

1. Institutional Agreement (IA)

- Authorize external IBC vendor to perform review on behalf of USC. **NOTE:** IA must be signed by an appointed USC officer.
- External vendor will provide the National Institutes of Health (NIH) Office of Science Policy (NIH/OSP) with a signed copy before a convened IBC meeting can be held.



2. Principal Investigator (PI) Curriculum Vitae (CV)

- Ensure CV is current and details clinical trials, research experience, and publications.
- External IBC vendor provides a Certification of Training and Responsibilities form to be signed by the PI that declares the PI's understanding of NIH Guidelines.



3. Training Records and Certificates

Secure training records and certificates of pertinent safety courses:

- The handling of potentially infectious materials (e.g., BBP, VVT) from one clinical staff member involved in the study - within 12 months.
- Shipping of Biological Materials within two years from one staff member responsible for shipping - within two years.



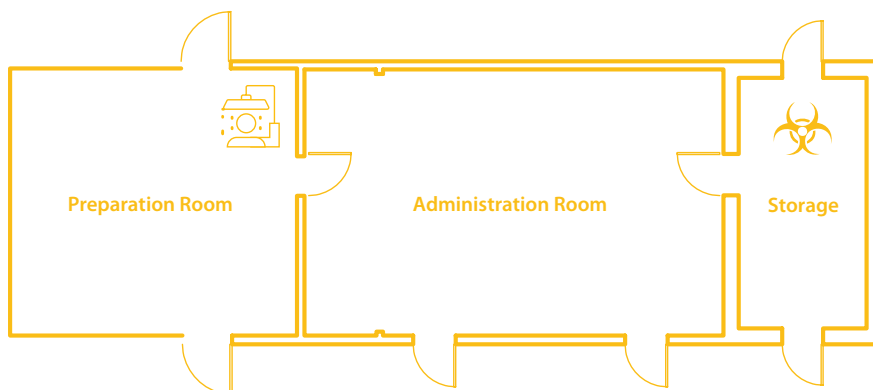
4. Annotated Floor Plan/Site Map

- Study Agent
 - Administration room(s)
 - Preparation room
 - Storage
- Central biohazard waste storage (if available)
- Sinks
- Emergency eye wash/shower station(s)

5. Photos of Study Areas

- Study Agent
 - Administration room(s) - Entire room or rooms
 - Preparation room - Entire room / close-up of the benchtop and Biological Safety Cabinet (BSC)
 - Storage - Entire room, preferably a wide-angle view from the door looking in.
- Central biohazard waste storage (if available) - Entire room and close-up of area where waste is stored prior to vendor collection.

Additional photos may be needed for larger, more complex spaces.



6. Close-up Photos of Site Equipment

- Biohazard-labeled refrigerator/freezer of IP storage
- Sinks within the preparation and/or administration rooms, hallway, or common areas
- Emergency eye wash/shower station(s)
- Disposable eye wash bottle(s)
- Biohazard waste containers in the preparation/administration rooms
- Sharps containers in the preparation/administration rooms
- Biohazard-labeled transport container (hard-sided with closeable lid. e.g., small cooler, tackle box) - transport of study agent(s) from preparation room to dosing room.



7. Close-up Photos of Disinfectant(s)

Take photos of the front and back labels of the proposed disinfectant(s) for study use. Ensure that the EPA No. is visible in the photos.



8. USC Biosafety Manual and Other Publications

Reference the following publications (include other applicable publications, SOPs as needed):

- USC Biosafety Manual <http://tiny.cc/uscehs-bio-manual>
- Pathogen Safety Data Sheets <http://tiny.cc/usc-psds>
- Biohazardous Spill Clean-Up Guide Sheet <http://tiny.cc/usc-bio-cleanup>



9. BSC Certification Report

- BSC must be certified at least annually, per NSF 49 standards
- The certification vendor will supply the report that verifies the BSC is working properly.

NOTE: Aseptic containment isolators (CACI) used in lieu of BSCs require certification reports as well.



10. Site Checklist

The external IBC vendor will provide a checklist based on Appendix G of the NIH Guidelines to be completed by the site Responsible Person(s).



11. Biohazard Sign

The external IBC vendor will provide Biohazard Signs to be posted on doors of rooms/areas when study agent is present. Posting locations: Storage Room(s), Preparation/Administration Rooms, Biohazard Waste Storage Room(s)



12. Biosafety Overview

The external IBC vendor will provide site-specific overview that includes relevant biosafety information regarding the storage, handling, and disposal of the study agent using information furnished by the site Responsible Person(s).



Adapted from Clinical Biosafety's [CBS Required Documents for IBC Review document \(PDF\)](#) with permission.

Additional resources from Clinical Biosafety are available [here](#).

