SMART IRB

Start-up Package for Reviewing IRBs

These resources will help you understand your roles and responsibilities as a Reviewing IRB.

WHEN TO USE? IF YOU ARE…	WHAT?	WHY?
IDENTIFYING REVIEWING IRB RESPONSIBILITIES	The SMART IRB Agreement ↗	Delineates the responsibilities of Reviewing IRBs and Relying Institutions for studies under the SMART IRB Agreement.
	Responsibilities Associated with the Review of Study Personnel ⬇	Recommendations ensure study personnel are appropriately trained and qualified to conduct the research under review.
CONSIDERING CHARGING IRB FEES	Fees and Costing Models under NIH sIRB Policy ⬇	Provides points to consider regarding charging, structuring, and justifying fees for Single IRB review, as well as federal regulations on direct/indirect costs.
COMMUNICATING PROCESSES AND REQUIREMENTS	Reviewing IRB Instructions for Relying Institution Point(s) of Contact (POCs) ⬇	Communicates to Relying Institution POCs key information about the reliance arrangement as well as next steps.
	Reviewing IRB Instructions for Relying Site Study Teams ⬇	Communicates key information to Relying Site Study Teams about the reliance arrangement and next steps.
	SOP Manual, SMART IRB ⬇	Default SOPs for establishing and implementing reliance under the SMART IRB Agreement.
SETTING UP AND DOCUMENTING A RELIANCE ARRANGEMENT	SMART IRB Participating Institutions List ↗	Identifies which institutions have joined the SMART IRB Agreement; institutions that have not yet joined may initiate the process at smartirb.org/join ↗.
	Joining SMART IRB: Guidance for Affiliates ⬇	This decision tree helps determine whether an affiliate of another institution must independently join SMART IRB.

WHEN TO USE? IF YOU ARE…	WHAT?	WHY?
SETTING UP AND DOCUMENTING A RELIANCE ARRANGEMENT (CONTINUED)	SMART IRB Online Reliance System ↗	Tracks and documents reliance arrangements under the SMART IRB Agreement; this free system facilitates coordination of reliance arrangements on a study-by-study basis.
	Template Letter of Acknowledgement ⬇	If a Reviewing IRB chooses not to use the SMART IRB Online Reliance System to document use of the SMART IRB Agreement ↗ they may use this letter to document a study-specific reliance arrangement, including of the site's agreement to cede IRB review and Reviewing IRB's agreement to provide oversight.
	Implementation Checklist for use of the SMART IRB Agreement ⬇	Documents how you will implement the SMART IRB Agreement's flexible provisions.
	Communication Plan for Single IRB Review ⬇	Documents who performs key communication roles for a study.
COLLECTING LOCAL CONTEXT/ CONSIDERATIONS	Informed Consent Documents: Inserting Local Context Language ⬇	Describes processes and roles for inserting local context language.
	Institutional Profile ⬇	Documents institutional, local, and state requirements that you may need to apply to your review and oversight of studies on behalf of Relying Institutions.
	Protocol-specific Document ⬇	Used to collect variations across sites regarding study teams (e.g., training and conflicts of interests) and study conduct (e.g., ancillary reviews; HIPAA; subject population).
	Overall PI & Lead Study Team Checklist ⬇	Helps the Overall PI and Lead Study Team understand and fulfill their responsibilities.

LEARN MORE WITH THESE VIDEOS

Serving as a Reviewing IRB ↗	This webinar helps institutions prepare to serve as a Reviewing IRB under the SMART IRB Agreement.
Implementing the SMART IRB Agreement ↗	This webinar provides an overview of how to implement the SMART IRB Agreement.
Getting Started with SMART IRB and the Online Reliance System ↗	This webinar introduces SMART IRB and the Online Reliance System ↗, a free resource that allows institutions to track and document reliance arrangements on a study-by-study basis.
SMART IRB Online Reliance System Walkthrough ↗	Walks through how an investigator submits a reliance request, and subsequently, how a proposed reviewing IRB is identified, institutions record decisions, and reliance determinations are issued.
Training for Investigators and Study Teams ↗	Visit the Learning Center for Investigators and Study Teams ↗ to view available presentations; download and customize ↗ these training resources to reflect local processes.