IRB, OCR, CTO Forum

August 24th, 2017
Research Data Ownership, Retention & Access

Melanie Zuñiga Rapp
Manager, COI & Research Integrity
Office of the Vice President for Research
Overview

• HOP 7.10.1- Research Data Ownership, Retention & Access

• Asserts and protects the rights of UTH ealth San Antonio and researchers in regard to research data.

• Applicable to entire UTH ealth San Antonio community
Research Data Defined

- Original observations, methods, and analyses.
- Recorded information, regardless of form or media.
- Information gathered in anticipation of a Report.
- Technical information, computer software, protocols, statistics, findings, conclusions, samples, physical collections, and other supporting materials.
- Tangible research property.
- Synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, genetic sequences and mapping information, crystallographic coordinates, plants, animals and spectroscopic data, and other unique compilations.
Key Points of the Policy

- Acquisition
- Custody
- Retention
- Access
- Transfer
- Ownership
New Process for Research Data Transfers

**Request to Transfer Research Data, Tangible Research Property or Equipment When Leaving the University**

**Purpose:** Use this form to request permission to transfer research data, tangible research property, or equipment when leaving the university. The HSC policy and procedures governing research data ownership, retention and access are addressed in HOP 7.10.1.

**Definitions:** *Research data* is recorded information, regardless of form or media, which constitute original observations and methods of a study and the analysis of the original data that are necessary for reconstruction and evaluation of the report(s) of a study made by one or more investigators. *Research data* also includes *tangible research property or equipment* (products of research that include, but are not limited to compositions, biologics, materials, illustrations and drawings, prototypes, devices and equipment) and *Unique Research Resources* (such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA as well as genetic sequences and mapping information, crystallographic coordinates, plants, animals and spectroscopic data, and other compilations formed by selecting and assembling pre-existing materials in a unique way).

This form does not constitute an Agreement to Transfer. Additional agreements and documentation may be required. Questions regarding this form should be directed to the Office of the Vice President for Research.

<table>
<thead>
<tr>
<th>Departing Investigator:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Departing Investigator’s Current Department:</td>
<td></td>
</tr>
<tr>
<td>Departing Investigator’s Forwarding Address:</td>
<td></td>
</tr>
<tr>
<td>Departing Investigator’s Forwarding Email:</td>
<td></td>
</tr>
</tbody>
</table>

Personal or Business

**1. Type(s) of Recorded Information**

- [ ] Original Observations
- [ ] Methods of study
- [ ] Analysis of original data
- [ ] Computer software
- [ ] Statistics
- [ ] Technical information
- [ ] **N/A** Not transferring recorded information
- [ ] **Other (describe in space provided below)**

Provide a brief description of the recorded information being transferred:
Contact Information

Melanie Zuñiga Rapp
zunigam5@uthscsa.edu
210.562.6838

Research Data Transfer Request Form
Single IRB Review for Multi-site Research

How does the process work locally?

Kimberly Summers, PharmD
Director Research Protection Programs
IRB, OCR, IAC UC
Overview

- Common Rule Changes related to single IRB review
- NIH mandate for single IRB review
- Institutional responsibilities that remain after ceding IRB review
- Using SMARTIRB to implement single IRB review
Time Line for Human Subject Research and Protection

Eugenics Movement

Nuremberg Code - 1947

WWII – 1939-45

Declaration of Helsinki - 1964

Tuskegee Study – 1932-72

Belmont Report - 1979

Common Rule - 1991

I.R.B.s
“Common Rule”

1. Subpart A45 CFR 46
2. Agreed to by 16 Federal Agencies
3. Effective August 19, 1991
4. Sets forth as a common rule requirements for the protection of human subjects involved in research conducted by Federal Departments and Agencies
Notice of Proposed Rule Making

• A Notice of Proposed Rulemaking (NPRM) was published in the Federal Register on September 8, 2015 (PDF 1063 KB) - PDF.

• The NPRM sought comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

• Mandate for the use of a single IRB for multisite research was included in the NPRM.

• Many commenters pointed out the importance of defining the sIRB’s role and scope of responsibility in relation to the responsibilities of the participating research sites.

• These commenters noted that responsibilities of IRBs defined by the 45 CFR 46 often constitute only one part of institutions’ overall human research protections program.

• Commenters called on the NIH to establish a common approach to the division of responsibilities by providing model authorization agreements or even a uniform agreement that should be used in all cases.

• June 2016 NIH established the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.

• The goal of this policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible.

• Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections.

• This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017.

• Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.
Many commenters pointed out the importance of defining the sIRB’s role and scope of responsibility in relation to the responsibilities of the participating research sites.

- Responsibilities assumed by IRBs would be limited to the responsibilities defined in 45 CFR 46.

- These commenters noted that responsibilities of IRBs defined by the 45 CFR 46 often constitute only one part of institutions’ overall human research protections program.

- Defining the continued responsibilities of the institutions that cede IRB review becomes critical.

- Commenters called on the NIH to establish a common approach to the division of responsibilities by providing model authorization agreements or even a uniform agreement that should be used in all cases.

- Develop of the NIH/NCATS SMART IRB initiative.
Final Revisions to the Common Rule

• On January 19, 2017, the U.S. Department of Health and Human Services (HHS) and 15 other federal departments and agencies released the final revisions.

• This rule is effective on January 19, 2018.

• The compliance date for this rule, with one exception, is January 19, 2018.

• Among the changes to the regulations, one of the most significant includes the mandate that a single Institutional Review Board (IRB) review and approve all multi-site research.

• Compliance date for use of single IRB for multi-site research is January 20, 2020.
Final NIH Policy Revised Implementation Date

• June 2017 NIH revised Notice replaces NOT-OD-17-027 to inform the research community that NIH is extending the effective date of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

• The policy will apply to all competing grant applications for due dates on or after January 25, 2018.

• Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.
Reviewing IRB Responsibilities

• Initial reviews in accordance with the Common Rule
  o 7 criteria for approval
    ➢ Risk to subjects are minimized
    ➢ Risks to subjects are reasonable in relation to anticipated benefits
    ➢ Selection of subjects are equitable
    ➢ Informed consent will be sought to extent required
    ➢ Informed consent will be appropriately documented to extent required
    ➢ When appropriate the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects
    ➢ When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

• Review of reportable events (noncompliance, unanticipated problems)
• Continuing review of the study
• All amendments including study wide and local to approved protocol
Relying Institutions Responsibilities
Research Personnel

Provide information or documentation to a Reviewing IRB regarding:

its research personnel’s education, training, and qualifications as requested
Institutional Communication with the Reviewing IRB

Local context that would affect the conduct or approval of the research at the Relying Institution, such as:

- State and local laws & regulations
- Institutional policies
- Local factors
- Ancillary reviews
Consent Documents

- Compensation for injury language
- Variations in costs
- Local contact information

Providing site-specific information in the customizable sections of the Reviewing IRB’s consent form, such as:
Conflicts of Interest (COI)

- Maintain & share COI policies
- Perform COI analysis (unless alternate arrangement agreed upon with Reviewing IRB)
- Communicate COI determinations (e.g., management plans, restrictions) to the Reviewing IRB
- Abide by Reviewing IRB COI determinations
HIPAA Privacy Rule

Work with Reviewing IRB to establish whether a separate HIPAA authorization form or combined consent/authorization will be used for the research

Provide any language specific to the Relying Institution to the Reviewing IRB

Notify the Reviewing IRB of any specific local requirements and restrictions on use and disclosure of protected health information (PHI) that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization for the Relying Institution
Injury Coverage

Ensuring the provisions of any applicable grant or contract that address financial coverage for research-related injuries in connection with research:

Are consistent with the approved research protocol and consent form

OR

That the approved research protocol and consent form, if more protective of human subjects, will control
Research Approval

- Step 1 AND If HSC IRB
  Step 2 Institutional and IRB sections
  OR If External IRB
  Step 2 Institutional only

- Institutional review and routing/coordination with other appropriate departments and institutions
- Document appropriate credentialing, experience, and training with the Research Scope of Practice
- Document other committee reviews have been completed (i.e., radiation safety, CTRC PRC)
- Evaluate drug or device storage if outside institutional pharmacy
- Route COI disclosures and obtain management plans
- Assist with study registration and reporting through clinicaltrials.gov and obtain NTC# if applicable
- Conduct clinical resource assessment (research vs clinical care)

- OR
- Regulatory pre-review
- IRB Review
- OR
- If External IRB Notification from reviewing IRB

- Reviewed for financial issues
- Billing Grid assessment
- Participant payments
- Coverage analysis (if billing risk)
- Budget analysis and negotiation

- COP (grant or contract)
- CDA
- Contract

- Identifies if willing to be a study site
- Institution-specific policy (e.g., credentials, security, etc.)
- Institution resource assessment (research vs clinical care)

- ENROLL SUBJECTS
- Institutional activation
- CTO Cleared
- OSP Cleared
- Institutional Committee approval
The SMART IRB Agreement is responsive to the NIH Single IRB Policy and proposed revisions to the Common Rule.
Advancing research together

SMART IRB Aims

- A roadmap to implement the NIH Single IRB Policy
- JOIN SMART IRB
- ENABLE multi-site research
- HARMONIZE across the nation
Using the Agreement
The following institutions have joined SMART IRB and may use the SMART IRB Agreement to enable IRB reliance for their studies.

https://smartirb.org/participating-institutions/
Using SMART IRB to streamline IRB review for multi-site research

As an IRB or INSTITUTION
Use the SMART IRB Agreement to facilitate single IRB review

As a PRINCIPAL INVESTIGATOR
Work with your institution’s SMART IRB Points of Contacts (POCs) to determine an appropriate reliance arrangement and discuss your responsibilities related to single IRB review

The Reviewing IRB
takes on all IRB oversight responsibilities

Relying Institutions
provide Reviewing IRB with local context regarding state law, study team member training / qualifications, and any applicable conflicts of interest
Office of Clinical Research

I need more information about...

- Training Requirements
- Personnel Changes
- External IRB – Initial Requests
- External IRB – Modifications
- External IRB – Prompt Reporting
- External IRB – Inactivation Request / Progress Report

Clinical Trials Placement

Trial Sponsor’s, CRO’s and External Investigators. Contact us as you look to place your clinical trial.

How Are We Doing?
Fill out the Feedback Survey

ClinicalTrials.gov Registration

News Flashes

Forums
The Agreement is a “master” agreement which means:

| No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB | Reliance arrangements, however, need to be documented for each study |
The SMARTIRB Online Reliance System
Request, track, and document reliance arrangements

For Investigators and Participating Institutions

Provides a single point of entry to standardize reliance processes
Serves as communication portal to eliminate tracking requests via email or other methods
Guides investigators and institutions through the workflow, making clear when action is required

Facilitates reliance arrangements on a study-by-study basis

Launched in beta May 4th
**Key Roles in the Reliance Process**

- **Overall PI**
- **Home Institution Point of Contact (POC)**
- **Reviewing IRB POC**
- **Relying Institution POC**
Need for a Reliance Arrangement

A researcher plans on conducting a multisite research project

Single IRB review is required by a funding agency

OR

Overall PI wants to streamline the regulatory process by using a single IRB
Overall PI (or designee)

Contact Overall PI’s Home Institution POC to discuss a reliance arrangement, including a proposed Reviewing IRB and mechanism to request single IRB review.
SMART IRB

If there are plans to utilize a single IRB for the review of multiple sites for the first time, contact the IRB staff prior to submitting (210-567-8250 or IRB@uthscsa.edu).

Several institutions have signed the SMART IRB Agreement that may allow the IRB from one site to review and approve a research study for all sites participating in the study. See the list here: https://smartirb.org/participating-institutions/

Learn more about SMART IRB in this video: https://vimeo.com/207505758

Available sites in San Antonio are limited to: UTHSCSA, University Health System (UHS)

Instructions for submission:

Stage 1

- The Lead PI/Study Staff will discuss reliance plans with a representative from the UTHSA IRB office.
- During this time, template forms will be administered and discussed with Lead PI/Study Staff
  - Communication Plan
  - Relying Institution PI Checklist
  - Overall Lead PI Checklist

Stage 2

- Follow SMART IRB's Online Reliance System (SIORS) - The system which allows for investigators to request, track, and document reliance arrangements.
  - Check the site to ensure collaborator sites are listed as a participating institution: https://smartirb.org/participating-institutions/
  - This process is initiated by the Lead PI.
Overall PI (or designee)

Submits a request for reliance via the SMART IRB Online Reliance System* and proposes a Reviewing IRB

* Or via other mechanism, as required.
NOTE: If the Overall PI will use the SMART IRB Standard Operating Procedures (SOPs), a Lead Study Team must be identified.
Determines if the study is eligible for single IRB review and, if so, either confirms the proposed Reviewing IRB or proposes a new Reviewing IRB.
Requesting Single IRB Review: Step 4

**Proposed Reviewing IRB POC**

*If PI’s Home Institution will serve as Reviewing IRB, this will be the same as the Home Institution POC.*

Review materials and confirms whether his/her institution will serve as Reviewing IRB for the study.

**Proposed Relying Institution POCs notified by Online Reliance System or via other mechanism**
Requesting Single IRB Review: Step 5

Proposed Relying Institution POCs

Review materials related to the request and communicate decision whether to rely on the proposed Reviewing IRB.

If agree to rely, also communicate key local context information.
Information Provided by Relying Institutions

If ceding review, Relying Institutions provide the Reviewing IRB POC with information about:

- State laws and/or institutional requirements that could affect the IRB’s review
- Confirmation of the training and qualifications of their study team throughout the life of the study
- Any conflicts of interest relevant to study and applicable management plans throughout the life of the study
- Locally required consent form language in 3 areas
  1. availability of treatment and compensation for research-related injury
  2. payment or reimbursement of research costs incurred by subjects
  3. local contact information
OCR - SMART IRB Agreement

The SMART IRB’s Online Reliance System (SIORS) allows for investigators to request, track, and document reliance arrangements.

The following institutions have signed the SMART IRB Agreement that may allow the IRB from one site to review and approve a research study for all sites participating in the study: https://smartirb.org/participating-institutions/

SMART IRB video: https://vimeo.com/207505758

Available sites in San Antonio are limited to: UTHSA, University Health System (UHS)

Pre-submission: OCR Consultation
Determine who should initiate submission to SMART IRB (normally the Lead PI)

- The Site PI/Study Staff must discuss reliance plans with a representative from the OCR (210-567-8555 or OCRMail@uthscsa.edu).
- During this time, the following SMART IRB resource forms will be administered and discussed with Site PI/Study Staff:
  - Communication Plan/Standard Operating Procedures
  - Relying Institution PI Checklist
  - Overall Lead PI Checklist

Note: Use of a commercial IRB may not require this information. However, it is very important to contact OCR prior to submitting in the SMART IRB system as institutional requirements and system access must be established for use of a commercial IRB.

Instructions for submission to SMART IRB:
IMPORTANT: Submission to the OCR (see below) is required within 24 hours of submitting through SMART IRB. Do not submit to SMART IRB prior to OCR consultation.
Requesting Single IRB Review: Step 6

After receiving decisions/info from other institutions, Proposed Reviewing IRB POC:

- Reviews provided local context information
- Confirms for which institutions the IRB will oversee the research
- Documents the reliance determination
- Communicates which SOPs it will follow

Note: If the Reviewing IRB is not using the SMART IRB SOPs, it must provide the applicable SOPs to Relying Institutions.
SMART IRB Online Reliance System Documentation: Determination Letter

Reliance Determination:

Overall Principal Investigator: Stacy Miller

The Reviewing IRB is: Belledale Institute
Federal Wide Assurance (FWA): FWA000000001
Point of Contact: Thomas Werner, institution_poc@belledale.org
Site Investigator: John Dorean

Reviewing IRB accepts review for:

Adams University
Federal Wide Assurance (FWA): FWA00000014
Site Investigator: Christopher Turk, example@test.com

Belledale Institute
Federal Wide Assurance (FWA): FWA00000001
Site Investigator: John Dorean, example@test.com

Golden Gate Eye Research Institute
Federal Wide Assurance (FWA): FWA00000002
Site Investigator: John Doe, jdoe@gmail.com

Ridgeview Research Facility
Federal Wide Assurance (FWA): FWA00000005
Site Investigator: Stacy Miller, applicant@ridgeview.net

The following institutions will NOT rely upon the Reviewing IRB:
Approval for each must be obtained from the IRB for that site (or through other arrangement, as applicable) prior to initiating study activity at that site. Please consult the institution’s Point of Contact for further instructions:

Salk University for Medical Sciences, Point of Contact: Sarah Alonzo, institution_poc@salk.edu

Identifies the Reviewing IRB

Identifies the institutions the IRB will oversee

Identifies the institutions the IRB will NOT oversee
### The Reliance System Is...

<table>
<thead>
<tr>
<th>For Investigators (or their designees)</th>
<th>For Institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A centralized mechanism to request single IRB review for their studies and track the status of those requests</td>
<td>A platform to review reliance requests and determine and record appropriate reliance arrangements for each study</td>
</tr>
</tbody>
</table>

### The Reliance System Is NOT...

| A mechanism to submit an application for IRB review and approval | A document storage system |
Educating Study Teams about their Responsibilities

Under the SMART IRB Agreement, institutions are responsible for ensuring their study teams are aware of and comply with the terms of the Agreement.

Investigators will need assistance in understanding their roles and responsibilities related to single IRB and how they differ when they are the Overall PI (or Lead Study Team) vs. a Relying Site Study Team, especially when the SMART IRB SOPs are followed.

Overall PI and Study Team Checklists are available at smartirb.org
Communicating with the Overall PI (or designee, such as the Lead Study Team)

The Reviewing IRB POC should reach out to the Overall PI (or designee) to:

- Communicate when the IRB application should be submitted for review
- Explain how to request approval for relying institutions (e.g., by creating separate applications vs. adding each new site as an amendment)
- Develop a communication plan
Elements of a Communication Plan

Clarify and document who will:

• Provide confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research

• Communicate local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study

• Submit studywide initial application and amendments to the Reviewing IRB

• Prepare site-specific applications and site-specific amendments to the Reviewing IRB

• Distribute IRB determinations and IRB-approved study materials to relying site study teams

Template Communication Plan available on the Resources page at smartirb.org
A key consideration is how IRB approvals and other determinations will be distributed to study teams (e.g., by providing access to the review system or posting documents on a shared secure platform).

The Reviewing IRB also must ensure the Overall PI (or designee) and Relying Site Study Team are aware of their relevant policies, such as:

- Reportable events: what needs to be reported, when, and to whom
- Personnel changes
Post Reliance Processes
After Initial Review: Reviewing IRB

The Reviewing IRB is responsible for overseeing:

- Reportable events (e.g., noncompliance)
- Continuing reviews for the entire study
- Study wide & local amendments
After Initial Review: Relying Institution

Relying Institutions must have processes in place to provide information to the Reviewing IRB after their site is approved, including mechanisms for:

- Ensuring personnel added to the study after initial approval are qualified and have completed required training
- Providing the Reviewing IRB with information regarding new or updated management plans for their personnel related to the ceded study
- Audits of ceded research
- Information/events that could affect the ceded research (e.g., serious noncompliance finding for the research team on another study)
Commercial IRBs

- The following utilize the SMARTIRB Authorization Agreement
  - Schulman Associates Institutional Review Board, Inc.
  - Quorum Review, Inc.
  - Chesapeake IRB

- The following are under an individual IRB authorization agreement UT Health SA
  - Western IRB (WIRB)
Questions and Discussion