SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-04S2.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

April: SMART IRB 2022: SMART IRB 2022: Where We've Been and Where We're Heading

May: No SMART Talk

June: Being a Single IRB for Studies with Many Sites

July: A Conversation with the VA and DOD about Single IRB

FYIs

Please provide feedback by completing the survey – a link will be posted in chat and emailed.

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

SMART IRB Updates

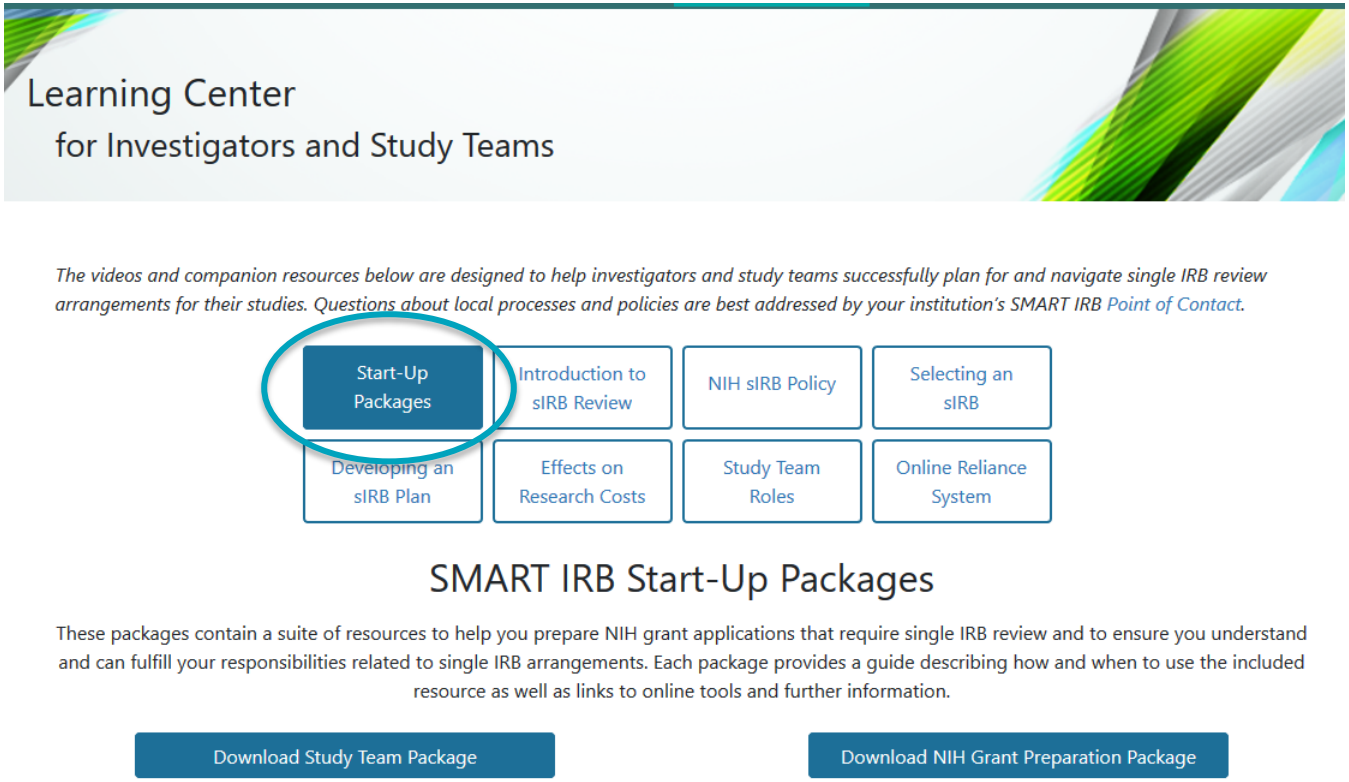
SMART IRB Boot Camp & Emerging Issues Workshop

- Boot Camp for those new to single IRB
- Emerging Issues Workshop – a smaller group invited to talk about barriers to single IRB adoption and efficiency and solutions

Harmonization Steering Committee Recommendations
https://smartirb.org/harmonization/

- Ancillary Review
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance

Investigator Guidance at smartirb.org/study-teams/



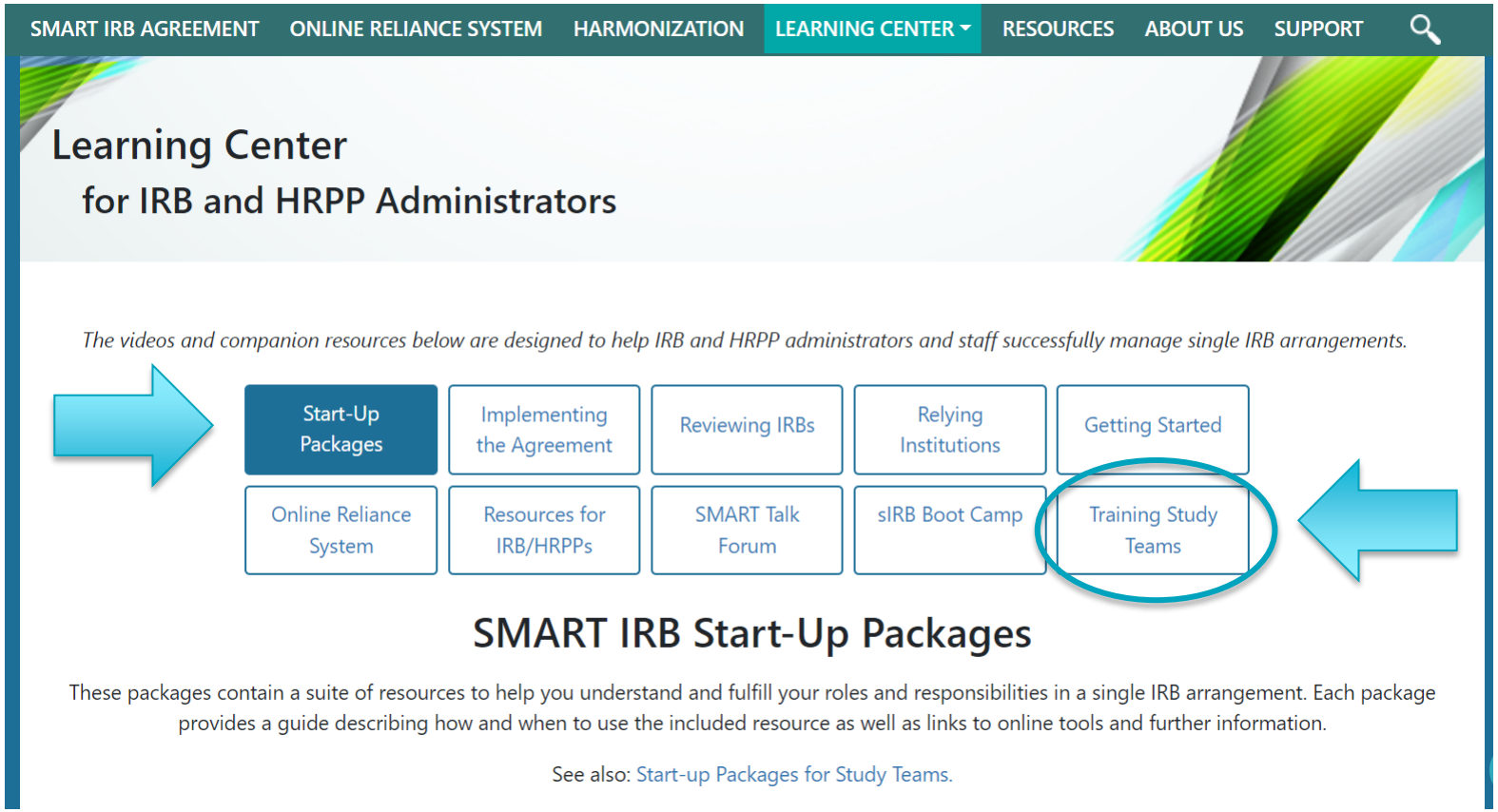
Study Team Packet

Start-up Package for Study Teams

*These resources will help you understand your roles and responsibilities related to single IRB review, including when you are part of a Lead Study Team. See also the **Start-up Package for NIH Grant Preparation**.*

WHEN TO USE? WHEN YOU ARE…	WHAT?	WHY?
IDENTIFYING A REVIEWING IRB AND REQUESTING A RELIANCE ARRANGEMENT	FAQs for Research Teams - Relying on an External IRB	Helpful hints for when your institution relies on an external IRB.
UNDERSTANDING STUDY TEAM RESPONSIBILITIES RELATED TO SINGLE IRB	Overall PI (and Lead Study Team) Checklist	Helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill their responsibilities under single IRB review.
	Relying Site Investigator Checklist	Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.
	Communication Plan for Single IRB Review	Helps IRBs, relying institutions, and study teams identify and assign key communication responsibilities for studies using a Single IRB.
REQUESTING AND TRACKING SINGLE IRB ARRANGEMENTS	SMART IRB Online Reliance System	Allows study teams to work with their home institutions to propose a Single IRB arrangement.
COLLECTING AND PROVIDING INFORMATION FOR IRB REVIEW	Relying Site Study Team Survey	The Overall PI/Lead Study Team may use this tool to obtain key information from relying site study teams and determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.
	Informed Consent Documents: Inserting Local Context Language	Provides guidance to IRBs, relying institutions, and study teams regarding the different roles that may be involved in inserting local context language in informed consent documents.

Training Resources at https://smartirb.org/irb-admin/



Customized Learning

https://smartirb.org/irb-admin/

Training for Investigators and Study Teams

Use this suite of training videos and resources as is, or customize to reflect local processes and policies.

Visit the Investigator and Study Team Learning Center to view available materials; send investigators here for self-guided learning.

Download presentations (no audio) to use for local training sessions or customize to reflect local processes.

To download the presentations with embedded audio, please use the links below:

- Developing a Single IRB Plan
- Overview of the NIH Single IRB Policy for Researchers
- Potential Effects of Single IRB on Research Costs
- Selecting a Single IRB
- Single IRB review and SMART IRB
- Study Team Roles Related to Single IRB

Single IRB from the Perspective of Research Teams

Jacinda Dariotis, Pampered Chef, Ltd., Endowed Chair in Family Resiliency and Professor and Director of the Family Resiliency Center, University of Illinois at Urbana-Champaign

Amy Franklin, Project Leader, Pragmatic Health Systems Research, Duke Clinical Research Institute

Mike Linke, SMART IRB Program Director, Education; Chair, University of Cincinnati IRB and StrokeNet Central IRB; Adjunct Professor of Internal Medicine, University of Cincinnati

Emily Serdoz, IRB Reliance Exchange Project Manager, Vanderbilt University

Angela Sow, Clinical Trial Manager, Ohio State University

Amy Trullinger, sIRB project Manager, Indiana University CTSA

Moderator: Nichelle Cobb

SMART IRB

Research Teams Project

Understand how investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies.

Goals of Research Team Project

1. Improve dissemination and utilization of current research team resources
2. Determine if additional resources are needed to address challenges to using SMART to implement and employ single IRB oversight.
3. Promoting/raising awareness of the available resources

Focus Groups

We conducted three focus groups (1 of 2)

1. Principal Investigators
   - Pediatric Studies
   - Sports Medicine
   - Social/Behavioral

We conducted three focus groups (2 of 2)

2. Study Team A
   - sIRB project manager - Liaison for study teams
   - Clinical Trial Manager - Large multi-center trials
   - Regulatory specialist – NIH funded multicenter trial
3. Study Team B
   - Project manager - Pulmonary research
   - Project manager - Psychology and Neurology research
   - Research program manager - Neurology research

Focus Group Feedback

Principal Investigators

Challenges Encountered

- Differences across sites with sIRB makes things difficult
- Local IRB replicates IRB review
- Difficulties with inexperienced sites
- Educating other sites/study teams is a burden for investigators – better done by that site's local IRB/HRPP staff

Positive Experiences

- A dedicated or highly knowledgeable and accessible reliance person at the local IRB/HRPP makes/can make a huge difference
- Do see benefit when this works well, esp. after initial review

Suggestions

- Have the local IRB/HRPP reach out and educate investigators
- Consider leveraging offices of research to push for local change – to harmonize policies & procedures, to educate new investigators, etc.

Study Team Members (1 of 2)

Challenges Encountered

- Staff turnover/loss of memory
- Some sites still want to use old reliance agreements
- Sites not understanding the process
- Relying sites where the Relying Institution performs duplicate review
- Lack of harmonization at Relying Institutions
- Sites that have not signed onto SMART IRB
- Costs add up for the reviewing IRB

Positive Experiences

- Not having to negotiate individual reliance agreements
- Most sites now members of SMART
- Coordinate use of SMART and IREx
- SMART IRB provision for local sites to manage their study personnel

Study Team Members (2 of 2)

Tools

- Homegrown Checklists “not one size fits all”
- Site surveys
- SOP for submissions
- Excel tracker, one drive and outlook to track what has been sent back and forth
- Share Point as the spot for final documents
- “SMART IRB website has a lot of resources”
- Communicating with sites through a once a month onboarding process
- Use consistent documents for all relying sites
- Need consistent and centralized way to communicate
- IREx users - rely on and use IREx tools to coordinate reliance process

Discussion & questions

Save the date for the next
SMART Talk
April 20, 2022
2:00-3:30 pm ET

SMART IRB 2022: Where We've Been and Where We're Heading

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

Sign up for our mailing list to be notified of future offerings