

FINAL STUDY REPORT/STUDY CLOSURE FORM

*Do not complete this form until all activities involving human subjects (including data analysis with individually identifiable or coded private information) have been concluded. Clearly type all portions of this form.*

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| STUDY TITLE | IRB PROTOCOL NUMBER | | EXPIRATION DATE OF STUDY APPROVAL |
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| Is this a multisite/multicenter study? Yes No  If yes, please identify the other sites/centers: | | | |
| I. PRINCIPAL INVESTIGATOR (PI) | | | |
| Principal Investigator (PI) (Last name, First name, MI, highest degree earned) | | FSU Faculty  FSU Staff  FSU Student  not affiliated with FSU | |
| Academic Title(s) | | Other: | |
| Department or Administrative Office or Institute/Center: | | Telephone number:  Fax number: | |
| Mailing address: | | Cell phone number:  Email address: | |
| Additional contact (e.g., study coordinator)  Name: | | Email address:  Telephone number:  Fax number: | |
| II. SPONSOR INFORMATION | | | |
| Government/Foundation  Government agency/Foundation name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| Corporation/Industry  Company/Industry name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| Internal/University funding | | | |
| Other sources  Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |

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| III. STUDY STATUS (Check all that apply.) |
| Study was never initiated/no study participants were ever enrolled/study was never funded. IF THIS OPTION IS SELECTED, PLEASE SKIP TO SECTION IX. AFTER SPECIFYING WHY THIS STUDY WAS NOT INITIATED.  Reason(s) why study not initiated: |
| Study has been discontinued/no further data collection (including long-term follow-up or re-contact with participants) or  analysis of identifiable/coded data. |
| Sponsor is discontinuing the study. |
| Principal Investigator and/or Co-Investigator leaving the University. |
| Study is completed. All enrollment, treatment, follow-up and data analysis are completed. |
| Jurisdiction transferred to another IRB. (Please answer the questions below. If any are not applicable, please put N/A in  the appropriate space.)  To whom?  Why?  Was prior IRB approval obtained? Yes No  What precautions were taken to protect the interests of the participants who were enrolled in the study at the time of  transfer?  Was the research data process completed? Yes No |
| IV. STUDY PROGRESS |
| Summarize the results of the study, including any plans for scholarly/scientific presentations or publications: |
| Summarize any IRB-approved amendments or changes made to the study since the last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation: |
| Discuss whether any significant new findings or other information should be provided to past participants: |
| V. PARTICIPANT ENROLLMENT/CHARTS/RECORDS/SPECIMENS ANALYSIS INFORMATION |
| Complete the following for the study approved by the FSU IRB:  (*The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all did not complete the study.)*   1. The maximum number of participants approved by the IRB \_\_\_\_\_\_\_\_\_\_\_\_ 2. Total number of participants actually enrolled in the study \_\_\_\_\_\_\_\_\_\_\_\_ 3. Number of participants enrolled since last IRB review (ongoing or continuing) \_\_\_\_\_\_\_\_\_\_\_\_ 4. If the total number of participants enrolled (b) differs from the maximum number of participants approved by the IRB (a), please explain: 5. The number of individuals screened (those who signed consent, including screen failures) \_\_\_\_\_\_\_\_\_\_\_\_ 6. The total number who actually completed the study \_\_\_\_\_\_\_\_\_\_\_\_ 7. The total number of dropped/withdrawn from the study \_\_\_\_\_\_\_\_\_\_\_\_   Due to adverse events \_\_\_\_\_\_\_\_\_\_\_\_  Other reasons (please specify) \_\_\_\_\_\_\_\_\_\_\_\_  (Total of f + g = b.) |
| VI. CHARTS AND SPECIMENS |
| Number of specimens and/or charts approved by the IRB \_\_\_\_\_\_\_\_\_\_\_\_  Did you review medical records, participant charts/records, or other pertinent information for the study?  Yes No If yes, # records reviewed: \_\_\_\_\_\_\_\_  Did you analyze specimens for this study?  Yes No If yes, # specimens analyzed: \_\_\_\_\_\_\_\_ |

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| VII. DEMOGRAPHIC INFORMATION |
| Did you collect demographic information during the conduct of this study? Yes No  If yes, please complete the table below. Provide a demographic breakdown of participants enrolled to date (totals should equal Item V.b. above).   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Adult | White/non-Hispanic | White/Hispanic | Black/non-Hispanic | Black/Hispanic | Asian/Pacific Islander | American Indian/Alaska Native | Other/Unknown | Total | | Male |  |  |  |  |  |  |  |  | | Female |  |  |  |  |  |  |  |  | | Total |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Children | White/non-Hispanic | White/Hispanic | Black/non-Hispanic | Black/Hispanic | Asian/Pacific Islander | American Indian/Alaska Native | Other/Unknown | Total | | Male |  |  |  |  |  |  |  |  | | Female |  |  |  |  |  |  |  |  | | Total |  |  |  |  |  |  |  |  | |
| VIII. PARTICIPANT COMPLAINTS AND VOLUNTARY WITHDRAWALS |
| Did any participants make complaints about the research? Yes No  If yes, list and describe each complaint and any actions taken to resolve the complaint(s): |
| Did any participants voluntarily withdraw from the research? Yes No  (Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.)  If yes, list and describe each withdrawal and any actions taken (e.g., changes to the research or consent process) in response to the withdrawal(s): |

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| IX. DATA MANAGEMENT/RECORD RETENTION | |
| FSU IRB policy requires research record retention for a period of at least five (5) years from the date of closure. Please confirm that your research data will be maintained for the required duration by initialing here: \_\_\_\_\_\_\_\_  Please provide the location where you will store your research data.  Who will have access to the identifiers collected for this research study?   |  |  | | --- | --- | | NAME OF INDIVIDUAL | DATE WHEN INDIVIDUAL COMPLETED HUMAN SUBJECTS PROTECTIONS TRAINING | |  |  | |  |  | |  |  | |  |  | |  |  |   Who is your data steward? (This is the person responsible for data management, entry, statistical analysis, etc. and should be a member of study personnel.) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please describe your plan to ensure that information about subjects and/or identifiers will not be improperly discussed.  Do you have up-to-date software (i.e., virus protection) to assume integrity and security of your data? Yes No  Is your computer password protected? Yes No | |
| X. SAFETY MONITORING | |
| Since the last IRB review (initial or continuing), did any unanticipated problems (adverse events and other problems) involving risks to subjects or others occur in the study approved by the FSU IRB?  If yes, have you completed and submitted a report for IRB review?  If no, please complete that report and submit it along with this closure report. | Yes No  Yes No |
| XI. PRINCIPAL INVESTIGATOR’S ASSURANCES | |
| I have followed all applicable policies and practices of Framingham State University, and federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:   * The research was performed as approved by the FSU IRB under the direction of the Principal Investigator by appropriately trained and qualified personnel; * Unanticipated problems were promptly reported to the IRB, as well an any other information necessary for appropriate oversight of the research; * Research-related records (and source documents) will be maintained in a manner that documents the validity of the study and the integrity of the data collected, while protecting the confidentiality of the data and privacy of subjects; * Study-related records will be retained and available for audit for a period of at least five years after the study ended (or longer, according to sponsor or publication requirements) even if I am no longer associated with the University; * IRB approval or exemption will be obtained before initiating any new research activities involving human subjects; and * All co-investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.   I verify that the information provided in this Final Study Report is accurate and complete.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Date | |