Chaminade University Institutional Review Board

Form IV

HUMAN SUBJECTS ANNUAL REPORT/FINAL REPORT FORM

DATE: (Current Date)

TO: (Name of Faculty Member)

FROM: Chair, CUH IRB

Protocol Number: (CUH IRB Assigned Number)

RE: **IRB PROTOCOL ANNUAL REPORT DUE BY** (Annual Report Due)

TITLE:

DATE OF IRB APPROVAL (Anniversary Date): (Approved Date)

According to Title 45 CFR 46.109(e), the above titled human subjects protocol is due for an 'annual' or 'final' review by the Chaminade University Protection of Human Subjects Committee (IRB). To avoid automatic termination of your protocol, please submit this completed form 2 weeks prior to the above listed anniversary date. The DHHS guidelines specifically state that all human subjects protocols that are reviewed by the IRB are approved for a maximum period of three years and shall be continually reviewed during this period by the IRB for intervals not less than once per year. The following reporting procedures have been established.

1) Prior to the anniversary date, an "Annual Report" is due to the IRB each year during the 3-year approval period.

2) If your protocol will end prior to the end of the 1-year approval period or at the end of the 3-year approval period, a "Final Report" is due to the IRB by the anniversary date.

3) If your protocol is approaching the end of the 1-year approval period and you wish to continue your protocol beyond the 1-year approval period, a new IRB FORM #I, II or III (Human Subjects Application) must be submitted for a new IRB review. Along with the submission of the new IRB Form I, II or III, a "Final Report" form must also be submitted for the initial 3-year approval period.

4) The initial 1-year protocol approval will be terminated if a new IRB Form I, II or III is not received and approved by the IRB by the anniversary date of the initial 1-year protocol approval.

Chaminade University Institutional Review Board

Form IV

HUMAN SUBJECTS ANNUAL REPORT/FINAL REPORT FORM

INVESTIGATOR REPORTING:

I. Check One: _____ **Annual Report** _____ **Final Report**

II. I am _____Faculty PI reporting on my own study
_____Faculty PI reporting on a student supervisee or adjunct faculty study

III. Check the statement or statements that apply to your protocol:

_____ I hereby certify that I have utilized humans in my research in accordance with the content of my protocol identified above.

_____ I have not begun data collection. I hereby certify that I will utilize humans in my research in accordance with the content of my protocol identified above.

_____ I have modified my protocol and request that the IRB re-approve my protocol with the attached modifications: (Use a separate sheet and describe modifications, including, but not limited to change in applicant name, change in project title, changes in protocol, changes in population, changes in procedures, changes in consent form, etc.). Please note that substantive changes, such as a change in category (i.e. from exempt to expedited or expedited to full review) will require submission of a new protocol and should be reported immediately, and prior to any research under the modified protocol commencing.

_____ I have completed my research on this Protocol as of (date)_____.

_____ No longer enrolling subjects but continue to monitor current subjects

IV. I expect this protocol to continue until (date, if applicable)_____

V. Were signed consent forms obtained? _____.
Are the consent forms in a secured locked location? _____.
Where are the consent forms located? _____.

Chaminade University Institutional Review Board

Form IV

HUMAN SUBJECTS ANNUAL REPORT/FINAL REPORT FORM

VI. Please attach a typed description of any problems or adverse events you have encountered working with human subjects and what measures you took to minimize risk.

If you have encountered no problems or adverse events, please indicate below.

_____ I certify that I have encountered no problems in my work with human subjects.

VII. Data Storage. Please describe where data is stored, how its security is maintained and how access to it will be maintained for the required 3 year period after the study end date.

.

I certify that I have been truthful and accurate in completing this form and that I will continue to abide by University policies and procedures regarding the use of human subjects in research. I understand any future use of data collected must comply with CUH IRB Charter.

Signature of Principal Investigator **Date**