The lead site or coordinating center for a multi-site study subject to sIRB (single IRB) review by the JHM IRB is asked to prepare the overall continuing review application for submission to the JHM IRB. To help the JHM IRB understand the activity across sites to date, please prepare a summary document for the continuing review submission that addresses the following:

**Overall enrollment summary, including:**

* Total number of participants consented across all sites
* Total number of participants enrolled across all sites
* The total number of sites that are currently enrolling.
* The total number of sites that have not yet started to enroll.

*(Please note: We have identified that some sites [in other SIRB CR applications] have not started enrollment because the site has not received local approval to begin enrollment. Please confirm that sites have obtained local approval to begin enrollment as you are reviewing the site enrollment summaries)*

* Plan for Opening of New Sites:
  + Are there any additional sites that will be added?
  + If so, how many? What is the timeline for submission?
* Any notable issues with enrollment and a plan to address these issues, as applicable.

**Please verify enrollment with each participating site. Any discrepancies must be resolved with the site before the Continuing Review Application is submitted to avoid delay in annual approval.**

**Please provide an aggregate report for protocol events requiring prompt reporting, adverse events and deviations (three aggregate reports) – do not upload the individual logs provided by each relying site. These logs should be used by sites to report their site-level data to the lead/coordinating site so aggregate reports can be prepared for the continuing review submission..If your study has developed a formal system for tracking protocol events requiring prompt reporting, adverse events and deviations you may compile this information and present it in a format that is different from the JHM IRB template logs. All fields included in the JHM IRB templates must be included in your aggregate reports.**

**The following summary level reports should be provided:**

* Adverse Events across sites
* Deviations across sites
* Protocol Events requiring Prompt Reporting across sites (for more information regarding JHM Prompt Reporting guidelines, please use the following link: <https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/protocol_deviations.html>)

**\*Please note: Within the summary reports, individual events should be attributable to specific sites so the JHM IRB may identify any pattern of events occurring at a single site.**

**In addition to providing the requested logs, please address the following questions in your summary report:**

1. Looking across all reports of adverse events across sites, are there any patterns that would suggest any new risks have been identified, or changes are needed to the consent form? If yes, please outline your plan to submit a change in research to incorporate this new information.
2. Looking across all reports of deviations across sites, are there any patterns of deviations that would suggest the need for a study-wide corrective action plan? [e.g., education about consent process; protocol changes needed to decrease deviations]
3. Looking across all sites, have there been any events that would require prompt reporting?

* If yes, have they been reported?
* If not, please outline a plan for reporting these events promptly and explain why they have not yet been reported.

**Additional Study-Wide Questions – Please review the summary of site-specific progress provided by each site and address the following in your summary report:**

1. Have any new Conflicts of Interest been identified that need to be submitted for IRB review?

* If so, please list the name of the site for which a new conflict has been identified and a planned timeframe for submission of a psite modification to report this conflict.

1. Have any sites been audited locally [apart from the planned study monitoring]?

* If yes, were there any audit findings to be addressed?