

*Externally Administered Institutional Biosafety Committees
(IBCs)*

Frequently Asked Questions

1. What is an externally administered IBC?

An externally administered IBC is one that is administered by an entity (i.e. institute, commercial entity, university, etc.) other than the institution performing research subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*.

2. Can an institution that does not have an IBC use an externally administered IBC to review and approve research subject to the *NIH Guidelines*?

Yes, an institution may use an externally administered IBC provided certain conditions are met as outlined below.

3. What are the conditions under which an institution may use an externally administered IBC?

The IBC must be registered by the institution that is conducting research subject to the *NIH Guidelines* (not by the entity administering the IBC).

The expertise and membership of the externally administered IBC must be appropriate for the registering institution and in keeping with research conducted at that institution, include plant or animal experts, a biological safety officer, or other expertise as appropriate. The IBC must also include at least two unaffiliated members who can represent the interests of the community surrounding the registering institution. If the entity administering the IBC and the registering institution are geographically distant, the unaffiliated members must be local to the registering institution (where the research is taking place).

The IBC must also provide documentation to OBA that (1) the IBC has knowledge of local institutional characteristics - such as investigator training, laboratory conditions, and operating procedures, and (2) an individual at the registering institution has the authority and responsibility to implement the IBC's directives. These requirements can be fulfilled by one individual (such as a biosafety officer or laboratory director).

4. What information must be sent to OBA to register an externally administered IBC?

Institutions wishing to register an externally administered IBC with OBA must submit the following information:

- A cover letter signed by an official at the registering institution indicating the institution's intent to register an IBC with OBA.

- A complete roster listing all members of the IBC; the roster should contain complete contact information for each committee member, including:
 - Name
 - Title
 - Business mailing address
 - Phone number
 - Fax number
 - Email
 - The role of each member, e.g., chair person, contact person, non-institutional member, special expertise as relevant, etc.
- Biographical sketches (e.g., a short summary of professional expertise or *curricula vitae*) for each member on the committee.
- Documentation signed by an official at both the institution establishing the IBC and the organization externally administering the IBC. The documentation should indicate that the institution that administers the IBC has agreed to be the IBC of record for the establishing institution and thus will fully comply with the requirements set forth in the *NIH Guidelines*. Also, the documentation should include a statement that the establishing institution is accepting the authority of the externally administered IBC.

5. Can a multi-site clinical trial use the same externally administered IBC to review and approve the trial at each trial site?

Yes, provided that each individual trial site registers the IBC with OBA, and the IBC fulfills the necessary membership and expertise requirements. This includes the requirement that the IBC have at least two unaffiliated members to represent the interests of the local community at each trial site.

6. Where should IBC registration materials be sent?

Submission of IBC registration information should be made to:

Office of Biotechnology Activities
 c/o Michelle Johnson-Lancaster
 National Institutes of Health
 6705 Rockledge Drive, Suite 750
 Bethesda, MD 20892-7985 (20817 for non-USPS mail)
 Telephone: (301) 496-9838
 Fax: (301) 496-9839
 Email: johnsom1@mail.nih.gov

7. How do I contact OBA for more information?

Questions regarding the registration of an externally administered IBC may be directed to OBA staff at oba@od.nih.gov. Staff may also be reached at (301) 496-9838.