IRB

# IRB Review of International Research

## Help ensure participants are protected anywhere in the world

Regulations governing the protection of human research participants vary country to country. Advarra reviews research in the United States, Puerto Rico, and Canada and limited minimal risk research outside of the U.S., Puerto Rico, and Canada. **For research in other countries that must be reviewed by local ethics committees, Advarra provides services to confirm compliance with U.S. regulations.**

### Review by a Non-Local Ethics Committee

In many parts of the world, research ethics review is conducted locally by institutionally based ethics committees (ECs). **Centralized research ethics review**, like the U.S. central institutional review board (IRB) model where a single, non-local committee oversees research at multiple sites, **is not common outside of North America.**

When only local ethics oversight is permitted, researchers must work with local regulatory agencies and research ethics committees to ensure they comply with all local requirements.

## Review Services for International Research

Advarra offers different IRB review options depending on whether the local EC has reviewed and approved the project.

### Protocol Review and Approval

**If the local EC has already provided its approval of the project,** submit protocol materials to Advarra for a new study review. Advarra's IRB will review the protocol to ensure it complies with U.S. regulations, recommend any necessary changes to protect participants, and provide an approval document as appropriate.

**In addition to standard new protocol submission requirements, you will also need to provide the final local EC approval letter and associated documents.**

This service provides you with the understanding of how research is reviewed according to U.S. regulations and can provide clarity on review standards.

**Note:** The IRB cannot oversee research sites outside of North America and relies on the local EC for this review.

## Advisory Review

**If no local EC approval has been obtained,**

request a review of your draft protocol and get answers to questions about study design, participant protections, and regulatory requirements.

An IRB advisory review can help ensure your protocol and other participant-facing materials meet U.S. regulatory and ethical standards, which can be helpful to a local ethics committee when they conduct their in-country review.

> The advisory review outcome letter documents compliance with US regulations and human participant protection standards, though it does not serve as formal IRB approval.

The advisory review may include recommendations and/or comments. **Include the advisory review letter with your local EC submission as a helpful resource in support of the local committee's review deliberations.**

### Review of Research Conducted Both in North America and Internationally

Advarra can provide IRB review of the protocol and North American-based sites (i.e., U.S., Puerto Rico, and Canada). Simply submit the study for review via the Advarra Center for IRB Intelligence (CIRBI) Platform. **Please note that the IRB cannot provide oversight for sites located outside of North America.**

## Additional Review Services for International Research

Institutional biosafety committee (IBC), data monitoring committee (DMC), and endpoint adjudication committee (EAC) oversight jurisdictions are not limited in the same way as the IRB. Work with Advarra's proven biosafety and biostatistical experts to ensure appropriate protections anywhere in the world. **Simplify trial oversight when you rely on Advarra's integrated review services for all your independent oversight committee needs.**

## Consulting Support for International Research

Navigate the complex web of international research regulations with the help of seasoned practitioners. Advarra Consulting's experts bring decades of industry experience to help your organization succeed globally.