

### **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**



719 Participating Institutions including all CTSA hubs

Join SMART IRB

SMART IRB AGREEMENT

ONLINE RELIANCE SYSTEM HARMONIZATION

LEARNING CENTER -

RESOURCES

ABOUT US SUPPORT

### Supporting single IRB review Advancing collaborative research

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

#### A roadmap to single IRB review



#### First step: Join SMART IRB

Streamline IRB review for multisite studies and eliminate the time and effort of negotiating IRB authorization agreements for each new study. Learn more about joining today.

#### **Investigators: Get Started**

Use SMART IRB to enable single IRB review.

Learn More

#### **Upcoming Event**

Rescheduled: Single IRB Bootcamp in **Boston** 



# **NEW!** Learning Center



719 Participating Institutions including all CTSA hubs

Join SMART IRB

SMART IRB AGREEMENT

ONLINE RELIANCE SYSTEM

**HARMONIZATION** 

LEARNING CENTER -

**INVESTIGATORS** 

RESOURCES

ABOUT US

SUPPORT

Supporting single IRB review Advancing collaborative research

**IRB/HHRP ADMINISTRATORS** 

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

#### A roadmap to single IRB review



#### First step: Join SMART IRB

Streamline IRB review for multisite studies and eliminate the time and effort of negotiating IRB authorization agreements for each new study. Learn more about joining today.

#### **Investigators: Get Started**

Use SMART IRB to enable single IRB review.

Learn More

#### **Upcoming Event**

Rescheduled: Single IRB Bootcamp in Boston



glossary

## 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 Approves an informed consent template, identifying specific Distributes informed Reviewing IRB areas that can be revised consent template\*\* to include appropriate local context information\* Works with the Reviewing IRB to ensure **Overall Principal** relying site study teams are aware of Investigator the process to provide local context information for the consent form (or designee) Works with the Overall Principal Investigator (or designee) to: Works with their local SMART IRB Point of Contact (POC) to: • Obtain a copy of the appropriate consent form template · Confirm the appropriate institutional language that can • Ensure they understand the sections that can be revised Relying Site be included in the template consent form to reflect local context language **Study Team** • Obtain sign off on the consent forms to provide to the • Confirm the process through which the local context Reviewing IRB with documentation, through the agreed language for that site should be provided to the Reviewing upon process, that the language was accepted IRB, once approved by the relying site's SMART IRB POC Works with their relying site study team to: Relying Site If additional areas of the consent • Ensure the appropriate institutional language is included form must be updated to SMART IRB in that site's consent form based on the template reflect state law or institutional Point of provided by the Reviewing IRB requirements, contacts Contact (POC) · Provide documentation that the local language included Reviewing IRB to discuss inclusion in the draft consent document(s) is acceptable

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.

SMART IRB encourages use and distribution of this content. If you extract any language, please cite SMART IRB as follows, "This information was obtained from [doc name] as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-0151."

<sup>\*</sup>Template areas that can be changed are usually limited to:

<sup>·</sup> Contact information for local study team

<sup>·</sup> Costs that differ for the relying site

<sup>·</sup> Relying site's language regarding the availability of and compensation for research-related injury

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

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

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