Chaminade University OF HONOLULU

Office of the Provost
Office of Sponsored Programs and Research Integrity

Human Subjects Policy and
Institutional Review Board (IRB00007927)

Charter and Standard Operating Procedures

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Table of Contents

INTRODUCTION

Chaminade University of Honolulu (CUH) 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 of Honolulu's 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 IV: The Authority of the IRB)

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 regarding 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 Administrator and 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 Administrator 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 https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.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.

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

3. 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.

4. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

5. 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.

6. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

7. 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.

8. 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: Procedures of the IRB)

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: Record Requirements), 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: Record Requirements), 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. Guidance can be obtained from the IRB website or IRB chair at irb@chaminade.edu. If the instructor has any doubt concerning the classification of these activities, they are encouraged to complete protocol in the online submission system, eProtocol, and select "Exempt" under the "Application Type Checklist". Official determination will be given by the IRB Chair. In the initial submission, the instructor should submit the protocol along with any accompanying consent form(s), instrument(s), and/or questionnaire(s) 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 person providing consent is from a vulnerable population. (See XII: Principles of Informed Consent)

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 and Research Integrity. 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

VI. 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 VIII: Procedures of the IRB 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.

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

E. The current roster for the Chaminade IRB is found below. An updated roster may be obtained at any time by the IRB Chair or Administrator at irb@chaminade.edu.

#	Member	Sex (M/F)	Earned Degree(s)	Scientist (S) or Non-Scientist (N)	Primary Specialty	Role
1	Joy Tanji	F	Ph.D.	S	Psychology	Chair
2	Blendine Hawkins	F	Ph.D., LMFT	S	Psychology	Vice-Chair
3	Emily Pujadas Liwag	F	Ph.D.	S	Biology	Administrator
4	Tracy Trevorrow	M	Ph.D.	S	Psychology	
5	Katrina Roseler	F	Ed.D.	S	Education	
6	Kathleen Burger	F	Ph.D., MSN, RN, CNE	S	Nursing	
7	Silvia Koch	F	M.Ed., Ed.D.	S	Psychology	
8	Heather Chapman	F	Psy.D.	S	Psychology	
9	David Coleman	M	Ph.D.	N	Religious Studies	
10	Michael Weaver	M	MPT	N	Historical & Political Studies	Ethicist
11	Junghwa Suh	F	D.Arch.	N	Architecture	
12	Laura Johnston	F	Ph.D.	Y	Psychology	
13	David Brown	M	Psy.D.	Y	Psychology	Community Member

VII. MANAGEMENT OF THE IRB.

A. The Chair of the IRB shall be a faculty or staff member with demonstrated expertise in human subjects research, compliance, or related fields. Tenure is preferred but not required, and the IRB Chair will be appointed by the Provost. The Chair has authority to sign all IRB action items. An appointed Vice-Chair may fulfill this role if the Chairs 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. The IRB Administrator is a voting member of the IRB and serves as the Senior Director of the Office of Sponsored Programs and Research Integrity. The IRB Administrator monitors federal, state, and institutional policy changes (e.g., 45 CFR 46, OHRP, FDA regulations) affecting IRB operations. They also perform the initial review of submitted protocols, oversee all eProtocol operations, compile reviewer comments, track protocol status, document meeting minutes, create agendas, and act as a liaison between the IRB members, researchers, and Key Solutions support.

D. 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.

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

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

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

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

I. 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 and Research Integrity 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 VIII: Procedures of the IRB and Section XIII: Conflict of Interest

Guidelines for IRB Members of this Charter and Standard Operating Procedures.

VIII. PROCEDURES OF THE IRB.

A. Initial Review.

1. No or Minimal Risk.

The IRB Chair will review all Exempt protocols eligible for exempt or expedited review. The Chair may delegate this initial review to designated voting IRB members (provided they have completed requisite training and have no conflicts of interest). The designee will be the person to facilitate the communication to the researcher and faculty mentor (faculty sponsor).

2. No or Minimal Risk: 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]. The exemption categories are listed in eProtocol under the "Exempt Categories" section. The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt.

There are eight categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). In eProtocol, the PI will select from the following applicable categories to assess if their research is exempt from expedited or full committee review:

I. **Educational Practices:** Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content of the assessment of educators who provide instruction. This includes most:
   - **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: This category does not apply to use of school records of identifiable students or interviewing instructors about specific students.

II. **Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior (Including Visual or Auditory Recording):** Research involving these procedures is exempt, IF one of the following is correct:
   - **i.** Any information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR
   - **ii.** Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; OR
   - **iii.** Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be identified, directly or through identifiers linked to the subjects, AND an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7) and the research is not subject to 45 CFR 46 Subpart D.

   NOTE: This exemption does not apply to children except for research involving observation of public behavior when the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior".

III. **Research Involving Benign Behavioral Interventions** in conjunction with the collection of information from adult subjects through verbal or written response (including data entry) or audiovisual recording, if the subject prospective agrees to the intervention and information collection, is exempt, IF:
   - **i.** Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be identified, directly or through identifiers linked to the subjects, OR
   - **ii.** Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; OR
   - **iii.** Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be identified, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

IV. **Existing Data:** Secondary Research involving collection or study of existing data, documents, records, or biospecimens, for which consent is not required is exempt, IF:
   - **i.** The identifiable private information or identifiable biospecimens are publicly available; OR

ii. Information, which may include information about biospecimens, is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects; OR

iii. The research involves only information collection and analysis involving the investigators use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subpart A and E, for the purposes of health care operations or research as those terms are defined at 45 CFR 164.501 or for public health activities and purposes as described under 45 CFR 1.512(b); OR

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 298(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 5521, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501et seq.

V. Research and Demonstration Projects Conducted by or Subject to the Approval of Department or Agency Heads: This research is exempt IF it is designed to study, evaluate, or otherwise examine:

i. Public benefit or service programs;

ii. Procedures for obtaining benefits or services under those programs; OR

iii. Possible changes in or alternatives to those programs, OR

iv. Changes in methods or levels of payment for benefits or services under those programs.

NOTE: Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts of consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 115A of the Social Security Act, as amended.

VI. Taste And Food Quality Evaluation and Consumer Acceptance Studies: This research is exempt, IF:

i. Wholesome foods without additives are consumed; OR

ii. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection

Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR

iii. A food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.

VII. Storage or Maintenance of Information for Secondary Research for Which Broad Consent Is Required: The protocol is eligible for exemption if:

i. It involves storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use; AND

ii. All the identifiable information or identifiable biospecimens that are to be stored and/or maintained for secondary research have been or will be collected for another primary purpose; AND

iii. Broad consent for the storage or maintenance of their identifiable information or identifiable biospecimens for secondary research use will be obtained from ALL subjects; AND

iv. The protocol does not include any activities that do not qualify for exemption; AND

v. The protocol is not for an FDA regulated clinical investigation; AND

vi. The IRB conducts a Limited IRB Review and makes the determinations required by 45 CFR 46.111(a)(8).

VIII. Secondary Research for Which Broad Consent Is Required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use is eligible for exemption, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); AND

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; AND

iii. An IRB conducts a Limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; AND

iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

3. No or Minimal Risk: 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:

I. Clinical studies of drugs and medical devices only when condition (i) or (ii) is met:

i. 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.)

ii. 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.

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

i. 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

ii. 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.

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

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

IV. 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) weighting 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.

V. 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).

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

VII. 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).

VIII. Continuing review of research previously approved by the convened IRB as follows:

i. 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

ii. Where no subjects have been enrolled and no additional risks have been identified; or

iii. Where the remaining research activities are limited to data analysis.

IX. 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.

X. Procedures for an exemption or expedited review:

i. Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must submit a proposal in eProtocol.

ii. 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.

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

iv. If it is determined that one of these protocols requires 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.

4. More Than Minimal Risk: Full Board Review.

Protocols for Full-board (IRB) review must be submitted prior to the deadline established by the IRB Chair. The deadline dates are available on the IRB website [see https://chaminade.edu/institutional-review-board/]. The prospective PI will submit a protocol in eProtocol. In the protocol, 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.

a. Actions of the IRB:

The IRB may take one of the following four actions regarding the proposed protocol and consent form, which are documented in the Meeting Minutes and in eProtocol under "Protocol Decision": *Approved Without Stipulations, Contingent, Moved, Not Approved, Tabled,* or *Withdrawn*.

I. *Approved Without Stipulations*

When a protocol has been approved, the IRB Administrator will document the decision in the Meeting Minutes and in eProtocol. The PI & Faculty Sponsor will receive an automated email from eProtocol, with an Approval Letter available for download in eProtocol.

Approval of the protocol will be based on the following:

i. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.

ii. In qualitative research, investigators must actively reflect on their positionality and potential biases, as these can influence data collection, interpretation, and participant experiences. Researchers are encouraged to engage in reflexive practices, such as journaling, peer debriefing, or consultation, to identify and mitigate power dynamics or assumptions that could pose risks to participants or compromise the integrity of the study.

iii. 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.

iv. 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.

v. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.

vi. Anticipated benefits, if any.

vii. The personal risk to the subject in relation to expected benefits.

viii. The adequacy of procedures for securing informed consent from the subject.

ix. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.

x. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

II. *Contingent*

When a protocol has been voted as Contingent, the IRB Administrator will document the decision in the Meeting Minutes and in eProtocol. The PI & Faculty Sponsor will receive an automated email from eProtocol.

Contingent means that the protocol has been approved subject to restrictions. The IRB Administrator will compile and condense comments from the IRB members, which will be sent to the PI and Faculty Sponsor in eProtocol. For CUH protocols, the restrictions will be sent via email. The PI then must respond to the restrictions as indicated by the IRB and edit the protocol accordingly. 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.

III. *Moved*
When a protocol has been moved, the IRB Administrator will document the decision in the Meeting Minutes and in eProtocol. The PI & Faculty Sponsor will receive an automated email from eProtocol. When a protocol has been moved, this means that the IRB was unable to make a final determination during the scheduled meeting. This protocol will be planned to discuss at the next scheduled IRB meeting.

IV. *Not Approved*
When a protocol has been disapproved, the IRB Administrator will document the decision in the Meeting Minutes and in eProtocol. The PI & Faculty Sponsor will receive an automated email from eProtocol. The PI will be informed via eProtocol and/or in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

V. *Tabled*
Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision and has been returned for revisions and resubmission. In this case, the PI is notified by the IRB Chair or IRB Administrator of the additional information necessary for completion. This notification will be sent as a "Return Note" in eProtocol. 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.

VI. *Withdrawn*
Withdrawn action means that the protocol has been withdrawn from IRB review procedures by the PI.

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 an automated email from eProtocol. This Status Report 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 via eProtocol and/or in writing.

When a completed Status Report 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 Status 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. The IRB will report any minor adverse event to OHRP within two weeks of notification by the Principal Investigator (PI). Any serious event will be reported within 3 working days.

3. Any adverse event involving a Chaminade University Investigator with a protocol that has been approved by another IRB committee and so therefore operated by an IRB not at the investigator's institution, will also be reported to Chaminade University's IRB Chair.

4. Principal Investigator(s) and any Chaminade University employee will report to the Chair of the IRB Committee, under pre-2018 Requirements at 45 CFR 46.103(a) and (b)(5) and 45 CFR 46.113 and the 2018 Requirements at 45 CFR 46.108(a)(4) and 45 CFR 46.113, these incidents include:

   a. Unanticipated problems involving risks to subjects or others; and

   b. Any suspension or termination of IRB approval.

   c. Any serious or continuing noncompliance with 45 CFR part 46.

   d. Any serious or continuing noncompliance with determinations of the IRB.

5. PIs must submit Adverse Event Reports in eProtocol. For CUH protocols, an Adverse Event Reporting Form (Form V) must be sent to the IRB Chair. Adverse Event Reports must be submitted within 5 business days of becoming aware of the event.

6. For studies that are HHS-supported and are also regulated by the FDA, additional reporting to FDA may be required by FDA. For more information on what must be reported and how to report to OHRP, please visit OHRP webpage at: https://www.hhs.gov/ohrp/compliance-and-reporting/index.html.

7. If research has been suspended or terminated, it may be important to consider how to appropriately and safely transition research participants off the study. While not OHRP guidance, you may find the following recommendations of the Secretary Advisory Committee on Human Research Protections to be helpful: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html

E. Types of Review.

Determination/ Initial Review	
Purpose:	Used to assess whether the proposed work constitutes Human Subject research or not. If not, then there is no IRB review required.
Process:	Initial review conducted by IRB Chair (or IRB Vice-Chair if Chair is recused) and IRB Administrator. Official determination is given by the IRB Chair or IRB Vice-Chair in the event of the Chair's absence or conflict of interest.
Requires a Full Committee Review/ IRB Meeting?	No

Exempt	
Purpose:	Used to assess Human Subjects Research that fall under one or more of the Federally designated Exemption Categories.
Process:	IRB Chair or IRB Vice-Chair will review & inform PI of decision.
Requires a Full Committee Review/ IRB Meeting?	No

Expedited	
Purpose:	Used to assess Human Subjects Research that does not fall under one or more of the Federally designated Exemption Categories & has minimal risk.
Process:	2 IRB members review; IRB Chair or IRB Vice-Chair inform PI of decision.
Requires a Full Committee Review/ IRB Meeting?	No

Limited Activity Determination	
Purpose:	Involves studies that normally would be classified as expedited but because of the focus or instrumentation used in the study needs full review by the IRB.
Process:	2 IRB members forward protocol to the full IRB for review; IRB Chair or IRB Vice-Chair will review & inform PI of decision.
Requires a Full Committee Review/ IRB Meeting?	Yes

Full Board	
Purpose:	Review of non-exempt research or review of any application that includes a vulnerable population (e.g. minors, prisoners) & has more than minimal risk.
Process:	At least 2 IRB members review; Requires quorum & a majority vote by those present; IRB Chair or IRB Vice-

	Chair will review & inform PI of decision.
Requires a Full Committee Review/ IRB Meeting?	Yes

Continuing Review
• All Expedited and Full-board reviews are approved for a period of three years. However, PIs must submit a Status Report annually in eProtocol. For CUH protocols, a Human Subjects Annual Report/Final Report Form (Form IV) must be sent to the IRB Chair via email annually. • Automated notifications will be sent to the PI and Faculty mentor ahead of protocol expiration. • After protocol approval, there will be an option for the PI to make amendments or request an extension.

F. Procedures for Reviews in eProtocol.

1. Determination/ Initial Submission.

a. Initially reviewed by IRB Chair or Vice-Chair, and IRB Administrator.

b. If the protocol does not meet the federal definition of Human Subjects Research, the PI & Faculty Mentor will be notified via email.

c. If the protocol meets the federal definition of Human Subjects Research, the protocol will be assigned to the IRB panel by the IRB Administrator. The PI & Faculty Sponsor will receive an automated email from eProtocol.

2. Exempt Review.

a. The IRB Administrator will assign either the IRB Chair or IRB Vice-Chair as a Primary Reviewer. All other IRB voting members will be assigned as “Non-Primary Reviewers” and will therefore not receive the protocol in their Reviewer Dashboard.

b. The PI & Faculty Mentor will receive an automated email from eProtocol.

c. The Primary Reviewers must submit their feedback via eProtocol. Comments will be compiled and forwarded to the PI by the IRB Administrator.

d. Once PI responses have been sent back, they will be reviewed by the IRB Chair (or Vice-Chair in the event of Chair recusal or absence). If approved, the IRB Administrator will set the Protocol Decision accordingly. An email will be sent to the PI and Faculty Mentor. If not approved, comments will be forwarded to the PI and Faculty Mentor by the IRB Administrator and the process will repeat until approved.

3. **Expedited Review.**

   a. The IRB Administrator will assign 2 IRB members as “Primary Reviewers”, with one of them selected as a Presenter. All other IRB voting members will be assigned as “Non-Primary Reviewers” and will therefore not receive the protocol in their Reviewer Dashboard.

   b. The PI & Faculty Mentor will receive an automated email from eProtocol.

   c. The 2 Primary Reviewers must submit their feedback via eProtocol. Comments will be compiled and forwarded to the PI and Faculty Mentor by the IRB Administrator.

   d. Once PI responses have been completed and submitted to the IRB, they will be reviewed and approved by the IRB Chair (or Vice-Chair in the event of Chair recusal or absence) and IRB Administrator. The IRB Administrator will set the Protocol Decision accordingly.

   e. The PI & Faculty Mentor will receive an automated email from eProtocol with an Approval Letter.

4. **Limited Activity Determination.**

   a. If during an Expedited review, the 2 reviewers assigned to review a protocol determine that a full review is needed to conduct a targeted review, especially when dealing with sensitive data, risks associated with instrumentation, and ensuring privacy and confidentiality. Limited IRB review is a type of expedited review that focuses on whether adequate protections are in place.

   b. The PI & Faculty Mentor will receive an automated email from eProtocol.

   c. The process will then follow that of Full Board review (see below)**.**

5. **Full Board Review.**

   a. The IRB Administrator will assign 2 IRB members as “Primary Reviewers”, with one of them selected as a Presenter. All other IRB voting members will be assigned as “Secondary Reviewers” and will therefore receive the protocol in their Reviewer Dashboard.

   b. The 2 Primary Reviewers will present their feedback in the meeting. The Secondary Reviewers must review the protocol and have the option to submit comments.

c. An IRB meeting will be held. If quorum is established, a vote can take place at this meeting, via a Google Form.

d. If the protocol has not been approved, or is contingent on certain stipulations being met, comments will be compiled by the IRB Administrator.

e. The PI & Faculty Mentor will receive an automated email from eProtocol which includes the compiled comments.

f. Once PI responses have been received, a review by the IRB will be scheduled. The full committee will review the PI's responses and if quorum has been established, a vote can take place during this meeting via a Google Form.

g. If the protocol has been approved, the IRB Administrator will set the Protocol Decision accordingly.

h. The PI & Faculty Mentor will receive an automated email from eProtocol with an Approval Letter.

6. Quality Improvement (QI) or Evidence-Based Practice (EBP) (QI/EBP) Protocols.

a. *CITI Training*
For DNP students and their Faculty Sponsors/ Chairpersons conducting Quality Improvement (QI) or Evidence-Based Practice (EBP) projects, the Biomedical Research – Basic/Refresher CITI course is required. The PI and all Key Personnel must complete this course and upload their certificates in the "Attachments" section of eProtocol.

Although QI/EBP activities may not always meet the federal definition of "human subjects research," these projects frequently involve patients, clinical staff, or access to identifiable health information. The Biomedical module provides essential training in protecting patient privacy, addressing potential risks, and applying ethical principles in clinical settings. These are all topics directly relevant to QI/EBP work. Requiring Biomedical training also ensures consistency with institutional and healthcare compliance standards. Ultimately, this training best prepares DNP students and their Faculty Sponsors/ Chairpersons to uphold ethical principles, safeguard participants, and align with professional expectations in clinical practice and research environments.

b. *Application Type Checklist in eProtocol*
In the Application Type Checklist section of eProtocol, PIs should select "QI/EBP or Full Board." This allows review of HIPAA, instruments, and

consent (when applicable), even if the project is not human subjects research under federal definitions.

c. *Faculty Sponsor Eligibility*
The CUH IRB typically limits PI eligibility to full-time faculty. However, for DNP students completing QI/EBP protocols, adjunct faculty may serve as the faculty sponsor in eProtocol. This exception applies only to these projects.

d. *Letter of Support*
In the Procedures section of eProtocol, the PI must indicate that securing MOUs from clinical sites is handled through a separate School of Nursing and Health Professions process. The PI should briefly describe that process and include an estimated timeframe. If there is any documentation associated with this process that contains approvals, the PI must upload this to the "Attachments" section in eProtocol.

IX. OPERATIONS OF THE IRB.

A. Meetings.

The IRB convenes twice per month or less frequently as required. Protocols requiring Full Board review must be submitted to eProtocol by 12:00 PM on the day following the posted submission deadline, which can be found on the IRB website or by contacting the IRB chair at irb@chaminade.edu. All other protocols, including those eligible for Expedited or Exempt review, are accepted and reviewed on a rolling basis. The meeting agenda, along with the place and time of the meeting and study materials for review, are distributed to IRB members by the IRB Administrator at least seven (7) days prior to the convened meeting. Detailed meeting minutes will be documented by the IRB Administrator. In the absence of the IRB administrator, detailed meeting minutes will be documented by the IRB Vice-Chair.

B. Review Assignments.

Upon official determination of application type by the IRB Chair or Vice-Chair, reviewer assignments will be made in accordance with federal regulations and institutional policy, as outlined below:

1. Full Board Review.

a. Two (2) primary reviewers will be assigned based on protocol content and reviewer expertise, consistent with 45 CFR 46.108(b) and 21 CFR 56.108(b). The IRB Chair or a voting member screener delegated by the

Chair will assign reviewers. This designee will facilitate communication to the PI and faculty sponsor.

b. One primary reviewer will serve as the presenter, responsible for providing an overview of the protocol, offering an assessment, and leading discussion at the convened meeting.

c. The second primary reviewer will provide an independent assessment of the protocol. Selection of this reviewer may also be based on their ability to provide relevant non-scientific perspectives, consistent with 45 CFR 46.107(a), which requires consideration of both scientific and non-scientific expertise.

d. All other voting IRB members will be assigned as secondary reviewers in eProtocol, granting access to the protocol and associated materials, and the ability to submit comments to the PI and respond to PI replies.

e. The IRB Administrator will document the final determination of the protocol following Board review in both the detailed meeting minutes and in eProtocol.

f. If external reviewers are engaged, they must comply with institutional conflict of interest policies and applicable regulations (45 CFR 46.107(e)).

2. Exempt Review.

a. The IRB Chair or Vice-Chair will serve as the sole primary reviewer, in accordance with 45 CFR 46.104.

b. All other voting IRB members will be designated as non-primary reviewers, without access to the protocol or associated materials.

3. Expedited Review and Limited Activity Determination.

a. A primary reviewer and secondary reviewer will be assigned by the IRB Chair or Vice-Chair, consistent with 45 CFR 46.110 and 21 CFR 56.110.

b. All other voting IRB members will be designated as non-primary reviewers, without access to the protocol or associated materials, and without the ability to submit or respond to PI comments during the review process.

C. Quorum and Voting Requirements.

a. *Quorum*
Except when an Exempt or Expedited review procedure is used (see Section VIII: Procedures of the IRB), a quorum of the IRB shall consist of a simple majority (one more than half) of voting members, duly convened through

written notice. Membership shall include individuals with varying backgrounds to ensure a complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas. This is consistent with 45 CFR 46.108(b).

b. *Approval of Research*
For research to be approved, it must receive the affirmative vote of a majority of voting members present at a convened meeting. Voting forms (i.e., Google Forms) will be accessible to IRB members during a convened meeting. IRB meetings conducted via telephone or videoconference are permitted, provided that all members can actively participate in the discussion, consistent with OHRP guidance (45 CFR 46.109).

c. *Principial Investigator Participation*
Principal Investigators (PIs), including those who are also IRB members, may present information and respond to questions about their protocols during a convened meeting. However, PIs and any key personnel of the protocol must recuse themselves and may not be present during deliberation or voting. If the PI's absence prevents quorum, the meeting shall be suspended until quorum can be re-established.

d. *Confidentiality and Public Access*
Although convened IRB meetings are open to the university community as observers, all materials submitted for review, discussions of research protocols, and individual votes are considered confidential. These matters shall not be disclosed outside the context of the IRB meeting. If at any point the IRB Chair determines the need for executive session, all visitors will be asked to leave until the session concludes.

D. Appeals.

The Principal Investigator (PI) may appeal an IRB decision when a protocol has been disapproved or approved with restrictions, and no mutually acceptable alternative can be reached. Upon receipt of a written appeal from the PI, the IRB will convene an *ad hoc* committee composed of three or more members, which may include IRB members, non-member faculty, and/or consultants. Committee members must be acceptable to both the PI and the IRB. The *ad hoc* committee will conduct a second review of the protocol in accordance with the procedures outlined herein and with applicable federal regulations (45 CFR 46). The committee's recommendation will be submitted to the IRB, and the PI will be promptly informed of both the ad hoc committee's findings and the IRB's final determination. Final disapproval by the IRB cannot be overridden by any institutional official.

E. Amendments.

1. Categories of Amendments.

Amendments to a research study are classified as minor modifications/ changes or significant modifications/ changes in accordance with federal regulations (45 CFR 46.103, 46.111).

Minor modification/change – A proposed change to research activities that does not substantially affect the assessment of risks and benefits or materially alter the specific aims or design of the study.

Significant modification/change – A proposed change to research activities that significantly affects the assessment of risks and benefits or materially alters the specific aims or design of the study.

Examples of **minor changes** include, but are not limited to:

- Addition or removal of study team members;
- Addition of procedures that do not significantly increase risk, consistent with the study's purpose and design;
- Removal of research procedures that reduce risk to participants;
- Addition of non-sensitive questions to surveys or interview procedures;
- Addition or revision of recruitment materials or strategies;
- Administrative edits to approved documents (e.g., corrections of spelling, grammar, or typographical errors).

Examples of **significant changes** include, but are not limited to:

- Addition of a new or separate participant population (e.g., control group, vulnerable population);
- Addition of research procedures involving greater than minimal risk;
- Addition of surveys, questionnaires, or interviews that could negatively affect participants' psychological well-being, financial standing, employability, insurability, or reputation;
- Removal of follow-up visits necessary for monitoring participant safety and welfare.

2. Level of Review for Amendments.

For **Exempt** protocols, significant modifications/ changes will be reviewed by the IRB Chair or Vice-Chair. For **Expedited** protocols, significant modifications/ changes will be reviewed at the same level of review at which the study was originally reviewed, or by the IRB Chair or Vice-Chair. If the IRB Chair determines that the amendment increases the level of risk beyond minimal risk, the amendment will be referred to the full IRB for review, consistent with 45 CFR 46.111(a)(1)-(7).

Minor modifications/ changes may be reviewed and approved through an

"Administrative review and approval" process. Administrative review and approval may be conducted by the IRB Chair or Vice-Chair. Notifications of these approvals will be placed on the agenda of the next convened IRB meeting, as appropriate, for concurrence.

For protocols requiring Full board IRB review, the IRB Chair or Vice-Chair will determine which of the following three tiers of review and voting process will apply, based on the nature and level of the requested modification:

I. **Tier 1 – Minor Modification/ Change (Administrative Review; No Vote Required)**
   Minor modifications/changes may be reviewed and approved through an "administrative review and approval" process conducted by the IRB Chair or Vice-Chair. These are changes that do not affect the study design, risks, benefits, or ethical considerations of the research. Examples may include administrative updates, corrections to documents, or minor clarifications that do not impact participant safety or study integrity. Approved minor modifications will be reported and documented on the agenda of the next convened IRB meeting for concurrence. A formal vote is not required.

II. **Tier 2 – Medium Modification/ Change (Vote Required; No Discussion Unless Requested)**
   Medium modifications/changes involve proposed changes in research activities that do not significantly affect the risk-benefit assessment but may modify the specific aims, procedures, or design of the study. Examples include:
   - Adjustments to inclusion/exclusion criteria that do not increase risk;
   - Addition of non-invasive procedures that do not increase participant risk;
   - Modifications to recruitment materials or advertisements involving minor content changes.

   Medium modifications/changes may be reviewed through an "administrative review" process by the IRB Chair or Vice-Chair. These modifications will then be presented for review at the next convened IRB meeting. No discussion is required unless specifically requested by the IRB Chair, Vice-Chair, or any IRB member. Quorum and majority vote are required for approval.

III. **Tier 3 – Significant Modification/ Change (Full Discussion and Vote Required)**
   Significant modifications/changes are those that may alter the level of risk to participants, significantly change the study design or objectives, or involve substantial revisions to informed consent materials related to new risks or procedures. Examples include:
   - Addition of study aims, invasive procedures, or interventions;

- Introduction of vulnerable populations not previously included;
- Substantial increases to potential risk or burden on participants.

All significant modifications will be reviewed and fully discussed at a convened IRB meeting. Quorum and majority vote are required for approval.

Tier	Type of Modification	Review Type	Action Required
Tier 1	Minor Modification/ Change	Administrative Review and Approval	No vote required; IRB Chair or Vice-Chair review and approve
Tier 2	Medium Modification/ Change	Administrative Review	Vote required; No discussion unless requested
Tier 3	Significant Modification/ Change	Full Board Discussion	Full discussion and vote at convened meeting

3. Sponsor Agency Modifications.

Modifications may only be implemented on IRB-approved studies. A sponsor agency may propose changes prior to IRB approval; however, investigators are advised to await IRB approval before implementing such changes.

Sponsor-generated modifications or addenda require IRB or Office of Sponsored Programs review and approval. Investigators must provide all relevant sponsor documentation and summarize the impact of changes on the approved protocol, including participant recruitment, enrollment, treatment, and follow-up, as guided by 45 CFR 46.103 and 46.111.

F. Grievances.

The IRB shall be informed of all grievances, such as complaints from research participants against a PI. Upon request, the IRB may provide advisory guidance regarding the grievance, consistent with 45 CFR 46.103 and 46.111.

G. Cooperative Activities.

Cooperative research activities involve Chaminade University and one or more external institutions. Normally, research must be reviewed and approved by all participating institutions' IRBs.

However, one IRB may rely on another institution's IRB if the following conditions are met, in alignment with 45 CFR 46.114:

- Both institutions hold **Federal Wide Assurances (FWAs)** approved by OHRP;

- Both institutions have an **Authorization Agreement** (or equivalent) outlining responsibilities;
- The FWA of the deferring institution designates the IRB of the approving institution.

If these conditions are not met, the PI must obtain approval from each institution's IRB and provide documentation of all approvals to the other participating IRBs. The IRB Chair will verify FWAs via the OHRP website.

X. RECORD REQUIREMENTS.

A. IRB Documentation.

In accordance with federal regulations (45 CFR 46.115; 21 CFR 56.115), the IRB shall prepare and maintain adequate documentation of its activities within the Office of Sponsored Programs and Research Integrity, including the following:

1. Copies of all research proposals (including scientific evaluations, when applicable) reviewed; approved sample consent documents; and progress reports or continuing review materials submitted by investigators.

2. Detailed minutes of IRB meetings, including:
   a. Attendance (with consultants, guests, and others listed separately);
   b. A summary of discussions of controverted issues and their resolution;
   c. The basis for IRB decisions;
   d. A record of voting (showing the number of votes for, against, and abstaining).

3. Documentation of continuing review activities, updated consent documents, and summaries of ongoing project activities. Approved consent documents must be date-stamped to indicate IRB approval and the expiration date of that approval, when applicable.

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

5. Statements of significant new findings provided to subjects, including unanticipated problems, risks, or adverse events, in compliance with 45 CFR 46.111 and FDA reporting requirements.

6. Reports of adverse events, unanticipated problems, and documentation of IRB review of such reports.

7. Reports of emergency use of investigational drugs, biologics, or devices, consistent with FDA requirements (21 CFR 56.104 and 56.115).

8. General information provided to subjects (e.g., fact sheets, brochures, recruitment materials)

In addition, the IRB and the Office of Sponsored Programs and Research Integrity shall maintain:

- A current and historical roster of IRB members (as required by 45 CFR 46.108 and 46.115);
- Written IRB policies and procedures (Standard Operating Procedures);
- Documentation of IRB evaluations, audits, and self-assessments.

B. Retention.

All IRB records must be retained by the investigator for at least three (3) years after completion of the research. Records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the Department of Veterans Affairs, or other federal oversight agencies, at reasonable times and in a reasonable manner (45 CFR 46.115(b); 21 CFR 56.115(b)).

Below is a checklist of required documents that must be retained for at least three (3) years after completion of the research:

- **Final approved protocol**
- **Consent forms or Waiver of Consent documentation**
    - **NOTE:** *Please ensure that your approved protocol includes a clear plan for obtaining informed consent.*
    - **NOTE:** *Depending on the nature of your study or funding requirements (e.g., longitudinal or biomedical research), signed consent forms may be required to be retained for a minimum of three years following the conclusion of the study.*
- **Final versions of instruments** (e.g., questionnaires, interview guides)
- **Approved recruitment materials** (e.g., flyers, emails)
- **IRB approval letter**
- **CITI and COI documentation** for all research team members
- **De-identified data**
    - **NOTE:** *This refers to data collected during the research study that has been cleaned of any personal or identifying details, such as names or contact information, so that participants cannot be linked to their responses. These data are considered part of the official research records and must be retained for a minimum of three years following the conclusion of the study.*
- **Annual or final status reports**

NOTE: *All research records listed above must be retained for a minimum of three years following the conclusion of the study and stored on a secure, campus-based drive at Chaminade University. If the Principal Investigator (PI) is not a faculty or*

*staff member of Chaminade (e.g., a graduate student), they are required to provide these records to their faculty mentor/ program coordinator, who will be responsible for storing them securely on the **approved campus-based drive**.*

C. Informed Consent Documentation.

1. Investigators are required to preserve all signed informed consent forms for a minimum of three (3) years after study completion, in accordance with 45 CFR 46.115(b) and 21 CFR 56.115(b).

2. If the Principal Investigator (PI) leaves Chaminade University, all signed consent forms must be transferred to the IRB Chair for secure storage within the appropriate department.

3. For certain FDA-regulated research, longer retention periods may apply (e.g., 21 CFR 312.62(c) and 812.140(d)), and investigators are responsible for complying with the stricter requirement.

XI. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB.

In accordance with federal regulations (45 CFR 46.103, 46.111, 46.115; 21 CFR 56.108, 56.111), investigators are required to provide the IRB with sufficient information to assess the ethical acceptability and regulatory compliance of proposed research involving human subjects. Documentation submitted to the IRB must include the following, as applicable:

A. Investigator Qualifications and Resources.

- Documentation of professional qualifications and relevant training to conduct the research, including Human Subjects Protection (CITI) training;
- Description of necessary support services and facilities available to carry out the research.

B. Application Materials.

- Completed Chaminade IRB application and protocol summary. Required attachments to be uploaded to the “Attachments” section of eProtocol include:
    - *CITI certificates* for PI and all other Key Personnel (i.e., faculty sponsor & committee member)
    - *COI disclosure forms* (fillable Form VI) for PI and all other Key Personnel
    - *Consent documents*
    - *Study Instruments* (i.e., questionnaires, recruitment materials, debriefing scripts, letters of agreement from cooperating organizations)
    - *Committee approval* if proposal is for dissertation/ thesis
- Copies of relevant grant applications, contracts, or sponsor agreements (if any).

C. Complete Study Protocol.

The study protocol must include:

1. Title of the study and summary of the proposed research;
2. Purpose of the study, including anticipated benefits and assessment of risks in relation to potential benefits;
3. Sponsor of the study (if applicable);
4. Subject inclusion/exclusion criteria, with scientific and ethical justification;
5. Justification for the use of any vulnerable populations (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically/educationally disadvantaged persons), consistent with Subparts B, C, and D of 45 CFR 46;
6. Study design and methodology, including rationale for chosen procedures;
7. Description of all study procedures to be performed;
8. Provisions for monitoring and managing adverse events and unanticipated problems;
9. Description of the informed consent process, including setting, considerations for autonomy, language accessibility, and protections for vulnerable populations;
10. Procedures for documenting informed consent, including assent from minors (defined under Hawai‘i law as individuals under 18), use of legally authorized representatives, witnesses, interpreters, and secure document storage (see Section XIII);
11. Remuneration and compensation for participation;
12. Provisions for compensation or medical treatment in the event of research-related injury (when applicable, per 21 CFR 50.25(a)(6));
13. Provisions to protect participants' privacy and maintain confidentiality of data (per 45 CFR 46.111(a)(7));
14. Any extra costs to participants related to study involvement;
15. Inclusion of women, minorities, and children, consistent with NIH Inclusion Policy (when applicable).

D. Study-Related Documents.

- Investigator's Brochure (if applicable);
- Case Report Forms (if applicable);
- Proposed informed consent documents, including translations tailored to likely participant populations; or requests for waiver/alteration of informed consent or waiver of documentation (per 45 CFR 46.116 and 46.117);
- Recruitment materials (advertisements, flyers, scripts, social media posts, etc.);
- Surveys, questionnaires, or other study instruments provided to participants.

E. Amendments and Reports.

- Requests for protocol modifications (including changes to consent forms and recruitment materials);
- Reports of unexpected adverse events and unanticipated problems involving risks to participants or others, including Data Safety Monitoring Board (DSMB) reports when applicable (per 45 CFR 46.103(b)(5));
- Continuing review/progress reports (when required), including protocol deviations, violations, and instances of noncompliance;
- Study closure reports upon completion or termination of the study.

XII. PRINCIPLES OF INFORMED CONSENT.

Informed consent is a fundamental principle of ethical research involving human subjects. The requirements for informed consent are set forth in federal regulations at 45 CFR 46.116 and 46.117 and, for FDA-regulated research, 21 CFR 50.

A. Right to Information.

When a research activity involves interaction with human participants, individuals are entitled to clear and complete information that a reasonable person would want in order to make an informed decision about participation. This includes a frank disclosure of all relevant facts, risks, benefits, alternatives, and options.

A signed copy of the informed consent document must be provided to the participant (or their legally authorized representative), and a copy must be retained by the investigator in accordance with recordkeeping requirements.

B. Who May Give Consent.

1. *Competent Adults:* Consent must be obtained from the subjects themselves, unless they are not legally or cognitively capable.

2. *Minors:* In the case of children (individuals under 18 in Hawai‘i), the IRB may approve a process requiring parental permission from one or both parents/legal guardians, along with the child’s assent, consistent with 45 CFR 46 Subpart D.

3. *Other Vulnerable Individuals:* For adults lacking decision-making capacity, consent may be obtained from a legally authorized representative (LAR), as defined under applicable state law.

4. *Special Populations:* When involving vulnerable groups (e.g., prisoners, pregnant women, individuals with impaired decision-making), additional protections per Subparts B, C, and D must be followed.

C. Definition and Process of Informed Consent.

"Informed consent" means ensuring that participants or their LARs are fully informed of all aspects of their participation, and that their choice is free from coercion, undue influence, fraud, or misrepresentation.

Consent must be presented in language understandable to the participant (i.e., using plain language, avoiding jargon). The revised Common Rule requires that the beginning of the consent form present "key information" to help participants quickly understand why they may or may not want to participate (45 CFR 46.116(a)(5)(i)).

Consent may be documented by:

- Written signature on an IRB-approved consent form;
- An IRB-approved waiver of documentation (see Section XII: Principles of Informed Consent);
- Alternative methods approved by the IRB (e.g., electronic consent, witnessed short form consent for non-English speakers, or consent conducted by telephone/video conferencing when documentation is appropriately handled).

When remote or telephonic consent is used, a copy of the signed consent form must be returned to the investigator (via mail, fax, courier, or secure electronic transmission), and a witness independent of the study team may be required.

The Informed Consent form must be uploaded to the "Consent Information" section in eProtocol.

D. IRB Review of Consent Content.

The IRB is responsible for ensuring that consent documents and processes:

- Provide a fair and accurate explanation of the research, procedures, risks, and potential benefits;
- Include all required elements of informed consent per 45 CFR 46.116(b) and (c), and, when applicable, additional elements under 46.116(d);
- Are written in clear, concise, and understandable language tailored to the subject population;
- Include debriefing procedures (when deception is used) to ensure participants are promptly and fully informed.

E. Injury Compensation Statement.

For research involving more than minimal risk, the consent form must include a statement regarding compensation and/or medical treatment for research-related

injury, consistent with 21 CFR 50.25(a)(6) (for FDA-regulated research).

F. Waiver or Alteration of Consent/ Waiver of Documentation.

The IRB may approve a waiver or alteration of informed consent, or waive the requirement for written documentation, provided regulatory criteria are met:

Waiver of Documentation of Consent (45 CFR 46.117(c)):

1. The only record linking the subject to the research is the consent document, and the principal risk is potential harm from a confidentiality breach; or
2. The research presents no more than minimal risk and involves no procedures for which written consent is normally required.

Waiver or Alteration of Elements of Consent (45 CFR 46.116(f)):
The IRB may waive or alter some or all elements of consent if:

1. The research involves no more than minimal risk;
2. The waiver/alteration will not adversely affect the rights and welfare of participants;
3. The research could not practicably be carried out without the waiver/alteration;
4. When appropriate, participants will be provided with additional information after participation

When documentation is waived, participants should be provided with a written statement about the research (e.g., an information sheet or cover letter).

G. Incomplete Disclosure and Deception.

In some studies, full disclosure of research aims may compromise the validity of the study. In such cases, the IRB may approve incomplete disclosure or use of deception only when justified by the study's value and when risks are minimal. The IRB must ensure that:

- The withholding of information does not adversely affect participants' rights or welfare;
- The deception is scientifically necessary;
- A complete and prompt debriefing is conducted after participation.

H. Request for Waiver of Informed Consent Form.

Under federal regulations (45 CFR 46.116 and 46.117), investigators may request a waiver or alteration of informed consent under specific circumstances. There are three common types that are included on the Request for Waiver of Informed Consent form:

1. *Waiver or Alteration of Informed Consent*

Permitted when the research poses minimal risk, cannot be practicably carried out without the waiver, and would not adversely affect subjects' rights or welfare. This is often used in secondary data analysis or when obtaining consent could harm or bias participants.

2. *Waiver of Parental Permission*
May be granted when parental consent is not legally required or would compromise the privacy or safety of minors (e.g., studies involving legally permitted behaviors like abortion or experiences with abuse).

3. *Incomplete Disclosure, Deception, or Delayed Consent with Post-Study Debriefing*
Allows researchers to request a waiver or alteration of informed consent when full disclosure of the study's purpose or procedures is not feasible prior to participation, often due to scientific necessity.

In such studies, participants may not be fully informed at the outset due to:

- **Incomplete disclosure** – withholding certain information about the study (e.g., specific hypotheses or conditions);
- **Deception** – intentionally providing false or misleading information to participants (e.g., use of a cover story);
- **Delayed consent** – obtaining participant consent only after the study has concluded (e.g., following debriefing).

All waivers require IRB approval and must be justified with compelling ethical and practical reasons. The Request for Waiver of Consent form must be uploaded to the "Consent Information" section in eProtocol.

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.

A. Definition of Conflict of Interest.

An IRB member is considered to have a conflict of interest whenever the member, or the member's spouse or dependent child:

1. Is an investigator or sub-investigator on the protocol under review;
2. Has a *significant financial interest* (as defined in the Chaminade Conflict of Interest Policy, consistent with 42 CFR Part 50, Subpart F) in the sponsor or an agent of the sponsor of a study being reviewed, such that the outcome of the research could reasonably be expected to affect the value of the interest;
3. Serves as an officer, director, or other key decision-maker for the sponsor or an agent of the sponsor of a study being reviewed; or
4. Has otherwise identified themselves or has been identified by the IRB Chair or IRB members, as having a conflicting interest (real or perceived) in relation to the matter under review.

B. Responsibility of IRB Members.

It is the responsibility of each IRB member to disclose any real or perceived conflict of interest related to a matter before the IRB. Members must avoid participating in reviews where such conflicts exist, or where a reasonable person could perceive that a conflict exists.

- If assigned as a reviewer for a matter in which a conflict may exist, the member must notify the IRB Chair immediately so the protocol may be reassigned.
- Members should review all assigned protocols promptly to determine if a conflict exists to prevent delays in review.

C. Participation in IRB Deliberations.

Federal regulations (45 CFR 46.107(e); 21 CFR 56.107(e)) prohibit IRB members with a conflict of interest from participating in the IRB's initial or continuing review of a study, *except to provide information requested by the IRB*.

- At the discretion of the IRB Chair, a conflicted member may remain during the discussion phase only to provide relevant information or clarification.
- The conflicted member must leave the meeting room (including electronic/virtual meeting spaces) for deliberations and voting on the matter.

D. Documentation in IRB Minutes.

IRB minutes must reflect:

1. The presence of a conflict of interest;
2. The member's absence (by name) from the meeting during deliberation and voting; and
3. That the member did not participate in the final action/vote.

XIV. APPENDICES.

Appendix 1: Class Projects.

Chaminade University recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might be viewed as research under the federal definition. According to the **Common Rule (45 CFR 46.102(l))**, research is defined as "a systematic investigation… designed to develop or contribute to generalizable knowledge." As a general rule, when activities are conducted solely to fulfill a course requirement and will not contribute to generalizable knowledge, the intent element is lacking, and IRB review is not required.

However, classroom assignments may still involve interactions with human participants that could present risks to privacy, confidentiality, or well-being. Therefore, recognizing its responsibility to safeguard participants, the IRB has determined that some classroom projects may require review if they fall outside the parameters below.

Projects Generally Not Requiring IRB Review
Classroom assignments involving human participants are typically **educational in nature** and not subject to IRB review when **all** of the following criteria are met:

1. **Type of Activity**
    a. The project is limited to surveys, questionnaires, interviews, observation of public behavior, minimal risk experimental activities, or standard educational exercises directly related to the course topic(s).
    b. Audio/video recordings may be permitted when used solely to ensure accuracy of data collection and are not disseminated beyond the classroom.

2. **Minimal Risk Content**
    a. Surveys, questionnaires, or interviews do **not** include sensitive or potentially stigmatizing questions (e.g., substance use, sexual behavior, criminal activity, mental health, medical history, grades/test scores).

3. **Participant Population**
    a. Participants are **not** drawn from populations requiring additional federal protections (e.g., children under 18, prisoners, pregnant individuals, or those with impaired decision-making capacity).

4. **Data Identifiability & Confidentiality**
    a. One of the following applies:
        i. No direct or indirect identifiers are recorded;
        ii. Only indirect identifiers are collected, but cannot reasonably be combined to identify participants; or
        iii. Identifiers are collected, but disclosure of the data could not reasonably place participants at risk of harm, including risks to

reputation, employability, financial standing, or potential criminal/civil liability.

5. **Use & Dissemination of Results**
    a. Results, including recordings, are shared only within the classroom context, or if conducted with/for an external organization, shared only with that organization, which agrees not to further distribute the data.
    b. Projects are **not intended for publication, public presentation, or future research use**.

When IRB Review is Required
Projects that do **not** meet the above criteria must be submitted to the IRB for review. Faculty are responsible for determining whether an assigned project can be classified as a course-related student project or whether IRB review is required. Faculty should consult with the IRB Chair when in doubt.

Faculty Responsibilities
- Provide instruction on **ethical principles of human subjects research** (e.g., respect for persons, beneficence, and justice, per the *Belmont Report*).
- Ensure students adhere to standards of privacy, confidentiality, and voluntary participation.
- Advise students on the appropriate management, storage, and disposal of data.
- Avoid assigning projects that involve vulnerable populations or sensitive topics unless IRB approval is obtained.

Administrative Considerations
The IRB may review student class projects individually or in groups to support the educational process. However, instructors should be mindful of IRB review timelines, especially during peak academic periods. Planning is encouraged to ensure adequate time for review if required.

Appendix 2: Action Research.

Action research is research conducted by educators, administrators, counselors, or others within an educational setting to improve practice, inform instructional strategies, or enhance the learning environment. It is generally defined as a systematic inquiry carried out by those with a vested interest in the teaching and learning process for the purpose of gathering information about how schools operate, how teaching occurs, and how students learn (Mills, 2011; Mertler, 2014).

Action research falls under the purview of **social and behavioral research** and, like other human subjects research, must remain within the ethical boundaries set forth in **federal regulations (45 CFR 46)** and institutional policies. The determination of whether IRB review is required depends on whether the project meets the federal definition of "research" with "human subjects" as defined by the Common Rule.

Specifically, action research requires **IRB review and approval** if:

- The project is intended to contribute to **generalizable knowledge** (e.g., dissemination beyond the classroom or workplace).
- The data will be used in a **thesis or dissertation**.
- The findings will be **published, presented publicly, or shared outside the immediate instructional/organizational context** (e.g., peer-reviewed journals, trade publications, professional conferences, CUH symposia/assemblies).

Action research **does not require IRB review** if the activity is limited to **internal program improvement or professional development**, and the results are:

- Used solely to improve teaching/professional practice.
- Shared only within the researcher's own school/organization.
- Presented only to supervisors, instructors, classmates, or CUH faculty, where there is no intent to contribute to generalizable knowledge.

When action research projects are conducted within a **semester timeframe**, it is strongly recommended that investigators plan projects in ways that either fall within the **Exempt categories** of IRB review (45 CFR 46.104) or are determined to be **Not Human Subjects Research (NHSR)**.

Faculty and students are encouraged to consult the IRB Chair early in the planning process to determine whether a project requires IRB submission and, if so, to allow sufficient time for review.

See **Appendix 3** for additional examples of action research activities that do or do not typically require IRB review.

Appendix 3: Examples of IRB Reviewable and Non-IRB Reviewable Projects.

Examples of Activities That Do Not Typically Require IRB Review

The following activities generally do not fall under the federal definition of "research with human subjects" (45 CFR 46.102) or are determined to be **Not Human Subjects Research (NHSR)** and therefore do not typically require IRB review:

- Teacher or student evaluations used solely by the institution for internal purposes.
- Class-related data collection projects (with adults, no more than minimal risk) conducted solely for didactic/educational purposes where results are **not disseminated outside the classroom**.
- Quality improvement (QI) or quality assurance (QA) activities conducted solely for **internal use** and not designed to contribute to **generalizable knowledge** (e.g., institutional surveys, benchmarking, or program assessment at less than minimal risk).
- Data collection activities conducted 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, or the sponsor.
- Journalism, documentary, or oral communication projects intended to document specific historical events, experiences, or perspectives but **not designed to test a hypothesis or contribute to generalizable knowledge**.
- Creative works such as theatrical productions, art exhibits, or self-ethnographies intended primarily for self-reflection or artistic purposes.
- Use of secondary data sets that are **publicly available** or where the information is recorded in such a manner that subjects cannot be identified (e.g., IPEDS data from the National Center for Education Statistics, ICPSR datasets designated as "public-use").

Examples of Activities That Do Typically Require IRB Review

The following activities generally meet the federal definition of "research with human subjects" and typically require IRB review:

- Oral history projects intended to contribute to generalizable knowledge (e.g., publication, public archiving, or broad dissemination).
- "Action research" conducted by graduate students or faculty in educational settings when intended for publication, presentation, or dissertation/thesis work.
- Class or institutional projects where results will be **disseminated outside the classroom** (e.g., scholarly publication, conference presentation) or that involve:
    - Sensitive populations (e.g., minors, prisoners, individuals with impaired decision-making capacity).
    - Sensitive topics (e.g., substance use, mental health, sexual identity).
    - Use of deception or incomplete disclosure.
    - More than minimal risk to participants.
- Collection of blood or other biological samples from any person other than oneself, unless clearly conducted for non-research/clinical purposes.

- Secondary datasets obtained from **non-public sources** (e.g., state agencies, nonprofit organizations, other universities, private sources) that will be analyzed for faculty or student research.

Important Notes

- **Evolving Projects**: Some activities may begin as non-research (e.g., course evaluations, QI/QA) but later spark a research question or evolve into projects intended for dissemination. At that point, they fall under IRB jurisdiction and require review.
- **No Retrospective Approval**: Retrospective IRB approval cannot be granted for studies already initiated or completed. Investigators must seek an IRB determination **before** beginning activities that may constitute human subjects research. Failure to do so may result in regulatory noncompliance, which can include a requirement that improperly collected data be destroyed.

Appendix 4: Training Guide.

Chaminade University IRB

Training Guide for Faculty and Research Staff

The Chaminade University IRB accepts CITI Human Subjects Training, which is required of all IRB members and collaborating faculty or staff. While not all trainings are required, investigators should seek all the trainings that they can to best inform their research and protect their subjects.

1. CITI Human Subjects Training Requirement

a. Chaminade University IRB requires all **Principal Investigators (PIs)**, faculty sponsors, and key personnel involved in a study to complete **CITI Human Subjects Training**. Faculty sponsors are responsible for ensuring student projects meet ethical and legal standards and must complete the training as well.

b. Most certifications are valid for 3 years

c. Upload all CITI certificates to the "Attachments" section in eProtocol

d. **NOTE:** The IRB may require additional CITI modules based on study type. While not all trainings are mandatory, investigators are encouraged to complete all relevant modules to strengthen research ethics and participant protection.

2. Required and Elective Training Modules

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

b. The list of required and elective trainings that the IRB has requested of CUH Investigators is shown in Attachment A, also found in this charter. There are two types of courses: 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 or IRB Administrator if you have question on which elective modules to take.

3. Registering and Enrolling for CITI Program Training

a. Navigate to the CITI Program Website: www.citiprogram.org

b. On the CITI Program home page **click "Register."**

i. **STEP 1: Organization Affiliation**
   - Click “Select Your Organization Affiliation”
   - Type in “Chaminade” and then select Chaminade University of Honolulu from the drop-down menu.
   - Click “I AGREE to the Terms and Services and Privacy Policy for accessing CITI Program materials.”
   - Click “I affirm that I am an affiliate of Chaminade University of Honolulu.”
   - Click “Create a CITI Program account”

ii. **STEP 2: Personal Information**
   - All sections with an asterisk (*) must be completed.
   - List your Chaminade e-mail address
   - Click “Continue to Step 3.”

iii. **STEP 3: Username and Password**
   - All sections with an asterisk (*) must be completed.
   - 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.”

iv. **STEP 4: Demographics**
   - All sections with an asterisk (*) must be completed.
   - Select “No” for “May we contact you to provide information about other courses and services after you complete your CITI Program coursework?”
   - Click “Finalize Registration.”

v. **STEP 5: CEU Credit**
   - Click “No” as a response to your interest in Continuing Education Credits as this is not required by Chaminade.
   - Click “Submit.”

vi. **STEP 6: Requested Information**
   - All sections with an asterisk (*) must be completed.
   - Click “Next.”

vii. **STEP 7: Course Enrollment**
   - After finalizing your registration, you will be able to select specific courses.
     - **NOTE:** For DNP students and their Faculty Sponsors/ Chairpersons conducting Quality Improvement (QI) or Evidence-Based Practice (EBP) projects, the **Biomedical Research – Basic/Refresher** CITI course is required. The PI and all Key Personnel must complete this course and upload their certificates in the “Attachments” section of eProtocol.

- Click “Submit.”

viii. **STEP 8: Course Completion**
- Courses selected in “STEP 7” will be listed on your learner page.
- To begin training, click “Start Now” 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.

ix. **STEP 9: Certification Completion**
- Upload your certificate(s) of completion as an attachment to your protocol in eProtocol before submitting your protocol to the IRB for review. These certificates for the PI and all Key Personnel must be uploaded to the “Attachments” section of eProtocol.

NOTES:
- All modules do not have to be completed at once.
- You must complete the course with at least an 80%.
- For technical problems, contact support@citiprogram.org. For other questions, contact the IRB Administrator (irb@chaminade.edu).

Training Guide Attachment A: CITI Course Matrix

Training Guide Attachment A. CITI Course Matrix

HSR Series Selection Form: Basic Course Options

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

Review the CITI Program recommendations in the BLUE 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 citisupport@med.miami.edu for implementation.

Available Basic HSR Modules

Basic Biomedical (Biomed) Modules	SAMPLE LEARNER GROUPS: Biomedical Researchers	Social-Behavioral-Educational Researchers	Biomedical Data or Specimens Only Researchers	IRB Members
	MODULE SELECTION (R,E,S) RECOMMENDATIONS FOR EACH LEARNER GROUP			
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)	-	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: 14928)	-	R	-	R
Additional Modules of Interest				
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	-	-	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	-	R
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
	ELECTIVE MODULE, PASSING SCORE, AND EXPIRATION RECOMMENDATIONS			
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.)	1	0	0	0
Please indicate the Passing Score for the course (not per module). The standard recommendation is 80%.	80%	80%	80%	80%
Please indicate how long the certification for passing the course lasts (in years) or write "No Expiration Date."	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: Required Elements of Informed Consent.

Consent Checklist:	
Does the informed consent:	
Include a statement that explains the purpose of the research, length of time subject is expected to participate, and description of procedures?	☐
Include a description of any benefits of the research to society and/or to the individual?	☐
Include a description of any potential risks to the subject, including physical, psychological, social harm, breach of privacy, discomfort, or inconvenience?	☐
Include a description of how confidentiality of records identifying the subject will be maintained?	☐
Include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled?	☐
Include a statement that the subject may withdraw from the study at any time without penalty?	☐
Include who to contact (PI details including email address and telephone) for answers to questions or in the event of a research-related injury or emergency?	☐
Include a statement that subjects may contact the Chair of the Institutional Review Board (IRB) answers to questions regarding their rights as research subjects, and contact details for the IRB chair (irb@chaminade.edu)	☐

Appendix 6: Examples of Informed Consent Documents.

TITLE OF STUDY
[Insert title]

PRINCIPAL INVESTIGATOR
[Name] [Department] [Address] [Phone] [Email]

INTRODUCTION
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.

PURPOSE OF STUDY
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.

PARTICIPANT RIGHTS
Your participation in this study is completely voluntary. You may choose not to participate or to stop at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled. You have the right to ask questions about the study at any point, decline to answer any questions that make you uncomfortable, and withdraw from the study without it affecting your relationship with [University/Institution] or any services you receive. Your privacy and confidentiality will be protected to the fullest extent possible under the law, and you may request a summary of the study's findings after its completion. If you have any questions about your rights as a research participant, you may contact the Chaminade University of Honolulu Institutional Review Board (IRB) at [phone number] or [email address].

CONFIDENTIALITY AND LIMITS TO ANONYMITY
Because this study involves a close-knit community and/or group settings, complete anonymity cannot be guaranteed. While your identity may be known to the research team, every effort will be made to protect your privacy and keep your information confidential. Data will be stored securely on password-protected devices and encrypted servers, with access limited to authorized research team members. In reports or publications, your name and other direct identifiers will not be used; instead, results will be presented in aggregate form or with pseudonyms to reduce the risk of identification. Despite these precautions, there is still a small chance that someone familiar with you could recognize your participation based on context or shared experiences.

PRIVACY

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.

BENEFITS
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.).*

RISKS
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.

SECURITY OF DATA
During the study, your data will be handled with care to ensure its security. Online interviews will be conducted using a HIPAA-compliant platform, and any recordings or transcripts stored temporarily on the platform's cloud will be downloaded to secure, encrypted university servers and then deleted from the cloud as soon as possible. Access to these files will be limited to authorized research team members, and all devices and files will be password-protected to maintain confidentiality.

DISTRIBUTION OF FINDINGS
The results of this study may be shared in academic publications, presentations, or reports. Any information shared will not include your name or other identifying details. Findings will be reported in aggregate or with pseudonyms to protect your identity, and care will be taken to ensure that no participant can be identified from the published materials. Your data will not be placed in your medical records.

CONTACT INFORMATION
If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator (PI), please contact the Institutional Review Board Chair, Dr. XXX at irb@chaminade.edu.

VOLUNTARY PARTICIPATION
Your participation in this study is voluntary. It is up to you to decide whether to take part in this study. If you decide to take part in this study, you will be asked to sign a consent

form. After you sign the consent form, you are still free to withdraw at any time without providing a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you are a student, deciding not to participate in a study cannot affect your grade in a course. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

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 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.

Confidentiality, 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 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 not divulge subjects' names, but also other details about them or their experiences that would allow them to be identified. Occasionally, it is important to the research to identify an individual who participated or subjects themselves may wish to have their contribution attributed to them. In such cases, it would be necessary for a participant 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 - a phone 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
If 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 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 considering 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 and that participants may withdraw without cause. 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 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."

Implied Consent for Online Surveys

Notes:
Implied Consent may be suitable for certain kinds or survey where (a) risk is minimal, (b) no Vulnerable Populations are to be surveyed and (c) survey is fully de-identified and anonymous, such that collecting signatures on an Informed Consent document would increase the level of identification of subjects.

Instructions:
Delete this paragraph once you have customized this document. **Blue text found throughout this document in boldface and brackets offers guidance and suggestions. Delete blue text once done.** Red text is sample statements that can be sculpted according to your study. Black text is the formatting that does not need to change. The following paragraphs should go at the top of the survey you give/send out. It can be smaller font than the survey. Please adapt it to your own project, in terms of your department or college, what the research is and why these people have been asked to participate. Please note that if you are using this template for an online consent, revise the text accordingly.

Sample Implied Consent
My name is _____, I am a **[graduate/undergraduate/faculty/staff member]** student at Chaminade University.

You are being invited to participate in this research study of **[list study name]**. I am interested in finding out about **[insert purpose of the survey/questionnaire]**.

Your participation in this study will require the completion of the attached **[questionnaire/survey]**. This should take approximately **[number of minutes]** minutes of your time. Your participation will be anonymous, and you will not be contacted again in the future. You will not be paid for being in this study. This survey involves minimal risk to you. The benefits, however, may impact society by helping increase knowledge about **[study topic]**.

You do not have to be in this study if you do not want to be. You do not have to answer any question that you do not want to answer for any reason. We will be happy to answer any questions you have about this study. If you have further questions about this project or if you have a research-related problem you may contact me, **[researcher's name]** at **[contact information]** or my advisor**, [advisor's name]** at **[advisor's contact information].**

If you have any questions about your rights as a research participant, you may contact the IRB Chair at irb@chaminade.edu.

The completion of this survey implies your consent to participate. If you choose to participate, please complete the attached survey and return it by **[return date]**. Thank you!

Sample Child Assent Form

We are doing a study to learn about people who tell the truth and people who lie. We are asking you to help because we don't know very much about whether kids your age expect people to lie or tell the truth.

If you agree to be in our study, we are going to ask you some questions about types of people. We want to know if you think they usually tell the truth or if they usually lie. For example, we will ask you if a teacher, parent, or other people usually lie or usually tell the truth.

You can ask questions about this study at any time. If you decide at any time not to finish, you can ask us to stop.

The questions we will ask are only about what you think. There are no right or wrong answers because this is not a test.

If you sign this paper, it means that you have read this and that you want to be in the study. If you don't want to study, don't sign this paper. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

_____

Print name of participant

_____ _____

Signature of participant Date

_____

Print name of investigator

_____ _____

Signature of investigator Date

Appendix 7: Principal Investigator Rights and Responsibilities.

Introduction

The Principal Investigator (PI) is ultimately responsible for ensuring compliance with all applicable Chaminade University of Honolulu IRB policies and procedures, U.S. Department of Health and Human Services (HHS) regulations (45 CFR 46 – the Common Rule), and, when applicable, Food and Drug Administration (FDA) regulations (21 CFR 50 and 56). The PI has full oversight of all aspects of the research study, including the informed consent process, data management, and reporting obligations. While a PI may delegate specific tasks to qualified members of the research team, ultimate responsibility for the ethical and compliant conduct of the study cannot be delegated.

Who May Serve as a Principal Investigator

Because PI responsibilities involve direct supervision of the research team and accountability for study oversight, a PI must be a current employee or enrolled student of Chaminade University who is conducting research within the scope of their university role. IRB oversight also requires long-term storage and availability of data, as well as ongoing responsibility for post-approval reporting (e.g., continuing review, study closure, unanticipated problems, adverse events).

Note: Due to the temporary nature of adjunct appointments, individuals holding only an adjunct appointment may not serve as PI. However, they may serve as co-investigators or collaborators.

Note: The CUH IRB typically limits PI eligibility to full-time faculty. However, for DNP students completing QI/EBP protocols, adjunct faculty may serve as the faculty sponsor in eProtocol. This exception applies only to these projects.

Eligible PIs

- **Faculty Members:** All full-time and eligible part-time faculty may serve as PI if their School permits them to apply for sponsored funding through the University. Adjunct faculty cannot serve as PI or Faculty Mentor, but they may be listed as co-investigators.

- **Staff:** Staff may serve as PI if they are appropriately qualified, have relevant training and expertise, and have written approval from their supervisor.

- **Students:** Students may serve as PI for their own research projects and are responsible for submitting the IRB application. A Faculty Sponsor must be listed on all student-led protocols. The IRB applies the same review standards to student research as to faculty- or staff-led research. Retroactive IRB approval is not allowed under federal regulations and University policy. Failure to obtain prior IRB approval may prevent use of collected data and can result in institutional sanctions.

PI Transitions

PIs who are leaving Chaminade University must notify the IRB as early as possible to either close the study or transfer PI responsibilities to another qualified, active Chaminade investigator. No research may continue without an active PI of record.

General Responsibilities of Principal Investigators

As a condition of IRB approval, the PI is jointly responsible for ensuring compliance with federal regulations and institutional policies, including (1) Minimizing risks to participants using sound research design and procedures that do not unnecessarily expose participants to risk; (2) Ensuring that risks are reasonable in relation to anticipated benefits and the knowledge expected to result; (3) Equitable selection of research participants; (4) Obtaining and documenting informed consent in compliance with 45 CFR 46.116 and 46.117; (5) Implementing a plan for monitoring data to ensure participant safety; (6) Protecting privacy and confidentiality of data; and (7) Providing additional safeguards for vulnerable populations, such as children, prisoners, and persons with impaired decision-making capacity.

Specific Responsibilities of Principal Investigators

The PI and co-investigators are responsible for (1) Communicating promptly with the IRB and submitting continuing review or closure reports on time; (2) Ensuring the study has sufficient resources and qualified staff; (3) Not enrolling participants until IRB approval is granted; (4) Providing appropriate training and oversight of the research team, including CITI and Good Clinical Practice (GCP) training where required; (5) Conducting the study exactly as approved and reporting protocol deviations immediately; (6) Submitting modifications to the IRB for approval before implementation unless eliminating an immediate hazard; (7) Reporting adverse events and unanticipated problems promptly; (8) Maintaining accurate and secure study records; and (9) Informing participants of new information that may affect their willingness to continue participating.

Methodological Oversight

While the primary responsibility of the IRB is to protect the rights and welfare of research participants, it may occasionally provide stipulations or recommendations related to research methodology when certain design elements could directly impact participant safety or risk. Such guidance is typically appropriate when methodological choices, such as data collection procedures, recruitment strategies, or interview length, could influence participant well-being, confidentiality, or the integrity of informed consent. The IRB may suggest modifications, additional safeguards, or clarifications to minimize risks associated with the study design, but it does not assume responsibility for overall scientific validity or general study outcomes.

Appendix 8: Student Participation in Human Subjects Research.

Overview of Student Rights as Research Participants

- Participation is voluntary, with no penalty for refusal or withdrawal.
- Students must receive clear and complete information before consenting.
- Privacy and confidentiality must be protected at all times.
- Students have the right to ask questions and receive answers before and during the study.
- Education records are protected under FERPA and cannot be accessed without proper consent.

1. Human Subjects Research at Chaminade

Research involving human subjects at Chaminade University is regulated by the Institutional Review Board (IRB). The IRB is composed of faculty, staff, and community members, and its primary role is to protect the rights, safety, and well-being of individuals who participate in research projects conducted under the university's jurisdiction.

Students may be invited to participate in faculty-led or student-led research as research participants (sometimes called "subjects"). Students should be fully informed of their rights and protections when asked to participate.

These protections are rooted in federal regulations, including the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 CFR 46, known as the Common Rule). OHRP emphasizes that "the involvement of students, employees, and other individuals in subordinate positions in research may present special concerns" because of the potential for coercion or undue influence.

Key guiding principles include:

- **Faculty must obtain IRB approval** prior to conducting any human subjects research (45 CFR 46.103). Students may ask to see documentation of this approval before deciding whether to participate.
- **Age of majority:** Participants must be at least **18 years old** in Hawaii to consent independently. Research involving minors (under 18), including 17-year-old college students, generally requires **both parental/legal guardian consent and the student's assent**.
- **Informed consent is required** unless the IRB has granted a waiver (45 CFR 46.116). Informed consent must ensure students are fully informed of risks, benefits, and their rights.
- **Voluntary participation:** Students must be free to decline or withdraw from participation at any time without penalty, including any negative effect on

grades or academic standing (45 CFR 46.116(a)(8)). Participants can decline or withdraw from participation without cause.

For more information on federal human subjects protections, visit:
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

2. **Recruitment and Avoidance of Coercion**
Because of the inherent power dynamics between faculty and students, extra care must be taken to ensure students do not feel pressured or coerced to participate in research.
Requirements for recruitment include:

- When recruiting through classrooms, student listservs, or student organizations, researchers must clearly explain why those students are the most appropriate participants.
- Students cannot be required to participate in research for course credit unless a comparable, non-research alternative is offered.
- Alternatives to participation must be equivalent in time, effort, and fulfillment of course requirements to ensure fairness and minimize coercion.
- Withdrawal without penalty: Students must be able to withdraw from a study at any time without academic or personal consequences. If the study provides course credit, students who withdraw must still receive full credit for participation.
- If payments or incentives are provided, credit for payment must accrue as the study progresses and cannot be contingent on study completion.

3. **Informed Consent**
Informed consent is both a process and a document. Students should receive clear, understandable information and have an opportunity to ask questions before deciding to participate.

The informed consent process typically includes:

- **Purpose of the research:** Why the study is being conducted.
- **Study procedures:** What participation involves, the expected duration, and any compensation provided.
- **Risks:** Any potential physical, psychological, social, or legal risks, along with steps taken to minimize them.
- **Benefits:** Potential benefits to the participant or to society.
- **Privacy and confidentiality:** How data will be protected and who will have access.
- **Contacts:** Whom to contact with questions about the study or participant rights.
- **Voluntary nature of participation:** A clear statement that participation is voluntary and can be stopped at any time.

- **Participant rights:** Participants have the right to ask questions, decline to answer any questions, or withdraw from the study at any time without penalty.
- **Security and maintenance of data:** Information must be stored securely on password-protected and encrypted systems, and access must be limited to authorized research team members.

Notes:

- Students should not sign a consent form until all their questions are answered.
- Signing does not waive legal rights or prevent a student from stopping participation later.
- Students must receive a copy of the signed consent form for their records.

4. Voluntary Participation

Participation in research is always voluntary. Students have the right to:

- Decline participation for any reason without penalty.
- Withdraw from a study at any time, even after signing the consent form.
- Refuse to answer specific questions during a study.
- Be assured that their decision will not affect their grades, standing, or access to services.

Faculty must clearly communicate these rights during recruitment and throughout the research process.

5. Safeguards for Privacy and Confidentiality

Because classroom or campus environments can make confidentiality challenging, researchers must take extra steps to protect student privacy:

- If stigma, peer pressure, or sensitive topics are involved, research should ideally take place **off-site** or outside regular class times.
- The extent of confidentiality and who may access personal data must be fully explained during informed consent.
- If classroom activities are being studied, researchers must clearly distinguish required class activities from optional research participation.
- When researchers need access to student educational records or recruitment via records, they must obtain:
    - A **letter of support** from an appropriate university authority (e.g., department chair or dean), and
    - **Written consent** from students if required by FERPA (see below).

6. Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (FERPA) is a federal law protecting the privacy of student educational records.

Key FERPA requirements for research:

- Student education records **cannot be accessed or used for research** without prior written consent, unless a specific FERPA exception applies.
- Consent must:
  - Be **signed and dated**,
  - Specify which records may be disclosed,
  - State the purpose of disclosure,
  - Identify to whom the records will be disclosed.

More information is available at: https://studentprivacy.ed.gov/ferpa

7. Reporting Concerns

If students have concerns or complaints about a research study, they may:

- **Contact the researcher** directly using the information provided in the consent form.
- **Contact the CUH IRB** at irb@chaminade.edu with any questions or to report potential violations of participant rights.
- Reports can be made confidentially and will be taken seriously by the university.