Single IRB Readiness Checklist for Lead Study Teams & Coordinating Centers: Reliance Arrangements

This checklist will help you identify the processes and resources you may need to facilitate a single IRB reliance arrangement for your multisite research study.

 **Any item on the checklist that prompts a “No” response means that you may need to address that gap.**

|  |  |  |  |
| --- | --- | --- | --- |
|  AREA | YES | NO | NOTES |
| 1. Have you contacted your local IRB or human research protection office regarding this study?You should contact them prior to completing this checklist. | [ ]  | [ ]  | *Enter Additional Notes* |
| 2. Have you identified a Reviewing IRB that is willing to serve as the Single Reviewing IRB? Often, but not always, the Reviewing IRB is at the Overall Principal Investigator’s institution.[Link to helpful Resource for Selecting a Single IRB](https://smartirb.org/study-teams/#selecting)  | [ ]  | [ ]  | *Enter Additional Notes* |
| 3. Have you identified the reliance agreement the Reviewing IRB will use for this study? | [ ]  | [ ]  | *Enter Additional Notes* |
| 4. Will the Reviewing IRB use the SMART IRB Agreement? | [ ]  | [ ]  | *Enter Additional Notes* |
| 5. Are all institutions involved in the study SMART IRB Participating Institutions?[Link to SMART IRB Participating Institutions list](https://smartirb.org/participating-institutions/)If an institution is not a SMART IRB Participating Institution, the Lead Study Team point person may need to assist the institution with signing on to the Agreement.[Link to information on joining the SMART IRB Agreement](https://smartirb.org/join/) To join the SMART IRB Agreement, Institutions must have a Federalwide Assurance number (FWA), unless they are an Independent IRB. Local investigators should contact their IRB or human research protection office to ensure their institution has an FWA.If you will not use the SMART IRB Agreement, you will be required to execute a reliance agreement for each participating site, unless the Reviewing IRB has a master agreement in place with those institutions. | [ ]  | [ ]  | *Enter Additional Notes* |
| 6. Will the Reviewing IRB require use of the [SMART IRB Online Reliance System](https://smartirb.org/reliance/) to document the reliance arrangement?The Lead Study Team is often responsible for initiating the reliance request in the SMART IRB Online Reliance System and needs to identify each participating site and activities that will occur at each site as well as provide any informed consent template(s).If the Reviewing IRB does not require use of the SMART IRB Online Reliance System, you need to discuss with the Reviewing IRB:* 1. How will they document reliance arrangements with each site?
	2. Any role they expect the lead study team/coordinating center to play in facilitating reliance arrangements; and
	3. How the lead study team/coordinating center will be informed when a reliance arrangement is finalized for a site?

[Link to Information about the SMART IRB Online Reliance System](https://smartirb.org/reliance/) [Link to checklist for initiating a request in the Online Reliance System](https://smartirb.org/assets/files/Reliance-Checklist.pdf) | [ ]  | [ ]  | *Enter Additional Notes* |