CONTINUING REVIEW/PROGRESS REPORT

In accordance with federal regulations, the IRB must review all more than minimal risk human research protocols at least annually, or more frequently at intervals appropriate to the degree of risk and degree of vulnerability of the subject population. **It is the investigator’s responsibility to submit the Continuing Review/Progress Report to the IRB before a study’s expiration.** The expiration of IRB approval is a violation of federal regulations. If the IRB has not reviewed and approved a research study by the established expiration date, research activities must stop and no new subjects may be accrued.

## 1. Adding a New Amendment:

Are you submitting a protocol amendment or change with this continuing review application?

Yes  No

If ‘YES’, you must complete an [IRB Amendment/Modification Form](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-amendmentapp.docx) and include it with this submission.

If you would like the Amendment reviewed prior to the Full Board Review of the Continuing Review Report, please submit the Amendment as a separate package in IRBNet.

## 2. Amendments Submitted During Review Period:

Please list all amendments that have been submitted to the DU IRB **within the last 12 months**. If none, please enter “none” in the box below.

Click here to enter text.

## 3. Current Study Status

Study Status: (check box for all that apply)

Study has not started

Study enrollment is open with no subjects enrolled to date\*

Study enrollment is open and subjects have been enrolled\*

Study enrollment is permanently closed.

Research remains active for **long-term follow-up of subjects only**

Remaining research activities are **limited to data analysis only**

Study is on hold, halted or has been suspended.

\*if the study plans to enroll or continues to enroll subjects, please provide a clean copy of all informed consent documents (informed consent, assents, parental permission forms) in order for the IRB to affix a new effective date on each document.

## 4. Study Accrual:

4.1. Number of subjects approved by the IRB to enroll in this study?

Click here to enter text.

4.2. Do you need to increase your subject enrollment number at this time?

Yes  No

If ‘YES’ you must complete an [IRB Amendment/Modification Form](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-amendmentapp.docx) and include it with this submission.

### Table 4.1.A. Subject Enrollment

Please provide the following information on your subject enrollment:

|  |  |  |
| --- | --- | --- |
|  | DURING THE PAST YEAR (#) | CUMULATIVE ACCRURAL (#) |
| Number Enrolled: This is the number of subjects who  signed a consent form; or who gave verbal consent on  a study conducted under a waiver of written documentation  of consent; OR the number of records reviewed if a retrospective study is conducted under a waiver of consent. | Click Here | Click Here |
| Number of subjects who read the consent form and/or discussed the study with study team as part of the consent process but refused to participate: | Click Here | Click Here |
| Number of consented subjects who voluntarily withdrew: | Click Here | Click Here |
| Number of consented subjects who are lost to contact: | Click Here | Click Here |
| Number of consented subjects who were withdrawn by the PI: | Click Here | Click Here |
| Number of consented subjects who completed the study:  (all interventions and follow-up are complete) | Click Here | Click Here |

4.3. To your knowledge, were there any subject complaints about the **research within the last 12 months:**

Yes  No

If ‘YES’ please explain below:

Click here to enter text.

## 5. Summary of Study Progress or Findings:

5.1. Please provide a narrative summary of the study progress to date. If your study is closed to enrollment and subjects are in follow-up, please detail your follow-up.

Click here to enter text.

5.2. Have there been any recent findings either from this study or a related study, which would have an effect on subject safety or the risk/benefit sections of the protocol and/or consent document(s)?

Yes  No

If ‘YES’, please explain below:

Click here to enter text.

## 6. Study Personnel

6.1. Listall **current** investigators on the project, including study personnel (i.e. students) having subject contact in a research role.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| NAME | CREDENTIALS | DEPARTMENT | POSITION/TITLE | EMAIL ADDRESS | ROLE |
| Click here to enter text | Click here to enter text | Click here to enter text | Choose an item | Click here to enter text | Choose an item |

To add additional personnel, click on the **+** at the end of each box.

### Table 6.1.A. Investigator/Study Personnel

\*Human Subject Protections training dates are not required if you have “linked” current training certificates (no more than 4 years old and affiliated with the University of Denver) to the Continuing Review package via the ‘tracking training’ feature in IRBNet. Copies of all research personnel training should be maintained with the other study documents (i.e., consents, protocol, etc.)

|  |  |  |
| --- | --- | --- |
| INVESTIGATOR/STUDY PERSONNEL NAME (FIRST, LAST) INCLUDING CREDENTIALS | HUMAN RESEARCH PROTECTION (HRP) TRAINING | COMPLETION DATE |
| example: John Smith, PhD | SBER curriculum | m/d/yyyy |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |

## 7. Data and Safety Monitoring Plan (DSMP)

7.1. Is there a Data and Safety Monitoring Plan for this study? DSMP’s are required for all studies that are classified by the IRB as More Than Minimal Risk.

No, the IRB did NOT require DSMP

Yes, no changes have been required or made to the original DSMP

Yes, an update on the DSMP report is attached

If ‘YES’, please summarize the DSMP updates below:

Click here to enter text.

## 8. Conflict of Interest (COI)

Please update your [Research Conflict of Interest Disclosure](https://udenver.qualtrics.com/jfe/form/SV_5p94trb6D0QHmAd) if you answer ‘YES’ to any of the following questions. To submit or update a Research COI Disclosure, go to [this link.](https://udenver.qualtrics.com/jfe/form/SV_5p94trb6D0QHmAd)

8.1. During the past year, did any of the participating study investigators or other key personnel (or their immediate family/significant other) have a financial or intellectual interest in, or receive compensation from, the sponsor or the drug, devices or technologies used in this research?

Yes  No

8.2. Do you have or anticipate (within the next year) any financial relationships (e.g., consulting, speaking, advisory boards, patents, equity, options) that could be perceived to overlap or present a conflict of interest with the current proposal?

Yes  No

8.3. Do you have a conflict of interest management plan (issued by the University of Denver) with the sponsor or funding agency?

Yes  No

## 9. Risk/Benefit Assessment

9.1. Summarize any Serious Adverse Events (SAEs) for the last review period (include date reported to the IRB):

Click here to enter text.

9.2. Summarize any Protocol Deviations you had in the last review period (include date reported to the IRB):

Click here to enter text.

9.3. Summarize any Unanticipated Problems at your site or study wide during the last review period (include date reported to IRB):

Click here to enter text.

### Table 9.4.A.

In the last review period, have there been any of the following:

|  | YES/NO | IF YES ENTER DATE SUBMITTED TO THE IRB |
| --- | --- | --- |
| Subject complaints / concerns | **Yes**  **No** | Click here to enter a date. |
| DSMB/monitoring committee or annual report | **Yes**  **No** | Click here to enter a date. |
| Significant new findings related to risk | **Yes**  **No** | Click here to enter a date. |
| Significant new findings provided to the subject | **Yes**  **No** | Click here to enter a date. |
| Site audit by an outside agency (OHRP, NIH) or Sponsor | **Yes**  **No** | Click here to enter a date. |
| Site audit by internal DU department | **Yes**  **No** | Click here to enter a date. |
| If ‘YES’, attach pertinent documents related to the outcome of the above to this submission | | |
| Enter any additional comments below: | | |
| Click here to enter text. | | |

9.5. Since initial IRB review or the last continuing review (renewal):

9.5.1. Has there been any literature or new information that relates to your research, such as information about possible risks to human subjects associated with this research or any significant new findings which may relate to the subjects’ willingness to continue participation?

Yes  No

If ‘YES’, please attach applicable documentation.

9.5.2. Have any preliminary results of the research come available since initial IRB review or the last continuing review (renewal)?

Yes  No

9.5.3. Have any publications been derived from this study?

Yes  No

If ‘YES’, please attach references.

## 10. Other Helpful Comments for the IRB

Click here to enter text.

## 11. Principal Investigator Assurance Statement

The Principal Investigator (PI) must electronically sign this submission in IRBNet prior to submitting the Continuing Review to the IRB for review. If the PI is a student, the Faculty Sponsor must also electronically sign the submission. **The IRB submission will not be reviewed without the PI’s electronic signature, or if applicable, the Faculty Sponsor signature in IRBNet. The IRB does not allow others on the project to sign on behalf of the PI.**

I have read and I agree with the following:

1. I certify that the information provided in this application is complete and accurate.
2. I understand that as the Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of human participants, and strict adherence to the study protocol and any stipulations imposed by the DU IRB.
3. I will ensure that the project is conducted by qualified personnel and that they comply with the approved IRB application and study protocol.
4. I will make no changes to the approved protocol or consent form without first having submitted those changes for review and approval by the DU IRB, unless the changes are necessary to eliminate an apparent immediate hazard to subjects.
5. I will report immediately to the IRB any serious adverse events and/or unanticipated problems which occur as a result of this study.