



Chaminade University

OF HONOLULU

**Office of the Provost
Office of Sponsored Programs**

Human Subjects Policy
and
Institutional Review Board (IRB00007927)

Charter and Standard Operating Procedures

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TABLE OF CONTENTS

INTRODUCTION.....	3
I. INSTITUTIONAL AUTHORITY.....	4
II. PURPOSE.....	4
III. BASIC PRINCIPLES.....	4
IV. THE AUTHORITY OF THE IRB.....	5
V. THE IRB'S FUNCTIONAL RELATIONSHIPS.....	7
THE MEMBERSHIP OF THE IRB.....	7
VI. MANAGEMENT OF THE IRB.....	8
VII. PROCEDURES OF THE IRB.....	9
A. Initial Review.....	9
A.1. No or Minimal Risk:.....	9
A.1.1. Exempt Research.....	9
A.1.2. Expedited Review.....	11
A. 2. More Than Minimal Risk.....	14
1. Actions of the IRB:.....	15
B. Continuing Review.....	16
C. Procedures Pertaining to Both Initial and Continuing Review.....	17
D. Adverse Event Reporting Guidance.....	18
VIII. OPERATIONS OF THE IRB.....	18
IX. RECORD REQUIREMENTS.....	22
X. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB.....	23
XI. PRINCIPLES OF INFORMED CONSENT.....	24
XII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.....	27
Appendix 1. Class Projects.....	29
Appendix 2. Action Research.....	31
Appendix 3. Examples of IRB reviewable and non-IRB reviewable projects.....	32
Appendix 4. Training Guide.....	33
Appendix 5. Sample Informed Consent.....	37

INTRODUCTION

Chaminade University encourages and supports the scholarly endeavors of its students, faculty, and staff. Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. Chaminade's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by University personnel are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the Chaminade University Institutional Review Board.

Some research projects involving human subjects are exempt from full IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and surveys or interviews in which the subjects volunteer and are not personally identified. Exemption must be approved by the IRB Chair.

The Institutional Review Board (IRB) for Human Subjects Research at Chaminade University has responsibility to oversee procedures for carrying out the University's commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the University using human subjects. (See VIII.A.1)

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

I. INSTITUTIONAL AUTHORITY.

This Charter and Standard Operating Procedures establishes and empowers the Chaminade University (Chaminade) human subjects protection committee. Currently Chaminade has one committee, registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board (IORG00006607, IRB00007927). This committee is hereinafter referred to as “the IRB.”

According to the terms of the Federal Wide Assurance, Chaminade University adopts the following reporting procedure:

All Principal Investigator(s) and all Chaminade University employees are required to report to the Chair of the IRB Committee any of the following upon knowledge of:

1. Unanticipated problems involving risks to subjects or others; and
2. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Chaminade University IRB committee, the Provost of Chaminade University, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

II. PURPOSE.

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

III. BASIC PRINCIPLES.

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (“The Belmont Report”), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

[see <http://ohsr.od.nih.gov/guidelines/belmont.html>].

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at Chaminade University to ensure that adequate safeguards are provided:

1. Subjects’ legal rights will be respected; their rights to

confidentiality, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be minimized and reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.
5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review *prior* to their initiation or *prior* to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year. (See VIII.B)

IV. THE AUTHORITY OF THE IRB.

A. Chaminade University holds a Federal Wide Assurance (FWA) through OHRP. As part of this Assurance, Chaminade agrees to consider *all* research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which Chaminade has an “IRB Authorization Agreement” as specified in Chaminade’s FWA) (See IX.H), or
2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which Chaminade has an “IRB Authorization Agreement” as specified in Chaminade’s FWA) (See

IX.H), or

3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible to take the initiative to identify any activities that require Institutional Review Board (IRB) approval. A decision guide can be obtained from the IRB chair at irb@chaminade.edu. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to complete an Exempt Protocol Summary Form for approval and submit it along with the protocol and any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance of the IRB regarding these activities.

B. The IRB reviews all projects and programs involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

D. The IRB has approval authority of human subject protocols, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Provost. However, the Provost may not approve the non-exempt research if it has not been approved by the IRB.

E. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population. (See XI.C.5)

H. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

V. THE IRB'S FUNCTIONAL RELATIONSHIPS.

A. The IRB functions administratively through the Office of Sponsored Programs. This structure provides for administrative coordination for the IRB with the various academic and administrative units at Chaminade.

B. The IRB advises and makes recommendations to the President and Provost, to policy and administrative bodies, and to any member of the Chaminade community on all matters related to the use of human subjects in research.

THE MEMBERSHIP OF THE IRB.

A. The IRB is composed of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. All appointments are made in accordance with Section VII and reported to OHRP and the University's President and Provost.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess competence sufficient to comprehend the nature of the research, as well as other competencies necessary for judgments as to acceptability of the research in terms of Chaminade regulations, relevant laws, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

C. The IRB must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with Chaminade.

The current roster for the Chaminade IRB is:

<u>Members</u>	<u>Position</u>	<u>Role</u>
Helen Turner, Ph.D	NSM, Chair	Scientist
Claire Wright, Ph.D	NSM, Vice-Chair	Scientist
Paul Fitzpatrick, STD, SM	HFA	Non-Scientist
Dale Fryxell, Ph.D.	Behavioral Sciences	Scientist
Darren Iwamoto, Ph.D	ED	Scientist
Tiffanie Kanayama, EdD	Nursing	Scientist
Raedeem Karasuda, Ph.D	Hawaiian Partnerships	Non-Scientist
JD Baker, Ph.D	UH, Anthropology	Community

An updated roster may be obtained at any time from irb@chaminade.edu.

D. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

VI. MANAGEMENT OF THE IRB.

A. The IRB Chair is a tenured faculty member appointed by the Provost. The Chair has authority to sign all IRB action items. An appointed Vice-Chair may fulfill this role if the Chair is absent or recused.

B. The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair.

C. Members and alternates of the IRB shall be appointed by the Chair of the IRB for a tenure of three (3) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

D. All IRB members are required to undergo CITI or NIH PHRP training at the time of their initial appointment (login details available from irb@chaminade.edu) The IRB Chair will maintain a log of training completion dates. Continuing education of IRB members is accomplished through CITI or other recertification.

E. IRB members do not receive compensation for their service.

F. Liability coverage for IRB members is provided through Chaminade's liability insurance coverage, whether or not the IRB member is an

employee of Chaminade.

G. Consultants with competence in special areas may be used when deemed appropriate on the recommendation of the IRB chair and approved by the Provost.

H. Conflict of interest policy and procedure

1. Investigators shall not be involved in the selection of IRB members.
2. Investigators will be asked in the Chaminade Conflict of Interest and Conflict of Commitment Disclosure Form whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.
3. Investigators and IRB members who are Chaminade employees and who apply for federal grants and contracts are subject to the Chaminade Conflict of Interest Policy.
4. The Office of Sponsored Programs will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.
5. Other conflict of interest guidelines specifically for IRB members are found in section XIII of this Charter and Standard Operating Procedures.

VII. PROCEDURES OF THE IRB.

A. Initial Review.

A.1. No or Minimal Risk:

Under the auspices of the IRB, the IRB Chair will review Exempt Protocol Summary Forms eligible for “exempt” (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review.

A.1.1. *Exempt Research*

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise [see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>]. Exempt types of research include:

(1) 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) (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation 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.

(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 paragraph (2) of this section, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

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

- (i) public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;

- (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
- (i) if wholesome foods without additives are consumed or
 - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or that is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must petition with an exemption request citing the specific exemption category and providing justification for the exemption. (Also see VIII.A.1.c)

A.1.2. Expedited Review

Under federal regulations certain types of research qualify for an 'expedited' review.

[See

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>]

These are activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use

of the product is not eligible for expedited review.)

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

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

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

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

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

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical

devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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

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

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

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

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

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional

risks have been identified; or

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

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

(10) Procedures for an exemption or expedited review
Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must submit Form I to the IRB.

The IRB Chair may recommend a protocol to the IRB for expedited review, for expedited review pending recommended changes/clarifications, or for review by the full board. The IRB Chair cannot “disapprove” of a protocol but may table action pending further information/clarifications. The IRB Chair will inform the PI of any of these actions. Any disagreement between the PI and the IRB Chair must be resolved by the IRB.

The PI will be notified of the IRB decision by the Chair.

If it is determined that one of these protocols require IRB review, it will be returned to the PI, with comments, for revision and submission to the full board. Upon receipt of the revised material from the PI, the IRB Chair will distribute copies to each IRB member.

A. 2. More Than Minimal Risk

Protocols for **full-board (IRB) review** must be submitted prior to the deadline established by the IRB Chair. The deadline dates are available at <http://www.Chaminade.edu/research/IRB.jsp>. The prospective PI will submit to the IRB Chair one (1) original and the required number of copies of the Form I, II or III. Copies of the form are available via <http://www.Chaminade.edu/research/IRB.jsp>. In the Petition, the investigator assures the IRB that he/she will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy.

The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

1. Actions of the IRB:

The IRB may take one of the following four actions in regard to the proposed protocol and consent form: *Approved, Approved Subject to Restrictions, Tabled, or Disapproved.*

Approved

When a protocol has been approved, the Chair completes the “Action of the IRB” form, signs and dates it, and distributes one copy of the form to the principal investigator, the IRB files, and, if appropriate, the performance site.

Approval of the protocol will be based on the following:

- a. The extent to which the protocol makes explicit in design and procedures the protection of subjects’ rights.
- b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification must be provided that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.
- c. Assurances of acceptable debriefing, if appropriate.

It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time.

There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

- d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects’ rights.
- e. Anticipated benefits, if any.

- f. The personal risk to the subject in relation to expected benefits.
- g. The adequacy of procedures for securing informed consent from the subject.
- h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.
- i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

Approved Subject to Restrictions

If the protocol is approved subject to restrictions, then the Chair completes the appropriate form, signs and dates it, and sends the form with a memo to the PI outlining the restrictions. The PI then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the protocol is then processed as an approved protocol and distributed as described above. The PI must respond to each restriction by either accepting the restriction or by presenting an argument as to why the restriction should be removed. The IRB considers the PI's response and for each restriction either continues the restriction or removes the restriction.

Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

Disapproved

If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

B. Continuing Review.

The IRB may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Principal Investigators will be informed of the annual review by receipt of a Continuing Review Questionnaire. This Continuing Review Questionnaire is to be completed

and returned to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The PI will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.).

When a completed Continuing Review Questionnaire is submitted to the IRB by the PI, the IRB Chair shall consider the following: changes to the research, protocol deviations and violations, since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports; and investigator compliance.

If the protocol and/or other documents used in the project have been amended within the past five years, the PI will be requested to submit a new protocol incorporating these amendments if such have not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected be used for research purposes.

C. Procedures Pertaining to Both Initial and Continuing Review.

1. The IRB shall have authority to determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review. Verification is particularly appropriate for: (i) complex projects involving unusual levels or types of risk to subjects; (ii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; or (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

2. PIs shall be informed at the time of protocol approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects;
3. PIs shall be informed at the time of protocol approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.
4. Serious or continuing noncompliance by an investigator, or any suspension or termination of activities, is to be reported promptly to the Office of Sponsored Programs so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

D. Adverse Event Reporting Guidance.

1. The Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).
2. Principal Investigator(s) and any Chaminade University employee will report to the Chair of the IRB Committee any of the following upon knowledge of such:
 - a. Unanticipated problems involving risks to subjects or others; and
 - b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

VIII. OPERATIONS OF THE IRB.

A. Meetings

IRB meetings are scheduled monthly. Materials for IRB consideration during a particular month are to be submitted by 4PM on the first of the month or the immediately prior working day if the first falls on a weekend or holiday. Materials are to be submitted by email to irb@chaminade.edu and copied to the Chair (currently hturner@chaminade.edu). The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

B. Review Assignments.

The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new protocol, who receive the complete study documentation for review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that protocol. Other IRB members review summary information only, but have access to complete study documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

C. Voting requirements

- Except when an expedited review procedure is used (see VIII.A.1.b), a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.
- In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.
- Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).
- Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

D. Appeals

The PI may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc*

committee of three or more IRB member or non-member faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

E. Amendments

1. Amendments to a research study are categorized into minor changes and significant changes.

Minor modification/change - A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of **minor changes** to a research study include but are not limited to, the following:

- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to subjects;
- Addition of non-sensitive questions to invalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

Examples of **significant changes** to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
- Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;

- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

2. Level of Review for Amendments

Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed, either by the screening committee or by the full IRB. However, if an amendment by the screening committee is determined to increase the level of risk beyond minimal risk, the screening committee will refer the amendment to the full IRB.

Minor modifications/changes may be reviewed and approved using an “administrative approval” process. Administrative approval may be given by the Office of Sponsored Programs. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrence.

3. Sponsor Agency Modifications

Modifications can be made only to IRB approved studies. A sponsor agency may modify the research protocol before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research protocol.

Sponsor agency generated modifications (or addenda) require review and approval by the IRB or Office of Sponsored Programs, as appropriate. The investigator should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

F. Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against a PI) and, if requested, the board will act in an advisory capacity.

G. Cooperative Activities

Cooperative activities relating to human subjects are those that involve Chaminade University and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

- Both institutions have Federal Wide Assurances (FWAs) approved by OHRP;
- Both institutions have entered into an Authorization

Agreement (or equivalent document) that stipulates the responsibilities of both parties; and

- The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

IX. RECORD REQUIREMENTS.

A. The IRB prepares and maintains adequate documentation of IRB activities within the Office of Sponsored Programs, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.
2. Detailed minutes of IRB meetings, showing:
 - a. Members present (any consultants/ guests/others shown separately).
 - b. Results of discussions on debated issues and record of IRB decisions.
 - c. Record of voting (showing votes for, against and abstentions).
3. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.
4. Copies of all correspondence between IRB and the investigators.
5. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.
6. Adverse reactions reports and documentation that the IRB reviews such reports.
7. Emergency use reports.
8. General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB and the Office of Sponsored Programs maintains a permanent record of the list of current IRB members, written procedures for the IRB, and self-assessments.

B. All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the PI leave Chaminade University, signed consent forms are to be transferred to the IRB Chair to be secured within the Office of Sponsored Programs.

X. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB.

A. Professional qualifications to do the research (including a description of necessary support services and facilities);

B. Appropriate Chaminade review form including protocol summary.

C. Complete study protocol which includes/addresses:

1. Title of the study and summary of the research to be conducted,
2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),
3. Sponsor of the study,
4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),
5. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons),
6. Study design (including, as needed, a discussion of the appropriateness of research methods),
7. Description of procedures to be performed,

8. Provisions for managing adverse reactions,
9. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations,
10. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Michigan as an individual under the age of 18), using legally authorized representatives (see XII.B. & C.), witnesses, translators and document storage,
11. Remuneration to subjects for their participation,
12. Any compensation for injured research subjects,
13. Provisions for protection of subject's privacy,
14. Extra costs to subjects for their participation in the study,
15. Inclusion/exclusion of women, minorities, and/or children;

D. Investigator's brochure (when one exists);

E. The case report form (when one exists);

F. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s); or request for waiver of the requirement to obtain informed consent;

G. Copies of advertisements and surveys, questionnaires, or other materials provided to subjects;

H. Copies of relevant grant applications (if any);

I. Requests for changes in study after initiation including changes to consent forms;

J. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports;

K. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XI. PRINCIPLES OF INFORMED CONSENT.

A. When an activity does not involve therapy, diagnosis, or management, and a professional/subject relationship exists, e.g., participation in a research project, the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions that a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the investigator or Chaminade as indicated below.

B. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative ("LAR"). The LAR must be authorized either by a power of attorney or a court order.

C. "Informed consent" means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>.

The IRB may approve a telephonic consent procedure under which the subject's legally authorized representative ("LAR") is sent a faxed or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.

D. The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay

language appropriate to the subject population).

E. For research involving more than minimal risk to subjects or if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.

F. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

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

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

The IRB may also choose to approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

G. Informed consent need not be based on full pre-study information.

However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects, and then setting the limits for such procedures.

XII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.

A. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an investigator or sub-investigator on the protocol;
2. Has a “significant financial interest” in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (see the Chaminade Conflict of Interest Policy for the definition of “significant financial interest”);
3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. Has identified him or her self for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

C. Typically, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation and actions (including vote). In general, IRB member(s) who have a real, or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair, during the discussion of the matter, in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

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Appendix 1. Class Projects

The University recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might be viewed as research. As a general rule, when those activities are conducted solely to fulfill a course requirement, an element of the definition of research (the intent to develop or contribute to generalizable knowledge) is lacking. However, it is also the case that some classroom research assignments could place participants at risk. Therefore, recognizing its role in the protection of human participants, the IRB has determined that some classroom assignments may require review by the IRB.

CUH considers classroom assignments involving research activities to be educational in nature, and not subject to IRB review, when all of the following criteria are true:

1. The project is limited to surveys, questionnaires, interview procedures, observation of public behavior, minimal risk experimental studies, or standard educational exercises directly related to the topic(s) being studied in an official University course. In general, audio and video recordings made as part of the interview procedure for the sole purpose of accuracy are allowed.
2. Surveys/questionnaires/interviews, if used, contain no sensitive personal questions (e.g., no questions about alcohol/drug use, sexual behavior/attitudes, criminal activity, medical history, grades/test scores) or other personal information that could "label" or "stigmatize" an individual.
3. The participants are not from a special population that requires extra protections (e.g., pregnant women, people in the criminal justice system, children under age 18, cognitively impaired individuals).
4. Either the information is recorded:
 - a) without any direct or indirect (e.g., race, gender, code number) identifier linking the participant to his/her data; or
 - b) no direct identifiers are recorded and any indirect identifiers could not be combined to ascertain the identity of some or all the participants; or
 - c) if direct or indirect identifiers are retained in the dataset, then the other data contained in the dataset could not reasonably harm the participant's reputation, employability, financial standing, or place the participant at risk of criminal or civil liability.
5. The results of the classroom assignment, including audio and video recordings, either do not leave the classroom, or, if the project involves gathering data from or about a company, agency, or organization, the data/results are shared only with that company, agency, or organization, and the company will not share the data or results with anyone else.

If any one of the foregoing criteria is not true, then the project must be sent to IRB for review. It is the responsibility of faculty to determine whether an assigned project

involving human participants can be classified as a course-related student project. Faculty should contact the IRB Office if assistance in making this determination is needed. It is also the responsibility of faculty to discuss general principles of research ethics with the class prior to the initiation of the project and ensure that those are followed.

The IRB is willing to review class research projects submitted by students individually or in groups, in order to support the educational process, but please recognize the traffic issues involved. The reviewers cannot always respond to applications from multiple classes during the two or three week window that may have been planned by the instructor for IRB review. Therefore, please do take into account the volume of applications that may be under review at a given time, particularly at certain points in the semester.

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Appendix 2. Action Research.

Action research is research that is specific to teachers and it involves a systematic inquiry completed by a teacher to improve one's practice. Action research is often conducted within the teacher's educational setting and is intended to inform and improve a teacher's practice. Action research is defined as any systematic inquiry conducted by teachers, administrators, counselors or others with a vested interest in the teaching and learning process or environment for the purpose of gathering information about how their particular schools operate, how they teach, and how their students learn (Mills, 2011). Action research is characterized as research that is done by teachers for themselves as a systematic inquiry into one's own practice (Mertler, 2014).

Action research is completed in an educational setting and falls under the purview of social and behavioral research. As with any social and behavioral research, action research must stay within the ethical boundaries set forth for human research.

Like thesis research, action research projects may need to be approved by the Institutional Review Board (IRB). If Action Research projects need to be completed within a semester time frame, it is imperative that they be planned so that they fall within the exempt category of the IRB guidelines or outside the IRB purview for review.

Action Research studies **require** IRB approval if the data:

- will be used in a dissertation or thesis;
- could potentially be published or shared publicly (including but not limited to trade journals, electronic sharing mechanisms, peer-reviewed publications);
- will be used to create a presentation or poster session that will be presented at peer-reviewed/professional conferences, or at CUH symposiums/assemblies;

Action Research studies **do not require** IRB approval if the data:

- are used for improving teaching/professional skills;
- will be shared only within the school/organization of which the individual works;
- will be presented only to the principal/supervisor or supervising CUH faculty member;
- will be presented only to instructor, class members, and other CUH students and faculty (not for a thesis or dissertation) in a CUH classroom setting

See Appendix 3 for more detail on examples of studies that do, or do not, typically require IRB approval.

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Appendix 3. Examples of IRB reviewable and non-IRB reviewable projects

Examples of projects that the IRB does not typically review are:

- Teacher and student evaluations used solely by the institution
- Class-related data collection projects (with adults and of no more than minimal risk) conducted solely for didactic purposes where the results are not disseminated outside the classroom
- Activities conducted for quality improvement/quality assurance intended solely for internal use and not designed to contribute to generalizable knowledge – these may include “institutional” surveys or other assessment projects that are less than minimal risk and are only intended for purposes of benchmarking or institutional assessment and are not publicly disseminated
- Data collection activities performed as a commercial service to inform business decisions regarding a specific process or product if the results will not be made public by the researchers, the business, and/or the sponsor (if other than the business)
- Journalism articles
- Theatrical productions
- Art exhibits
- Self-ethnographies
- Secondary datasets available online without permission (e.g., IPEDS data accessed through the National Center for Education Statistics website), or data obtained from well-known secondary public data sources that anyone can access but involve a standard registration process (e.g., data obtained from the ICPSR).

Examples of projects that typically are considered research and thus need IRB review include:

- Oral history projects
- “Action” research conducted by graduate students or faculty in education settings
- Class or institutional projects that will be disseminated for a scholarly purpose, or that involve data collection on sensitive populations or subjects (e.g., minors, substance abuse, mental health, sexual identity, prisoners), involve deception of potential participants, or otherwise present more than minimal risk to participants
- Taking blood or other biological samples from any person other than oneself, unless it is clearly for non-research purposes
- Secondary datasets obtained from a state agency, nonprofit organization, other university researchers, or other private source which are then going to be used for faculty or student research

It is possible that some activities will begin as non-research activities (such as course evaluations) and later spark a research question or otherwise evolve into research, at which time they fall under IRB jurisdiction, and thus require IRB approval to use data that has already been collected. When the intent of the activity becomes dissemination to a wider audience and contribution to the general knowledge base in a field, IRB approval is necessary.

Please note that retrospective approval cannot be granted for research studies that have already begun. Investigators must seek a determination and/or IRB review of projects

that may fit the definition of research as described above, or risk being found in regulatory noncompliance, which typically results in a finding that the data must be destroyed.

Appendix 4. Training Guide

Chaminade University IRB

Training Guide for Faculty and Research Staff August, 2015

The Chaminade University IRB accepts two forms of Human Subjects Training, which are required of all IRB members and collaborating faculty or staff. Note that for certain types of applications the IRB reserves the right to request CITI training in addition to PHRP, and to request additional training modules be completed by the PI prior to proposal approval. While not all trainings are required, investigators should seek all of the trainings that they can to best inform their research and protect their subjects.

Option 1. Complete the NIH Protection of Human Research Participants

1.1 Website

<https://phrp.nihtraining.com/users/login.php>

1.2. Registration

Register, selecting your Research Discipline from the following options:

- Biomedical Research
- Behavioral Research
- Basic Research
- Other

Decline CME credit option

1.3. Training

Complete training, and save your certificate to be emailed to the CUH IRB with your application.

Option 2. Complete CITI Training.

2.1. Required and Elective Training Modules.

The CITI Training is pre-programmed with different selections of courses for CUH Biomedical and Social/Behavioral/Educational Researchers.

The list of required and elective trainings that the IRB has requested of CUH Investigators is shown in Attachment 1. There two types of courses are: R (required) and E (elective). Your choice of electives should focus on the type of research you are planning to engage

in.

For example, a criminology researcher should take the module on working with Prisoners, and educational researchers should take the module on Working in Public and State Schools. Please contact the IRB Chair if you have question on which elective modules to take.

2.2. Registering and Enrolling for CITI.

2.2.1 Go to the CITI WEBSITE: <https://www.citiprogram.org>

2.2.2. On the CITI home page under CREATE AN ACCOUNT click **“Register.”**

STEP 1: ORGANIZATION AFFILIATION

Type in “Chaminade” and select Chaminade University of Honolulu from the drop down menu.

Click “Continue to Step 2.”

STEP 2: PERSONAL INFORMATION

All sections with an asterisk (*) must be completed.

List your **Chaminade e-mail address** as your primary email.

Click “Continue to Step 3.”

STEP 3: USERNAME and PASSWORD

Create your **CITI Username** (4 characters minimum).

Create a **CITI password** (8 characters minimum).

Select a **Security Question** from the drop down menu and include a **Security Answer.**

Click “Continue to Step 4.”

STEP 4: DEMOGRAPHICS

CITI requests that gender, ethnicity, and race be provided for each learner.

However, you may Select **“Prefer Not to Answer”** for each of these questions.

Click “Continue to Step 5.”

STEP 5: CEU CREDIT

Click “no” as a response to your interest in Continuing Education Credits as this is not required by Chaminade.

Click “yes,” “no,” or “ask me later” for contact regarding participation in research surveys.

Click “Continue to Step 6.”

STEP 6: CHAMINADE CONTACT INFO

All sections with an asterisk (*) must be completed.

Click “Continue to Step 7.”

STEP 7: COURSE ENROLLMENT

Here you will asked to designate whether you are a:

- Basic Biomedical Investigator
- Social Behavioral Educational Investigator

- Research with data or laboratory specimens investigator
- IRB Member

Select the courses you wish to take per Attachment A.
Click “Complete Registration.”

2.3. Course Completion

Courses selected in STEP 7 will be listed on your learner page. To begin training, **click on the course you wish to take**. You will see a list of the required modules. After you read the educational information provided in a module, you may be asked to complete a quiz covering that information. Complete training, and save your certificate to be emailed to the CUH IRB with your application. Please provide also a printout of the breakdown of courses you took.

NOTES

- All modules do not have to be completed at one time.
- You must complete the course with at least an 80% score.
- For technical problems, contact citisupport@med.miami.edu. For other questions, contact Chrystie Naeole (chrystie.naeole@chaminade.edu).

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Training Guide Attachment A. CITI Course Matrix

HSR Series Selection Form: Basic Course Options

Review the CITI Program recommendations in the **BI/UC** columns. Enter your organization's requirements in the **GREEN** columns. Once you have completed all sheets within this document, be sure to save the form and return it along with any other instructions to citicupport@questtraining.com for implementation.

Module Selection Key
R = Required: All required modules must be taken in order to earn a completion report.
E = Elective: A set of elective modules are listed and a subset of them must be completed
S = Supplemental: These optional modules become available to the learner after required

SAMPLE LEARNER GROUPS			
Biomedical Researchers	Social-Behavioral-Educational Researchers	Biomedical Data or Specimens Only Researchers	IRB Members

Available Basic HSR Modules

Basic Biomedical (Biomed) Modules

- Belmont Report and CITI Course Introduction (ID: 1127)
- History and Ethics of Human Subjects Research (ID: 498)
- Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)
- Informed Consent (ID: 3)
- Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)
- Records-Based Research (ID: 5)
- Genetic Research in Human Populations (ID: 6)
- Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)
- Vulnerable Subjects - Research Involving Prisoners (ID: 8)
- Vulnerable Subjects - Research Involving Children (ID: 9)
- Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)
- Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)
- Avoiding Group Harms - International Research Perspectives (ID: 14081)
- FDA Regulated Research (ID: 12)
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)
- Research and HIPAA Privacy Protections (ID: 14)

MODULE SELECTION (R,E,S) RECOMMENDATIONS FOR EACH LEARNER GROUP

Module	Biomedical Researchers	Social-Behavioral-Educational Researchers	Biomedical Data or Specimens Only Researchers	IRB Members
Belmont Report and CITI Course Introduction (ID: 1127)	R	-	R	R
History and Ethics of Human Subjects Research (ID: 498)	R	-	R	R
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	R	-	R	R
Informed Consent (ID: 3)	R	-	S	R
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	S	-	S	R
Records-Based Research (ID: 5)	R	-	R	R
Genetic Research in Human Populations (ID: 6)	R	-	R	R
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	R	R	R	R
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	S	-	S	R
Vulnerable Subjects - Research Involving Children (ID: 9)	S	-	S	R
Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	S	-	S	R
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	S	-	S	R
Avoiding Group Harms - International Research Perspectives (ID: 14081)	S	-	S	R
FDA Regulated Research (ID: 12)	S	-	S	R
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	R	-	S	R
Research and HIPAA Privacy Protections (ID: 14)	R	S	S	R

Basic Social-Behavioral-Educational (SBE) Modules

- Belmont Report and CITI Course Introduction (ID: 1127)
- History and Ethical Principles - SBE (ID: 490)
- Defining Research with Human Subjects - SBE (ID: 491)
- The Federal Regulations - SBE (ID: 502)
- Assessing Risk - SBE (ID: 503)
- Informed Consent - SBE (ID: 504)
- Privacy and Confidentiality - SBE (ID: 505)
- Research with Prisoners - SBE (ID: 506)
- Research with Children - SBE (ID: 507)
- Research in Public Elementary and Secondary Schools - SBE (ID: 508)
- International Research - SBE (ID: 509)
- Internet Based Research - SBE (ID: 510)
- Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14926)

Module	Biomedical Researchers	Social-Behavioral-Educational Researchers	Biomedical Data or Specimens Only Researchers	IRB Members
Belmont Report and CITI Course Introduction (ID: 1127)	-	R	-	R
History and Ethical Principles - SBE (ID: 490)	-	R	-	R
Defining Research with Human Subjects - SBE (ID: 491)	-	R	-	R
The Federal Regulations - SBE (ID: 502)	-	R	-	R
Assessing Risk - SBE (ID: 503)	-	R	-	R
Informed Consent - SBE (ID: 504)	-	R	-	R
Privacy and Confidentiality - SBE (ID: 505)	-	R	-	R
Research with Prisoners - SBE (ID: 506)	-	S	-	R
Research with Children - SBE (ID: 507)	-	S	-	R
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	-	S	-	R
International Research - SBE (ID: 509)	-	S	-	R
Internet Based Research - SBE (ID: 510)	-	S	-	R
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14926)	-	R	-	R

Additional Modules of Interest

- Cultural Competence in Research (ID: 15166)
- Conflicts of Interest in Research Involving Human Subjects* (ID: 488)
- External IRB Review (ID: 16711)
- Hot Topics (ID: 487)
- Humanitarian Use Devices (HUDs) (ID: 16306)
- I Have Agreed to be an IRB Community Member. Now What? (ID: 13018)
- International Studies (ID: 971)
- Students in Research (ID: 1321)
- The IRB Administrator's Responsibilities (ID: 13813)
- The IRB Member Module - "What Every New IRB Member Needs to Know" (ID: 816)
- Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)
- Stem Cell Research Oversight (Part I) (ID: 13882)
- Stem Cell Research Oversight (Part II) (ID: 14584)
- Research with Decisionally Impaired Subjects (ID: 16610)
- Research with Critically Ill Subjects (ID: 16592)
- Gender and Sexuality Diversity (GSD) in Human Research (ID: 16556)
- Research with Persons who are Socially or Economically Disadvantaged (ID: 16539)
- Research with Older Adults (ID: 16502)
- Illegal Activities or Undocumented Status in Human Research (ID: 16656)
- Research Involving Subjects at the End of Life (ID: 16658)
- Research with Subjects with Physical Disabilities & Impairments (ID: 16657)

Module	Biomedical Researchers	Social-Behavioral-Educational Researchers	Biomedical Data or Specimens Only Researchers	IRB Members
Cultural Competence in Research (ID: 15166)	S	S	S	R
Conflicts of Interest in Research Involving Human Subjects* (ID: 488)	R	R	R	R
External IRB Review (ID: 16711)	S	S	S	S
Hot Topics (ID: 487)	S	S	-	R
Humanitarian Use Devices (HUDs) (ID: 16306)	-	-	-	S
I Have Agreed to be an IRB Community Member. Now What? (ID: 13018)	-	S	-	R
International Studies (ID: 971)	S	-	-	R
Students in Research (ID: 1321)	S	S	-	S
The IRB Administrator's Responsibilities (ID: 13813)	-	S	-	S
The IRB Member Module - "What Every New IRB Member Needs to Know" (ID: 816)	-	S	-	R
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	R	S	-	S
Stem Cell Research Oversight (Part I) (ID: 13882)	S	-	S	S
Stem Cell Research Oversight (Part II) (ID: 14584)	S	-	S	S
Research with Decisionally Impaired Subjects (ID: 16610)	S	S	S	S
Research with Critically Ill Subjects (ID: 16592)	S	S	S	S
Gender and Sexuality Diversity (GSD) in Human Research (ID: 16556)	S	S	S	S
Research with Persons who are Socially or Economically Disadvantaged (ID: 16539)	S	S	S	S
Research with Older Adults (ID: 16502)	S	S	S	S
Illegal Activities or Undocumented Status in Human Research (ID: 16656)	S	S	S	S
Research Involving Subjects at the End of Life (ID: 16658)	S	S	S	S
Research with Subjects with Physical Disabilities & Impairments (ID: 16657)	S	S	S	S

If using the Elective feature, please indicate how many modules the learner must complete out of the total number of Elective modules selected. (Note: Minimum number is 1.)
 Please indicate the Passing Score for the course (not per module). The standard recommendation is 80%.
 Please indicate how long the certification for passing the course lasts (in years) or write "No Expiration Date."

Elective Module	Passing Score	Expiration	Recommendations
1	0	0	0
80%	80%	80%	80%
3	3	3	3

* The module labeled with an asterisk is intended to complement, but not necessarily replace, the more comprehensive courses that researchers normally take when they are seeking to satisfy the training requirements relating to federal regulations, their funding source, or employer.

set as "Supplemental." The "Supplemental" feature can give your learners access to additional content that they may review voluntarily. The "Elective" feature allows learners to choose a subset of modules that they must complete from a total number of "Elective" modules selected.

Appendix 5. Sample Informed Consent.

INFORMED CONSENT RELEASE

Investigator:

“My name is *(name of investigator)*, and I am a/an *(undergraduate/graduate student, faculty member, etc.)* at *(name of institution/facility)*. I am inviting you to participate in a research study. Involvement in the study is voluntary, so you may choose to participate or not. I am now going to explain the study to you. Please feel free to ask any questions that you may have about the research; I will be happy to explain anything in greater detail.

“I am interested in learning more about *(state what the research is about)*. You will be asked to *(state what the participant will be asked to do.)* This will take approximately () min./hrs. of your time. All information will be kept *(either confidential, in the case where subjects' identities need to be retained or can be associated with their responses, or anonymous and confidential, in the case where data collection does not allow responses to be connected with a particular subject)*. If anonymous, this means that your name will not appear anywhere and no one except me will know about your specific answers. If confidential, I will assign a number to your responses, and only I will have the key to indicate which number belongs to which participant. In any articles I write or any presentations that I make, I will use a made-up name for you, and I will not reveal details or I will change details about where you work, where you live, any personal information about you, and so forth.

“The benefit of this research is that you will be helping us to understand *(topic of research)*. This information should help us to *(benefit of the research, better understanding, etc.)*. The risks to you for participating in this study are *(state the risks to subjects)*. These risks will be minimized by *(state the procedures you will use to minimize the risks)*. If you do not wish to continue, you have the right to withdraw from the study, without penalty, at any time.”

Participant - “All of my questions and concerns about this study have been addressed. I choose, voluntarily, to participate in this research project. I certify that I am at least 18 years of age [or have a signed parental consent form on file with the _____ department].

print name of participant

signature of participant

date

print name of investigator

signature of investigator

date

TO THE RESEARCHER: ISSUES TO BE AWARE OF WHEN OBTAINING INFORMED CONSENT.

Abuse

If a researcher is asking about care-taking practices or observing in a child's home, the researcher would need to indicate what his/her reporting responsibility is in the event of suspected child abuse. Another example might be if the researcher determined that subjects were at risk for harming themselves or others. If the researcher felt bound to notify someone about that risk, subjects should be notified of that obligation when asking for their participation.

Anonymous and Confidential Data Collection

Indicate whether data collection will be (a) anonymous or (b) confidential.

The term "anonymous" is used when the investigator collects no identifying information about subjects and, thus, an individual data sheet cannot be connected with a specific subject (by the investigator or anyone else) once the data are collected. As an example, tape-recording, by its very nature, cannot be considered anonymous.

The term "confidential," in contrast, refers to collected data that can be linked to an individual subject. For example, assigning subjects numbers, but then keeping a "key" that links the numbers to identifying information, is a procedure one might use in order to preserve confidentiality. Not identifying subjects by name or by any other identifying information in reports and presentations also is a measure taken to preserve confidentiality. If individual subject data are used as illustrative examples, you must assure subjects that this will be done in a way that does not allow identification of the participant. Care must be taken to not only protect subjects' names, but also any details about them or their experiences that would allow them to be identified. Occasionally, it is important to the research to identify a subject who participated, or subjects themselves may wish to have their contribution attributed to them. In such cases, it would be necessary for a subject to sign a release form indicating their willingness to be so identified.

Audio- and Videotaping

If you wish to tape subjects, please include a request to tape explaining the type (e.g., videotaping in the classroom, audiotaping, single or group interviews, etc.), and the disposition of the tape(s) when the study is complete. If the tapes will be used for any other purpose, clearly state the who, where, and why of the other use; if there is no other use of the tape, simply stating that it will be erased when the study is complete is sufficient.

Benefit to the Participant

If it is too strong a statement to say that the subject will benefit from the research, perhaps the better statement would be that the subject may benefit from the research.

Contact Information

Include contact information (telephone number and/or e-mail address) where subjects may reach you. If a student is conducting the study, the advisor's name and phone number should also be provided.

Identifying References

In the event that potentially identifying references need to be included in publications or presentations in order to maintain the basic integrity of the study, the researcher needs to specifically include that fact in the written informed consent statement.

Illegal Activities

Researchers must indicate the limits of the protection of confidentiality. If the researcher plans to ask subjects about their or others' illegal activities (underage drinking, drug use, etc.), the consent form must indicate that the researcher's data can be subpoenaed. The consent forms should include the following sentence: "The researcher is not immune to legal subpoena about illegal activities. Although it is very unlikely, if law enforcement officials asked to see my data, I would have to comply with that request."

Problematic Language

Language used in the informed consent form should be simple and direct.

Consider the following examples: (1) Problematic language: "The purpose of this study is to validate the concept of citizenship and to determine the public's view on the rights and responsibilities citizenship entails." (2) Preferred language: "This study is designed to find out about what being a citizen means to you."

Use of Minors

The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children. Considerations must be taken of the benefits, risks, and discomforts inherent in the proposed research and to assess the justification in light of the expected benefits to the child-subject or to society as a whole.

Withdrawal from Study

You must state that participation is voluntary and that subjects "may withdraw at any time up until the study has ended." You also must indicate that subjects will not suffer in any way from withdrawing. Wording of this may depend upon the specifics of the study. Examples: (1) If subjects are receiving a service from the agency where the research is occurring, they should be told that they will still continue to receive services even if they decide not to continue participating in the study. (2) If subjects are students in a class or employees in a company, they should be told that their decision to stop participating will not negatively affect a grade or performance evaluation, or participants will be informed on the consent form and by the test administrator that "participation in the study is voluntary and that they can withdraw from participation at any time without penalty."

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