|  |  |
| --- | --- |
| **Study Title** |  |
| **Lead Principal Investigator** |  |
| **JHM IRB Protocol #**  |  |
| **Participating Site**  |  |
| **Participating Site Principal Investigator**  |  |

***Please Note****: A Continuing Review Summary Sheet is not required for pSites that have terminated during the last approval period, as pSites provide their closeout enrollment data, deviations, AEs, etc via the pSite Termination Report.*

**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

1. Please select the activities that will be performed at your site and/or performed by your site’s employees (select all that apply):

[ ] Enrolling/Consenting

[ ] Coordinating Center

[ ] Only Data/Specimen analysis

[ ] Funding Only

[ ] Other: Please Describe:

**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:
2. Number of participants at your site who signed a consent form, gave oral consent or were studied under a waiver of consent: (this number includes all screen failures and participants lost to follow-up, if applicable):

|  |  |  |
| --- | --- | --- |
|  | \*Since last approval | Since original approval |
| Male Adults |  |  |
| Female Adults |  |  |
| Male Children |  |  |
| Female Children |  |  |

\*If this is your first continuing review, please provide enrollment numbers starting from the date your site was approved as a participating site.

1. During the last approval period, were any participants withdrawn from the study at your site due to problems, events, deviations, non-compliance or for other reasons (other than screening failures)?

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

***If yes, please describe:***

[Textbox]

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

1. Please review the [JHM IRB policy on events requiring prompt reporting](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/prompt_reporting_policy.html). Have any events occurred at your site during the last approval period that meet the JHM IRB requirements for prompt reporting?

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

* 1. *If yes,* upload a problem event report log
1. Have any adverse events occurred at your site during the last approval period that did not meet the prompt reporting requirements?

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

* 1. *If yes*, upload an adverse event log
1. Have any [protocol deviations](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/protocol_deviations.html) occurred at your site during the last approval period that did not meet the prompt reporting requirements?

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

* 1. *If yes*, upload a deviation log
1. Did you learn of any grievances or complaints from study participants?

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

Please describe below:

**Section 5: Site Monitoring**

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

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

If yes, please summarize the monitoring/audit activities in the textbox below, 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 COI 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.

1. 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.

1. Please confirm that your institution’s FederalWide Assurance [FWA] status is active [ ]

*If your FWA was renewed during the last approval period, please indicate the new expiration date below:*