

Commercial IRBs (WCG, Advarra)

Commercial IRBs are independent pay-for-service IRBs that provide regulatory and ethical review services for academic and non-academic institutions to conduct reviews of research involving human subjects. Commercial IRBs will not review research on behalf of GWU researchers without a reliance agreement that George Washington iRIS has cleared the study for commercial IRB oversight noting that the Commercial IRB will be the IRB of record.

Types of studies that qualify for commercial IRB review:

- Clinical trials (all phases)
- Industry sponsored
- Non-industry sponsored, at the discretion of GWU Office of Clinical Research
- Others at the discretion of the GWU Office of Clinical Research

GWU has established service agreements with the following commercial IRBs:

Advarra (Chesapeake IRB, Schulman IRB, Advarra IRB)
WCG (WIRB-Western IRB, Copernicus IRB, New England IRB)

Each commercial IRB has their own submission requirements, which are detailed on their websites.

GWU Study Coordinator or PI creates and submits a reliance agreement in the IRB electronic submission system

Applications to applicable ancillary committees can be submitted in parallel to the IRB reliance registration. GWU regulatory committee(s)' required language must be added to the GWU site-specific consent/assent forms based on the regulatory committee(s)' request(s).

GWU iRIS designated staff screens the reliance agreement submission for completeness and will notify the submitting party via the IRB electronic submission system for any additional requirements.

- A. Once the submission is acceptable, GWU iRIS will provide the submitting party with the "External Review Accepted" letter attesting that GWU has agreed to cede IRB review responsibility to the commercial IRB.
- B. The designated party submits the appropriate application, including the "External Review Accepted" letter, to the commercial IRB using their online system.
- C. The commercial IRB reviews the submission and will communicate directly with the submitting party with respect to any required revisions and/or additional information as needed.
- D. The submitting party will concurrently communicate with GWU ancillary committees as applicable.

The commercial IRB will communicate directly with the submitting party contact and, when the review is completed, will provide an approval notice and stamped versions of the GWU site-specific consent and recruitment documents (if applicable).