Chaminade University IRB

FORM I: IRB Determination Form

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.

Investigators should complete sections 1-6 of this form. 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 to the Provost's Office: CT Ching Hall

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, if applicable):

Requested Project Start Date: **End Date:**

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. Provide a concise summary of the purpose and rationale of the activity (what is the question/hypothesis to be addressed).

4.2. Describe the proposed methods and study procedures

4.3. Describe how data collection will occur and the type of information to be collected about the subjects? Indicate whether data will be identified, de-identified or coded. If coded, explain whether the code will be accessible to the investigators. If this is a Secondary Study see question 4.4.

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:

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

Prior IRB Approval: Yes: ☐ No: ☐ Approval Date:
Approving Institution:

Please provide a copy of the approval letter with your application.

4.5. Do you intend to publish or present your results outside of a classroom?
Yes: ☐ No: ☐

5. Determination of whether the proposed work constitutes Human Subjects Research

5.1. Federal Definition of Research: check all that apply

A. ☐ The activity employs a systematic approach involving predetermined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.

B. ☐ The activity is intended to contribute to generalized knowledge by extending the results beyond a single individual or an internal unit (e.g. publications or presentations).

C. ☐ The investigator obtains specimens or data through intervention or interaction with a living individual (e.g. interviews, surveys, physical procedures, manipulations of the subject's environment, private or limited access internet sites, or any other direct contact or communication with a subject).

D. ☐ The investigator is obtaining identifiable private information about living individuals (e.g. chart reviews, lab studies on tissues or specimens, information from data or tissue repository).

E. ☐ The data or specimens are received by or provided to the investigator with identifiable private information

F. ☐ The data or specimens are coded and the investigator has access to a link that would allow the data or samples to be identified

5.1. Federal Definition of Research (continued): check all that apply

G. ☐ Your project is limited to analysis of de-identified publicly available data. The IRB recognizes that the analysis of de-identified, publicly available data does not constitute human subjects research as defined in federal regulations, and that it does not require IRB review but does require an action of the IRB to designate it as non-human subjects research. Some examples of data available from large data consolidation bureaus and consortiums are Inter-University Consortium for Political and Social Research (ICPSR), U.S. Bureau of the Census, National Center for Health Statistics, National Center for Education Statistics, National Election Studies.

H. ☐ Your project is limited to course-related activities designed specifically for educational or teaching purposes; where data is collected from and about human subjects as part of a class exercise or assignment and is not intended for use outside of the classroom.

I. ☐ Your classroom research involving collection or utilization of data on human subjects will meets all of the following conditions:

I (a) ☐ The research results are not conducted with the purpose of creating generalizable knowledge.

I (b) ☐ The course instructor has completed human subjects research ethics training.

I (c) ☐ The research does not involve vulnerable populations (children, prisoners, pregnant women, or handicapped or mentally disabled persons).

I (d) ☐ The research poses minimal risk to the participants, meaning 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

J. Scholarly and journalistic activities that focus directly on specific individuals about whom the information is collected (information not generalizable). However, if an interview of a single person is to be perceived as 'representative' of a population then this IS research.

J (a) ☐ Non generalizable journalistic activities

J (b) ☐ Generalizable journalistic activities

K. ☐ Subjects are not living (does not apply to secondary research on biospecimens or existing datasets, ask the IRB Chair for clarification if needed)

6. Project Submission Checklist

☐ 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.

7. Outcome of Determination (to be completed by the IRB Chair only)

*If 5A and 5B are checked and at least one of 5 C-F is checked then the project **DOES** CONSTITUTE Human Subjects Research.*

*If J (b) is checked then the project **DOES** CONSTITUTE Human Subjects Research.*

*If G, H or I, K (including all subcomponents of I) or J (a) are checked then your activity is in a category that the IRB has determined **DOES NOT** represent human subject research and no further submission of Form II or III is required. However, it is recommended you document this determination by placing a copy of this completed application in your files to address any future queries about the project. This form may still be submitted for an official determination by the IRB if required by the sponsor.*

IRB Chair Certification:

Based on the information provided this proposal:

DOES ☐ *constitute Human Subjects Research and the Investigator should submit Form II or III for further review of the protocol. Research cannot start until Form II or III is approved by the IRB.*

DOES NOT ☐ *constitute Human Subjects Research and the IRB will not review it further. However, if changes to the proposed research plan occur that makes the protocol IRB-reviewable, the Investigator is required to complete a new Form I and Forms II or III as required.*

Signed,

IRB Chairperson *Date*