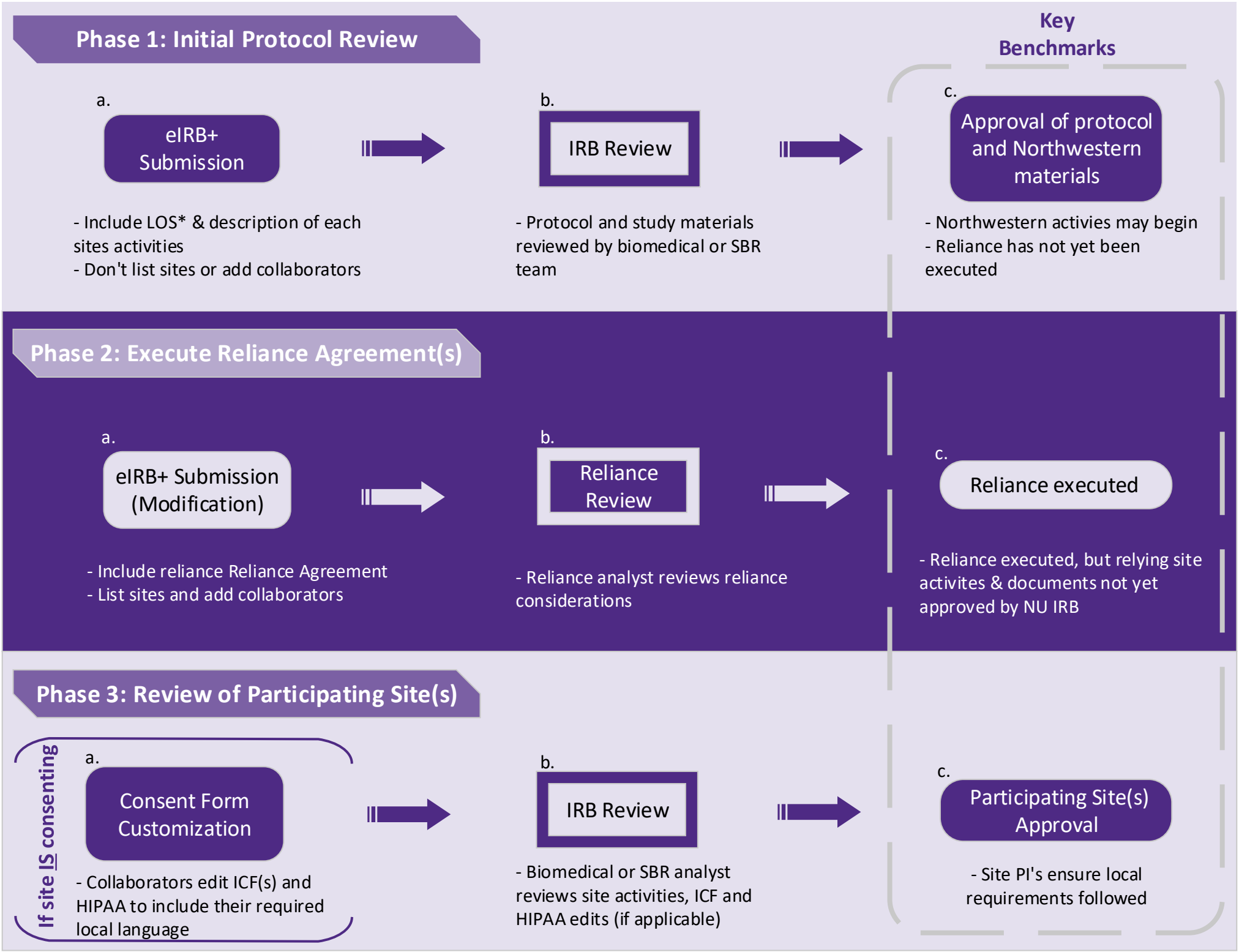
Key Benchmarks
Phase 1: Initial Protocol Review
a.
eIRB+ Submission
- Include LOS* & description of each sites activities
- Don't list sites or add collaborators
b.
IRB Review
- Protocol and study materials reviewed by biomedical or SBR team
c.
Approval of protocol and Northwestern materials
- Northwestern activies may begin
- Reliance has not yet been executed
Phase 2: Execute Reliance Agreement(s)
a.
eIRB+ Submission (Modification)
- Include reliance Reliance Agreement
- List sites and add collaborators
b.
Reliance Review
- Reliance analyst reviews reliance considerations
c.
Reliance executed
- Reliance executed, but relying site activites & documents not yet approved by NU IRB
Phase 3: Review of Participating Site(s)
If site IS consenting
a.
Consent Form Customization
- Collaborators edit ICF(s) and HIPAA to include their required local language
b.
IRB Review
- Biomedical or SBR analyst reviews site activities, ICF and HIPAA edits (if applicable)
c.
Participating Site(s) Approval
- Site PI's ensure local requirements followed