

Required Documents for IBC Review



1. Institutional Agreement (IA)

Authorize CBS to **perform the review on behalf of the Institution.**

CBS must 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.



i The IA must be signed by the Institutional Official (an individual who can sign legal documents on behalf of the Site/Organization).

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



Current Curriculum Vitae (CV): contain a detailed list of clinical trials, research experience, and publications.

Principal Investigator Certification of Training and Responsibilities (CTR) Form - provided by CBS to be signed by the PI certifying that they understand the *NIH Guidelines* and their responsibilities under them.

3. Training Records



Handling of Potentially Infectious Materials taken within 12 months (e.g. **OSHA Bloodborne Pathogen Training, Infection Prevention, etc**) Required from one clinical staff involved with the study to show a program is in place.

Dangerous Goods Shipping (International Air Transport Assoc. (IATA), good for 2 yrs) Required from one staff member responsible for shipping to show a program is in place.





4. Annotated Floor Plan/Site Map to show study areas:



Study agent storage room



Study agent preparation room



Study agent administration room(s)



Central biohazard waste storage (if available)



Sinks



Emergency eyewash station(s)

5. Photos of Study Areas



Storage room of study agent: entire room*



Preparation room of study agent: entire room & closeup of the benchtop and/Biological Safety Cabinet (BSC)



Administration room(s) of Study agent: entire room



Biohazard waste area(s): entire room & closeup of the area where the waste is stored prior to vendor collection

*Wide-angle view of the room from the door looking in, to capture the majority of the room (area) as a whole. Additional pictures may be needed for larger, more complex spaces.



6. Closeup Photos of Site Equipment



Refrigerator/Freezer of IP storage (with biohazard sticker affixed)



Sinks within the preparation and/or administration rooms, hallway or common areas



Emergency eyewash station(s)



Disposable eyewash bottle(s)



Biohazard waste containers in the preparation/administration rooms



Sharps containers in the preparation/administration rooms



Transport container: hard-sided with closable lid (with biohazard sticker affixed). The container used to transport study agent(s) from the preparation room to the dosing room

Examples: Tupperware™ container, small cooler, or tackle box

7. Closeup Photos of front and back labels of the proposed disinfectant(s) for study use.



Please ensure that the EPA# is visible on the photos





8. Laboratory Safety Manual

Acceptable substitutes include: OSHA Exposure Control Plan (ECP) or Infection Control Manual

An Emergency (Spill) Response Plan is required only if this document does not contain spill cleanup procedures.



9. Certification Report



- 1** Must be certified at least annually, per NSF 49 standards.
- 2** The certification vendor will be able to provide the report that the BSC is working properly.

In some cases an aseptic containment isolator (CACI) is used in lieu of a BSC, which also requires certification records.

10. Site Checklist

CBS will provide a Checklist based on **Appendix G** of the *NIH Guidelines* to be completed by the Site.



11. Biosafety Overview



CBS will provide the Site-specific Overview that includes biosafety-centric information regarding the storage, handling, and disposal of the study agent using information furnished by the Site.

12. Biohazard Sign



CBS will provide the Site-specific Biohazard Sign 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)

