Supporting single IRB review. Advancing collaborative research. Together.

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SMARTIRB.org  
Funded by the NIH Clinical and Translational Science Award (CTSA) program, grant number UL1TR001102-04S1.

Overview
Single IRB Review: Regulations have long allowed for sIRB review.

- FDA: 21 CFR §56.114 Cooperative research

  In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

- OHRP: 45 CFR §46.114 Cooperative research

  Cooperative research projects are projects covered by this policy that involve more than one institution.

  An institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

### Long recognized issue trending to sIRB regs

<table>
<thead>
<tr>
<th>Year</th>
<th>Document</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>2000</td>
<td>OPRR Guidance on IRB Knowledge of Local Research Context</td>
<td>Evaluation of IRBs should include necessary information about local research context.</td>
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<tr>
<td>2005</td>
<td>Report on Workshop on Alternative Models for IRB Review (OHRP, AAMC, ASCO, NIH, VA)</td>
<td>Recommended development of OHRP and FDA guidance regarding the responsibilities of alternative review mechanism and those appropriately retained by local IRB.</td>
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<tr>
<td>2006</td>
<td>FDA Guidance on “Using a Centralized IRB Review Process in Multicenter Clinical Trials”</td>
<td>Recommended centralized IRB review process should include meaningful consideration of relevant local factors.</td>
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<td>2008</td>
<td>SACHRP Letter to HHS Secretary</td>
<td>Requested HHS Secretary to encourage NIH Director to explore more widespread use of collaborative IRB models, including expanded use of Centralized IRBs for NIH-sponsored research.</td>
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<td>2009</td>
<td>OHRP ANPRM</td>
<td>Sought public comment on whether regulations should enable OHRP to enforce compliance directly against IRBs; Provision included in 2011 Common Rule ANPRM.</td>
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<td>2010</td>
<td>OHRP Policy</td>
<td>Clarified that OHRP agreed with the FDA’s position on the benefits of relying on a single IRB for multi-site research, and that OHRP no longer favored local IRB review over review by a non-local IRB.</td>
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<tr>
<td>2011</td>
<td>Common Rule ANPRM</td>
<td>Proposed requiring the use of a single IRB for multi-site studies.</td>
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<tr>
<td>2014</td>
<td>NIH draft sIRB Policy</td>
<td>Requested comments on the expectation for using a single IRB for multi-site studies.</td>
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<tr>
<td>2015</td>
<td>Common Rule NPRM</td>
<td>Proposes requiring the use of a single IRB for multi-site studies.</td>
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Now: NIH Single IRB Review Policy

But... (not insurmountable) challenges remain

Reluctance to defer IRB review stems from real and considerable concerns:

- Liability
- Administrative challenges and processes to operationalize
- Lack of clarity regarding roles and responsibilities
- Trust: Quality of review by other IRBs
- Ensuring local and state requirements are addressed
How can we address these real issues in single IRB review? We can advance Research Together

**SMART IRB AIMS**

- Implement NIH Single IRB Policy
- JOIN SMART IRB
- ENABLE multi-site research
- HARMONIZE across the nation

**Funded by NCATS:** July 2016-April 2018
Harvard University, University of Wisconsin-Madison & Dartmouth College
A team of SMART IRB Ambassadors from CTSAs across the nation

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**What is SMART IRB?**
It a system of component parts to support IRB Reliance on a national scale

- Guidance & Standard Operating Procedures (SOPs)
- A team of SMART IRB Ambassadors
- Online sharing through open-source platforms
What SMART IRB is not...

IRBrely and SMART IRB are two separate national reliance agreements.

Use of SMART IRB is mandated.

SMART IRB provides a single IRB.

SMART IRB is only for NIH funded studies.

SMART IRB is an extension of IRBrely, and remains a “treaty” model.

- Participation is NOT mandated, nor is it exclusive.
- Participation does NOT even establish whether reliance will be used for a study.

- SMART IRB is written as a reliance model but supports one-way reliance too such as cIRB and independent IRBs.
- SMART IRB does NOT establish which IRB will review nor which institutions will rely.

No, Regardless of funding or funding status SMART IRB may be used for any externally or internally funded study.

SMART IRB Agreement
A master agreement to support collaboration across the nation

8 CTSAs came together to develop a national IRB reliance agreement
- Public & private universities
- Academic healthcare centers

Shared with 72 Institutions
- 25 CTSAs in 19 states
- Community hospitals
- Independent/commercial IRBs

Shared with 115+ Institutions
- 64 CTSAs in 33 states
- NIH agencies

Agreement sets a default allocation of responsibility but permits parties to reach individual agreements on certain terms

Agreement Layout:

1. Eligibility and Process To Participate in the Agreement
2. Agreement Scope
3. Collaborative Process for Consideration of Ceded Review Requests and Determination of Reviewing IRB
4. Responsibilities of the Participating Institution(s)
5. Responsibilities of the Reviewing IRB(s) and Reviewing IRB Institution(s)
6. Responsibilities of the Relying Institution(s)
7. Term; Termination
8. Miscellaneous

Check out the Agreement at smartirb.org
Institutions can participate in SMART IRB if they meet the eligibility criteria

1. **FWA or IRB Organization:** Unless it is an IRB organization, your institution must maintain a Federalwide Assurance (FWA) approved by the Office for Human Research Protections (OHRP).

2. **Quality Assessment:** If your institution has an IRB or is an IRB organization, it must have undergone or initiated an assessment of the quality of its human research protection program (HRPP) within five years prior to joining SMART IRB (through accreditation from an external organization, participation in OHRP's Quality Assessment Program, or equivalent approach).

3. **Point of Contact:** Your institution must establish a Point of Contact (POC) who will be responsible for, and communicate on behalf of, your institution regarding initial and ongoing implementation of the SMART IRB Agreement.

Regional Ambassadors are available to answer questions and assist in the joinder process.

### Criteria 1:
Institutions must maintain an FWA and provide institutional oversight

**ALLOWS FOR “CHECKED” OR “UNCHECKED” BOX ON FWA**
- By policy or otherwise, must require IRB review and provide institutional oversight of human subjects research.
  - Regardless of funding source or scope of FWA.

**MUST MAINTAIN FWA UNLESS IORG**
- Maintenance of an FWA is a baseline indicator of institution’s accountability for compliance of its human subjects research program with federal and ethical norms and standards.
- Unless it is an IRB Organization. IRB Organizations must register with OHRP.

**MUST JOIN INVIDUALLY**
- Each institution must individually join SMART IRB (i.e., must execute its own Joinder Agreement) in order to participate.
- Any institution with its own FWA or IRB Organization number must execute its own joinder, regardless of any pre-existing affiliations.
Criteria 2: Institutions must have assessed quality

**WITHIN THE LAST 5 YEARS**
- Institutions with IRBs must have assessed the quality of their HRPP within 5 years of joining SMART IRB.

**SUBSTANTIAL EQUIVALENCY ALLOWED**
- Accreditation through external organization (e.g. AAHRPP or OHRP’s Quality Assessment Program) or a proxy (substantial equivalent).

**QA/QI PROGRAMS, FUNCTIONS AND/OR ACCESS**
- Each institution must maintain, implement, or have access to a human subjects research QA/QI function, program, or service.

Criteria 3: Institutions need to name a Point of Contact

**NAME ONE POC**
- Each institution must designate a POC for agreement-related issues and reliance determinations; alternate POC allowed too.

**POC MAY BE FROM OUTSIDE THE IRB OFFICE**
- Often associated with the IRB; some institutions will not have an IRB or will choose to a POC from outside the IRB office.
Sign once and implement

Choose to use SMART IRB on a study-by-study basis

Default allocation of roles and responsibilities

Flexibility allows for individual agreements on certain terms
- Who serves as privacy board
- Who reports reportable events
- Need for insurance (or waive)
- Etc.

SMART IRB SOPs
Flexible alignment of processes

SMART IRB SOPs provide clarity on key roles and responsibilities

Use of SMART IRB SOPs is not mandated

SMART IRB supports networks with existing SOPs

Institutions communicate whether other policies/procedures apply to the research

ROLES & RESPONSIBILITIES
Key Roles

SMART IRB Points of Contact (POCs)
Identified individual at each institution who can make or facilitate determinations of IRB reliance on behalf of the institution

Reviewing IRB
"IRB of record" to which authority for review and oversight has been ceded for an instance of Research under the Agreement

Relying Institutions
Participating Institutions that cede IRB review to a Reviewing IRB for an instance of Research under the Agreement

Overall PI & Lead Study Team
The Overall PI has ultimate responsibility for conduct of the Research; appoints a Lead Study Team to ensure study coordination, communication, and the routing of IRB submissions

Site PI
The Site Investigator responsible for the conduct of the Research at his/her institution

Relying Site Study Team
Study team from a Relying Institution; carries out applicable procedures described in the Agreement and SOPs

Institution Points of Contact (POCs)
Serve as local resource for the institution and local study teams

Determine whether to serve as Reviewing IRB or cede review

Communicate institution decisions regarding IRB reliance requests
When POC for a Relying Institution

- Provide local context information to Reviewing IRB (e.g., institutional and state requirements)
- Provide local restrictions or requested substitutions to informed consent documents to Reviewing IRB for review/approval
- Authorize certain changes to confirm institutional requirements have been met
- Affirm local study team personnel have completed institutionally-required training
- Respond to requests for assistance/information from Reviewing IRB POC (e.g., gather information on reportable events at site)

Reviewing IRB

“IRB of record” for an instance of Research under the Agreement

- Oversees study on behalf of relying sites from “cradle to grave”
  - Initial submission
  - Amendments
  - Continuing review
  - Reportable events
  - Approves limited site-specific consent form language
- Reviews COI management plans provided by the relying institution
  - Can be more restrictive than provided plan
- Acts as “HIPAA Privacy Board”
  - Makes determinations regarding waivers and alterations of authorization
Relying Institutions
Participating Institutions that cede IRB review to a Reviewing IRB

KEY RESPONSIBILITIES
- Ensure study teams are trained
- Review COIs; disclose management plans to the Reviewing IRB
- Ensure research teams comply with conditions of IRB approval, institutional policies, and applicable regulations
- Notify Reviewing IRB of:
  - Relevant changes in institution/research team status
  - Unanticipated problems or findings of serious/continuing noncompliance
  - Any suspension or restriction of a Study Team member(s) to conduct human subjects research
- Notify Reviewing IRB of any communications about studies covered under the Agreement to/from FDA, OHRP, and/or other regulatory agencies
  - e.g., regarding unanticipated problems or serious and continuing noncompliance

The Study Team

**Overall Principal Investigator**
generally, the initiating or funding principal investigator

**Site Investigator(s) (Site PIs)**
Responsible for conduct of the Research at their institution

**Lead Study Team**
Designated by the Overall PI to ensure study coordination, communication, and routing of IRB submissions (in collaboration with the Reviewing IRB)

**Relying Site Study Team(s)**
Study team(s) whose institution has ceded review to the Reviewing IRB
Includes Site Investigator and local personnel designated to carry out communication, coordination, and administrative procedures
**Overall PI & Lead Study Team**

- **Overall Principal Investigator**
  - Assumes leadership and has ultimate responsibility for conduct of the research
  - Designates Lead Study Team*

- **Lead Study Team**
  - Submits materials to the Reviewing IRB for all sites, including study-wide and site-wide changes of protocol, continuing reviews, and reportable events
  - Provides draft study materials to all study teams, including proposed consent form template
  - Provides IRB-approved materials/determinations to all sites

*The Lead Study Team is often (but not always) the study team at the Reviewing IRB's institution; may be a coordinating center.

**Site PIs & Relying Site Study Teams**

- Follow policies and procedures of Reviewing IRB (e.g., for reportable events, personnel changes)
- Use the Reviewing IRB's consent form template (excepting limited local language that can be added/changed)
- Provide information about study progress and local events to Lead Study Team for continuing review (e.g., unanticipated problems, noncompliance) so that it can be reported to the Reviewing IRB
- Obtain authorization from their institution's SMART IRB POC(s) (e.g., for personnel changes, COI updates, or changes that may be affected by state law or institutional requirements)

In cases where the Lead Study Team is from an institution other than the Reviewing IRB Institution, the roles and responsibilities of the “Relying Site Study Team” also apply to the study team at the Reviewing IRB's institution.
SMART IRB communication model

Reviewing IRB

Lead Study Team

Lead Study Team operates similar to a coordinating center

Relying Institution IRB/HRPP

Relying Site Study Team

Join SMART IRB
Join SMART IRB Today
Get started at www.smartirb.org

1. Review the SMART IRB Agreement

2. If you have questions, connect with a SMART IRB Ambassador

3. Join online at smartirb.org/join
IRB administrator or other research compliance personnel should initiate the process.

Website: smartirb.org

Supporting single IRB review. Advancing collaborative research.

Advancing research together.

SMART IRB is a platform designed to ease common challenges and burdens associated with initiating multisite research. Through a flexible master IRB reliance agreement, standard operating procedures, and complementary tools and resources, SMART IRB supports and encourages collaboration and harmonization across the nation.

Shared benefits.

For Investigators
SMART IRB agreements streamline IRB review for multi-site studies, streamlining the time and effort typically required to negotiate an IRB reliance agreement for each new study. View the SMART IRB Agreement PDF.

For Institutions
Standard operating procedures (SOPs) provide clarity during the review and conduct of research using the SMART IRB Agreement. The SOPs and additional educational materials, tools, and checklists are available on our discussion page.

Access to expertise across the nation
A team of SMART IRB ambassadors are knowledgeable in the processes and practicalities of IRB reliance and available to assist institutions in joining and implementing the SMART IRB Agreement and SOPs.

Online Sharing
An open-source, web-based collaboration tool allows investigators to join SMART IRB and create an institution profile. A reliance determination system (RDS) development will currently facilitate decision-making on a study-by-study basis.
Join: SMART IRB Joinder Platform

My institution would like to join SMART IRB

Please fill out the information below to initiate the process of joining SMART IRB and download a copy of the SMART IRB Agreement. Due to the nature of the information required in subsequent steps, IRB administrators or other research compliance personnel will be best suited to initiate this process.

All fields are required.

First Name
Last Name
Email

When selecting your institution, please make sure the appropriate PWA is listed. If you do not see your Institution or PWA please contact us at help@smartirb.org

SMART IRB joinder workflow

Institutions join SMART IRB by generating, signing, and submitting an institution-specific, pre-filled Joinder Agreement

Step 1: User requests to join SMART IRB

Step 2: SMART IRB team verifies applicant (offline process) and invites to submit a joinder

Step 3: User registers institution and downloads, signs and submits Joinder Agreement

Step 4: SMART IRB team reviews application and activates/does not activate institution, or sends back for revisions

Step 5: Activation complete
Ready to submit Joinder Application

When you are ready to proceed, submit your institution’s signed joinder agreement.
Your latest upload is shown below. This file will be included with your submission.

Signed Joinder Submitted

Thank you for submitting a signed joinder agreement for 2M Research Services, LLC.
A member of the SMART IRB team will review the information provided for this institution, along with the signed joinder Agreement. Please do not proceed with any activities under the SMART IRB Agreement until you have received notification confirming your institution’s participation in SMART IRB.

You, the listed POCs, the notices, and the signatory official will be notified by email once this submission has been reviewed.
Email: Institution Activated

Welcome to SMART IRB! The Joint Agreement provided on behalf of 2M Research Services, LLC has been reviewed and your institution's participation in SMART IRB is now activated.

2M Research Services, LLC may now use the SMART IRB Master Agreement to effect reliance arrangements for human subjects research as outlined in that document; please review the responsibilities for all Participating Institutions, Reviewing IRBs, and Relying Institutions, and ensure that research teams are informed of their responsibilities for studies using the SMART IRB Agreement.

Visit SMARTIRB.org for more information about the SMART IRB platform, and to access available resources, including Standard Operating Procedures (SOPs) and Frequently Asked Questions (FAQs). Please note, the contact information for the primary Point of Contact, a.a, will be publicly available on the SMARTIRB.org website.

Questions? Contact: help@smartirb.org

Additional Comments:

Your institution is now activated.

Thank you

Regional ambassadors are available to assist institutions in joining and implementing SMART IRB

smartirb.org/ambassadors
So far, so good!
As of 11/15/16 41 institutions have already joined

1. Boston Medical Center Corporation
2. Boston University Medical Campus
3. Broad Inst, Inc.
4. Cambridge Health Alliance
5. Columbia University
6. Columbia University Medical Center
7. Forsyth Institute
8. Georgia Institute of Technology
9. Harvard T.H. Chan School of Public Health
10. Harvard University
11. Harvard University Faculty of Medicine
12. Hebrew SeniorLife
13. Icahn School of Medicine at Mount Sinai
14. Johns Hopkins University School of Medicine
15. Marshall University
16. Massachusetts Institute of Technology
17. Medical University of South Carolina
18. New York University School of Medicine
19. New York-Presbyterian Hospital
20. Oregon Health & Science University
21. Schulman IRB
22. Stanford University
23. University of Texas Health Science Center at San Antonio
24. Trustees of Dartmouth College
25. Tufts Medical Ctr, Inc
26. Tufts University Health Sciences
27. University Hospitals Cleveland Medical Center
28. University of Alabama at Birmingham
29. University of Kansas Medical Center
30. University of Kentucky
31. University of Miami
32. University of Minnesota
33. University of New Mexico Health Sciences Center
34. University of Pennsylvania
35. University of Rochester
36. University of Southern California
37. University of Southern California - Health Science Campus
38. University of Utah
39. University Wisconsin-Madison Vanderbilt
40. University Medical Center
41. Yale University

Visit smartirb.org/participating-institutions for the most current list of institutions that have joined

Join and help us pilot the SMART IRB Reliance Determination Tool

We’re currently looking to pilot the system with studies that match the following:

1. Study has not been reviewed nor approved by an IRB.
2. Study involves 2-5 sites AND all sites hold FWAs and are known when initiating the reliance request.
3. Reviewing IRB must be from the Overall Principal Investigator’s Home Institution.
4. Institutions’ decisions of whether to cede review should be unknown or not yet finalized.
5. Reviewing IRB must be experienced serving as a single IRB for multi-site studies.
6. Overall PI should have experience in this role for a multi-site study using single IRB review.
We are piloting the reliance determination system with eligible studies among participating institutions - contact help@smartirb.org for more information.
Reliance Reached

ID: 2 - Advances in Knee Bracing Technology for Prevention of Knee Injuries

Principal Investigator (PI): Peter T Herkstra
Carnegie University

Requested Reviewing IRB: Ridgeview Research Facility

NCT Number: NCT01111111
Protocol Number(s):

Summary
Overall Status: Reliance Reached

No Action Required

Roles:
- Overall PI’s Home Institution: Carnegie University, Site Involved (Reviewing)
- The Reviewing IRB will notify the Overall PI of its decision to approve or disapprove this study, any required modifications, and the date by which renewal of approval is required.

Reviewing IRB
- Carnegie University will review for: Belvedere Institute
- Carnegie University
- Dakota College of Advanced Studies
- Syracuse Community College
- William Penn Medical School
- Determination

Not Relying
- Syracuse Community College
- William Penn Medical School

Protect Participants Together

Solving the problem of single IRB review for all
by building capacity and community across the nation

- Reduce negotiations with a Master Agreement - sign once
- Maximize flexibility while respecting autonomy with the Agreement and SOPs
- Enabling all types of research studies regardless of funding or type of review
- Determine reliance on a study-by-study basis
- Access expertise across the nation
- In community, prioritize and harmonize approaches
- Together, build tools and inform education to enable single IRB review
THANK YOU!
Contact us with questions at help@smartirb.org

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SMART IRB Ambassadors
https://smartirb.org/ambassadors/