Chaminade University IRB

FORM II: IRB Review Including Request for Exemption from Full Review.

Chaminade University's policy and federal regulations do not allow investigators to determine if their work or activity is human participants research and may require IRB review and approval. This form is designed to determine whether research is being conducted and if this research constitutes human participants research as defined by federal regulations (See the Federal Register, 45 cfr 46.102). This form may be submitted to funding agencies when the agency requires documentation that the IRB has made the determination that IRB approval is not necessary to conduct the work.

The completed form can be e-mailed to: irb@chaminade.edu. The subject line should be entitled, "Determination of Human Subject Research." The completed form can also be delivered in person or by mail to the IRB Chair.

Note: If children or minors are subjects then Full Review (Form III) is required.

1. Project Personnel

Principal Investigator Name: **Position:**

Faculty: ☐

Staff: ☐

PI Contact email: **Phone Number:**

Division:

Student co-investigator name (if applicable):

Other co-investigator name:

Other co-investigator position: Faculty: ☐ **Staff:** ☐

Date of Submission:

2. Project Overview

Title:

Name of Funding agency (if applicable):

Funding period (start and end dates, is applicable):

Requested Project Start Date: End Date:

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3. Required Training

List participants and date of completion of Humans Subject Certification. Attach copies of Certifications. Note that for Determination (Form I) only PI Certification is required to be completed. For Protocol approval (Form II or III) all participants must complete training.

Name	Certification Completed	Date of Completion
	CITI	
	CITI	
	CITI	
	CITI	

4. Protocol Description.

4.1. Abstract. Provide a 300-500 word abstract of the proposed research. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the participants

4.2. Statement of Research Question or Hypothesis. Clearly state the question this research is intended to address, or the hypothesis that it will test.

4.3. Risk Classification (check one)

☐ Minimal (According to Federal Regulations §46.102(i), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

☐ Greater Than Minimal Risk

4.4. Secondary Studies. If your proposed research utilizes a pre-existing data set then IRB approval cannot be given retroactively unless the data set meets ethical collection standards. Please check those which apply:

Prior IRB Approval ☐ please state approving institution, and of approval and provide approval letter copy

Informed consent was obtained ☐
Informed consent was not required ☐
Investigator will not re-identify subjects ☐
Investigator will not contact subjects ☐

Supporting documentation for each of these must be provided in your application if you are applying for a Secondary Study protocol.

4.5. Do you intend to publish or present your results outside of a classroom or outside of a submission of coursework?

Yes: ☐ No: ☐

5. Research Proposal

Provide a description of the proposed research with each of the following sections addressed. Proposals lacking any of these sections will be returned without review.

5.1. Introduction: describe the context within your field and motivation for your proposed research (0.5-1 pages suggested to provide reviewers with sufficient background to understand your proposal).

5.2. Specific Aims/Goals. Outline the proposed workflow and methodologies for the study.

5.3. Methods of data collection and analysis (qualitative and quantitative). Describe any instruments or surveys, and attach copies of those instruments. Describe data analysis plan, including statistical tests and steps taken to assure that data are significant.

5.4. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)

5.5. Statement of potential research benefits to subjects (Monetary compensation is not a benefit of participation)

6. Inclusion Criteria and Recruitment Plan

Indicate which of the following are intended participants or subjects in this research

- ☐ Children or minors
- ☐ Cognitively impaired persons
- ☐ Institutionalized persons
- ☐ Prisoners
- ☐ Non-English speaking persons
- ☐ Students
- ☐ Senior Citizens
- ☐ Employees

6.1. Recruitment Plan. What are the Inclusion Criteria for the study? Who will the subjects be? Where will they be recruited from and how? How is diversity and equity assured within the study group?

6.2. Students. If students are participants/subjects, explain here the steps you will take to prevent coercion?

7. Confidentiality and Privacy.

7.1. Confidentiality. Describe what identifiers will be collected on the participants. If participants will be identified, describe the procedures in place to protect their confidentiality.

7.2. Privacy. Explain provisions to protect privacy interests of participants. This refers to how investigators will contact participants and/or access private information from or about participants during and after their involvement in the research (e.g. time, place, etc. of research procedures).

8. Data Security Plan.

Explain where data will be stored, what measures protect the data, how access to data will be preserved for three years after the end of the study as required by law.

9. Consent

Describe the type of consent to be obtained

Informed Consent

- ☐ Written, and signed by participant
- ☐ Online, with identifier such as email address
- ☐ Online, consent by participation (implied consent)
- ☐ Parental consent
- ☐ Assent of a minor
- ☐ A Waiver of Informed Consent will be Requested (contact IRB Chair as a separate application is needed)

Attach a copy of the consent instrument you intend to use.

10. Exemption.

Certain types of study are exempt from Full Review. Check the Exemption Request category that applies. In order for a study to be exempt, at least ONE of the six categories listed below must apply. Please select the one that is appropriate and indicate why this category is justified based on the nature of the research. (NOTE: Use of prisoners as participants is prohibited under ALL exempt categories. Contact the IRB Chair for information involving the use of prisoners as participants).

☐ **Exempt Category 1:** Educational Exemption. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods .

Unless there are perceived adverse effects on the ability of students to learn or educators to instruct.

☐ **Exempt Category 2:** Surveys, Interviews, Educational Tests and Observational of Public Behavior. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures interview procedures, or observation of public behavior.

Note: This exemption does not apply to the following types of research; I) research involving children that includes surveys, in interviews, and observations of public behavior when the investigator is a participant in the activities being observed; and 2) research in which information is recorded in such a manner that participants can be identified and disclosure of the information could reasonably place the participants at risk. It also does not include studies with interventions, the collection of biospecimens, those where there is a link to additional personally-identifiable data or research with children (except for educational tests or some public observation, these do fall under this exemption).

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☐ **Exempt Category 3:** Benign Behavioral Interventions. Research involving the collection of data via an interaction (e.g. survey, interview, audio/visual recording) from adult subjects with prospective agreement. Note – this is not applicable to research with children, if there is deception (unless prior consent to this is obtained), studies where physiological data are collected (e.g. EEG, wearable devices, such as FitBit™, blood pressure monitors) and studies linking to personally-identifiable data.

☐ **Exempt Category 4:** Secondary Research (Identifiable private information/biospecimens). Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

This includes prospective data review, the maintenance of identifiers (if ALL study data is protected health information PHI), research that is conducted by, or no the behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities.

Note: All of the data or materials must exist prior to proposing the research.

☐ **Exempt Category 5:** Public Benefit/Service Program Research (Federal Demonstration Projects). Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or other wise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Note: In order to be eligible for this exemption, all of the following must apply:

- The research is conducted pursuant to specific federal statutory authority.
- The research has no statutory requirements for IRB review.
- The research involves no significant physical invasions or intrusions upon the privacy interests of the participant.
- The research has authorization or concurrence by the funding agency (if funded).

Note – the project must also be published on a federal website.

☐ **Exempt Category 6:** Taste/Food Quality Evaluation and Consumer Acceptance

Taste and food quality evaluation and consumer acceptance studies:

- if wholesome foods without additives are consumed; or
- if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the US Department of Agriculture(USDA).

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☐ **Exempt Category 7:** Storage/Maintenance of Identifiable Data/Biospecimens Obtained with 'Broad Consent'. Research that will store data and/or specimens in a repository, with identifiers maintained, that were collected under an approved IRB protocol with 'Broad Consent' for future secondary research use.

☐ **Exempt Category 8:** Use of Identifiable Data/Biospecimens Obtained with 'Broad Consent'. Secondary Research with the use/analysis of identifiable data/biospecimens that were collected under an approved IRB protocol with 'Broad Consent'.

Certain studies may be eligible for a Limited IRB Process in which only the IRB Chair or a designated expert reviewer provides review. Its purpose is to ensure privacy/confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data (exemptions 2, 3 and 8) and, for exemption 7, that "broad consent" was obtained and (if appropriate) documented according to an approved protocol. For exempt studies involving access to PHI (e.g., from medical records), the required Privacy Board review may be integrated with Limited IRB Review by the same assigned reviewer. Eligibility for this fast track review will be determined administratively after the Form II is received by the IRB.

11. Project Checklist and Investigator Signatures

Copy of PI ethics training certificate ☐
Copy of co-investigator(s) ethics training certificate(s) ☐
Copy of conflict of interest forms for all investigators ☐
Copy of survey/data gathering instrument(s) ☐
Copy of consent form or waiver of consent ☐

Note: if the research proposed is a Secondary Study, all of the documents pertaining to the approval of the primary study should be submitted too.

PRINCIPAL INVESTIGATOR: I will conduct the study identified above in the manner described on the attached narrative. If I decide to make any changes in the procedure, or if a participant is injured, or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to the CUH Institutional Review Board.

Name (s) Signature Date

CO-INVESTIGATORS (Including students). We agree to participate in the study as described (all must sign).

Name (s) Signature Date

FACULTY ADVISOR declaration: (If there is a student co-investigator the supervising faculty must sign this declaration): I have read and approve of this protocol. I believe this is research as defined by Department of Health and Human Services (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the student is competent to conduct the activity as described herein. I understand that I am responsible for all annual reporting, final reporting, data storage (for 3 years) and data security for this project.

Name Signature Date