

# The Single IRB Mandate

The single IRB (sIRB) mandate is a set of complementary federal policies requiring certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. This information may also be useful for multi-site studies not federally-funded, but wish to use a single IRB.

## Definition of “multi-site” research

“**Multi-site**” means the same research procedures (i.e., protocol) are being conducted at one or more domestic sites and each site is under the control of a local participating investigator. This typically involves a lead site that receives the grant or contract directly from NIH and then establishes a subaward or subcontract to each participating site. The research could be a clinical trial, an observational study, or a basic clinical research study.

“**Same research protocol**”. Protocols addressing the same research questions, involve the same methodologies, and evaluate the same outcomes are considered to be the “same research protocol.” Additionally, sites accruing research participants for identical studies except for variations due to local context consideration would be considered to be conducting the “same research protocol.” If a study involves a separate site for study coordination or coordination of data and statistical analyses, and the site is conducting the same protocol as the other participating sites, then all sites would be expected to rely on the designated single IRB.

\*\*If you are unsure, please contact the [VT IRB office](#).

## Exceptions

**Types of awards.** The NIH sIRB policy does not apply to:

- Exempt human subjects research
- Career development, research training, or fellowship awards (“K”, “T”, and “F” grants)

**Types of sites.** The NIH sIRB policy does not apply to the following types of participating sites in multi-site research:

- Veterans Administration sites
- Foreign sites (though domestic sites of the same study must be reviewed by a sIRB)
- Sites involving tribal nations
- Sites for which review by the proposed sIRB is prohibited by a federal, tribal, or state law, regulation, or policy

Note that a study may involve sites that must comply with the policy **and** other sites that are not required to comply.

NIH will consider [requests for exceptions](#) if there is a compelling justification, but it has stated that exceptions will be rarely granted.