

STATUS REPORT FOR REQUEST FOR EXTENSION / CONTINUING REVIEW

*Complete this form to request an extension for previously approved IRB research. 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 PROGRESS |
| Summarize the current status 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: |
| Provide a justification for the request for extension. Please indicate why additional time is needed and the benefits of an extension: |
| IV. 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.) |
| V. 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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| VI. 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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| VII. 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 status report. | • Yes • No  • Yes • No |
| VIII. 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 to date has been 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 three (3) 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 Status Report is accurate and complete.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Date | |