



THE UNIVERSITY  
OF VERMONT

# WHAT YOU NEED TO KNOW ABOUT SINGLE IRB

NOVEMBER 22, 2019

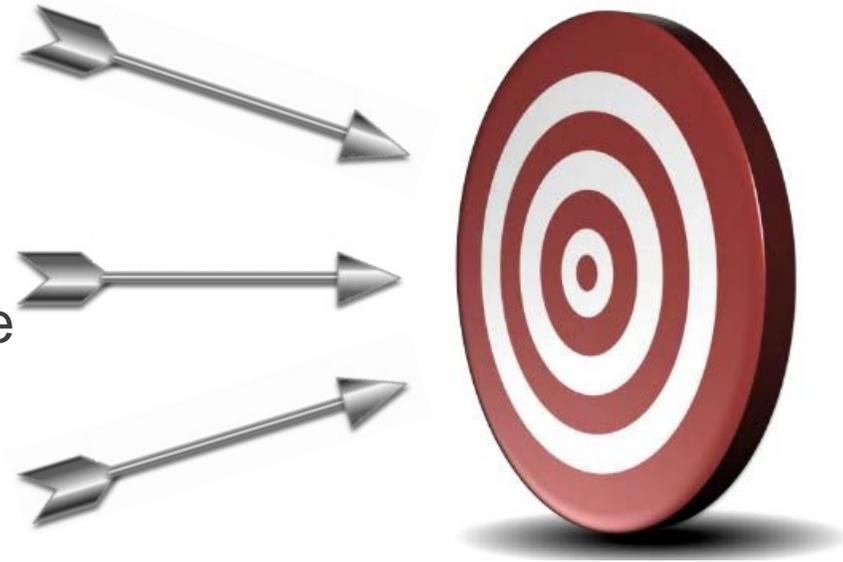
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# Aims of this Presentation

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- ❖ Summarize information regarding this regulatory requirement
- ❖ Experiences with single IRB that have occurred since regulatory compliance date
- ❖ Review UVM reliance request process



# What is Single IRB Review

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- ❖ **Single IRB review** – a legal arrangement that allows one IRB to review the research on behalf of other engaged institutions
- ❖ **Reviewing IRB** – the IRB that reviews and makes the required regulatory determinations (IRB of Record, External IRB)
- ❖ **Relying Site** – the institution that relinquishes IRB review responsibilities to the Reviewing IRB (Participating Site)
- ❖ **Reliance Agreement** – a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subject research activities for more than one site and outlines the responsibilities of each site.

Redundant  
Local IRB  
Re-review



Single IRB Review

# Why Is Single IRB Necessary

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- ❖ Use of a Single IRB for NIH-funded multi-site research was required as of January 25, 2018
- ❖ New: Use of a Single IRB for multi-site research where each site will conduct the same protocol supported or conducted by HHS is required as of January 20, 2020
  - Does not apply to career development, research training or fellowship awards
  - Does not apply to industry-sponsored protocols
  - Does not apply to international protocols
  - Does not apply to exempt protocols
- ❖ Ongoing multi-site trials still recruiting
  - Single IRB policy applies to all competing grant applications (new, renewal, revision, or resubmission)
  - **NOT** expected to follow the policy **UNTIL** the renewal application

# What We Have Learned

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## ❖ Since January 25, 2018

- UVM has relied on 8 external IRBs for 143 studies
- NCI CIRB has reviewed 135 on our behalf
- Seven other different IRBs have reviewed 8 Studies on our behalf
- Each Reviewing IRB requests different information and we cannot control the order of events
- Jury still out on whether less work, different work
- UVM PIs are not reaching out to us. Often times it is the Reviewing institution/IRB that reaches out to the UVM IRB.
- All the Reviewing IRBs (exception NCI CIRB) have utilized the SMART Reliance Agreement



# What is SMART IRB

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The SMART IRB, Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform, is an initiative developed under an award from the National Center for Advancing Translational Sciences (“NCATS”) of the National Institutes of Health (“NIH”) to support single Institutional Review Board (“IRB”) review in facilitation of multi-site human subjects research.

The **SMART IRB is not a single IRB** that institutions can use. It is a platform for executing reliance agreements. Institutions who participate have already been vetted and have executed a master agreement that enables institutions to more readily participate in collaborative multi-site research under a single IRB.

The number of participating institutions is over 600 at this time.

Information regarding [SMART IRB](#)

# Requests for UVM to be IRB of Record

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- ❖ As a general rule, the UVM IRB will not be acting as the Reviewing IRB. If a UVM PI is the lead he/she may choose to have one of the collaborating sites be the Reviewing IRB or enlist the services of the Western IRB.
- ❖ UVM already has a reliance agreement in place with the Western IRB and contact information is located on our website at <https://www.uvm.edu/rpo/western-irb>

# Requests to Rely on External IRB

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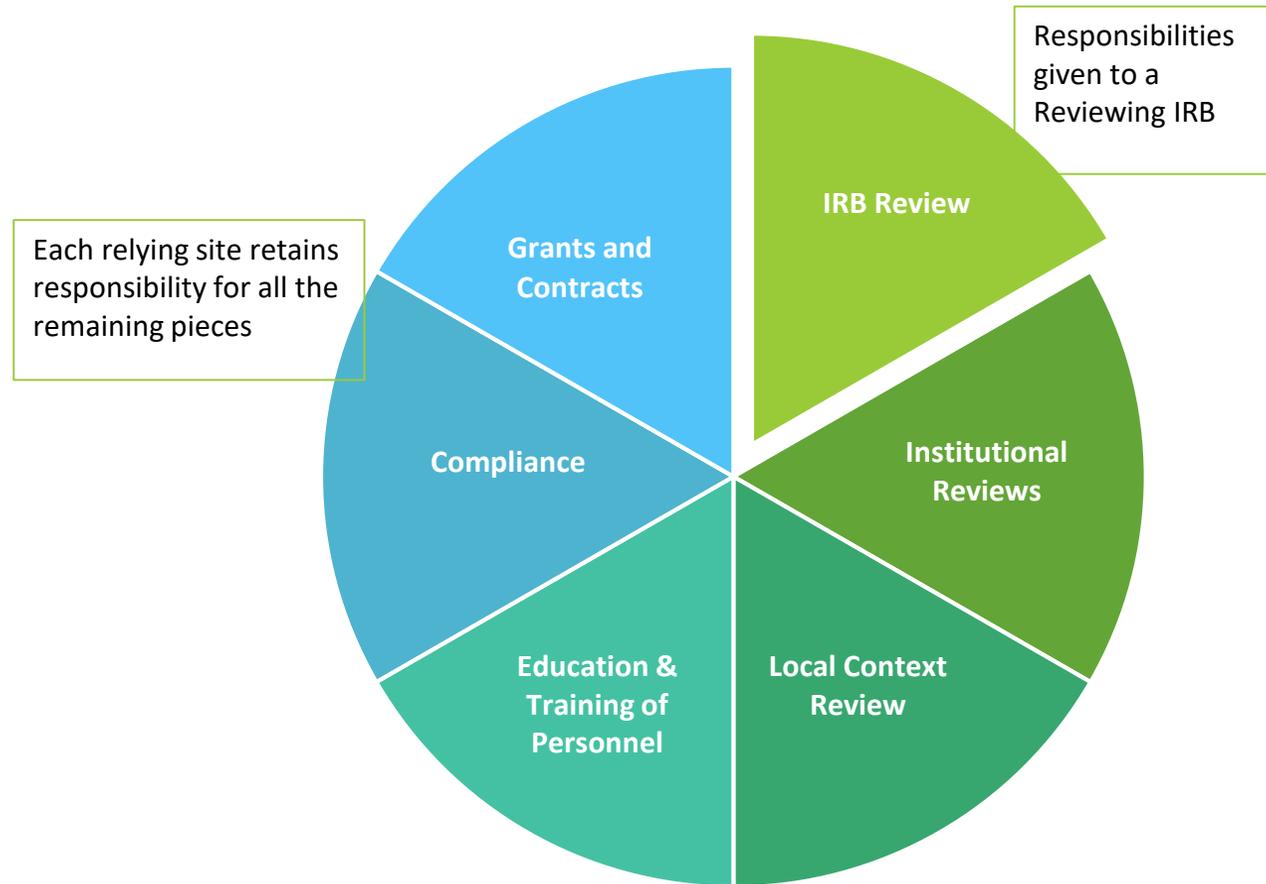
UVM investigator/designee needs to be in contact with their assigned IRB research analyst to make them aware of the intention to rely on another IRB.

- Step 1.** UVM PI requests reliance through UVM Click following UVM procedures, Section 13.3. Reviewing IRB requests local context information.
- Step 2.** Single IRB meeting between IRB staff and study team.  
Simultaneously a reliance agreement is negotiated between the two IRBs.  
Simultaneously required local ancillary reviews are taking place.
- Step 3.** UVM develops and submits materials required for the reviewing IRB.
- Step 4.** All single IRB-approved protocol materials are submitted to the UVM IRB.
- Step 5.** Receipt of site approval from reviewing IRB. UVM IRB conducts final check of all required items and grants formal permission to begin work at UVM.

**Work Begins**

# Single IRB Review Does not Equal Single Institutional Review

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# What types of things do relying sites remain responsible for?

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- ❖ **Institutional Reviews:** Ensuring all applicable institutional reviews required for the research to be conducted at that site are performed [e.g. billing compliance, radiation safety review, COI review, etc.].
- ❖ **Local Context Review:** Communicate to the Reviewing IRB the requirements of any local laws, ancillary reviews, etc. and provide any required site-specific information for the consent form, where applicable.
- ❖ **Education/Training:** Ensuring that its research personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of subjects.
- ❖ **Compliance:** Ensuring research personnel comply with determinations of the reviewing IRB and all applicable laws/institutional requirements.
- ❖ **Grants/Contracts:** Negotiating and maintaining sub-awards, clinical trial agreements, data use agreements.

# Institutional Reviews

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- ❖ Department Chair signs off on Request to Rely form to indicate acceptance by UVM department to allow reliance
- ❖ Assign all applicable institutional ancillary reviews required for the research to be conducted at time of initial request submission [e.g. billing compliance, radiation safety review, COI review, etc.]
- ❖ Determine from the reviewing IRB if they will act as HIPAA Privacy Board
- ❖ Research team members must be in compliance with the University's [Financial Conflict of Interest policy](#)

# Local Context Review

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## ❖ What is local context

- Local context in single IRB means the local requirements of state laws (e.g. age of majority, legally authorized representatives, telehealth), institutional requirements (e.g. required ancillary review completion and as well as any required site-specific information for the consent form).

## ❖ Response

- Vermont does not have laws that are specific to research, so UVM IRB models the UVMMC clinical policies as necessary
- Local permission to begin activities at UVM/UVMMC is held until certain ancillary reviews are complete. The PI needs to communicate that to the reviewing IRB.
- A checklist for required consent language can be found on the IRB webpage

Local context document and consent checklist can be found [here](#)

# Education/Training

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## ❖ What

- Ensuring that research personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of subjects. This includes ensuring personnel are credentialed to perform the research procedures.

## ❖ How

- UVM PI confirms that research staff have completed CITI Human Subjects in Research training and Good Clinical Practice Training, as applicable
- UVM PI provides and documents protocol-specific training
- UVM PI ensures that any UVM employed researchers have been credentialed to carry out procedures in the hospital

# Compliance

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## ❖ What

- UVM PI must
  - comply with determinations of the reviewing IRB
  - comply with all UVM applicable laws/institutional requirements.
  - be in compliance with the approved protocol
  - ensure proper consent
  - ensure appropriate management and security of data



## ❖ Demonstration of the above can be accomplished by

- Consistent and documented self-audit – tools available on IRB and Commons websites
- Planned or standard-cycle UVM IRB monitoring visit
- UVM IRB monitoring visit requested by PI

# UVM PI Responsibilities to the Reviewing IRB

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- ❖ Communication with the lead PI is crucial
- ❖ UVM PI and staff need to be aware of and follow the Reviewing IRB policies and procedures
- ❖ Follow all determinations of the Reviewing IRB
- ❖ Implement changes only after Reviewing IRB has approved them
- ❖ Notify Reviewing IRB of any reportable events or noncompliance
- ❖ Provide access to study records for audit by the Reviewing IRB
- ❖ PI and research staff may need to learn a separate electronic protocol submission system

**Act as though the Reviewing IRB is us. Follow their policies and procedures.**

# UVM PI Responsibilities to UVM IRB

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- ❖ Communicate with your IRB analyst early and often
- ❖ Submit changes in key personnel to ensure required training is complete
- ❖ Assurance that research team members' financial interests continue to be assessed following the institutions' COI policies
- ❖ Ongoing submissions to UVM include reportable events, changes in PI or key personnel, noncompliance, protocol closure
- ❖ Notify UVM IRB if you receive notification of any reviews or audits by regulators or others related to the research protocol

# More Information

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## SINGLE/EXTERNAL IRB (COOPERATIVE RESEARCH) *UPDATED 10/25/19*

In January 2018 the NIH mandated the use of Single IRB for all NIH-sponsored multi-site protocols. Over the last year UVM has entered into multiple agreements to rely on other IRBs. On January 20, 2020, the last requirement under the 2018 Final Common Rule, Single IRB for all federally funded multi-site protocols, will be in effect. Below are links to instructions, forms, and educational materials in this regard.

- ❖ [Procedures for Requesting Reliance on an External IRB \(Manual Section 13.3\)](#)
- ❖ [Forms and Data Entry Instructions](#)
- ❖ [Western IRB Information specific to UVM](#)
- ❖ [SMART IRB](#)
- ❖ [NIH FAQs](#)
- ❖ [Secretary's Advisory Committee on Human Research Protections – Single IRB Points to Consider](#)

# Questions

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There is a path but it is not always this clear. We are here to help you.

