Research Protections Office
Committees on Human Research
The University of Vermont

Steps to Rely on an External IRB

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Presentation Outline

- Introduction
- Reliance Agreements
- Additional Reliance Documentation
  - Local Context / Site Information Forms
  - Communication / Responsibility Plans
  - Master agreement addenda / Letters of indemnification
- Submission of External IRB Studies to UVM
  - Local Context Review steps
- Submission to External IRBs
- Roles & Responsibilities of UVM PI and Study Team

Introduction to External IRB Research

- **Single IRB review** is a legal arrangement that allows one IRB (External IRB, Reviewing IRB, IRB of Record) to review the research and make regulatory determinations on behalf of other, engaged institutions (Relying Site, Participating Site)
- **NIH Single IRB Policy** required single IRB review as of January 25, 2018 for NIH-funded, multi-site research
- **Revised Common Rule Single IRB Regulations** (45 CFR 46.114(b)) required reliance on a single IRB for all domestic, cooperative research conducted or supported by a Common Rule department or agency as of January 20, 2020
- **Exceptions**
  - Review by more than one IRB is required by law (i.e. tribal law)
  - Federal agency/dep't determines and documents that single IRB is not appropriate

Introduction to External IRB Research

Reliance Request

- Contact UVM IRB
- Agreement
- Online platforms
- Site Info and/or Communication Plan
- Obtain study docs

Local Context Review (UVM)

- UVMClick submission
- Local Context Review
- Ancillary Reviews
- Contracts/grant
- Study Team mtg

Review by External IRB

- Regulatory review
- Site approval
- UVM approval to begin local research activities

Ongoing Submission Requirements

- All to External IRB per their policies
- Specific to UVM IRB per our policies

Reliance Agreements

- Also called **IRB Authorization Agreement or IAA**
- Document signed by two or more institutions engaged in HSR that permits one or more institutions to cede review to another IRB
- **Master Reliance Agreements** allow an institution to rely on an External IRB repeatedly without needing to renegotiate an agreement for each study

CIRB
FOR THE NATIONAL CANCER INSTITUTE

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY
Funded by a Grant from the National Institutes of Health

SMART IRB

wcg IRB

Reliance Agreements

- Process for establishing reliance varies between institutions
- UVM PIs are often approached by Lead Sites or Reviewing IRBs directly
- Guidance should be sought from the UVM IRB early in the process to ensure:
  - the request to rely is approvable (meets UVM criteria for reliance)
  - all necessary steps are followed in order
- Reliance is established before Local Context Review at UVM and regulatory review at External IRB

Reliance Agreements

SMART IRB Master Agreement

- UVM PI indicates interest in cooperative research to Lead Site
- Lead Site enters reliance request in SMART IRB Online Reliance System
- UVM IRB receives notification of reliance request and reviews in ORS
- UVM IRB confirms with UVM PI
- UVM IRB agrees to rely within ORS

IRB Authorization Agreement

- UVM PI indicates interest in cooperative research to Lead Site
- Lead Site or Reviewing IRB provides IAA to UVM PI or directly to UVM IRB
- UVM PI provides IAA to UVM IRB for review (via email or UVMClick)
- UVM IRB Reliance Administrator reviews IAA
- UVM Institutional Official signs IAA

Other methods of documenting reliance include a SMART IRB Letter of Acknowledgement, IRB Reliance Exchange (IREx), REDCap, other platforms, email

Additional Reliance Documentation

In addition to the Reliance Agreement, some External IRBs request the following:

Institutional Profile

- collects details about a site's HRPP, IRB, and reliance preferences
- allows External IRB to determine if they're comfortable serving as the Reviewing IRB for the site

Site Information / Local Context Form

- collects information about site policies and procedures, local and state laws and regulations, COI, and community information
- aids the External IRB's review of a site for a particular study

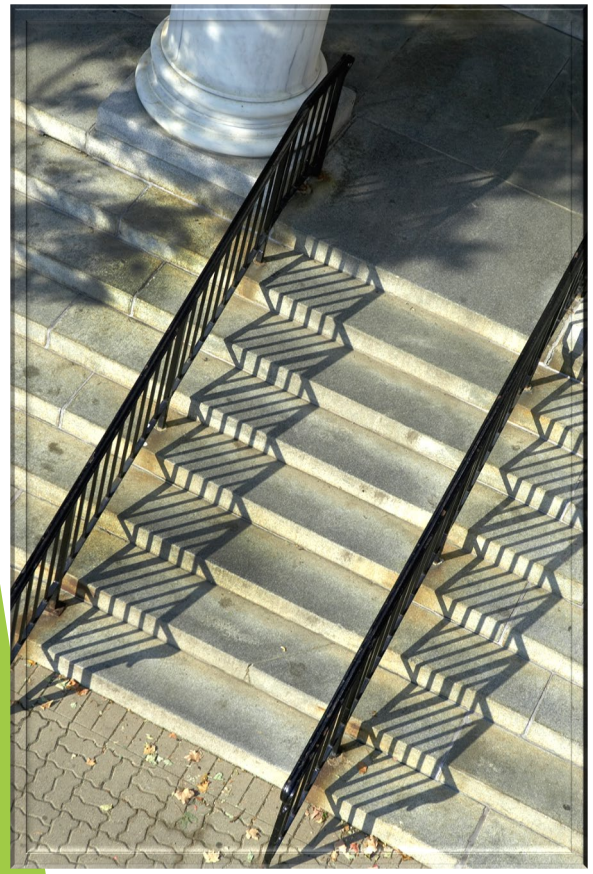
Communication / Responsibilities Plan

- sets expectations for Lead Site, Reviewing IRB, Relying Institution, Relying PI

Smart IRB Addendum / Flexible Terms

Letter of Indemnification

Submission of External IRB Studies to the UVM IRB for Local Context Review



- UVM PI or Proxy submits a new External IRB study in UVMClick
- IRB Reliance Administrator reviews submission, and clarifications are requested as applicable
- Concurrently, Ancillary Reviews are conducted
- Facilitated Review may be conducted by IRB Member
- UVM Study Team are told they may submit the local materials to the External IRB for regulatory approval
- Meeting between IRB Reliance Administrator and UVM Study Team
- “Reliance Confirmed” in UVMClick → “Pending sIRB Review” status

Submission of External IRB Studies to the UVM IRB for Local Context Review

- Required documents:
  - Protocol approved by the External IRB
  - Lead Site's Consent/HIPAA template + version edited to include UVM required local language
    - (See UVM form: "Consent/HIPAA Checklist for Required Language")
  - Separate HIPAA Authorization if External IRB is not Privacy Board (UVM form)
  - Documentation of Waiver or Alteration of HIPAA Authorization (UVM form) if applicable
  - Data Management and Security Plan (UVM form)
  - Completed Request to Rely on an External IRB form (UVM form)
  - The initial, study-wide approval memo from the External IRB

Submission of External IRB Studies to the UVM IRB for Local Context Review

- Additional documents and UVMClick Smart Form entries:
  - Reliance agreement
  - Local context form
  - A site-specific research plan (if local research activities differ in scope from the approved protocol)
  - A local recruitment and/or consent plan
  - Sponsored Projects Administration Funding Proposal Number (FP#)
  - Financial Conflict of Interest Management plan(s)
  - All local key personnel + CITI training
  - Study Team meeting checklist

Submission to the External IRB

- UVM PI or Designated Contact is responsible for communicating with the Lead Site and/or External IRB
- Determine what documents are needed for review and the procedures for submission
- It is expected that the required materials will have undergone local context review by the UVM IRB prior to this step
- UVM Ancillary Reviews do not have to be completed prior to this step

Following External IRB Approval

- UVM PI or Proxy must submit in UVMClick:
  - External IRB approval memo for UVM site, PI, and local materials
  - Final, sIRB-approved protocol (if different from version already submitted to UVM)
  - Final, sIRB-approved local consent form(s)
  - Any changes to local key personnel or the original Data Management and Security Plan since local review

Following External IRB Approval

The UVM PI may not begin protocol activities until they receive notification from the UVM IRB that they have met the local requirements and are allowed to begin local research activities.

Following External IRB Approval

- UVM IRB will review the final materials to ensure that all local requirements are met and that Ancillary Reviews are complete
- sIRB decision recorded in UVMClick → "Post Review" status
- "*Approval to Begin Research Activities Reviewed by an External IRB*" memo will be sent to the UVM PI, Primary Contact, and PI Proxies through UVMClick → "Active" status
- Local research activities may begin

Roles and Responsibilities of UVM Principal Investigator & Study Team

- **UVM/UVMHN PIs have the overall responsibility for the local conduct of the protocol**
  - See Section 5.1 of the UVM IRB Policies and Procedures
- Adherence to policies and procedures of External IRB and UVM IRB
- Adherence to regulatory determinations of External IRB
- Prepare and submit site-specific study materials to External IRB (or lead site or coordinating center)
- Communicate clearly and promptly with both the External IRB and UVM IRB
- Ongoing submission requirements to the External IRB
  - modifications, continuing reviews, reportable new information, audits, and corrective actions
- Ongoing submission requirements to the UVM IRB

Ongoing Submission Requirements to the UVM IRB

- Changes to UVM PI or Key Personnel
  - UVM must ensure appropriate training, qualifications, and COI management of study team
- Changes in Funding
- Reportable New Information reports
  - External IRB determinations of: Unanticipated Problems, Protocol Deviations, Noncompliance, Local Adverse Events, Participant Complaints, and Investigation by External IRBs or Federal Agencies, **per Section 18 of the UVM IRB Policies and Procedures**
- Protocol changes affecting required UVM consent/HIPAA language
  - Changes not affecting required local language do not need to be submitted
- Protocol closure

Questions?

“Betty” May 2, 2023 @ Perkins Pier