

Glossary

CEDE REVIEW

An institution agrees to transfer IRB review and oversight authority for specified research to another institution's IRB (reviewing IRB).

CIRB

<<<< insert definition >>>>

LEAD SITE

<<<< insert definition >>>>

LEAD PRINCIPAL INVESTIGATOR (LEAD SITE PI)

The study wide lead Principal Investigator with ultimate responsibility for the conduct and integrity of multisite research.

LOCAL CONTEXT

Unique legal requirements, cultural or religious values, or other site-specific variables that exist at a site where subjects are enrolled in research.

PARTICIPATING SITE (PSITE)

<<<< insert definition >>>>

PARTICIPATING SITE PRINCIPAL INVESTIGATOR (PSITE PI)

The lead investigator at each institution participating in multisite research usually responsible for the conduct of the research at the participating institution.

RELIANCE

<<<< insert definition >>>>

RELIANCE AGREEMENT (ALSO KNOWN AS AN AUTHORIZATION AGREEMENT)

An agreement between two Organizations engaged in human subject research that documents respective authorities, roles, responsibilities, and communication between the reviewing and relying IRBs.

RELIANCE NEGOTIATION

<<<< insert definition >>>

RELYING INSTITUTION

A participating Institution that cedes IRB review to the IRB of record (reviewing IRB) designated under a Reliance Agreement.

RELYING IRB

<<<< insert definition >>>

REVIEWING IRB

The IRB which is responsible for conducting IRB review and approval as described in 45 CFR 46.109 for cooperative human subject research.

SIRB

<<<< insert definition >>>

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