

IRB Standard Operating Procedure

IRB Reliance Agreements (Inter-Institutional Agreements)

The Reliance Agreement, also called an Inter-Institutional Agreement (IIA), is a document signed by two institutions that are engaged in human participant research authorizing one of the institutions to serve as the reviewing IRB (IRB of Record). In multi-site research, the Reliance Agreement permits a single IRB to review human participant research activities for more than one site.

"IRB of Record" is the term used to identify the IRB that assumes the primary responsibility for the review and approval of the project as part of a Reliance Agreement. The "Relying IRB" is the IRB that cedes review to the IRB of Record.

A Reliance Agreement avoids duplicate IRB review and can lessen administrative burden and regulatory oversight by permitting one IRB to serve as the IRB of Record for multiple sites in a research project.

No College of Charleston investigator may begin research with human participants until the Reliance Agreement has been signed by Signatory Officials at both institutions and returned to the College.

The IRB Reliance Agreement will include the following information:

- IRB of record and the relying institution,
- FWA numbers
- Project information, including external funder if applicable
- A communication plan, and
- Signatures of authorized signatories.

Another Institution as IRB of Record

In the event that a College of Charleston (the College) Principal Investigator (PI) needs to conduct human participant research that has been approved or is currently under review at IRB outside of the College, the College may enter into a Reliance Agreement.

Note: If the human participants include members of the College community (faculty, staff or students), then the research may need to be approved by the College's IRB, not through a Reliance Agreement unless a single IRB is required by a funding source, the other IRB is uniquely qualified to review the research (e.g. medical research), or the project is a multi-institutional collaborative study.

In order to enter into a Reliance Agreement, the following steps must be taken:

1. The College PI will contact the Office of Research and Grants Administration (ORGA) at compliance@cofc.edu and provide the following information/materials:

- A completed Reliance Agreement Form (this form may be initiated by the other institution, but must comply with College of Charleston IRB requirements).
 - The protocol as submitted or approved by the IRB of record, including attachments.
2. ORGA will provide these materials to the IRB Chair for review.
 3. The Chair may approve, request further information, or request full board review.
 4. After Chair (or full IRB) has granted approval, the College's authorized signatory (Susan Anderson or her designee) may sign and send the Agreement to the IRB of Record's institution.
 5. A fully-executed copy is returned to ORGA**

College of Charleston as IRB of Record

In the event that a non-College of Charleston PI needs to conduct human participant research that has been approved or is currently under review at the College's IRB, the College may enter into a Reliance Agreement with non-College's PI institution. The steps outlined above will be followed, but with the College serving as the IRB of Record.