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 3UL1TR002541-01S1.

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

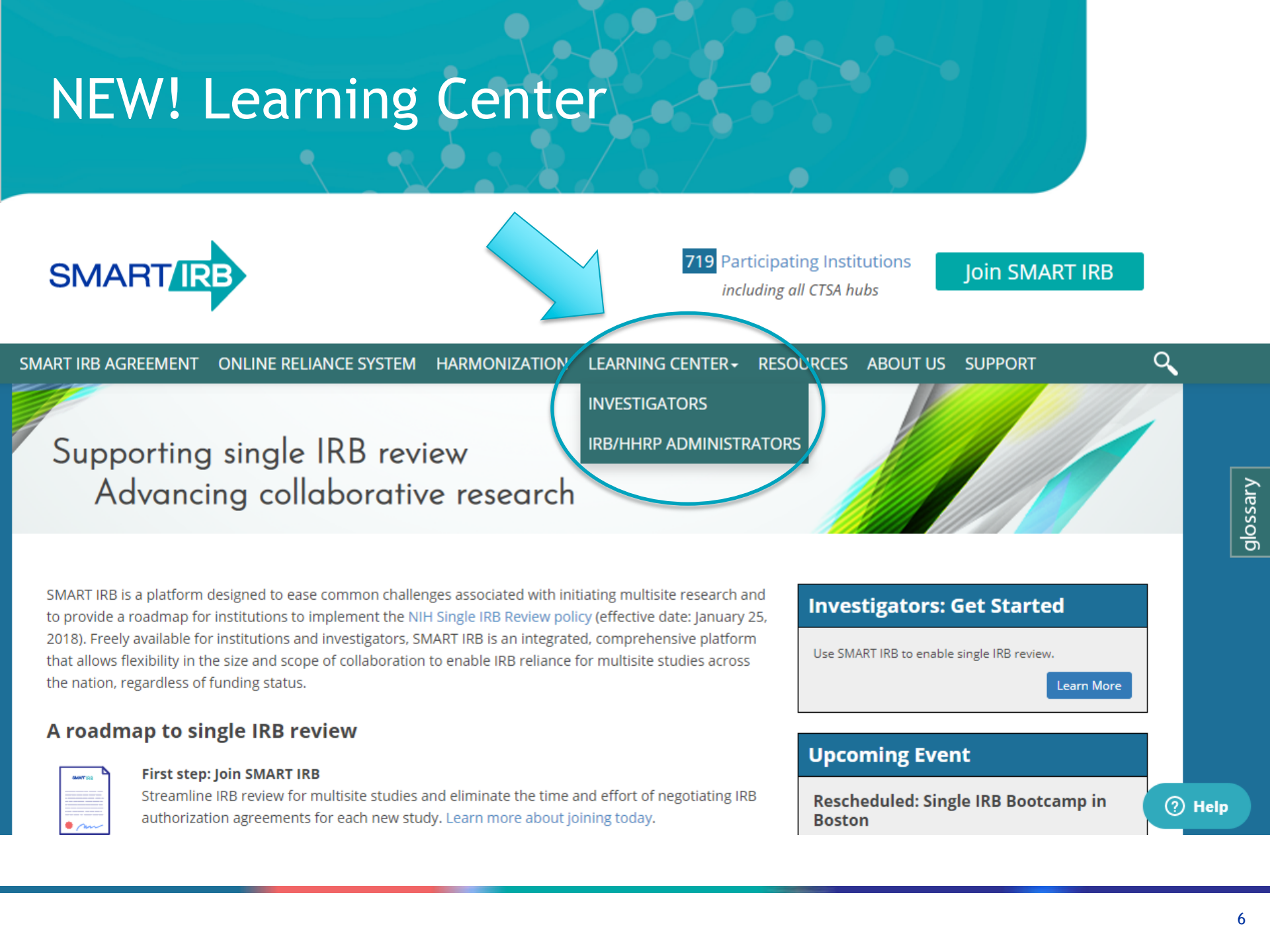
- APRIL: To Be Announced
- May: Single IRB Training & Education Resources for Researchers
- Single IRB FAQs Answered
- Updates about Single IRB from NIH

Past sessions available at SMARTIRB.ORG

- LAST MONTH (available at SMARTIRB.ORG): Review of Personnel Changes: recommendations from the SMART IRB Harmonization Steering Committee
- Getting Ready for the 2020 Single IRB requirements
- A Follow-Up Conversation: Getting Ready for the 2020 Single IRB Requirements
- Operationalizing an HRPP under Single IRB
- Managing Reliance with the SMART IRB Online Reliance System
- Harmonization - Reportable Events

NEW! Learning Center

NEW! Learning Center



For Investigators & Study Teams

Learning Center
for Investigators and Study Teams

The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution's SMART IRB Point of Contact.

- Introduction to Single IRB Review and SMART IRB
- Overview of the NIH Single IRB Policy
- Selecting a Single IRB
- Developing a Single IRB Plan
- Potential Effects of NIH Single IRB Policy on Research Costs
- Study Team Roles Related to Single IRB
- Using the SMART IRB Online Reliance System

For IRB/HRPP Administrators

Learning Center
for IRB and HRPP Administrators

The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements

- Implementing the SMART IRB Agreement
- Serving as a Reviewing IRB
- Responsibilities of Relying Institutions
- Online Reliance System Walkthrough
- Getting Started with SMART IRB and the Online Reliance System
- SMART IRB Resources for IRB and HRPP Personnel
- SMART Talk Monthly Community Forum
- Training for Investigators and Study Teams

Other Key SMART IRB Resources at SMARTIRB.ORG

- For reliance arrangements
  - Master Reliance Agreement
  - Implementation Checklist for use of the SMART IRB Agreement
  - Online Reliance System
  - SMART IRB SOP Manual
- For study teams
  - FAQs for Research Teams - Relying on an External IRB
  - Overall PI (and Lead Study Team) Checklist
  - Relying Site Investigator Checklist
  - Grant Applications: Template Description of SMART IRB
- For reviewing IRBs
  - Communication Plan for Single IRB Review
  - Reviewing IRB Instructions for Relying Institution Point(s) of Contact
  - Reviewing IRB Instructions for Relying Site Study Teams
  - **Local Considerations: Institutional Profile**
  - **Local Considerations: Protocol-specific Document**

SMART IRB Agreement & SOPs: What They Say About Informed Consent

SMART IRB Master Reliance Agreement - Consent

- Reviewing IRB Responsibilities:
  - Provide to each Relying Institution Point of Contact (POC) and Site Investigator(s) with a template informed consent form(s) which indicates areas where the Relying Institutions must add information (e.g. local context)
  - Permit a Relying Institution/Site Investigator to customize limited site-specific sections of the form, generally the sections on the availability of treatment and compensation for research-related injury, payment or reimbursement of research costs incurred by subjects, and local contacts. Any such modifications will be subject to approval by the Reviewing IRB, which will then provide a final approved consent form(s) to the Relying Institution/Site Investigator for use.
  - Will ensure that any conflict of interest (COI) disclosures from a management plan are included in the approved consent form.

SMART IRB Master Reliance Agreement
HIPAA Authorization

- Reviewing IRB Responsibilities:
  - When HIPAA Authorization is required, the authorization language will be provided by the reviewing IRB and may be incorporated into the consent.
    - Ensure that the authorization permits PHI to be used by and disclosed to the Reviewing IRB, Reviewing institution and Relying institutions as necessary.

SMART IRB Master Reliance Agreement - Consent

- Relying Institution Responsibilities:
  - Require its research personnel to maintain all research records including informed consent forms.
  - Provide the Reviewing IRB with the site-specific information requested/identified in the customizable sections of the Reviewing IRB's consent form.
  - The Relying Institution will not, and will require that its Site Investigator(s) not, make any change to the consent form without obtaining prior approval of that change from the Reviewing IRB.
  - Ensure that the provision of any grant or contract that address financial coverage for research-related injuries are consistent with the protocol and/or consent form.

SMART IRB - SOPs

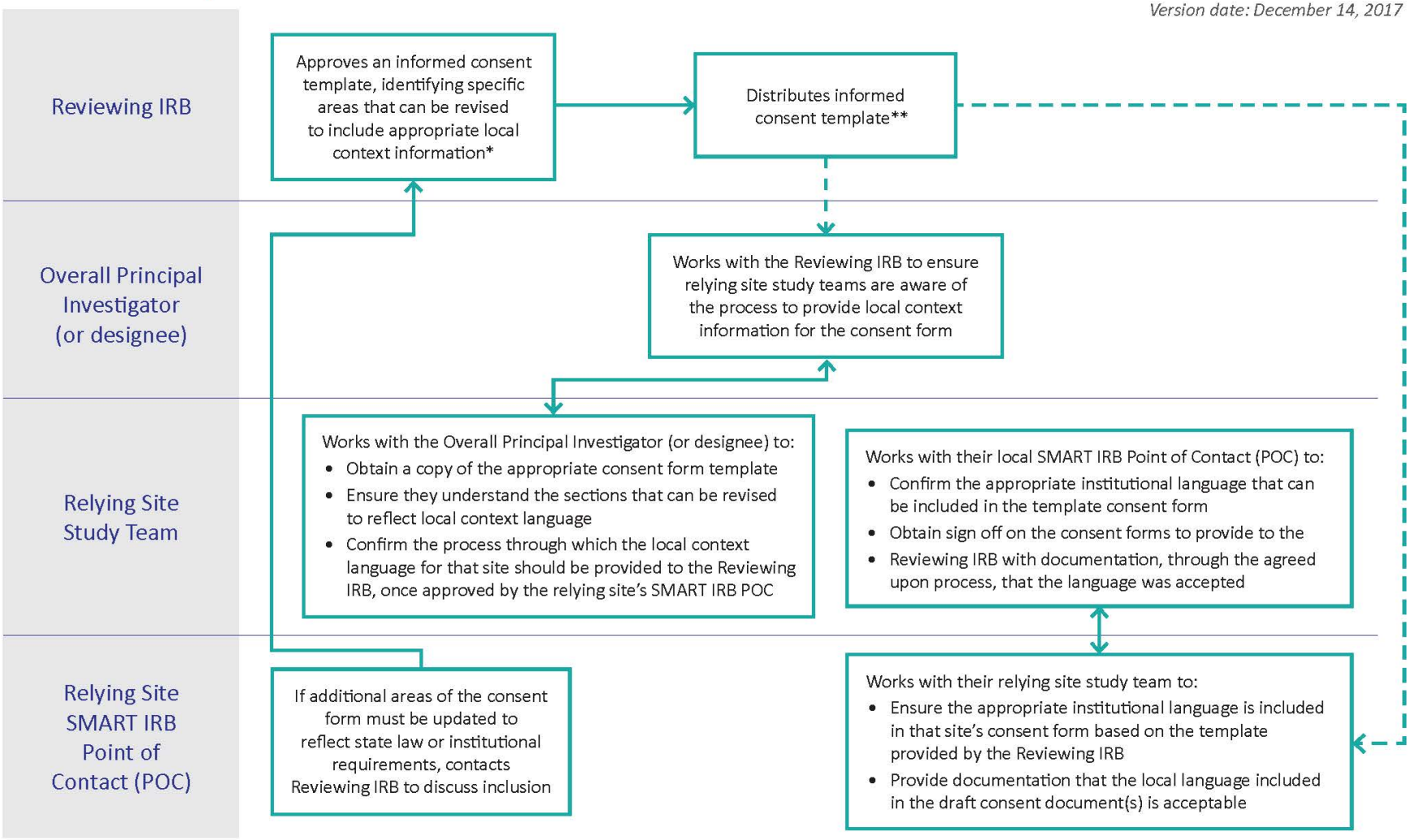
- Overall PI Responsibilities
  - Establish a process to ensure Relying Site Study Teams have the most current version of the consent form(s) and other documents.

SMART IRB - Resource

- **SMART IRB Guidance:** Inserting “Local Context” Language in Informed Consent Documents
- This guidance describes the different roles that may be involved in inserting local context language in informed consent documents.

SMART IRB Guidance:
Inserting "Local Context" Language in Informed Consent Documents

Version date: December 14, 2017



*Template areas that can be changed are usually limited to:
- Contact information for local study team
- Costs that differ for the relying site
- Relying site's language regarding the availability of and compensation for research-related injury

**The Reviewing IRB can distribute the template to the Overall Principal Investigator (or designee) AND/OR the Relying Site SMART IRB POC.

www.smartirb.org Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

Because we canceled the SMART IRB Bootcamp, join us for the next SMART Talk
April 15, 2020
1 pm ET

Topic under development!

Questions?
Contact help@smartirb.org

Register at smartirb.org

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

Tackling Informed Consent Under the Single IRB Model

Speakers:
Sara Harnish, Executive IRB Chair, Advarra

If available:
Dr. Ann Johnson, IRB Director, University of Utah

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