**Documents To Be Submitted for Continuing Review**

The documents required for continuing review have been separated into **two groups** below. **Group 1** includes a list of documents that all studies, regardless of review type, must be turned in for a continuing review. **Group 2** includes a list of documents that **may or may not** be applicable to your study. Please review both groups of documents and submit all documents in Group 1, and Group 2 documents that are **applicable** to your study. All submissions to COMIRB must be submitted electronically via the eRA(InfoEd) system. Click [here](#) for instructions.

**Group 1 – Documents required for continuing review of all studies:**

- **Cover letter** listing what documents are contained in the submission, and providing any important information/updates on the status of the protocol.
  - If the study involves the VA, the following statement should be included in the cover letter (unless COMIRB has granted a waiver of consent or waiver of consent documentation): "I, the PI, certify that all subjects entered onto the master subject list for this study signed an informed consent form prior to undergoing any treatment interactions or interventions."
  - If you are requesting that COMIRB close the study, the cover letter should include a request for closure as well as the reason for closure (e.g., data analysis has been completed).

- A completed copy of the **Continuing Review Form**

- An **unstamped** copy of the most recently approved version of the **Application for Protocol Review**, depending on which application form is relevant to your study.

- An **unstamped** copy of the most recently approved version of each **Attachment (A-T)** that is relevant to your study. **Note:** The Application Form and Attachments should be thought of as one document and always submitted together. If possible, please combine the Application Form with the relevant Attachments into a single PDF document. Make sure the Application/Attachments have a version date (only update this version date when changes are made). The new "Smart PDF" Application has the Attachments built into it.

- An **unstamped copy** of the most recently approved version of the study **Protocol**.

- An **unstamped copy** of the most recently approved version of the **consent form and assent form**. This could include multiple consent and/or assent forms. **Note:** Your study may not have a consent form or assent form.

- A **stamped “Approved” copy** of the most recently approved version of the **consent form and assent form**. This could include multiple consent and/or assent forms. **Note:** Your study may not have a consent form or assent form.
In addition, investigators involved with your study may need to update their Conflict of Interest Disclosure through the eRA(InfoEd) system, and complete the required CITI online instruction courses, if they have not done so, or if these requirements are not up-to-date. COI Disclosures need to be completed every year, while CITI courses need to be completed every 3 years. Click here for further information.

**Group 2 – Documents that may be required for continuing review if they are applicable to your study:**

- An unstamped copy of the most recently approved version of the HIPAA A and/or HIPAA B form(s) if you are enrolling subjects, or plan to re-consent subjects. Note that many studies now combine the consent form and HIPAA B authorization into one form.

- A table that summarizes Adverse Events that do not meet the definition of Unanticipated Problem (UAP) that took place since the last continuing review. An Adverse Event is any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable or definite). *In place of the Adverse events table: If the COMIRB-approved Data Safety Monitoring Plan includes an oversight mechanism (Safety Officer, Data Monitoring Committee, Data Safety Monitoring Board), then COMIRB delegates that responsibility of assessing trial safety to that oversight body. COMIRB expects all relevant oversight reports generated since the time of the last continuing review to be submitted in place of the Adverse Events table.

- A table that summarizes Deviations/Violations from the Protocol that do not meet the definition of Unanticipated Problem (UAP) that took place since the last continuing review. A Protocol Deviation/Violation means an accidental or unintentional change to the COMIRB approved protocol or other noncompliance.

- Any DSMB / DMC / Safety Officer Reports. Safety reports do not need an accompanying Unanticipated Problem Report form (UAP) unless they meet the definition of a UAP (and were not previously submitted to COMIRB).

- Any relevant multi-center trial reports.

- Any relevant recent literature/changes in the field.

- Copies of any abstracts/publications resulting from this study.

- Copies of IRB approvals from other sites (if UCD or affiliate is the lead site).