Application for Continuing Review: Principal Investigator/Study Chairs

***This form is to be used to request continuing approval from the VA Central IRB for the PI/SC approved main study application. To request study closure, do not use this form. Instead, submit VA Central IRB Form 117a Project Closure Report.***

**Application Instructions**

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| * The Principal Investigator/Study Chair (PI/SC) must complete this form and submit it to the VA Central IRB by the deadline established by the VA Central IRB as stated in the Continuing Review Email notifications
* The PI/SC must also include in the application and/or submit the following documents with the Continuing Review application as applicable:
* Each section of the PI/SC application must contain a response. For each study team member serving in an investigator role, indicate whether there has been any change in the investigator’s conflict of interest status from the previous year or initial approval of the study.
* Continuing Review Applications from all participating Local Sites (VA Central IRB Forms 115b)
* Abstract with all required elements as instructed in Section VII
* VA Central IRB-approved Protocol
* Copy of the VA Central IRB currently approved model informed consent document that must include current VA Central IRB approval date. A PDF is acceptable.
* Current approved Consent waiver
* Current approved HIPAA Waiver
* Copy of VA Central IRB Determination or Acknowledgement from review of Informed Consent, Regulatory Audit(s), or any other reports from oversight agencies conducted by local RCO or equivalent since last Continuing Review application. If audit was not previously submitted and reviewed by the VA Central IRB, please submit the audit with this continuing review report.
* Upon completion of the entire application package, the documents must be uploaded to the secure VA Central IRB SharePoint site under the “Initial Submissions/Continuing Review Submissions” folder/subfolder. Other documents submitted with this application as checked below must also be submitted.
* File names should be kept short, but should include the study number and, type of document (e.g., 08-01 Model Consent).
* An amendment should not be submitted with this application unless it has a direct bearing on the review and approval of this application. Otherwise, submit all amendments separately.
* Please contact the assigned VA Central IRB Staff members listed in your initial notification of the continuing review requirement if you have any further questions or call the VA Central IRB toll free line at 1-877-254-3130.
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***Please remove/delete this instruction page prior to submitting your completed file to the Study PI/SC.***

Application for Continuing Review: Principal Investigator/Study Chair

**I. Project Identification**

|  |  |
| --- | --- |
| 1. Title of Project
 |  |
| 1. VA Central IRB Study Number
 |  |
| 1. Principal /Co-Principal Investigator/Study Chair (PI/SC)

*If more than two Co-PIs, add additional rows.* | PI Name:       Phone:      VA E-mail:        Co-PI Name:       Phone:      VA E-mail:        |
| 1. PI/SC VA Medical Facility Name with Location
 | Name:Location (City): |
| 1. Project Coordinator(s)

*If more than two Project Coordinators, add additional rows.* | Name:       Phone:      E-mail:        Name:       Phone:      E-mail:        |

**II. Project Team Members**

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| ***Please list all PI/SC project team members currently working on this project and those being added with this report. Additional rows may be inserted into the table as needed. Investigators can’t be added with this report; a separate amendment request (VA Central IRB Form 116) must be submitted.*** |
| **Name** | **Project Role** | **Obtaining informed consent?** **Y/N** | **Date of Current Human Subjects Protection Training** | **Staff added and approved by the IRB since last Continuing Review**  | **Staff being added with this Continuing Review report** | **Confirm** **Scope of Practice on file/ Staff Credentialed & Privileged** |
|  |  |  |  | **[ ]**  | [ ]  | **[ ]**  |
|  |  |  |  | **[ ]**  | [ ]  | **[ ]**  |
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|  |  |  |  | **[ ]**  | **[ ]**  | **[ ]**  |
| ***All personnel serving in an investigator role are required to indicate whether there has been any change in their conflict of interest status since initial approval or the last continuing review. Please indicate for each investigator if there has been a change below.*** |
| **Name of Investigator** | **Indicate if a change in Conflict of Interest Status** | ***Note: For any investigator for which there has been a change, a VA OGE Form 450 must also be submitted, as well as a copy of the OGE review and any agreed upon resolution with the site and/or OGE regarding any new conflicts. If there was a conflict and now there is not one, only the form needs to be submitted.*** |
|  | [ ]  Yes [ ]  No |  |
|  | [ ]  Yes [ ]  No |  |
|  | [ ]  Yes [ ]  No |  |
|  | [ ]  Yes [ ]  No |  |
|  | [ ]  Yes [ ]  No |  |
| ***Please list all personnel who have left the project since the last Continuing Review. Additional rows may be added as needed.*** |
| **Name of Departed Staff Member** | **Role on Study Team** | **Date Departed** |
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**III. Current Project Status**

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| **The PI/SC *must* check one of the following to indicate the overall status of the study:** |
| **[ ]**  | 1. Study not yet open to enrollment
 |
| **[ ]**  | 1. Open to enrollment; no participants enrolled.
 |
| **[ ]**  | 1. Active and open to enrollment; participants are undergoing interventions per approved project.
 |
| **[ ]**  | 1. Closed to enrollment at all sites; participants continue to undergo interventions per protocol.

 **Date Closed to Enrollment:**       |
| **[ ]**  | 1. Closed to enrollment at all sites; participants are in follow-up only and data being accessed is only from interventions as part of regular clinical care

**Date Participant Intervention Ended**:      |
| **[ ]**  | 1. No further patient interventions or follow-up at any sites; data analysis of private identifiable information only ongoing.

**Date Follow-up Ended**:       |
| **[ ]**  | 1. Study is a data analysis only study; there are no interventions and data analysis is ongoing
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**IV. Participant Recruitment Issues and Complaints**

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| ***For the below questions, do not include any issues reported in the Local Site Application pertaining to study-specific issues. Only include if the issue affected the overall study.*** |
| 1. Provide the total number of participants that have been approved for each of the following:
2. Total Number of Participants initially approved for this project:
3. Total Number of Additional participants approved via amendments:
4. Total Number of Participants currently approved for this project:
5. Total Number of Records approved to screen for eligibility:
6. Have there been any systemic difficulties in the recruitment of participants since initial approval or since the last Continuing Review application that may delay study completion?

 **[ ]** No. [ ]  Yes. If yes, please explain below any recruitment difficulties that were or are currently being  experienced:  1. Have you received any complaints from participants or others since initial approval or the last Continuing Review application that have not already been reviewed by the VA Central IRB?

 **[ ]** No [ ]  Yes. Please describe below the complaint(s), indicate its status, and explain why it was not reported  to the VA Central IRB. 1. What is the current estimated completion date for this study?
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**V Abstract**

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| ***Please attach an abstract as a separate PDF document. Abstract must be updated each year with current information. Do not exceed 5 pages.***  |
|  Submit an abstract containing all the following headings and information except where indicated:  * **Purpose**: as stated in approved protocol
* **Methods**: short description of eligibility criteria, interventions/interactions, evaluations, etc.
* **Progress**: briefly describe the progress of the research and highlight all progress, if any, that

has been made since the last continuing review.. * **Observations/Interim Findings**: briefly describe any significant preliminary observations/interim findings since initial approval or the last report. Do not duplicate information in a DSMB report if submitted with this Continuing Review application.

 * **Recent Literature**: summarize any recent (within the last year) literature from peer reviewed publications relevant to your research project
* **Additional Information** ***(Optional):*** provide any additional information specific to this project not addressed in the Continuing Review application (e.g., presentations or publications).
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**VI 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 Central IRB. Do not duplicate reports previously submitted by local site investigators.*** |
| 1. Does this project have a Data Safety and Monitoring Board (DSMB)?

 [ ]  No. Skip to question 2.[ ]  Yes. Indicate the date of the last meeting and attach summary results. If results are not yet  available, or have already been provided, indicate below.  Date of last DMC/DSMB meeting:   Date provided report to VA Central IRB:  1. Have all unanticipated, serious, and related or probably related adverse events and any unanticipated problems involving risks to subjects or others since the last Continuing Review been reported to the VA Central IRB?

[ ]  No. If no, **immediately** submit a VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Serious Unanticipated Problem (UAP) Involving Risks to Participants or Others for each separate SAE or UAP.  [ ]  Yes.  [ ]  N/A There have been NO events or problems since last Continuing Review ***PLEASE NOTE:*** *The PI/SC should not duplicate reporting of unanticipated serious adverse events serious unanticipated problems involving risks to participants or others if the reportable event or problem was previously reported to the VA Central IRB by the Local Site Investigator and no additional information needs to be conveyed.* 1. Since the last Continuing Review application, have there been any other adverse events occurring that have NOT already been reported to the VA Central IRB?

[ ]  No. [ ]  Yes. If yes, give overall total and summarize the events or problem types below or attach a separate summary report or table. 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 expectations?

 [ ]  No. [ ]  Yes. Explain below: 1. Since the last Continuing Review application, has any new information affected the reasonableness of the risk associated with the research in relation to the anticipated benefit, and/or affected the willingness of the participants to enroll, or to continue in the research?

 [ ]  No  [ ]  Yes. Explain below: 1. Has the risk-potential benefit ratio changed compared to when the project was last approved by the VA Central IRB?

 [ ]  No [ ]  Yes. Explain below:  |

**VII Document Verification and Ongoing Local Monitoring**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Since the **last** Continuing Review application, have you submitted any amendments to the PI/SC Application and received approval from the VA Central IRB?

 [ ]  No  [ ]  Yes. Complete the table below.

|  |  |  |
| --- | --- | --- |
| Amendment Number | Date of IRB Approval | Amendment Main Content |
|  |  |  |
|  |  |  |
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 *Add additional rows as necessary.* 2. Has a Regulatory Audit been conducted on this study by your local facility RCO since the last  Continuing Review? [ ]  No  [ ]  Yes. Indicate the date of the audit:  Has this audit report been reviewed by the VA Central IRB?  [ ]  Yes Submit the VA Central IRB determination or correspondence [ ]  No Submit a copy with the Continuing Review report. 3. Has an informed consent audit(s) been performed since the last Continuing Review? [ ]  N/A. PI site is not a local site obtaining informed consent. [ ]  No  [ ]  Yes. Indicate the date of the audit:  Has this report been reviewed by the VA Central IRB? [ ]  Yes Submit the VA Central IRB determination or correspondence [ ]  No Submit a copy with the Continuing Review report.   4. Have any audits been conducted by any other entities NOT previously reported to the VA Central IRB?   [ ]  No  [ ]  Yes. Attach a copy of the audit. ***Note: If any RCO report not previously reported indicates “apparent serious noncompliance” submit immediately; do not wait to include with this report.*** |

**VIII Summary of Participating Local Sites**

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| **Local Site Investigator** | **VA Facility Location****\* If a site has closed, please still list and indicate (closed)** | **Number of Enrolled Subjects (Charts Reviewed) Since Previous VA Central IRB Approval** | **Total Number of Enrolled Subjects (Charts Reviewed) Since Initial VA Central IRB Approval** |
|       |       |       |       |
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| ***Insert additional rows above as needed****.***Total Number of Enrolled Participants** |       |       |
| **The term enrolled denotes those participants who signed informed consent forms and later were screen failures or they withdrew or were withdrawn. \*\*\*The above figures should match those provided on the Local Site Investigator Continuing Review Applications. If they do not, please provide justification:**       |

**IX Principal Investigator/Study Chair Certification/Assurance**

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| ***The Principal Investigator/Study Chair must check each box and sign and date the form.*** |
| [ ]  | 1. I have completed this Continuing Review application and included all applicable supplemental documents. I have also 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 or there is no mechanism for review locally and the applicable OGE Forms 450 are included in this submission.
 |
| [ ]  | 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.
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| [ ]  | 1. I understand it is my responsibility to submit all project changes to the VA Central IRB for approval prior to initiating such change, except when necessary to eliminate apparent immediate hazard to the participant.
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| [ ]  | 1. I understand that if Continuing Review approval has not been completed prior to the VA Central 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 Central IRB Co-Chair who will determine, in consultation with the Chief of Staff at participating facilities, whether participants may continue receiving the research interventions and interactions.
 |
| 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 Central IRB approval of this project.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Principal Investigator/Study Chair Signature Date |

**Contents of Application Package**

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| **Please check all documents included in this package:**[ ]  Application for Continuing Review 115a: Principal Investigator/Study Chair[ ]  Applications for Continuing Review 115b: Local Site Investigators; Indicate number submitted \_\_\_\_\_[ ]  Abstract with all required elements as instructed in Section VI[ ]  VA Central IRB-Approved Protocol [ ]  Current VA Central IRB-approved Model Informed Consent Document [ ]  Current Model HIPAA authorization[ ]  Current approved HIPAA waiver[ ]  Current approved Consent waiver[ ]  Copy of Informed Consent Audit(s) or Regulatory Audit(s) Conducted at PI/SC’s VA Facility or any other report from an oversight agency **not previously reviewed** by the VA Central IRB[ ]  Copy of VA Central IRB audit determination letters or Correspondence from previously reviewed audits since last Continuing Review[ ]  OGE Forms 450 electronically completed with digital signature for all study staff serving in an investigator role indicating a change in their conflict of interest status.**Please include below a list of any other documents included as part of this Continuing Review application** [ ]  Other:       [ ]  Other:       [ ]  Other:   |