Chaminade University Institutional Review Board (IRB)

Form III

Application for Non-Exempt Human Research

Updated: November, 2015

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1. DATE OF SUBMISSION:

2. PRIMARY INVESTIGATOR INFORMATION:

Name:
Department:
Email:
Position in University (if student, must indicate faculty sponsor):
Faculty Sponsor Name:
Faculty Sponsor Email:

3. PROJECT TITLE:

4. PROJECT TIME FRAME – Anticipated beginning and ending dates of Research Project:

Start Date: End Date:

5. PROJECT EVALUATION - Please **Check** ALL of the following that apply.

Target Populations Include:

- ☐ Children 0-18 (Parental Consent required)
- ☐ Developmentally or physically disabled
- ☐ Elderly
- ☐ Persons convicted of a crime
- ☐ Persons in treatment for mental or emotional ailment
- ☐ Persons over the age of 18 ONLY
- ☐ Prisoners or persons on parole
- ☐ CUH employees
- ☐ CUH students
- ☐ College Students (non-CUH)
- ☐ Victims of crime

Site of Data Collection:

- ☐ Health care facility
- ☐ Military or government-operated installation
- ☐ CUH campus
- ☐ Other – Specify:_____

Type of Data Collected/Method of Storage:

- ☐ Data will be collected anonymously
- ☐ Data will be stored anonymously
- ☐ Data will be stored with participant's identity
- ☐ Photographs will be taken (must be noted in consent document!)
- ☐ Audio- or Video-recordings will be made (must be noted in consent document!)
- ☐ Data will be linked to participants through code numbers or pseudonyms
- ☐ Deception will be used
- ☐ Medical records (HIPAA releases and HIPAA Training may be required)

Instrument/Method of Data Collection:

- ☐ Interviews or Focus groups
- ☐ Surveys or questionnaires
- ☐ Cognitive Performance Tests
- ☐ Physical Performance/Endurance

Tests

- ☐ Psychological tests
- ☐ Use of physiological devices

Reason for Research:

- ☐ Faculty/Staff research
- ☐ Undergraduate research
- ☐ Graduate research
- ☐ Other reason for research (specify): _____

Does Your Research Involve Any of the Following Topics?

- ☐ Alcohol or Drug use
- ☐ Emotional stress
- ☐ Illegal activities
- ☐ Gambling
- ☐ Law enforcement
- ☐ Sexual habits or Sexual orientation

6. **PROJECT STAFF:** *Please list personnel, including students, who will be working on this protocol (insert additional rows as needed). This includes anyone who interacts with participants or handles non-anonymous data. All personnel conducting non-exempt research must have completed CITI Program Training in Human Research Protections within the past three years.*

Name, Title & Degree	**Role** (*Specify whether person is authorized to obtain consent*)	**Date of CITI Training** (Attach certificates)

7. **SITE INFORMATION:** *Where will data be collected? NOTE: Documentation of site approval is required for all off-campus data collection.*

Data Collection Location(s):

Are Multiple IRBs reviewing? If so, which has major oversight?

8. **RESEARCH ABSTRACT:** *Please provide a brief description in LAY language of the aims of this project, using the following headings: Background and Purpose, Participants, Methods. (Limit to 250 words)*

9. **PURPOSE STATEMENT/RESEARCH QUESTION(s):** *What purpose does the research serve?*

What question do you hope to answer with your research? Include hypotheses, if possible. (Please limit to 1-2 sentences)

10. BRIEF REVIEW OF THE LITERATURE THAT PROVIDES SUPPORT FOR YOUR RESEARCH QUESTION(S): *List references at end of application (section 21). (Please limit to 500 words.)*

11. STUDY POPULATION, RECRUITMENT/SCREENING PROCEDURES: *Attach electronic copies of advertisements/brochures used for recruitment.*

Study Population:

Screening and Recruitment:

Sample Size Estimation Procedure (if applicable):

Total number of Participants:

Age range of Participants:

Inclusion Criteria:

Exclusion Criteria:

12. PROCEDURES AND METHODS INCLUDING REFERENCES, as appropriate*: *This is the most important part of your application! *For each subsection below, please provide references that provide support for your methodology. If the methods are novel, please address the rationale and justify your use of the methods and include references to the extent possible. List references at end of application (section 21). Describe in detail all procedures, and include electronic copies of all surveys and outcome measures used. Include here all tests, measurements, equipment, interventions, manipulations, etc. used in data collection. You must also include all data collection sheets to be used in the research. Use as much space as required to provide a* ***complete description*** *of the procedures proposed.*

Study Design and Procedures:

Outcome Measures - Surveys, Questionnaires, Physical or Cognitive Performance Measures (*include copies of forms as PDF attachments with your application*):

Materials, Instruments and Equipment:

13. RISKS AND BENEFITS*: NOTE: If there are 3 or more risks identified, the researcher should present the risks in a TABLE, along with the steps taken to minimize/mitigate each risk. Cite prior*

studies in the literature, if possible.

Potential Risks *(All risks should be listed in the consent document!):*

Steps Taken to Minimize Risk:

Potential Benefits:

Use of Deception, if applicable: *Will the participants be deceived in any way? Please explain why deception is necessary and justify its use. Fully describe the nature of any deception either by actively misleading or lying to the participant, or through the omission of pertinent information. Investigators cannot deceive participants about significant aspects of the study that would affect their willingness to participate, such as physical risks, etc. When participants are deceived, they must be offered the opportunity to withdraw their data from the study during the debriefing.*

Emergency procedures, if applicable *(must address if research is greater than minimal risk):*

14. DATA:

Data Analysis and Reporting:

Data Management, Storage and Destruction:

15. CONFIDENTIALITY: *How will participant identity and confidentiality be protected? Will participants be audiotaped, photographed or videotaped during this study? (This must be mentioned in consent document!) How long will identifiable data be kept?*

16. ATTACHMENTS/APPENDICES. These must be attached as a PDF to the Form III application packet.

- ☐ Documentation of Training in Human Research Protections (i.e. CITI or PHRP training).
- ☐ Consent forms.
- ☐ Child assent forms (if applicable).
- ☐ If you will be accessing or gathering personal health information, include HIPAA authorization form
- ☐ Data collection forms to be used in this research, if applicable.
- ☐ Advertisements used to recruit participants (e-mail, brochure, fliers, etc.)
- ☐ Surveys or questionnaires to be used in this research, if applicable.

17. OTHER APPROVALS - Submit ALL that apply with application.

- ☐ Has this protocol been submitted to any other IRBs? If so, please submit all the associated documentation with your application.

- ☐ If you will be collecting data OFF-CAMPUS, you must provide documentation of approval by

an administrator at that site (e.g., school principal, clinic director). This must be attached as a PDF to the Form III application packet.

☐ If you are a STUDENT, your faculty advisor (1) read your IRB application, and (2) approves the research as proposed. Your FACULTY ADVISOR must sign to this effect in Section 22 below.

18. IS THIS PROJECT EXTERNALLY FUNDED? *(If so, please list the funding source, award number, award period, award title)*

19. COMPENSATION: *Will participants be compensated for participation? If so, please include details. Please review the IRB Guidance on Tax Implications of Research Incentives. Describe in detail how compensation will be administered. Describe how recordkeeping will be handled. What is the source of the funds?*

20. DISCLOSURE OF FINANCIAL INTERESTS:

21. REFERENCES (*list references used in your application here*)

22. SIGNATURES.

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.

Signature. Printed Name Date

FACULTY ADVISOR (IF THE INVESTIGATOR IS A STUDENT, A FACULTY ADVISOR MUST SIGN BELOW): 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.

Signature. Printed Name Date

SAVE THIS FORM AS A PDF AND SEND TO IRB@CHAMINADE.EDU and

hturner@chaminade.edu