

## Institutional Review Board - Continuing Review Form for IRB Approved Studies.

**All studies, at the time of IRB approval, receive an approval time frame for up to 1 year from the approval date. If a continuing review is not conducted, the IRB administrator contacts the investigators to notify them that the study has been closed. Investigators should submit this continuing review form 6 weeks prior to the expiration of their study if they wish to continue to conduct research. Otherwise, a study closure form should be completed instead.**

|  |  |
| --- | --- |
| **Protocol Information:** | Title: Click here to enter text.Protocol Date/Version#:Click here to enter text.Principal Investigator: Click here to enter text.Co-Investigators: Click here to enter text. |
| **Reviewer**: | Name/Credentials/Degrees: Click here to enter text. | Continuing Review Date: Click here to enter text. |

|  |
| --- |
| **Please answer each question:** |
| 1. Have there been any changes in study team personnel?

[ ]  YES [ ]  NOIf Yes, please list: Click here to enter text. |
| 1. Have there been any changes in the Conflict of Interest for any member of the study team?

[ ]  YES [ ]  NO If Yes, *Attach a new signed and dated Conflict of Interest Statement* |
| 1. Is there any new information regarding this study?

(Note: For Revisions or Amendments, please use separate IRB Amendment Form)Click here to enter text. |
| 1. Since last review, have there been any changes made to the Study Protocol or Informed Consent documents?
 |
| [ ]  YES [ ]  NOIf yes, have these been submitted to IRB for review and approved\*?[ ]  YES [ ]  NO\*Any study modifications require submission to and approval by the IRB prior to implementation.  |
| 1. Total Number of Subjects Entered since Initial IRB Approval:
2. Anticipated Number of Subjects:
3. Total Number of Subjects Entered **since** **Last Periodic/Continuing** Review:

 [ ]  N/A |
| 1. Describe any unanticipated Adverse Events and/or Benefits experienced from any and all Study Sites that have NOT been previously reported. If these new unanticipated Adverse Events and/or Benefits are inconsistent with those previously reported, please let us know. (use separate sheet, if necessary).
2. Have there been any problems with the study since the last review that are not adverse events (e.g. subject complaints, data loss, or breach of confidentiality)?
3. Have there been any problems with the study since the last review that are not adverse events (e.g. subject complaints, data loss, or breach of confidentiality)?
4. State how many Subjects have withdrawn from the Study **and** summarize the reasons for the withdrawal(s).
 |
| 1. Please check which one of the following statements applies to this study:

[ ]  There are no subjects enrolled at this time.[ ]  At least ONE enrolled subject is still active (e.g., participating in study activities, data collection, or active treatment).[ ]  All subjects have completed study activities/treatments and will now be monitored on Follow-up.[ ]  Data collection is complete. Analysis of identifiable data will continue.[ ]  Study has concluded. No further contact with subjects OR use of identifiable data is planned. (Please submit a completed Study Closure Report)[ ]  Other (Explain): Click here to enter text. |
| 1. Is this Study still **open** to further Accrual?

[ ]  YES If yes, are any changes proposed to the current, IRB-approved Informed Consent?\*[ ]  YES [ ]  NO [ ]  N/A[ ]  NO If no, are you following any previously enrolled subjects?[ ]  YES [ ]  NO \*If changes to informed consent are desired, describe changes **and** attach the **current, IRB-approved Informed Consent & a revised version** (Please use track changes or another method of mark-up to clearly indicate the changes being made.) |
| **PRINCIPAL INVESTIGATOR SIGNATURE:** |  |
| **DATE SIGNED:** |  |

|  |
| --- |
| IRB Documentation: |
| ☐ | Approve for one year with suggestions |
| ☐ | Approve for one year |
| ☐ | Approve for period of less than one year. **Approve for** Click here to enter text. **(Designate time frame e.g. 6 months)** |
| ☐ | Conditional approval pending modifications/clarifications and review by Chair or designee.* Modifications/clarifications needed: Click here to enter text.
 |
| ☐ | Rejected. Study has been closed by IRB. Please submit study closure form.* Reason must be provided: Click here to enter text.
 |

|  |  |  |
| --- | --- | --- |
| Signed (Chair or Designee) |  | Date |