;
- 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 unanticipated problems involving risks to subjects or others**;

Research approved by the IRB may be monitored for compliance.

Principal Investigator's Responsibilities for Reporting Unanticipated Problems

If unanticipated problems occur during research, the Principal Investigator must report the following to the APU Institutional Review Board:

- Research number as assigned by the IRB, 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 changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

Unanticipated problems must be reported promptly. Unanticipated problems that are serious adverse events should be reported to the Research Integrity Officer at 626.812.3034 within one week of the investigator becoming aware of the event. Any other unanticipated problem should be reported to the IRB within two weeks of the investigator becoming aware of the problem.

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.

Privacy and Confidentiality

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.

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

Recording Data

In recording data, keep two simple rules in mind to avoid problems later, should someone ask about or question your 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. Do not use loose-leaf notebooks or simply collect pages of evidence in a file. Do 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 you collect your data electronically, you must be able to demonstrate that they are valid and have not been changed.

As you record your 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)

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.
- 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 3 years following the submission of the closure report. Some government programs require retention for up to 7 years. APU requires that data be kept for 3 years after the closure report unless a longer retention is required by a specific agency. Before discarding notebooks or files, or erasing your computer memory, give consideration to who might benefit from or ask to see your data in the future.

Request for Revision or Addition to approved research

Researchers who will in any way modify their research which has been previously submitted to and approved by the IRB must submit a Request for Revisions or Additions Review form found in the Appendix, page 56. Approval must be received from the IRB prior to commencing the revised protocol. Deviations from the approved protocol may prompt an investigation by the Research Integrity Officer and may result in termination of IRB approval by the IRB.

Renewals for Continuing Research

After the initial approval, all studies must undergo 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. By federal regulation, 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 three weeks prior to the anniversary date of the original 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**, the Request for Renewal of Continuing Research form may be submitted to and approved by the full IRB. If the initial approval was an **expedited review** procedure, only the IRB Chair (or designated IRB member) receives the request form. If a study is not re-approved before the study's expiration date, the research study is automatically suspended. Renewal form can be found in the Appendix, page 54.

Closure Report of Research Study

The Closure Report must be submitted after all data collection and de-identification is complete, and PRIOR to the one-year anniversary date of your approval. The Closure Report of Research Study form is found in the Appendix, page 58. IRB applications from researchers who are delinquent on closure reports from previous research will be delayed until closure reports are filed.

The Institutional Review Board (IRB)

Membership

APU follows the guidelines of the *Common Rule* that requires 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[d]).

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. Completion Reports will be placed on file with the Institutional Review Board Coordinator.

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 meetings 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.

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 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, pregnant women, or mentally disabled, 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 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.

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

2014-15 **Institutional Review Board**

Appendix

AZUSA PACIFIC UNIVERSITY

2014-15

Institutional Review Board Application for EXPEDITED or FULL BOARD REVIEW

Use this form for an expedited or full board review of any student, faculty, or staff research project involving human subjects. For studies that require a full review, please note that the IRB meets once a month and to be considered the project must be submitted ten working days prior to the board meeting.

Principal Investigator:

Phone:	**Email:**

Are you:

☐ **APU student**		
	Responsible faculty	Department
	Phone	Email
☐ **APU faculty or staff**		
	Chair, dean, or supervisor	Department
	Phone	Email
☐ **Unaffiliated with APU**		
	Institutional Affiliation and Address	
	Faculty Advisor or Chair	Email

List here the names and email addresses of all persons who consent participants, implement research procedures, and collect research data.	
Name	**Email address**

Project Title:

Is this a Pilot Study?	☐ **Yes** ☐ **No**

If *Yes*, who is your target sponsor?

Is this research funded by award? ☐ **Yes** ☐ **No**

If *Yes*, list the following:

1. **Funding Agency :**
   (if NIH funded, attach certificate of compliance)
2. **Study Initiator:** ☐ **Local Investigator** ☐ **Funding Agency**
3. **Award Number:**
4. **Confirmed or estimated amount of award**

If there is a contract related to this study of which APU is a party, has the office of the General Counsel approved the contract?

☐ **Yes** ☐ **No** ☐ **N/A**

Is the research project a clinical trial: ☐ **Yes** ☐ **No**

Expected Research Start Date **Expected End Date**

Recommendation for IRB Review Category (see IRB instructions)

☐ **Full Board Review**

☐ **Expedited** Category # _____ (see page 6 in this handbook)

If you are requesting Expedited review, give rationale for doing so.

Please confirm the following:

Vulnerable population? ☐ No
Sensitive topic? ☐ No
Exceeds minimal risk? ☐ No

Paginate your application once it is complete. Place the page numbers as found in your application into the Index below. Some items may not be needed for your application.

Index for IRB Application	
Application	**Page #**
Informed Consent form	**Page #**
Potential Conflict of Interest Disclosure form(s)	**Page #**
Instrument(s)	**Page #**
Letter(s) of agency approval	**Page #**
Participant Recruitment (email, poster or verbal invitation)	**Page #**
Scholarly research references	**Page #**
International Research - verification of cultural sensitivity	**Page #**
California Experimental Subjects Bill of Rights	**Page #**
Authorization for Use of Private Health Information	**Page #**
CITI Completion Report or NIH training certificate(s)	**Page #**
Other	**Page #**

2014-15 Institutional Review Board Application form, continued

Please complete the following sections in enough detail for the IRB to understand the nature, intent, and procedure of your project. Enter the following information within this document.

1. Title:

2. Project Summary: Summarize your project, listing goals, participants, researcher interventions (for experimental research) and measures. (Limit – 120 words)

3. Research Question: State your research questions and hypotheses if applicable:

4. Foreseeable Benefits:

a. What, if any, is the immediate benefit of this research to the *participant?*

b. How does this research benefit the *population of persons similar to participants?* Provide citations and a brief summary:

c. Summarize scholarly research with citation. Please limit summary to 500 words. Place references on a separate page with this application.

5. Target Sample Demographics:

a. How many total subjects?

b. What is the age range?

c. Inclusion and exclusion criteria

6. Recruitment of Participants

a. How will you obtain names and contact information of potential participants?

b. Who will make initial research contact with the participants?

c. What is the venue for recruitment activities?

d. Provide a copy of the script or text used to recruit participants.

e. Provide letter(s) of approval from an authorized representative of the agency or agencies that will host data collection.

7. Protection of potential participants from perceived coercion in recruitment process

a. What is the PI's professional relationship with potential participants?

b.

- Will professors be recruiting participants from their current classes? ☐Yes ☐ No
- Is there any unequal power relationship that could influence a person's decision to participate in the research? ☐ Yes ☐No
- Will large tangible rewards that might induce a potential participant to take unusual risks be offered? ☐Yes ☐No
- Will participants be expected to reveal residency status or legal status? ☐Yes ☐No

If you answered *Yes* to any of the above, please comment.

8. Process to protect privacy

Privacy is defined as having control over extent, timing and circumstance of sharing oneself with others. Threats to privacy are mitigated by the participant's informed consent of participation in the research.

a. What are the specific research related issues that the participant needs to understand in order to give informed consent?

What personal information are you asking the participant to reveal?

b. How do you plan to educate potential participants about possible risks in the research?

c. How will the participant affirm they understand?

d. List names of all persons who will discuss Informed Consent documents with potential participants or their guardians.

Name :

e. Does that person(s) speak the same language as the potential participants? ☐Yes ☐ No
If no, translations will be required of the recruitment scripts, the Informed Consent forms, and the survey instruments for participants. In *some* cases the translation can be done by the researcher. Additionally, a back translation must be completed independent of the original translator.

f. How will you train those people to properly follow the procedures of Informed Consent and to be aware of confidentiality and privacy issues?

g. Do all persons who will have any interaction with participants have current certification in the protection of human subjects? ☐ Yes ☐No
Do all persons who will have access to research data have current certification in the protection of human subjects? ☐ Yes ☐ No

Include a copy of all CITI Completion Reports with the application. CITI training must have been completed within the prior three years. If a member of the research team is currently affiliated with another institution, include a copy of their training certificate as required by that institution.

h. After the participant has read the informed consent form, will you affirm with your signature that you believe the participant understands the content of the Informed Consent? ☐Yes ☐No

i. Include a copy of the Informed Consent document, prepared according to the template (found in the Appendix) for face-to-face consent or the template for electronic consent. If children are participants, address the Informed Consent to parents and address an Assent Document to children. If the research involves a focus group, the Informed Consent must state that the Primary Investigator cannot guarantee that participants will honor privacy pledges. Informed Consent templates can be found in the Appendix on pages 42-46.

9. Confidentiality

a. Will you store the Informed Consent forms and research data separately? ☐Yes ☐No

b. How will you de-identify research data?

c. Is there a document that links participants' names with corresponding research code numbers? ☐Yes ☐No

If *Yes,* is the document stored separately from the research data? ☐Yes ☐No

d. How will you protect the security of the documents?

e. Do you plan to use electronic surveys? ☐Yes ☐No

If *Yes*, do you agree to decline the privilege of access to personally identifiable data? ☐Yes ☐No

10. Risks for physical discomfort and emotional distress associated with research procedures

a. What components of the research procedures might cause physical discomfort or emotional distress for participants?

b. What is the anticipated evidence of physical discomfort or emotional distress?

c. How will the researcher respond to evidence of physical discomfort or emotional distress?

d. What resources are available to the participant that may experience distress?

11. International or Cross Cultural Research

Do potential participants reside outside the US? ☐ Yes ☐No

Will the research be conducted in a cross cultural setting? ☐Yes ☐No

If *Yes* to either question provide evidence that research procedures are sensitive to the local research context. Possible sources of evidence are approval from an IRB in the host country, or written approval from a governmental health or education agency in the host country. See page 11 in the handbook for more information.

Some research will require translations of Informed Consent forms and survey instruments for participants. Translations are generally done by someone other than the researchers. Additionally, a back translation must be completed independent of the original translator.

12. *Quantitative* Research – *Survey Methods*

a. For paper and pencil questionnaires, identify who will distribute questionnaires to participants and how participants will return marked questionnaires to the researcher.

b. For web platform responses to questionnaires, identify materials for directing the participant to the platform and how participant will respond.

c. Describe the evidence that questionnaires are appropriate for the participants.

d. Describe your plan for analyzing questionnaire data. List a specific statistical technique (univariate or multivariate).

13. *Quantitative* Methods – *Experimental*

a. Describe research question and relevant hypotheses

b. Describe independent and dependent variables

c. Describe your procedure for random selection and assignment of participants to experimental and control groups.

d. Describe venue for research activities

e. Describe independent variable materials or activities

f. What experimental interventions will be used to measure independent and dependent variables

g. Describe activities and/or materials for the control group

h. Describe other procedures designed to enhance internal and external validity.

i. Identify data collection intervals

j. Describe plan for monitoring treatment integrity

k. Describe evidence that experimental and control materials and/or activities are appropriate for participants

l. Describe evidence that measures are appropriate for participants

m. Describe your data analysis plan

14. *Qualitative* Research Methods

a. Explain theory/conceptual framework guiding data collections, including reference to established researchers who have conducted studies with similar procedures.

b. Explain steps taken to ensure methodological and data analytic rigor (including but not limited to the utilization of qualitative analysis software programs), including reference to established researchers who have conducted studies using similar procedures.

c. Do you plan to interview participants? ☐Yes ☐No

d. Interview questions are found on page_____

e. Data analysis procedures, including coding and software

f. Do you plan a focus group? ☐ Yes ☐No
If *Yes,* focus group questions are found on page____

g. Data analysis procedures, including coding and software

15. Research Plan

List approximate dates for major activities in your research plan.

16. California Experimental Subjects Bill of Rights

If your research involves an experimental clinical procedure, have you included the California Experimental Subjects Bill of Rights with your application? ☐Yes ☐No ☐N/A

17. Use of Private Health Information

If your research requires medical records, have you included the Authorization for Use of Private Health Information with your application? ☐Yes ☐No ☐N/A

18. What is your plan for sharing your findings with the scholarly community?

19. I have read and understand Azusa Pacific University's policy on Integrity in Research

☐Yes ☐ No

☐ If a survey of Azusa Pacific University students, faculty, staff or alumni will be used for this research, the researcher agrees to contact the Office of Institutional Research and Assessment.

SIGNATURES:

***All applications must include a current CITI Completion Report for the applicant and the reviewers*.**
Reviewers certify that the application has been reviewed for clarity, validity, and the protection of human subjects.

For STUDENT Applications:

Principal Investigator: If more than one investigator, include names and signatures)

_____ _____ _____
Print Name Signature Date

Reviewed by Faculty Advisor with current human subject protection certification:

_____ _____ _____
Print Name Signature Date

Department Chair or designee with current human subjects protection certification: I have reviewed this application and determined that the departmental requirements are met, the investigator(s) has/have adequate resources to conduct the research, and the research design is sound and has scientific merit.

_____ _____ _____
Print Name Signature Date

Dean or dean designee:

_____ _____ _____
Print Name Signature Date

For FACULTY/STAFF Applications:

Principal Investigator (If more than one investigator, include list of names with email addresses and signatures)

_____ _____ _____
Print name Signature Date

Department Chair or designee with current human subjects protection certification:
I have reviewed this application and determined that the departmental requirements are met, the investigator(s) has/have adequate resources to conduct the research, and the research design is scientifically sound and has scientific merit.

_____ _____ _____
Print name Signature Date

Dean or dean designee:

_____ _____ _____
Print name Signature Date

THE COMPLETED, SIGNED APPLICATION WITH SUPPORTING DOCUMENTS MUST BE SENT IN ONE .pdf FILE TO:

Joanie Stude, IRB Coordinator, at jstude@apu.edu

Please note: The Institutional Review Board (IRB) at Azusa Pacific University (APU) is charged with oversight of the protection of human subjects in experimental research. Receiving IRB approval does not constitute institutional approval of the project by APU. If the responsible investigator believes that the project might be inconsistent with the mission and values of APU or potentially not represent the University in a favorable light, it is recommended that the responsible investigator contact their Dean.

For IRB Use Only

☐Approved by **Expedited Review**

No further review needed unless the protocol changes or research continues past one year.

Signature: IRB Chair or Designee _____

Date of Approval _____ Date Approval Expires _____

☐Approved by **Full Board Review** ☐ **Not Approved – Resubmission Required**

Signature: IRB Chair or Designee _____

Date of Approval _____ Date Approval Expires _____

AZUSA PACIFIC UNIVERSITY

2014-15 Institutional Review Board EXEMPT STATUS Request form

There are six categories of regulatory requirements allowing human subjects research to be exempt from IRB review. Those are described on page 8 of the IRB handbook. If your research plan includes any of the following, it *cannot* qualify for Exempt Status. An application for Expedited or Full Board review should be submitted for Institutional Review Board (IRB) review.

- Research involving interaction with children (except in normal educational practices)
- Research involving vulnerable populations including but not limited to prisoners and pregnant women.
- 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 that what would be expected in daily life
- Research where a key exists that may link subjects with data and where disclosure of the participant's responses outside the research could reasonably place the participant at risk.

Research Title:

Principal Investigator (PI):	
Email Address:	Phone:
School/College:	Department:
On a separate page list all additional investigators who will have any interaction with research participants including those conducting informed consent and those collecting data. Include email addresses and signatures of additional investigators. All must be currently certified in human subject protection in research.	

FOR STUDENT PROJECTS (Required when the principal investigator is a student)	
Name of Professor/Supervising Faculty:	
Email Address:	Phone:
School/College:	Department:

Is this research funded by award? ☐ Yes ☐ No If "Yes" list funding agency and amount of award.

ASSURANCE:

- I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted for internal or external funding sources.
- Misrepresentation of the research described in this or any other IRB application may constitute non-compliance with federal regulations and/or academic misconduct.
- I agree to provide proper surveillance of this project to ensure that the rights and welfare of the human subjects are protected. I will report any problems to the IRB.

- I agree that modifications to the research as submitted will not take place without prior review by the IRB.
- I agree that the research will not take place without the receipt of permission from any cooperating institutions, when applicable.
- I agree that all activities will be performed in accordance with all applicable federal, state, local, and Azusa Pacific University policies.
- I have read and understand Azusa Pacific University's policy on Integrity in Research.
- I understand the following:

  Research that qualifies for Exempt status includes:

  - Research that does not involve interaction with children (except in normal educational practices)
  - Research that does not involve vulnerable populations
  - Research that does not involve deception or withholding of information from subjects
  - Research that does not involve intense physical exercise
  - Research that does not cause emotional distress or discomfort greater that what would be expected in daily life
  - Research where there is no key to link subjects with data.
  - Research where there is a key that links subjects to data but where disclosure of the participant's responses outside the research would not reasonably place the participant at risk.

Principal Investigator:

_____	_____	_____
Print Name	Signature	Date

Professor/Supervising Faculty with current human subjects protection certificate (required if Principal Investigator is a student)

_____	_____	_____
Print Name	Signature	Date

Department Chair or designee with current human subjects protection certificate

I have reviewed this application and determined that the departmental requirements are met, the investigator(s) has/have adequate resources to conduct the research, and the research design is scientifically sound and has scientific merit.

_____	_____	_____
Print Name	Signature	Date

Dean or dean designee:

_____	_____	_____
Print name	Signature	Date

Part B: General Overview

Provide a brief summary of the purpose of your study:

Provide a brief summary of your research design:

Describe your recruitment and informed consent process, if applicable:

Identify the specific site(s) where data collection will occur:

Part C: Exemption Categories

☐ **Yes** ☐ **No** **1. Are you conducting research on Educational Practices (e.g., instructional techniques, curriculum effectiveness, etc.)? If *Yes*, please answer questions 1a through 1e. If *No*, please proceed to question 2.**

☐Yes ☐No 1a. Will the research be conducted only in an established or commonly accepted educational setting, such a classroom, school, professional development seminar, etc.? If no, please specify.

☐Yes ☐No 1b. Will the research procedures and activities involve normal educational practices (e.g., activities that normally occur in the educational setting)? Examples include research on regular or special education instructional strategies or the effectiveness of instructional techniques, curricula, or classroom management methods.

☐Yes ☐No 1c. Will the research procedures include anything **other than** normal educational practices? If *Yes*, please specify:

☐Yes ☐No 1d. Will the procedures include randomization into different treatments or conditions, radically new instructional strategies, or deception of subjects?

☐**Yes** ☐**No** **2. Does your research involve use of educational tests, survey procedures, interview procedures, or observations of public behavior? If *Yes,* please answer questions 2a through 2d. If *No,* please proceed to question 3.**

☐Yes ☐No 2a. Will the research involve one or more of the following?
☐The use of educational tests (cognitive, diagnostic, aptitude, achievement)
☐Surveying or interviewing adults
☐Observations of public behavior of adults
☐Observations of public behavior of children, when the researcher will not interact or intervene with the children

☐Yes ☐No 2b. Will the information be obtained and recorded in a manner that would allow for identification either directly or through identifiers linked to the participants?

☐Yes ☐No 2c. Could any disclosure of the human participants' responses outside the research reasonably place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing , employability or reputation?
Note: This question is about the risks to subjects if accidental disclosure were to occur, not about how you will maintain confidentiality.

☐Yes ☐No 2d. Are all of the participants elected or appointed public officials or candidates for public office?

☐ **Yes** ☐ **No** **3. Does the research involve the collection or study of *currently existing* data, documents, records, pathological specimens, or diagnostic specimens? If *Yes*, please answer question 3a, and 3b. If *No,* please proceed to question 4.**

☐Yes ☐No 3a. Are **all** data, documents, records, or specimens **publicly** available?

☐Yes ☐No 3b. Will the information be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects?

Part C: Additional Information

☐ **Yes** ☐ **No** **4. Does your research involve any procedures that do not fit into one or more of the categories in items #1-#3 listed above, such as the following? (Check all that apply.)**

☐Usability testing of websites, software, devices, etc.
☐Collection of information from private records when identifiers are recorded
☐Procedures conducted to induce stress, moods, or other psychological or physiological reactions
☐Presentation of materials typically considered to be offensive, threatening, or degrading
☐Video recording or photographing non-public behaviors
☐Use of deception (e.g., misleading participants about the procedures or purpose of the study)
☐Physical interventions, such as
- ☐Blood draws
- ☐New collection of biological specimens
- ☐Use of physical sensors (ECG, EKG, EEG, ultrasound, etc.)
- ☐Exercise, muscular strength assessment, flexibility testing
- ☐Body composition assessment
- ☐Measuring of height and weight
- ☐x-rays
- ☐changes in diet or exercise

☐Tests of sensory acuity (i.e., vision or hearing tests, olfactory tests, etc.)
☐Consumption of food or dietary supplements
☐Clinical studies of drugs or medical devices
☐Other; please specify: ____

☐ **Yes** ☐ **No** 4a. If *Yes,* is your research conducted in an established educational setting **and** are the checked procedures part of normal educational practices given that setting? If *Yes,* please describe:

☐ **Yes** ☐ **No** **5. Does the research, directly or indirectly, involve or result in the collection of any information regarding any of the following? (Check all that apply.)**

☐ Use of illicit drugs
☐ Criminal activity
☐ Child, spousal, or familial abuse
☐ Mental illness
☐ Episodes of clinical depression
☐ Suicidal thoughts or suicide attempts
☐ Health history
☐ History of job losses
☐ Exact household income other than in general ranges
☐ Negative opinions about one's supervisor, workplace, teacher, or others to whom the subject is in a subordinate position
☐ Opinions about race, gender, sexual orientation, or any other socially sensitive or controversial topics
☐ Sexual preferences or behaviors
☐ Religious beliefs
☐ Any other information that is generally considered to be private or sensitive given the setting of your research; if so, please specify: _____

Send this completed, signed application with the following supporting documents in ONE .pdf file to Joanie Stude, IRB Coordinator, at jstude@apu.edu:

- Potential Conflict of Interest Disclosure form
- Informed Consent Document(s)
- Survey instrument(s), interview questions
- Letter of agency approval if working with an agency/institution other than APU
- Recruitment document(s) (flyers, emails, verbal recruitment scripts etc.)
- Current CITI certificate for protection of human subjects in research for each researcher, faculty, and chair who has signed the Exempt Status Request form.

If you have questions, please call the IRB office at 626. 815.2036.

AZUSA PACIFIC UNIVERSITY

[List Project Title]
[List Researchers Involved]
[List IRB # once assigned]

2014-15 **INFORMED CONSENT FORM**
(This is a template to be customized for your research)

Voluntary Status: You are being invited to participate in a research study conducted by the researchers listed above. You are being asked to volunteer since you meet the requirements for enrollment into this study. Your participation is voluntary which means you can choose whether or not you want to participate. You may withdraw any time without penalty. If you decline to continue, any data gathered to that point may be used in data analysis. If you choose not to participate, there will be no loss of benefits to which you are entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the study, and they will give you this consent form to read. You may also decide to discuss it with your family or friends. If you find some of the language difficult to understand, please ask the researcher and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

If applicable, see also: Informed Consent for Electronic Survey Questionnaires
Student Assent Form (ages 12-17)

Purpose: The study for which you are being asked to participate is designed to **… [*insert 3 to 5 sentences about the study]***

Procedure: To be a voluntary participant in this study, you will be asked to… [***insert brief procedure for the study].***
Include if applicable ⇨ The study asks that you grant the researchers permission to view your medical or clinical record. You should know that the researchers will copy the information from your chart, but not include your name or any other identifying information such as your medical record number, birth date or social security number. You will also be asked to sign a separate form that specifically addresses using your protected health information (PHI) for the purposes of research.

Commitment and Compensation: Your total participation in the study will take approximately [ ] days or hours over [ ] sessions. Each session will last approximately [ ] minutes or hours.
Include if applicable ⇨ As a token of our appreciation for your participation in this project, you will receive an honorarium of $___. **OR** You will not receive financial compensation for participation in the study.

Possible Risks & Benefits: It is expected that participation in this study will provide you with no more than minimal risk or discomfort which means that you should not experience it as any more troubling than your normal daily life. However, there is always the chance that there are some unexpected risks. The foreseeable risks in this study include an accidental disclosure of your private information, or discomfort by answering questions that are embarrassing. If you feel uncomfortable or distressed, please tell the researcher and he/she will ask you if you want to continue. Because this is research and

does not have anything to do with the current services you are receiving, you can withdraw from the study at any time without penalty.
You will not receive any direct benefits from participating in this study; however, your participation in this study will help improve the knowledge about [list expected outcomes in the study]. Your participation may also benefit other people with similar concerns.

Confidentiality & Consent: The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Your identity will be kept strictly confidential by [describe coding procedures and plans to safeguard data]. [Explain how the data will be stored, handled, etc.] [Disclose those parties that could potentially have access to the research data.]

This document explains your rights as a research subject. If you have questions regarding your participation in this research study or have any questions about your rights as a research subject, please contact the Principal Investigator using the information at the bottom of this form. Concerning your rights or treatment as a research subject, you may contact the Research Integrity Officer at Azusa Pacific University (APU) at (626) 812-3034 or at dguido@apu.edu.

New Information: During the course of this study, we may discover information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

[FOR BIOMEDICAL STUDIES ONLY] Injury: If you have a medical emergency during the study you may contact the Principal Investigator at the bottom of this form. You may also contact your own doctor, or seek treatment outside of the [list study setting]. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at [list study setting] in collaboration with APU. Ask them to call the telephone numbers at the bottom of this consent form for further instructions or information about your care.

In the event of any physical injury resulting from research procedures, you will not be provided medical treatment through Azusa Pacific University, however, you may seek treatment with your primary care physician or [if research is conducted at a hospital list hospital – make sure and coordinate this aspect of the consent with your site supervisor]. APU will not provide you with financial compensation if you are injured in this study.

[FOR TREATMENT STUDIES ONLY] Treatment Choices: There are alternative treatments available to you, including [list alternative treatments and where they may be received]. If you agree to participate in this treatment study, you will be given an opportunity to discuss alternative treatments with the researcher or [another professional].If you choose not to participate in this study, or choose to withdraw from the study, the researcher will refer you to someone who will discuss treatment alternatives for your condition. You do not need to participate in this study to have your [insert condition] treated.

Conflict of Interest: The Principal Investigator has complied with the Azusa Pacific University Potential Conflict of Interest in Research policy.

Consent: I understand that my participation in this study is entirely voluntary and that I may refuse to participate or may withdraw from the study at any time without penalty. I understand the procedures

described above, and I understand fully the rights of a potential subject in a research study involving people as subjects. My questions have been answered to my satisfaction. I agree to participate in this study. I have received a copy of this consent form.

☐ I agree to be audio taped ☐ I do not agree to be audio taped

_____	_____	_____
Participant Name Printed	Participant Name Signed	Date

I have explained the research to the subject or his/her legal representative and answered all of his/her questions. I believe he/she understands the information described in this document and freely consents to participate.

_____	_____	_____
Signature of Principal Investigator	Date	Time

[Signed by researcher or certified assistant after participant has demonstrated understanding of research procedures through questions and answers]

PI Name, Printed
Address
Phone
Email address

Informed Consent for *Electronic Surveys*

Voluntary Status: You are being invited to participate in a survey research study. Your participation is voluntary which means you can choose whether or not you want to participate. You may withdraw any time without penalty.

Purpose: The study for which you are being asked to participate is designed to…[insert a brief explanation about the study]

Possible Risks: It is expected that participation in this study will provide you with no more than minimal risk or discomfort which means that you should not experience it as any more troubling than your normal daily life. While there are no direct benefits to participating, your response will help us to better understand the research topic.

Confidentiality: The investigator involved with the study will not be collecting any personal information for the study. All responses to this survey are anonymous and confidential. Your name or identity will not be linked in any way to the research data. Concerning your rights or treatment as a research subject, you may contact the Research Integrity Officer at Azusa Pacific University (626) 812-3034.

Consent: I understand that my participation in this study is entirely voluntary and that I may refuse to participate or may withdraw from the study at any time without penalty. I have read this entire form and I understand it completely. By clicking below and completing the online assessments that follow I am giving my consent to participate in this study.

Student Assent Form
(For research participants ages 12-17)

What is this research about?
This study of youth is conducted by _____ (names) at

_____ (institution or organization.) We are interested in finding out

_____.

- I am free to participate or not participate in this study.
- The study involves about ___ hours of my time.
- All information I provide will be kept confidential and anonymous.
- I am free to skip a question if I feel uncomfortable.
- I am free to withdraw from the study at any time.
- I understand that this study poses no known threat or harm to me.
- I have been given the chance to look over the questions that will be asked of me.
- I understand that there will be no direct benefits from participating in this study.
- I will receive _____ if I participate in the research. (If applicable)

I wish to participate in the _____ study.

Student's Name: (Please print) _____

Student Signature: _____ Date_____

Researcher's Signature: _____ Date _____

Questions? See information below to contact me.

Primary Investigator
Institution or Organization
Address
Email Address
Phone Number

AZUSA PACIFIC UNIVERSITY

Potential Conflict of Interest Disclosure Form

Everyone engaged in research at Azusa Pacific University (see definition of *covered individual*) must complete the "Potential Conflict of Interest Disclosure Form," at least annually during the conduct of research, per the *Policy for Conflicts of Interest in Research* (the "Policy"). The form must be completed no later than the time of application for funded research (with the Grants Routing Form), or when a researcher is applying for IRB or IACUC approval, whichever is first, regardless of the source of research funding. If there are subsequent changes to any response, a new form must be filled out within 30 days. Based upon the information provided on this form, the university will determine, through the *Committee for Conflicts of Interest*, whether the researcher has any conflicts of interest. The full policy, including definitions of key terms (italicized on this form), may be found at www.apu.edu/grants/policies. Questions about this form or the policy may be directed to Dr. Diane Guido, Research Integrity Officer, at dguido@apu.edu or (626) 812-3034.

Name: _____ Date: _____

Title of Proposed Research: _____

Potential or Secured Funding Source: _____

Submitted with: □ Sponsored Research Routing Form □ Annual Update
□ IRB or IACUC Proposal □ Other (e.g., change of circumstances)

1. Do you have any *significant financial interest* (as defined in the *Policy*) that, to an independent observer, would reasonably appear to be affected by research in which you are involved or that exist in entities whose financial interests to an independent observer would reasonably appear to be affected by your research (e.g., stock values, etc.)?
   Yourself: __Yes ___ No Your spouse or dependent children: ___Yes ___No

2. Separate from *regular research payments* (as defined in the *Policy*), have you received in the last 12 months or will you receive in the next 12 months more than $5,000 in cash or of monetary value from an entity that could reasonably appear to be affected by this research?
   Yourself: __Yes ___No Your spouse or dependent children: ___Yes ___No

3. Do you consult or have a financial interest with any commercial funding source that also sponsors clinical trials or other research at the University in which you simultaneously are responsible for the design, conduct or reporting of the University project?
   Yourself: __Yes ___ No Your spouse or dependent children: ___Yes ___No

4. Do you serve as an officer, director, employee, or member of an advisory committee or review board of an organization (whether paid or unpaid) that is related to your research interest (or that could reasonably appear to be affected by your research)?
   Yourself: __Yes __ No Your spouse or dependent children: ___Yes ___No

5. Would your school or academic department receive anything of value from any commercial funding source that sponsors your research (other than compensation disclosed in the budget submitted to the Office of Research and Grants with your grant proposal)? ___Yes ___No

6. Do you use or propose to use University facilities or personnel to conduct research or testing for any outside interests other than sponsored projects approved by the University? ___Yes ___No

7. Do you engage in external professional or commercial activities (e.g., external consulting) related to your research? ___Yes ___No

8. Did you receive any reimbursement for travel or sponsored travel related to your institutional responsibilities from an entity other than a federal, state, or local governmental agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education? ___Yes ___No

9. Do you have a *conflict of interest* (as defined in the *Policy*) or the appearance of any *conflict of interest* (including bias) between your personal financial, relational, or other interest and your involvement in this research project? ___Yes ___No

10. Is there anything not covered in the above questions that you believe might constitute a potential conflict of interest or create the appearance of being a conflict of interest related to this research? ___Yes ___No

If you answered "yes" to any question above (#1-10), attach a separate page describing the nature and amount of any interest noted.

Are you the Principal Investigator or are you responsible for the design and conduct of this research project? ___Yes ___No

If yes, please identify faculty, staff, students, and other collaborators who will be working with you on this research project.

Name, Affiliation: _____
Name, Affiliation: _____
Name, Affiliation: _____
Name, Affiliation: _____

If any of the *covered individuals* listed above has IRB approval from another institution related to this study, please provide a copy of that IRB approval.

I attest that I have disclosed any and all significant financial and other interests, as well as those of my spouse and children, which, to an independent observer might reasonably appear to affect or be affected by my research.

_____

Signature **Department/Division** **Date**

Submit this form with the Grant Routing Form to the Office of Research and Grants, or with the IRB and IACUC applications to the appropriate IRB/IACUC Coordinator for review. (Revised 8-13)

Selected Definitions from the Policy for Conflicts of Interest in Research

For a complete copy of the policy, see www.apu.edu/grants/policies or contact Dr. Diane Guido, Research Integrity Officer, at dguido@apu.edu or (626) 812-3034.

"Conflict of interest" refers to a divergence between the individual's personal financial, relational, or other interests and his/her professional obligations to the University – whether through teaching, involvement in research, contracting, purchasing, or performing other administrative duties – such that an independent observer might reasonably determine that the individual's professional actions or decisions are, or potentially could be adversely affected, distorted or otherwise compromised by the individual's personal interest. The term conflict of interest is broader and encompasses more professional activities than the term financial conflict of interest in research, defined below.

"Covered individual" includes any faculty member (whether full-, partially-, or non-salaried), staff member, administrator or other employee who, under the aegis of the University, is involved in research, or conducts research pursuant to the review and approval of a University research panel), or is otherwise identified as involved in research by a principal investigator, chair or unit head, or other University administrative officer responsible for research activities. It also includes any student, fellow, or trainee who works (whether paid or unpaid) on a federally funded research project.

"Significant financial interest" means anything of economic or monetary value that to an independent observer would be or reasonably appear to be affected by research, with inclusions and exclusions as set forth below:

(1) Inclusions. Significant financial interest includes, but is not limited to, any economic or monetary interest of the following types or categories that is held either i) by a covered individual (or his or her spouse or dependent children), or ii) by any entity in which a covered individual (or his or her spouse or dependent children) has a financial or fiduciary interest:

a) *"Compensation interest,"* meaning non-university salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts, "in kind" compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 months exceeded $5,000, or are expected to exceed that amount in the next 12 months;

b) *"Equity interest,"* meaning i) any equity interest (or entitlement to the same), in a publicly-traded financially interested entity that exceeds $5,000 in value or represents more than 5% ownership interest in any single entity (see exclusions below), or ii) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same);

c) *"Intellectual property interest"* meaning i) royalty income or the right to receive future royalties under a patent license or copyright, whether the research is directly related to the licensed technology or work; or ii) any other direct or indirect interest in a patent, trademark, copyright,

trade secret, know-how or other intellectual property right where the research is directly related to the interest;

d) *"Extraneous research payments,"* meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested *entity* or from the institution;

e) *"Fiduciary relationship,"* meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, regardless of whether remuneration is received for such service.

f) *"Travel expense,"* meaning any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that disclosure is not required for travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

(2) Exclusions. Significant financial interest excludes, and therefore is not meant to refer to, the following types of categories of economic or monetary interest:

a) *"Mutual fund interests and retirement accounts, "* meaning interests of any amount in publicly traded, diversified mutual funds or retirement funds as long as the Investigator does not directly control the investment decisions made by these vehicles;

b) *"De minimis equity interests,"* meaning stock or stock options in a publicly traded company that, when aggregated for the covered individual (and/or his or her spouse or dependent children) meets both the following tests: it does not exceed $5,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;

c) *"Outside payments." m*eaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (and/or his or her spouse or dependent children), over the next 12 months, are not expected to exceed $5,000;

d) *"Regular research payments,"* meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;

e) *"University compensation,"* meaning salary, royalties, and other remuneration for services from the University;

f) *"Income from service,"* meaning income for service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;

g) *"Income from lectures,"* meaning income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

AZUSA PACIFIC UNIVERSITY

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental clinical procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

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

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

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

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

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

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

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

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

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

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

I have carefully read the information contained above in the "California Experimental Subject's Bill of Rights" and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_____ _____ _____

Patient Name Signature Date

_____ _____ _____

Parent/Legal Guardian Name Signature Date

If signed by other than the patient, indicate relationship: _____

Witness: _____ Date _____

AZUSA PACIFIC UNIVERSITY	**INSTITUTIONAL REVIEW BOARD** **Authorization for Use of Private Health Information** **Azusa Pacific University • 701 East Foothill Blvd • Azusa, CA 91702** **(626) 812-3034 (voice) / (626) 815-3807 (fax)**	

Title of Study:

Principal Investigator:

Others who will use, collect, or share PHI:

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: Name, address, length and type of disability, any orthopedic injuries or cardiovascular disorders.

The individual(s) listed above will use or share this PHI in the course of this study to the Institutional Review Board (IRB) of Azusa Pacific University, the sponsor of the study and its affiliates, government agencies such as the Food and Drug Administration (FDA), other research sites involved in this study, health care providers who provide services to you in connection with this study, central labs, central review centers and central reviewers.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete. The authorization expires upon the conclusion of this research study.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health

information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator directly or the Research Integrity Officer at (626) 812-3034.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered.

……

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient or Patient's Legal Representative	**Date**
Printed Name of Legal Representative (if any)	**Representative's Authority to Act for Patient**
Signature of Person Obtaining Authorization	**Date**

AZUSA PACIFIC UNIVERSITY

Institutional Review Board - REQUEST FOR RENEWAL OF CONTINUING RESEARCH

This form is used for continuing research that was initially approved by either an expedited or a full board review by the IRB. This request must be submitted three weeks PRIOR to the anniversary of the previous approval so that continuing approval may be received.

Current date: Date of previous approval:

IRB #:

Project Title:

Principal Investigator:

_____

Printed Name Signature Date

Phone #: Email:

If Student Project, **Faculty Advisor:**

_____

Printed Name Signature Date

Phone#: Email:

Department Chair:

_____

Printed Name Signature Date

Phone#: Email:

Since the previous approval (of one year or less), please identify any of the following:
Please check one:

☐Data collection in process **OR**

☐Data collection completed (If all data have been collected and have been completely de-identified, that is, no key exists that would allow connection of a participant with their data, renewal is not required. A Closure report form should be submitted.)

Institutional Review Board - REQUEST for RENEWAL OF CONTINUING RESEARCH, continued

The number of subjects studied to date_____

Changes in risks - If changes, explain_____

Changes in benefits to subjects - If changes, explain_____

_____

Changes in informed consent/safeguards - If changes, explain_____

Attach a summary of the following **since the last IRB review/approval**:

a. any adverse events and any unanticipated problems involving risks to subjects

b. any withdrawal of subjects for the research

c. any complaints about the research

d. a summary of any relevant recent literature and interim findings

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For IRB use only

☐ Renewal approved

Signature: IRB Chair or Designee _____

Date of Approval _____ Date Approval Expires _____

AZUSA PACIFIC UNIVERSITY

Institutional Review Board
REQUEST for REVISIONS or ADDITIONS to previously approved research

This form is used for continuing research that was initially approved as either expedited or by a full board review of the Institutional Review Board. This request must be submitted and approved prior to commencing any revisions or additions to ongoing research.

Current date: Date of previous approval:

Project Title:

IRB #:

Principal Investigator:

E-mail: Phone #:

1. Revision or addition description:

Please select one or more items below; select all that apply. Please describe under #3 below.

☐ Revision to currently approved Informed Consent
☐ Revision to currently approved Research Application
☐ Revision to a currently approved sponsor protocol
☐ Other revision or addition. Please describe. For example, revised questionnaire, etc.

2. Does this revision or addition involve only minor changes to the study? ☐Yes ☐No

3. Describe the revision request or addition:

4. Does this revision or addition affect risks to participants?

☐ This revision does not affect risks to participants.
☐ This revision decreases risks to participants.
☐ This revision adds a newly identified risk or side effect to the protocol and consent form.
☐ This revision does increase risks to participants. (If risks are increased, include an explanation of the increase in #3 above and have this form signed by your NIH certified department chairperson.)

REQUEST for REVISIONS or ADDITIONS – continued

5. Does this revision or addition change the expected benefits, if any to participants?

☐Yes ☐No

If *Yes*, please explain.

6. If the consent form has been revised, do you recommend providing currently enrolled participants with the information in the new consent form? ☐Yes ☐No ☐NA

Please explain.

Principal Investigator:

_____

Printed Name Signature Date

Faculty Advisor (if this is a student research project):

_____

Printed Name Signature Date

Department Chair (if risks to participants are increased as a result of the requested change):

_____

Printed Name Signature Date

For IRB Use Only

☐Re-approved by Expedited review. No further review needed unless protocol changes or data-gathering extends beyond time limit.

Signature: IRB Chair or Designee _____

Date approved _____ Project approval expires_____

☐Re-approved by Full Review ☐ Not approved. Re-submission required.

Signature: IRB Chair or Designee _____

Date approved _____ Project approval expires _____

Send the completed, signed form and any supporting documents contained in one .pdf file to: Joanie Stude, IRB Coordinator, at jstude@apu.edu.

Institutional Review Board - CLOSURE OF RESEARCH REPORT form

This form is used as a final report for research that was initially approved by the Institutional Review Board by either an expedited or a full board review, and is to be submitted after all data collection and de-identification has been completed. This report is due PRIOR to the one-year anniversary date of your approval for research. If you intend to continue research past the anniversary date of your approval, submit a Request for Renewal form three weeks prior to the expiration date of your current approval.

Principal Investigator:

Phone #: e-mail:

Date of most recent IRB approval or re-approval:

Project ID# and Title:

☐ **I certify that since the last approval:**

a. There were no adverse events or any unanticipated problems involving risks to subjects.
b. No previously enrolled subjects withdrew from the research.
c. No complaints about the research were received.
d. There were no changes to the IRB-approved protocol.

☐ **I certify that since the last approval, one or more of the following occurred:**

Change(s) in the IRB-approved protocol, complaint(s), unanticipated problem(s), and/or withdrawal of subject(s). Attached is an explanation of any issues.

Number of research participants _____

Principal Investigator:

_____

Printed Name Signature Date

If student project, **Faculty Advisor:**

_____

Printed Name Signature Date

Department Chair:

_____

Printed Name Signature Date

Send the completed, signed form by .pdf file to: Joanie Stude, IRB Coordinator, at jstude@apu.edu