

Non-Voting Site Contact

Certain criteria must be met when using an externally administered Institutional Biosafety Committee (IBC) to oversee research that is subject to the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, aka [NIH Guidelines](#).



The IBC must identify an individual at the Site with the authority and responsibility for implementing IBC directives and recommendations.

IBC Responsibilities

The IBC must provide documentation to the National Institutes of Health's Office of Science Policy (NIH OSP), which registers the IBC, confirming that the Committee has knowledge of local institutional arrangements at the Site, including understanding how and where the study agent will be stored, prepared, and administered; training of investigators and staff handling the study agent; and operating procedures.

Site Contact Responsibilities

- Represents the Institution and is appointed to the IBC as a non-voting member of the Committee
- Should be located at the Institution's facilities where the study will be conducted
- Should be familiar with the proposed facilities and operations at the Site and knowledgeable about the proposed research/clinical study

What Does the Site Contact Need to do?

1. Engage with Sabai throughout the study's conduct
2. Attend IBC meetings when the study is reviewed to assist the Committee with their review of the Site
3. Ensure that all IBC directives and/or recommendations are implemented at the Site
4. Immediately report any spills or exposure incidents involving the study agent to Sabai IBC Services
5. Immediately report to Sabai any changes in:
 - IBC approved Principal Investigator
 - IBC approved location(s) for study agent storage, preparation, or administration
 - IBC approved Personal Protective Equipment (PPE)
 - Such changes may require IBC review during a convened meeting
6. Provide Sabai with copies of new or updated Sponsor documents as soon as they are received - Updates to Sponsor documents may result in the need for additional IBC review
7. Notify Sabai if the Site Contact is no longer employed by the Site



Although Site Contacts may occasionally be copied on roster-related email correspondence from NIH OSP, Sabai will manage all correspondence with the NIH. Site Contacts are not required to respond to email(s) received from NIH OSP.

Sources

- [FAQs on Externally Administered IBCs - Office of Science Policy \(nih.gov\)](#)
- [Homepage - Office of Science Policy \(nih.gov\)](#)
- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules - April 2024](#)