**Single IRB Review Process**  
**September 2023**

1. **Start**
   - Lead PI/Study Team notifies IRB that relying sites will be added to the study

2. **IRB confirms that it can serve as the Reviewing IRB**
   - Lead PI/Study Team submits initial study via iStar

3. **IRB-A takes ownership of study in iStar**
   - IRB sends Lead PI/Study Team reliance documents, and Master and Site Specific Consent template(s) for amendment(s) to add Relying Sites

4. **Lead PI/Study Team submits amendment via iStar**
   - IRB-A takes ownership of study in iStar

5. **Amendment submitted?**
   - Yes: Lead PI/Study Team submits amendment
   - No: All relying site documents complete?

6. **All relying site documents complete?**
   - Yes: Reliance Agreement executed?
   - No: Send study back w/ "incomplete change"

7. **Reliance Agreement executed?**
   - Yes: Send study back w/ "reliance change"
   - No: All docs complete/present?

8. **All docs complete/present?**
   - Yes: Amendment ready for approval?
   - No: Send study back w/ "docs change"

9. **Amendment ready for approval?**
   - Yes: IRB-A forwards to designated reviewer (IRB-A or Chair)
   - No: Changes requested for Relying Site documents

10. **Designated reviewer Approves or Approves w/contingencies**
    - Yes: IRB-A reviews all requested changes
    - No: Send approval letter and approved documents to Lead PI/Study Team via iStar

11. **Any contingencies?**
    - Yes: IRB-A reviews all requested changes
    - No: Send approval letter and approved documents to Lead PI/Study Team via iStar

12. **Send approval letter and approved documents to Lead PI/Study Team via iStar**
    - IRB-A reviews all requested changes

13. **IRB-A reviews all requested changes**
    - Yes: IRB-A forwards to designated reviewer (IRB-A or Chair)
    - No: IRB-A forwards to designated reviewer (IRB-A or Chair)

14. **Initial Study is approved**