

## IRB Authorization Agreements

### I. DEFINITIONS

*IRB Authorization Agreement:* A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying Institution. Agreements are generally used to cover a single research study, categories of research studies, or research studies within a research program.

*Federalwide Assurance (FWA):* A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects.

*IRB of Record:* A reviewing IRB that assumes IRB responsibilities for another institution and is designated to do so through an approved Federalwide Assurance on file with the federal Office for Human Research Protections.

*IRB Reliance and Relying Institution:* IRB reliance is a term to describe partnerships or agreements among different IRBs to rely on each other to provide IRB oversight for research studies. The relying institution accepts the review of the IRB of record.

### II. SCOPE

IRB Authorization Agreements apply only to research that requires review at the expedited or full IRB levels of review. As a relying institution, the BSC IRB will only enter in Authorization Agreements with IRBs with Federalwide Assurance.

### III. PROCEDURES

- A. BSC IRB as IRB of Record: Authorization Agreements with the BSC IRB as the IRB of record will generally be submitted by principal investigators. Approval from the Chair of the BSC IRB must be obtained before submitting the agreement for approval.
- B. BSC as the Relying Institution: The Authorization Agreement shall be submitted to the Chair of the BSC IRB for review and approval. The BSC IRB Chair, or the Chair's designee, shall review and approve or disapprove submissions for authorization agreements where BSC is the relying institution. Investigators seeking an IRB Authorization Agreement where BSC will be the relying institution shall complete the [BSC IRB Authorization Agreement form](#) and supply supporting documentation as required. If the agreement is approved by the Chair of the BSC IRB or the Chair's designee, it will be forwarded to the Provost for final approval or disapproval. Only agreements with IRBs having Federalwide Assurance will be approved.

If the BSC IRB is the IRB of record or if BSC is the relying institution, no research covered by an agreement shall commence until the agreement is formally approved by the cooperating institutions. The Chair of the BSC IRB shall inform the full BSC IRB of all Authorization Agreements, and the IRB Administrator shall record the approval of all Authorization Agreements in the minutes of a regular full IRB meeting.