



Clinical Trials Requiring IBC Review: Guidance and Required Documents

Any human clinical trial that utilizes an investigational product that is classified by the NIH as a either a Human Gene Transfer (refer to NIH Guidelines III-C-1) or a Live Vaccine clinical trial must be submitted for IBC review. To help determine if a clinical trial requires IBC review, the primary indicator is if the investigational product (vaccine or otherwise) has been recombinantly modified. Keywords such as “vector”, “transduced”, “transduction”, “recombinant”, etc. may be used within the Investigator’s Brochure (IB). If unsure of CU Denver | Anschutz IBC review needs, please send the IB for the investigational product as an email attachment to the IBC Office (IBC@CUAnschutz.edu) for consideration.

Some clinical trials that are exempt from NIH review requirements still require IBC review due to state or institutional requirements. These studies may involve trials using hazardous/infectious products manufactured on-campus or other clinical research activities of concern. Please email the CU Denver | Anschutz IBC Office with all IBC clinical trial submissions and any questions.

Documents Required for IBC Review:

The CU Denver | Anschutz IBC requires a clinical trial submission package including *all* required documents (listed below) prior to review consideration at the next IBC meeting. Please refer to the [Research Committee Support webpage](#) for upcoming CU Denver | Anschutz IBC meeting dates, submission deadlines, and clinical trial application documents.

Documents Required for New CU Denver | Anschutz IBC Clinical Trial Application:

1. A cover letter including the following information:
 - The Institutional Review Board (IRB) name reviewing the specific study
 - Specify if this is the first site for the study; if not, how many other sites are active.
 - If sites outside of CU Denver | Anschutz are active, note if there have been any serious adverse events (SAE) or unanticipated problems (UAPs) at these other sites.
 - If required information such as scientific abstract, etc. is included in a different document, please note the document name and page within the cover letter.
 - If the clinical trial is being initiated at the institution with any documents that indicate amendments, please note the version numbers on the Cover Letter.
2. The completed CU Denver | Anschutz IBC clinical trial application
3. The proposed, current clinical protocol – including tables, figures, and any relevant publications
4. The proposed IB with any appendices
5. The scientific abstract
 - If referenced in other submitted documents, include the document name and page number within the cover letter.
6. The summary of preclinical studies conducted in support of the proposed clinical trial
 - If referenced in other submitted documents, include the document name and page number within the cover letter.



7. The standard operating procedures (SOPs) regarding the handling of the investigational product, spill response, disposal, etc.
 - Please utilize the CU Denver | Anschutz Biosafety Site-Specific SOP.
 - Additional materials may include SOPs from the sponsor that will be adhered to by the administering clinical team, hospital-specific SOPs, or department/unit-specific SOPs. If there are multiple SOPs present, please ensure that there is no contradictory information prior to submission.
 - SOPs that reference chemotherapeutics are not adequate to address work with humane gene transfer (HGT) biological investigational products.
8. The curriculum vitae (CV) of Principal Investigator (PI) at the CU Denver | Anschutz site in the NIH bio sketch format.
 - Only one clinician may be listed as the PI on the IBC application. CVs will be required for all co-investigators listed on the form.
9. The summary of SAEs or UAPs that have occurred at other sites prior to the clinical trial protocol initiation at CU Denver | Anschutz
10. Pharmacy manual(s) if available

Follow-up/Amendment Submissions of IBC-Reviewed CU Denver | Anschutz Clinical Trials:

The CU Denver | Anschutz IBC must be notified of all SAE/UAP events, changes to the IB or IBC clinical trial protocol, personnel changes involving the PI or primary contact, and administration of the final dose of an investigational product.

- **SAE/UAP Submissions:**

All SAE/UAP events/documentation must be emailed to the IBC Office. This includes reports for such events that occurred at different clinical sites, but fall under the same FDA IND, etc. If this event occurs, please email the following to the IBC Office:

1. The summary of SAE/UAP events
2. A cover letter
3. The date of SAE/UAP, site of incident (if not on-site, specify the location), determination of cause (if available), etc.
4. All relevant SAE/UPA reports submitted to IRBs

- **Follow-up/Amendment Submissions:**

Document changes that are of concern to the IBC include modified IB, pharmacy manuals (if available), protocol documents, as well as PI/primary contact changes. Patient-facing documents, ICFs, etc. do not require IBC review. If any of these changes occur, please email the following to the IBC Office:

1. A cover letter summarizing the changes that were included in the amendment (including any IB/manual/protocol changes).
2. A redlined version of the amended file along with a clean version of the updated file



3. An approval from the IRB of record for the follow-up submission
4. Confirmation from the PI that they are aware of/approve the follow-up/amendment submission
5. As applicable, an updated personnel file indicating the new PI name and/or contact name(s)
6. As applicable, a PI change form for PI changes

IBC Clinical Trial Closure/Administration of the Last Dose of an Investigational Product:

IBC oversight for an IBC-approved clinical trial ends once the last dose of the investigational product has been administered (i.e., the IBC no longer needs to receive updates). To confirm closure, please email the following to the IBC Office:

1. An email from the clinical trial contact (copying the PI) indicating that the last dose has been administered
2. Confirmation files that have been sent to the IRB confirming that all dosing has been completed

After final dosing has been indicated, the IBC Office will process the closure of the CU Denver | Anschutz IBC clinical trial protocol. If the clinical site or sponsor would like to reopen the study at a future date, the CU Denver | Anschutz IBC Office must be emailed with all required submission documents outlined above so that the IBC clinical trial protocol submission package can be reviewed and discussed at the next IBC meeting.