Application for Continuing Review

Syracuse VA Institutional Review Board

(Syracuse , Canandaigua & Bath VAMC)

**Name of Project:**

**MIRB#**

**PI Name:**

**VA Facility Name:**

**Date:**

**Scheduled IRB Continuing Review Date:**

**Application Instructions**

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| * The Principal Investigator (PI) must complete this form and submit it to the VA IRB by the above Application Due date. * The PI must also submit the following documents with the continuing review application as applicable: * Continuing Review Application * Protocol Abstract * Copy of the current VA approved model informed consent document * Copy of the current approved model HIPAA authorization * Copy of Informed Consent or Regulatory Audit(s) conducted by RCO or equivalent   any other reports from oversight agencies since last continuing review application at PI’s VA Facility   * Subject tracking log |

**Contents of Application Package**

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| **Please check all documents included in this package:**  Application for Continuing Review: Principal Investigator  Continuing Review Application  Protocol Abstract  Current VA IRB-approved Model Informed Consent Document (VA Form 10-1086)  Current approved Model HIPAA authorization  Copy of Informed Consent Audit(s) or Regulatory Audit(s) Conducted at PI’s VA Facility  or any other report from an oversight agency.  If enrollment is still open, please submit a clean copy of the informed consent document for re-approval.  **Please include below a list of any other documents included as part of the continuing review application. If the documents have been modified from currently approved documents (e.g., informed consent document), please use the Microsoft Word track changes function to indicate modifications. Submit both tracked and untracked versions of the documents if changes were made.**  VA Form: Request to Amend or Modify an Approved Project  VA Form: Report of Serious Adverse Events and Unanticipated Problems  Other:  Other:  Other:  Other:  Other:  Other: |

**I. Project Identification**

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| 1. Title of Project |  |
| 1. VA IRB Project # |  |
| 1. Principal Investigator (PI) | Name:       Phone:  E-mail: |
| 1. PI VA Medical Facility |  |
| 1. Project Coordinator | Name:       Phone:  E-mail: |

**II. Project Team Members**

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| ***Please list all local site project team members currently working on this project and indicate personnel added since the last review and approval by the VA IRB. Include CVs or biosketches, Scopes of Work, and COI for new personnel as applicable. Check the applicable boxes if training is current for personnel listed and if COI or Scopes of Work has changed for any personnel. If COI has recently changed, a new COI determination must be attached if not previously reported. If Scope of Work has recently changed, a new Scope of Work must be attached if not previously reported.***  ***Note: Additional project members may be added by inserting more rows in the table.*** | | | | | |
| **Name** | **Project Role** | **Check if added since last review** | **Check if all training is current** | **Check if any change in COI** | **Obtains Consent** |
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**III. Current Project Status**

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| **The PI/SC *must* check one of the following:** | |
|  | 1. Enrollment has not started. |
|  | 1. Open to enrollment; no participants enrolled. |
|  | 1. Open to enrollment; participants enrolled. |
|  | 1. Active and open to enrollment; participants are undergoing interventions per approved project. |
|  | 1. Closed to enrollment; participants continue to undergo interventions per approved project.   **Date Closed to Enrollment:** |
|  | 1. Closed to enrollment; participants are in follow-up (e.g. survival) only or ongoing data analysis of private identifiable information.   **Date Closed to Enrollment**: |
|  | 1. Other (Chart Reviews etc.): |
| Check this block if you are requesting **expedited VA IRB review** for this continuing review application. | |

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| **Note: If this is the first continuing review application, please complete any question in the remaining sections requesting information “since the last continuing review application” with information since the project was initially approved by the VA IRB.** |

**IV.** **Participant Enrollment Summary**

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| **Check if your project utilizes records or specimens versus human participants**. ***When the application asks for the number of subjects, document the number of records or specimens that have been reviewed or collected.*** | |
| 1. Total Number of Participants Approved for this Project |  |
| 2. Total Number of Participants Enrolled Since the Last Annual Review |  |
| 3. Total Number of Participants Enrolled |  |
| 4: Demographics*:*  *Did you collect demographic information during the conduct of this study?*  *No.*  *Yes. Complete the table below.*  The categories in the table below are based on *DHHS Guidance;* please visit<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf> | |
| |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Participant Breakdown: | White/ Non-Hispanic | White/ Hispanic | Black/ African American Non-Hispanic | Black/ African American Hispanic | Asian | Native Hawaiian or Other Pacific Islander | American Indian or Alaskan Native | Other  or  Unknown | | Male |  |  |  |  |  |  |  |  | | | Female |  |  |  |  |  |  |  |  | | | |

**V. Participant Recruitment Issues and Complaints**

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| 1. Have there been any systemic difficulties in the recruitment of participants since the last continuing review application?   No  Yes. If yes, please explain any recruitment difficulties that were or are currently being  experienced:   1. Have you received any complaints from participants or others since the last continuing review application not addressed by local investigators?   No  Yes. If yes, please explain and address whether the complaint(s) was resolved:   1. Are you requesting any changes in the groups of individuals (e.g., vulnerable populations) recruited into the project with this continuing review application?   No  Yes. Please explain. |

**VI. Informed Consent and HIPAA Authorization**

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| Are you requesting any changes in the informed consent process or documentation or HIPAA authorization?  No  Yes. If yes, please attach a VA Form: Request to Amend or Modify Approved  Project, with this continuing review application. |

**VII. Data Safety Monitoring and Risk/Benefit Assessment**

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| ***Please answer the following questions concerning adverse events, unanticipated problems, and complaints that have occurred since the last review of the project by the VA IRB. Do not duplicate reports previously submitted by local site investigators.*** |
| 1. Does this project have a Data Safety and Monitoring Board (DSMB)?   No  Yes  If Yes, are there any reports or interim findings generated by the DSMB?  No  Yes. **If yes, please attach a copy of the most recent report or interim findings. If a copy of the charter was not previously submitted, please include with this continuing review application.**   1. Have all unanticipated problems and serious or unexpected adverse events been reported to the VA IRB since the last continuing review application?   No. **If no, please attach VA IRB: Report of Serious Adverse Events and**  **Unanticipated Problems, with this continuing review**  **application for each separate unanticipated problem or serious adverse event.**  Yes     1. Since the last continuing review application, have there been any unanticipated problems involving risks to subjects or others?   No  Yes. If yes, please summarize:   1. Since the last continuing review application, has the profile of adverse events (in terms of frequency, severity, or specificity) changed from previous experience or from protocol expectation?   No  Yes. If yes, please explain:   1. Since the last continuing review application, has any new information affected the reasonableness of the risks associated with the research in relation to the anticipated benefits, and/or affected the wiliness of the participants to enroll, or to continue in the research?   No  Yes. If yes, please explain:   1. Has the risk-potential benefits ratio changed compared to when the project was last approved by the VA IRB?   No  Yes. If yes, please explain:   1. Has the Data Security PI Certification Form changed from original approval   No  Yes. **If yes, please provide revised Data Security Checklist for PIs:**  8. Any services provided by the clinical lab, pharmacy and/or nursing staff are within their normal duties and have not changed over the past year of approval.  No  Yes. If yes, please explain: |

**VIII. Abstract**

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| Include an updated 1-5 page (do not exceed 5 pages) abstract containing the following content (as applicable). Please attach a separate word document.   * Purpose * Research question * Study aim or Hypotheses * Methods (eligibility criteria, interventions or interactions, evaluations, follow-up) * Data Safety Monitoring Plan * Data Analysis * Progress since last approval |

**IX. Additional Information**

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| 1. Since the last continuing review application, were all amendments to the protocol submitted to the VA IRB for approval? (Please consult your protocol history as provided)   Yes.  No. If no, please describe the protocol change requested:   1. Are there any significant preliminary observations/interim findings during the last approval period? (Do not duplicate information in a DSMB report if submitted with this continuing review application.)   No significant preliminary observations or interim findings at this time  Yes. Briefly describe the observations or findings below:         1. Has there been any recent (within the last year) literature from peer reviewed publications (if they exist) relevant to your research project?   No  Yes. Please summarize below and describe their relevance to your project.     1. Please provide any additional information specific to this project not addressed in the above sections and/or supplementing the continuing review application (e.g. presentations or publications). |

**XI. Principal Investigator Certification/Assurance**

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| ***The Principal Investigator must check each box and sign and date the form.*** | |
|  | 1. I have completed this continuing review application and included any applicable supplemental documents. |
|  | 1. I have submitted continuing review applications from participating local site investigators and maintained a copy of the continuing review application forms and supplemental documents in my research records. |
|  | 1. I and my project team, to include any additional team members added in Section II of this Application, have no conflicts of interest in regard to the conduct of this project or, if a conflict has arisen, the conflict has been reviewed by this site and a copy of the determination is attached. |
|  | 1. All members of the project team, to include any additional team members added in Section II of this Application, are appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice. |
|  | 1. I understand it is my responsibility to submit all project changes to the VA IRB for approval prior to initiating such change, except when necessary to eliminate apparent immediate hazard to the participant. |
|  | 1. I understand that if continuing review approval has not been completed prior to the VA IRB expiration date, I must stop all research activities, including data analysis. If I have participants currently enrolled receiving interventions or interactions, I must immediately submit a list of names to the VA IRB Chair who will determine, in consultation with the Chief of Staff at participating facilities, whether participants may continue receiving the research interventions and interactions. |
|  | 1. I certify that all subjects entered onto the master list of subjects for the study signed the consent document prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver of the consent process or a waiver of the requirement for a signed consent document. |
| By signing below, I attest that the project continues to be scientifically and ethically sound. I and my project team have the competencies and resources to continue to conduct the research described in this continuing review application. I and my study team will continue to meet the ethical standards for research involving human participants and will comply with requirements for VA IRB approval of this project.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator Signature Date | |