



Clinical Trials Requiring IBC Review- Guidance & Required Documents

Any human clinical trial that utilizes an investigational product that is classified by the NIH as 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 in the Investigator's Brochure (IB). If you are unsure of IBC review needs, please send the IB for the investigational product to ibc@ucdenver.edu for consideration.

Additionally, 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 our campus, or other clinical research activities of concern. Please contact ibc@ucdenver.edu if you are unsure of the review needs for your clinical trial.

Documents Required for IBC Review

The IBC requires a full submission package of documents before a new clinical trial can be accepted to the IBC's agenda for review. Please refer to the Office of Research Committee Support (ORCS) webpage (<https://research.cuanschutz.edu/committee-support/home/institutional-biosafety-committee>) for submission deadlines, and contact ibc@ucdenver.edu for the appropriate application file.

Documents Required for New Clinical Trial IBC Application

- Cover letter including the following information:
 - The IRB reviewing the study
 - If this is the first site for the study or if not, how many other sites are active
 - If other sites are active, note if there have been any SAE/UAPs at other sites
 - If required information such as scientific abstract, etc. is included in a different document, please note the document name & page in the cover letter
- Completed CU Denver | Anschutz IBC clinical trial application
 - 3 options are available - Human Gene Transfer, Infectious Product/Vaccine, or NIH Exempt
 - Please discuss your study with the IBC Coordinator or ORCS Director and they will provide the correct & current application form for completion
- Proposed current clinical protocol, including tables, figures, & any relevant publications
- Proposed Investigator's Brochure with any appendices
- Scientific abstract (if referenced in other submitted documents, include document name & page number on cover letter)
- Summary of preclinical studies conducted in support of the proposed clinical trial (if referenced in other submitted documents, include document name & page number on cover letter)
- SOPs regarding the handling of the investigational product, spill response, disposal, etc.
 - These 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 prior to submission that they do not contradict each other.
- If sponsor or internal SOPs do not fully address the use of an HGT biological investigational product (for HGT trials), complete & submit the Biosafety Office's HGT site specific SOP as well.
 - SOPs that reference chemotherapeutics are not adequate to address work with HGT biological investigational products.
- CV of Principal Investigator at the CU Denver | Anschutz site in NIH bio sketch format.
 - Only one clinician may be listed as the PI on the IBC application, but if there are co-investigators listed on the form as well, please also provide their CVs.
- SAEs or UAPs that have occurred at other sites prior to protocol initiation at this institution.
- If the trial is being initiated at our institution with any documents that indicate amendments, please note on the Cover Letter the version numbers that are relevant to study at initiation on our site.
- IBC review and approval should be completed prior to IRB review & approval

Follow-up Submissions of IBC Reviewed Clinical Trials

- The IBC must be notified of all SAE/UAP events, changes to the IB or Protocol, personnel changes involving PI or primary contact, and administration of final dose of investigational product.
- **SAE/UAP submissions**
 - All SAE/UAP events/documentation must be sent to the IBC (reports for such events that occurred at different clinical sites, but under the same FDA IND, etc. are included in this).
 - Cover Letter
 - Include date of SAE/UAP, site (if not ours, state other location), if a determination of cause has been reached, etc.
 - All relevant reports as submitted to IRBs regarding the SAE/UAP
- **Follow-up submissions that require submission to the IBC**
 - Document changes that are of concern to the IBC are modified IB and protocol documents (not patient facing documents, ICFs, etc.). Additionally, if the PI or primary contact changes, the IBC needs to be notified. If any of those changes occur, please send the following:
 - Cover letter summarizing the changes that were included in the amendment (including the IB/protocol changes).
 - Redlined version of the amended file, along with a clean version of the updated file
 - Approval from the IRB of record for the follow-up submission
 - Confirmation from PI that they are aware of/approve the follow up submission
 - If applicable, updated personnel file indicating new PI name &/or contact name.
- **Any other clinical trial follow-up submission**
 - If a clinical trial submission (amendment, CR, notice, etc.) does not contain any of the changes as noted above, then no submission needs to be made to the IBC.



IBC trial closure (Administration of last dose of investigational product)

- IBC oversight for clinical trials ends once the last dose of the investigational product has been administered.
 - Once the last dose has been administered, the IBC no longer needs to receive updates. To confirm closure, the following should be sent to the IBC:
 - Email from clinical contact (copying PI) indicating that last dose has been administered.
 - Confirmation files sent to the IRB confirming that all dosing has been completed.
 - After final dosing has been indicated, the IBC will close the protocol. If the clinical site or sponsor would like to reopen the study at a future date, the IBC must be notified (with all relevant submission documents provided as indicated by the IBC Coordinator at that time) and the trial will be re-review/discussion will be placed on the next open IBC agenda.