***As the PI responsible for the IRB review of multiple institutions, it is important to remember that the continuing review submitted to the BCH IRB must include collective information from all relying sites. This form may assist you in gathering the required information from all sites. It is the Overall PI’s responsibility to submit cumulative information from all sites at the time of the BCH continuing review. This form should NOT be submitted to BCH with your continuing review*. *It is a tool to help collect the information you need from each site.***

|  |  |
| --- | --- |
| **Study Title** |  |
| **BCH IRB Protocol #**  |  |
| **BCH Principal Investigator** |  |
| **Relying Institution** |  |
| **Relying Site Principal Investigator** |  |

**Section 1: Study Status**

1. Check the current status of the study at your site [please select only one option]:

[ ]  Enrollment has not started

[ ]  Active enrollment

[ ]  Enrollment closed

[ ]  Participants are receiving research-related interventions

[ ]  All research-related interventions are completed and the study is open for follow-up only

[ ]  Research activities are limited to data analysis only

[ ]  My site is no longer engaged in human subjects research

**Section 2: Renewal Summary**

1. Provide a detailed progress report of the study at your site during the last approval period:

**Section 3: Site Enrollment Information**

1. Explain whether recruitment is on target at your site and, if not, the plan to reach target.

1. If your protocol involves any approved method of obtaining informed consent (e.g. written consent, verbal consent, consent by voluntary completion of a survey), complete the following enrollment summary to provide the total number of enrolled subjects (individuals who provided consent, including those who did not complete study participation for any reason such as ineligibility, loss-to-follow-up, withdrawal).

|  |
| --- |
| **# OF SUBJECTS WHO PROVIDED CONSENT** |
| 1. **Total number enrolled since last IRB review.**

*Signed a consent form, gave oral consent or were studied under a waiver of consent. This includes all screen failures and participants lost to follow-up, if applicable.* | **i.**  |
| 2. **Total number enrolled to date.**    *Please break down this total for* ***SITE*** *subjects as follows:    items****a - h****below should equal total enrollment to date.* | **i.**  |
|    **a.** Subjects deemed ineligible (after screening) |  |
|    **b.** Subjects currently active on study |  |
|    **c.** Subjects who completed study       without events leading to early termination |  |
|    **d.** Subjects withdrawn at their own/family request       (*e.g. subject signed consent and then changed mind or stopped at their request)* |  |
|    **e.** Subjects withdrawn by PI due to toxicity or adverse events |  |
|    **f.** Subjects withdrawn by PI due to other reasons      (*e.g. lack of compliance, pregnancy)* |  |
|    **g.** Subjects lost to follow-up |  |
|    **h.** Subjects no longer participating for other reasons | **Specify reasons:** |

**Section 4: Problems, Events and Deviations**

1. Please review the. BCH IRB requirements for reporting (see Section 5: Reporting, Unanticipated Problems, Noncompliance) Have any unanticipated events or noncompliance occurred at your site during the last approval period that meet the BCH IRB requirements for reporting to the IRB?

[ ]   **YES** [ ]   **NO**

*If yes,* please explain

1. Did you learn of any grievances or complaints from study participants?

[ ]   **YES** [ ]   **NO**

*If yes,* please explain

**Section 5: Site Monitoring**

1. Has your site been audited or monitored this year?

[ ]   **YES** [ ]  **NO**

*If yes*, please summarize the monitoring/audit activities, addressing the following points:

• The nature of the monitoring/audit: routine or for-cause

• Who conducted the monitoring/auditing visit (e.g., institutional, a Contract Research Organization, FDA, etc.)

• When the monitoring/audit occurred

• When the Lead Site PI was notified

• A description of any findings requiring follow-up

• A summary of any corrective actions(s) undertaken in follow-up

**Section 6: Site-Specific Updates**

1. During the last approval period, did your institution identify any new relevant individual or institutional financial COIs for this protocol?

[ ]  **YES** [ ]   **NO**

*If yes*, please submit a participating site modification that includes a summary of the conflict and management plan or documentation.

2. During the last approval period, have you added any new personnel to your local study team?

[ ]  **YES** [ ]  **NO**

*If yes*, please confirm that local approval was granted and that training is current for all study team members at your local site