

INSTITUTIONAL REVIEW BOARD (IRB) FAQ

WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

An IRB is a group of individuals who have been formally chosen to review and monitor research studies that involve humans. Under FDA regulations, an IRB has the right to approve, require changes to or reject a study.

IRBs review study documents like protocols, informed consents and recruitment materials. This group review serves a key role in the protection of the rights and well-being of research participants.

DOES AN IRB NEED TO REGISTER WITH FDA BEFORE REVIEWING STUDIES?

Yes, each IRB in the United States is required to register with the Department of Health and Human Services (HHS). The FDA is an HHS agency that regulates clinical investigations of products under its jurisdiction.

HOW OFTEN SHOULD A STUDY BE REVIEWED AND APPROVED BY AN IRB?

Continuing studies should be reviewed once a year.

WHEN SHOULD STUDY PARTICIPANTS BE NOTIFIED OF CHANGES TO A STUDY?

All study protocol amendments need to be reviewed and approved by an IRB before being implemented, unless an immediate change is needed to protect the well-being of participants.

All active participants need to be made aware of the changes if they might relate to their willingness to take part in the study. The FDA does not require reconsenting of individuals who have already completed their active participation in the study or of individuals who are still actively participating. The change is only implemented for future participants.

WHAT FACTORS SHOULD BE CONSIDERED WHEN SELECTING AN IRB?

There are many factors to consider when choosing an IRB for a registry study. These factors include, but are not limited to:

- The fees of the IRB
- The turnaround times of the IRB
- The reputation of the IRB
- The capacity of the IRB for new studies

WHERE CAN I FIND INFORMATION ON SELECTING AN IRB?

There are various IRBs to choose from when developing a patient registry. Below are a few examples:

1. **Advarra:** advarra.com/irb-services
2. **BRANY:** brany.com
3. **WCG:** wcgirb.com/services/irb-review
4. **North Star Review Board** at 877-673-8439 (toll free) or patseymour@northstarreviewboard.org