Date:

To: **NHGRI IRB**

From:

Subject: Continuing Review Cover Memo

Protocol ID#:

Protocol Title:

Expiration Date of Continuing Review:

This cover letter and the PTMS Continuing Review (CR) Application Form should cover all of the requirements for CR found in SOP 9, Section 9.6. Confirm that all fields are completed in the PTMS Continuing Review Application Form. If the field is not answered, provide an explanation as to why. In addition, complete all sections of this memo as numbered, using “n/a” for sections that do not apply to this protocol. Confirm consistency and accuracy of staff listed in the protocol document as well as in PTMS. If the protocol document is not correct, an amendment must be submitted.

**Continuing Review Checklist Reminder**

|  |  |
| --- | --- |
| □ | NIH Intramural Clinical Research Protocol Continuing Review Application. |
| □ | Current IRB-approved, dated protocol, if changed from the previous year, with version number, page numbers and all amendments incorporated. |
| □ | The current IRB-approved informed consent/assent document(s), unless enrollment is complete. |
| □ | The IC-approved Cumulative Inclusion Enrollment Report (CIER) |
| □ | Any monitoring reports for the last review period, such as Data and Safety Monitoring Board (DSMB) or Committee (DSMC) reports, as applicable. |
| □ | Most recent Annual Report to the FDA (e.g., IND annual Report), as applicable |
| □ | Aggregated summary reports of UPs, PD, UADE, (PTMS CR Application Form) |
|  |  |

1. Description of protocol progress/findings from this research since last CR. (Same as PTMS CR Application Form question VIII, please copy and paste).
2. Participant enrollment data
	1. Provide a participant Enrollment summary:

|  |  |  |
| --- | --- | --- |
| ***Note:* *If this is the first continuing review application, you need only complete the Column “Since Initial IRB Approval.” Otherwise, complete both columns*** | **Since Initial IRB Approval** | **Since Last IRB CR Report Submission** |
| **Total** Number of enrolled participants:*(Enrolled means participants who signed an informed consent form, gave verbal consent under an IRB approved waiver of documentation of informed consent, or are participants under a waiver of informed consent.* ***This includes screen failures after consent and participants who have withdrawn or were withdrawn by the study team.)*** |  |  |
| Number of enrolled participants who failed screening if applicable: [ ]  Check here if your project does not have screening procedures after consent.  |  |  |
| Number of enrolled participants who withdrew or were withdrawn:*(withdrawn by PI; self-withdrawal; lost to follow-up)***If there were withdrawals, indicate reasons and totals** |  |  |

Note: The IRB recognizes that the study team may not have recorded these participant numbers since initiating the study. The expectation is that this information is being collected and reported moving forward.

* 1. Total number per cohort or subpopulation who started study (for example: pediatric subjects, number of patients/index cases vs. number of relatives/healthy volunteers).
1. If there has been no or less than expected enrollment (either overall or in specific subcategories, such as race, ethnicity, sex, or catergories described in 1.b.), please explain. If necessary, what is the plan to enhance enrollment?
2. Have expected Adverse Events occurred at greater frequency or severity than previously expected? (If this occurs, the aggregate information may also qualify as a UP and must be reported as such. See [SOP 16](http://ohsr.od.nih.gov/OHSR/pnppublic.php).)
3. Provide a summary of Serious, Continuing, and Minor (not serious and not continuing) Non-Compliance since the initial approval or the last CR submission as applicable.
4. Provide a summary of any research-related complaints from subjects since the initial approval or the last CR submission as applicable.
5. Provide a summary of the all of the monitoring reports completed during this review cycle.If you have a DSMB/SMC and it has not met, explain why it has not convened since the last review or indicate N/A.
6. Based on any previous IRB stipulations, report on any activities where follow up information was requested (e.g. disclosure of secondary findings, sedation on children, use of specific procedures, etc.).
7. Do you need and/or have an approved Genomic Data Sharing Plan? <http://inside.genome.gov/20009049>
8. Is the protocol approved to use the short-form process to enroll non-English speakers?
	1. If yes, has the short-form consent process been used in the past year?
	2. If yes, state number of participants enrolled with short form process.

*(If the CC Short Written Consent Form has been used three times for the same language since the start of the study, the informed consent document must be translated to that language.)*

1. Any other information about which you would like to inform the IRB or IRB Office Staff.
2. Confirm that all of those working on this protocol who are required to take HRPP training under OHSRP [SOP 25](http://ohsr.od.nih.gov/OHSR/pnppublic.php) (Training requirements for the NIH Human Research Protections Program) have completed all required training.
3. If NHGRI IRB is the IRB of oversight for multiple enrollment sites for this study, provide answers to relevant questions for each site as a supplement to this cover letter.
4. Provide the name, email address, and phone number for the primary research contact for the IRB for this protocol.