ADVARRA®
advancing better research

IBC Review and Consulting Services

No more waiting for a standing meeting. No submission deadlines. Responsive and flexible—only 10 business days or less from submission to institutional biosafety committee (IBC) review.*

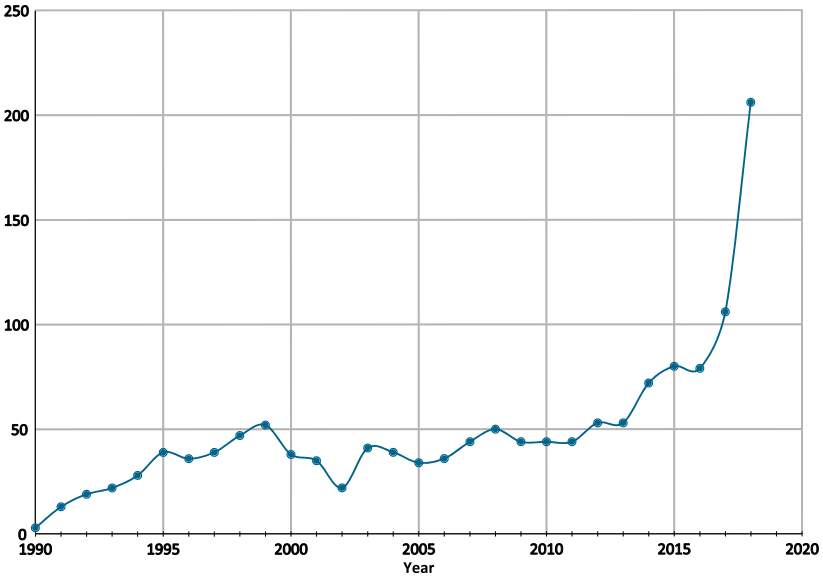
There's an altogether better way to perform IBC reviews.

**If Advarra is registered as an IBC for the site at the time of submission.*

Gene Therapy Research Is Growing—

How Will You Stay Ahead of the Curve?

Gene Therapy Product IND Submissions to FDA



Source: FDA

Gene therapy research is on the verge of exploding. With this growth comes competition for sites and institutions that are gene therapy ready.

Advarra has the experience to prepare you for the aggressive timelines of industry-sponsored gene therapy research.

Streamline Study Startup

Study startup is already a challenging process, with researchers juggling study activation goals, accrual rates, and endpoints. Why add the complication of IBC reviews that take more than a month to complete?

Advarra's standard IBC review turnaround time is 10 business days or less. In a case study of 52 consecutive IBC submissions for NCI-designated cancer centers, we completed reviews in an average of 6.5 business days. Across 65 COVID-19 trials, we completed reviews in an average of 4.1 business days.

The less time it takes to complete IBC reviews, the more attractive sites are to industry sponsors and CROs—and the faster patients can gain access to clinical trials.

Proven Solutions to Accelerate Research

≤ 10 days from submission to review

Oncology gene therapy expertise

Coordinated IRB/IBC review

IBC Services

Biosafety Solutions

IBC setup & registration support

- Establishment of local biosafety committee(s)
- Recruitment and staffing of qualified personnel
- Implementation of industry-leading laboratory safety procedures
- Management of regulatory registration

Protocol review & approval

- Review of research protocols
- Issuance of regulatory approvals
- Ongoing monitoring and support solutions

Education, training, & operations consulting

- Research staff training
- Laboratory safety
- Biohazard education
- Protocol, SOPs, and informed consent consulting

IBC compliance & management

- Year-round compliance management
- On-demand review services
- Clinical, non-clinical, and preclinical support
- Site audit capabilities

IBC-Ready™ local IBC submission support

- Assistance with completing local IBC forms accurately and efficiently
- Available regardless of whether Advarra® serves as central IBC

Coordinated IBC and IRB Reviews for Added Efficiency

When Advarra serves as a study's central IBC and IRB, we coordinate concurrent reviews to streamline the process. No need to wait for one committee's approval before the other review can begin. Our concurrent reviews accelerate the regulatory approval process.

Turnaround Times

Turnaround can depend on a site's experience with and preparation for IBC review. For sites where Advarra is already registered with the NIH as an IBC, human gene transfer studies can often be reviewed and approved in 10 business days or less. For sites that don't have a registered IBC and that may be new to gene therapy research, this timeline may be extended by 4-6 weeks to allow the NIH to complete the IBC registration. Advarra utilizes site inspectors located in proximity to the research site, saving additional time and travel expenses.

2/3 of Gene Therapy Studies Are in Oncology

Accelerate your study's activation timelines and stay ahead of the 90-day startup for NCI subject accrual. Advarra's IBC and IRB include robust oncology gene therapy expertise, and our IRB offers a dedicated Central Oncology Review (COR) panel. Our reviewers understand the latest techniques and discoveries, asking the right questions to get your study up and running faster.

Gene Therapy Expertise

- Oncology
- Immunology
- Infectious Diseases
- Vaccines
- Genetic Diseases
- Regenerative Medicine
- Neurology
- Metabolic Diseases
- Cardiovascular
- Opthalmology
- And More

Complimentary Services

IBC assessment of protocol

Not sure if your study requires IBC review? Advarra can conduct a quick assessment of your protocol to determine whether IBC review is necessary.

NIH registration for sites

Any site planning to conduct gene therapy research must first register its IBC with the NIH Office of Science Policy (OSP). This process can take several weeks, and Advarra recommends completing this registration as soon as possible so the site is ready to roll as soon as it receives its first gene therapy study. Eliminate this common study startup delay—ask Advarra to help complete this registration.

- No cost or obligation
- One time-only exercise
- Registration is specific to the site, not the study or PI
- NIH allows more than 1 IBC to be registered at a site

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

75% of Operation Warp Speed
US-based coronavirus vaccine clinical trials are supported by Advarra's IBC.

Advarra IBC

With a diverse roster of career biosafety professionals and a secure user-friendly submissions platform, Advarra routinely performs IBC reviews for gene therapy research in 10 business days or less from receiving a complete submission. IBC reviews and site inspections (if necessary) can be completed before, after, or concurrent with IRB reviews.

Ready to make your research **altogether better**?
Contact **businessdevelopment@advarra.com** to get started.

ADVARRA®
ADVARRA.COM