PLEASE COMPLETE THIS SECTION FIRST

IRB #: Study Title:

Date of submission of this form: Principal Investigator:

Wyoming Department of Health Institutional Review Board

Application for Continuing Review or Study Closure

Please complete ALL sections of this form whether applying for Continuing Review or Study Closure.

1. STATUS OF THE RESEARCH

Check the one choice that best describes the current state of this research study:

☐ No participants have been enrolled to date.

☐ Recruitment and/or enrollment of new participants or review of records/specimens continue.

☐ Study is no longer enrolling, but participants still receive research-related interventions, (e.g., still receiving treatment, obtaining blood draws)

☐ Study is no longer enrolling and participants have completed research-related interventions. The study remains active only for long-term follow-up.

☐ Study enrollment is permanently closed, participants have completed all research-related interventions, and long-term follow-up has been completed. The remaining research activities are limited only to data analysis that may require contact with records or specimens.

2. CLOSE THE STUDY

Please provide a final study report, progress reports, and publications to the IRB as they become available.

☐ Close the study. Enrollment and follow-up are complete and no further contact with participants/records/specimens is anticipated. Describe the reason for closure (i.e., enrollment goals achieved, reason for early termination) ***:***

3. SUMMARY OF PROGRESS SINCE INITIAL IRB REVIEW OR PREVIOUS CONTINUING REVIEW APPROVAL

Record numbers reflective of activities where a WDH investigator is involved in the conduct of the research or is responsible for regulatory reporting (i.e., adverse events, progress reports):

_____ Total number of participants approved by WDH IRB
_____ Total number of participants consented to participate to date, including withdrawals
_____ Total number of participants consented since the previous IRB continuing review approval*
_____ Total number of participants that consented but did not complete the study since the previous IRB continuing review approval* (include explanation for each)

Provide a description of study activities to date, including any difficulties in recruiting subjects, in the space below:

Select one answer for each question:

4. ☐Yes ☐No Since the initial IRB review or previous IRB continuing review approval, have any unanticipated problems involving risks to participants and/or serious, unanticipated and research-related adverse events occurred?

If "Yes", attach all written summaries and/or progress reports since previous IRB continuing review approval.

_____ Total number of events/problems since initial review or previous IRB continuing review

4a. ☐Yes ☐No Have these events been reported previously to the IRB?

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5. ☐Yes ☐No Have any relevant clinical findings, literature, reports or other information (particularly information about risks associated with the research) become available since the last IRB continuing review approval*? If "Yes", please describe:

6. ☐Yes ☐No Have there been any complaints about this research since the last IRB continuing review approval*? If "Yes", please describe:

7. ☐Yes ☐No Have there been any modifications to this research study since the initial IRB review or last IRB continuing review approval*? If "Yes", please answer question 7a. & describe all modifications:

7a. ☐Yes ☐No Was the IRB notified about the modifications at the time they were implemented?
If no please explain why not:

8. ☐Yes ☐No Did the IRB require the use of a written informed consent document for this study? If "Yes", submit a copy of the currently approved informed consent document.

9. INVESTIGATOR'S CONFLICT OF INTEREST STATEMENT

☐Yes ☐No Do you or any other person responsible for the design, conduct, or reporting of the research have an economic interest in, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If "Yes" and the IRB has not yet been notified, submit a letter to the IRB describing the conflict immediately.

10. CONTACT INFORMATION

Principal Investigator's e-mail address: _____

Phone #: _____ Fax #:_____ Pager #:_____

Study contact name (if different than PI): _____

Study contact e-mail address: _____

Phone #: _____ Fax #: _____ Pager #: _____

***In addition to the above responses, I confirm that a current IRB-approved consent form has been signed, dated, and is retained in my files for every participant enrolled in this study and a copy was provided to the person who signed the form (if use of a consent form was required). I also confirm that no changes to study procedures or the consent form(s) were initiated without prior IRB approval*.**

_____ _____

Principal Investigator's Signature Date