Institutional Biosafety Committee (IBC) Reviews

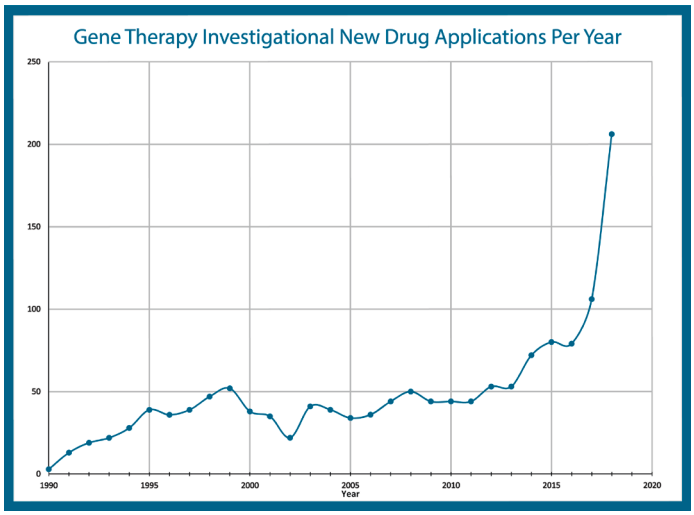
What Is an IBC?

An IBC is an oversight body that **assesses the risks to research staff, participants, facilities, and communities** that handle, store, manipulate, transport, and dispose of investigational products containing engineered genetic materials. IBCs help ensure compliance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, first published in July 1994 and most recently updated in April 2019.

What Types of Research Require IBC Review?

IBC review involves the deliberate transfer of engineered genetic materials to human research subjects, including the following types of studies:

- Gene therapy
- Gene editing
- Vaccines containing engineered genetic material
  - E.g., virus-based vaccines, genetic vaccines, mRNA based vaccines
- Genetically modified cellular therapy and immunotherapy
  - E.g., CAR T cells, engineered T cell receptor
- Genetically modified microorganisms
- Regenerative medicine



Who Serves on an IBC?

An IBC is comprised of at least 5 people who collectively **possess the expertise to assess the risks for the proposed research**. At least 2 members must be community members, who are people not associated with the site or the study and who work or live within 50 of the research site.

What's the Difference Between an IRB and an IBC?

IRBs help ensure the ethical conduct of research involving human participants. **IBCs help ensure research involving engineered genetic materials is conducted safely**. IBCs may oversee clinical trials or non-clinical research involving cells, microorganisms, plants, or animals.

In addition, an IBC must register with the NIH for each site it will review. **Advarra facilitates this registration process at no cost or obligation to the site, sponsor, or CRO**. Registration is a one-time exercise.

When Is IBC Review Required?

IBC review is required for all recombinant or synthetic nucleic acid research within the United States, its territories, or abroad, **if the research is conducted at or sponsored by an organization that receives any NIH support for recombinant or synthetic nucleic acid research, including research performed directly by NIH**. This includes research collaboration or contractual agreements, not simply provision of research materials or NIH funding.

Even if there are no NIH funds involved, IBC review is a best practice. NIH Guidelines state that "individuals, corporations, and institutions not otherwise covered by the NIH Guidelines are encouraged to adhere to the standards and procedures set forth" (Section IV-D-1).

How Long Does IBC Review Take?

All IBC reviews are site- and study-specific. **Advarra commits to completing IBC reviews within 10 business days from the time a complete site submission is received**, if Advarra is already registered with the NIH as an IBC for the site when the submission is received.

The NIH customarily takes 4-6 weeks to process a registration request, so it's a good idea to register well in advance of study activation. **Advarra can facilitate the registration process for a site weeks (or even months) in advance of study activation**.

Gene Therapy Ready

Demonstrate your site's commitment to research quality and make your research program more appealing to industry sponsors. With Advarra's Gene Therapy Ready program, our biosafety experts help ensure your site and staff are prepared to conduct gene therapy research, including:

- NIH registration
- SOP review
- Site inspection
- Staff training

Ready to get started?

Contact BusinessDevelopment@advarra.com for support.

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