

# Reliance Process Flowchart: Northwestern serving as the IRB of Record

## Phase 1: Initial Protocol Review

**a.** **eIRB+ Submission**

Upload sIRB Letter of Support (if federally funded), describe each site's activities in the protocol.



**b.** **IRB Review**

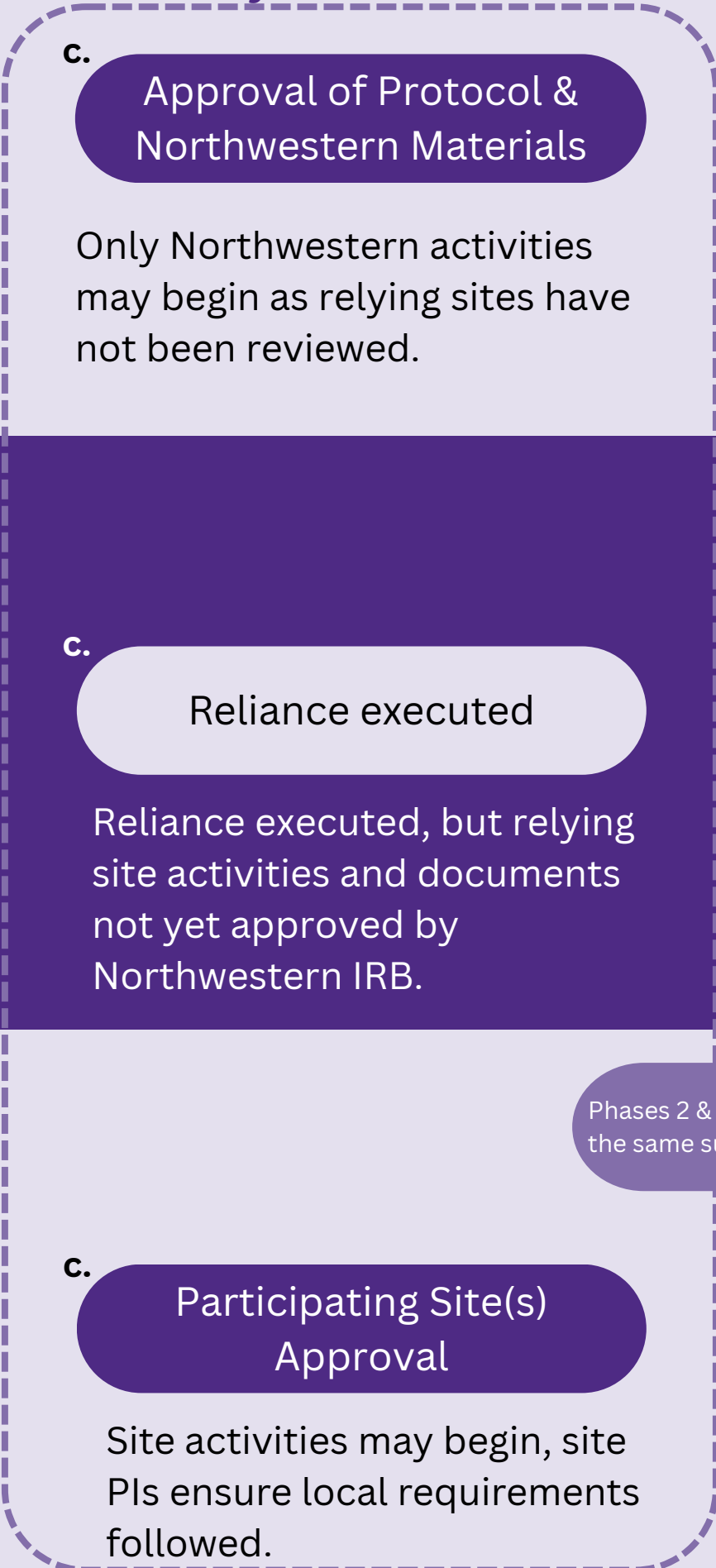
Protocol and study materials reviewed by Biomedical or Social Behavioral (SB) team.



**c.** **Approval of Protocol & Northwestern Materials**

Only Northwestern activities may begin as relying sites have not been reviewed.

### Key Benchmarks



## Phase 2: Execute Reliance Agreement(s)

**a.** **eIRB+ Submission (Modification)**

Upload draft reliance agreement(s), list site(s) and collaborator(s).



**b.** **Reliance Review**

Reliance analyst reviews reliance considerations, facilitates inclusion of local context form(s) and signature on reliance agreement(s).



**c.** **Reliance executed**

Reliance executed, but relying site activities and documents not yet approved by Northwestern IRB.

## Phase 3: Review of Participating Sites

**a.** **Consent Form Customization**

Collaborators edit ICF(s) and HIPAA to include their required language.



**b.** **IRB Review**

Biomedical or SB analyst reviews relying site(s) activities, local context information, ICF and HIPAA (if applicable).



**c.** **Participating Site(s) Approval**

Site activities may begin, site PIs ensure local requirements followed.

Phases 2 & 3 occur in the same submission

If Site is Consenting