



Required Documents for Annual IBC Review

1. Annual Review Report

Approximately 60 days prior to the study's expiration, an email will be sent to the Site from MySabai, Sabai's online portal system, to complete the Annual Review Report.

Verify no exposures or incidents with study agent in the past year.

Verify if dosing is ongoing and if study agent is still on site.



If the study is closed, no additional dosing will be done in the future, and all study agent has been removed from the site - the study may be eligible for IBC oversight closeout

2. Current Training Records



Handling of Potentially Infectious Materials taken within 12 months (e.g. OSHA Bloodborne Pathogens 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.

3. Past Meeting Recommendations



Updated photos, site maps, and other documents.



Ask your AP if you have questions about previous recommendations.

4. 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.



5. 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.

6. 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**.



7. Site Changes



Expected changes, including new locations, new PI, changes to the IBC approved rooms, and changes to the IBC approved documents.

All changes must be pre-approved by your IBC prior to implementation.