Continuing Review / Study Closure Information

1. * Specify enrollment totals:

Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:	0	0
Study-wide:	0	

2. IMPORTANT! To close the study and discontinue IRB oversight, the first four research milestones below must be true and checked. Closing the study is an irreversible action.

Research milestones: (select all that apply)
(For HSPO-overseen multicenter clinical research: Choose selections regarding enrollment at this organization only.)

- [x] Study is permanently closed to enrollment OR was never open for enrollment
- [x] All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- [x] Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- [ ] Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- [x] Remaining study activities are limited to data analysis
- [ ] Study remains active only for long-term follow-up of subjects

3. * Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?

( ) Yes (•) No Clear

4.

Check the items that are true since the last IRB continuing review (or initial approval if the study is reaching the end of its first year) for all* sites involved in the study:
*(*For HSPO-overseen multicenter clinical research ONLY: Answers to the first five checkboxes [harm, benefits, subject withdrawing, unanticipated problems involving risks to subjects or others, and complaints] need only consider subjects enrolled by Penn State Hershey investigators, not those enrolled by other sites.)*

- [x] NO subjects experienced harm (expected or unexpected)
- [x] NO subjects experienced benefit
- [x] NO subjects withdrew from the study
- [x] NO unanticipated problems involving risks to subjects or others
- [x] NO complaints about the study
- [x] NO publications in the literature relevant to risks or potential benefits
- [x] NO interim findings
- [x] NO multi-center trial reports
- [x] NO data safety monitoring reports
- [x] NO regulatory actions that could affect safety and risk assessments
- [x] NO other relevant information regarding this study, especially information about risks
- [x] In the opinion of the PI, the risks and potential benefits are unchanged
- [x] All modifications to the protocol have been submitted to the IRB
- [x] All problems that require prompt reporting to the IRB have been submitted

5. Attach supporting documents, and include an explanation for each item left unchecked in Question 4 above: (include any Data and Safety Monitoring Board/Data Monitoring Committee/Independent Data Monitoring Committee report, Annual Reports to the FDA, and publication references)

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