Renewal for Participating Sites

(IRISS Multisite Studies)

This form is to be used for IRISS studies which contain multiple study sites. The lead site is to complete the renewal smart form within IRISS, while the participating site completes this form.

After this form is completed and signed by the participating site principal investigator it is to be uploaded to the renewal file within IRISS by using the “Log Comment to REB Admin” and selecting the owner of the file.

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| --- |
| Study Information |
| Ethics #:       |
| Study Title:       |
| Protocol #:       | Sponsor:        |
| Study Originally Approved by: [ ] Delegated Review [ ] Full Board Review |
| Principal Investigator Participating Site:       |
| Participant Interaction |
| Does this study involve direct interaction with human participants?[ ]  Yes (i.e. interventional controlled clinical trials, observational studies with questionnaires/ surveys, interviews, focus groups, recruitment activities, etc.[ ]  No (i.e. chart reviews, biological sample collection, imaging, participant data from a repository or registry, etc.) |
| If “yes” go to section C. If “no” go to section D. |
| Interaction with Human Participants Only complete this section if the study involves interaction with human participants. |
| 1. Total number of participants approved for recruitment:
 |
| 1. Indicate the recruitment status at this site:
 |
|  [ ]  **a) No recruitment in the last 12 months or to date** |
| Explain why there has been no recruitment in the last 12 months or to date:        |
|  [ ]  **b) Currently recruiting participants** |
| 1. Number of participants consented and enrolled in the last 12 months:

 If “0”, please explain:       |
| 1. Number of participants withdrawn from the study in the last 12 months (including lost to follow-up):

 If applicable, provide the reason for withdrawal:       |
| 1. If this is a clinical trial, provide the number of participants in follow-up in the last 12 months:
 |
| 1. Comments:
 |
|  [ ]  **c) Recruitment complete** |
| 1. Date recruitment complete:
 |
| 1. Select all that apply:

[ ]  Participants undergoing assessment or receiving treatment[ ]  Post-intervention follow-up and data collection only[ ]  All data collection and follow-up complete – analysis, data clarification, data transfer ongoing |
| No Interaction with Human Participants Only complete this section if the study DOES NOT involve interaction with human participants.  |
| 1. Total number of records/samples approved to be accessed:
 |
| 1. Regarding accessing source data (charts, biological samples, images, data sets, etc.) the current status at this site is:
 |
|  [ ]  **a) No access in the last 12 months or to date** Explain why there has been no data accessed in the last 12 months or to date:       |
|  [ ]  **b) Currently accessing source data** Describe how many samples/records have been accessed in the past 12 months:       |
|  [ ]  **c) Access to source data complete** Describe how many samples/records have been accessed in the past 12 months:       |
|  [ ]  **d) Other** Describe other:       |
| 1. Have there been any challenges/problems with the research in the past 12 months? [ ] Yes [ ] No
 |
| If yes, briefly describe the challenges/problems:        |
| 1. Describe other pertinent information that the Committee should be made aware of:
 |
| General Information |
| 1. Have all modifications been requested and approved? [ ] Yes [ ] No
 |
| If no, briefly describe why modification requests were not submitted:        |
| 1. Have there been any complaints about the research? [ ] Yes [ ] No
 |
| If yes, briefly describe the complaints:        |
| 1. Has there been any new or relevant information about the risks associated with the research in the last 12 months? [ ] Yes [ ] No
 |
| If yes, briefly describe this new or relevant information:        |
| 1. Have all protocol violations or deviations been reported? [ ] Yes [ ] No
 |
| If no, briefly describe why reporting was not undertaken:        |
| 1. Have all serious adverse events been reported? [ ] Yes [ ] No
 |
| If no, briefly describe why reporting was not undertaken:       |
| 1. Are there any outstanding actions that the REB, study sponsor or a regulatory body has requested of the site? [ ] Yes [ ] No
 |
| If yes, briefly describe the outstanding action:        |
| 1. Have there been any changes in conflict of interest of the PI over the past 12 months? [ ] Yes [ ] No
 |
| If yes, briefly describe the change:        |
| Sign-off |
| Person Completing Form |
| Name:        | E-mail:        | Date:        |
| Principal Investigator Participating Site |
| Signature: | Name (printed):        |
| Date:        |