

1. Institutional Agreement (IA)

Authorizes Sabai IBC Services to **perform the review on behalf of the institution.**

Sabai 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.



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): containing a detailed list of clinical trials, research experience, and publications

Principal Investigator Certification of Training and Responsibilities (CTR) Form: provided by Sabai IBC Services 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) if applicable



Administration room(s) of study agent: entire room



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

*Wide-angled 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 for 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: Secondary sealable plastic bag. Tertiary 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. Clinical Biosafety Manual

Your AP will provide you with the Clinical Biosafety Manual. This document is intended to supplement the site's existing biosafety manual and biosafety SOPs and policies.



9. Biosafety Cabinet (BSC) Certification Reports



- 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, a compounding aseptic containment isolator (CACI) is used in lieu of a BSC, which also requires certification records.

10. Site Checklists

Your AP will provide you with an electronic form to complete in our online portal. The Checklist is based on **Appendix G** of the *NIH Guidelines*.



11. Biohazard Sign



Sabai IBC Services 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 room(s), Biohazard Waste Storage room(s)