The University of Vermont

SINGLE IRB AT UVM:

WHAT WE'VE LEARNED AND WHERE WE ARE NOW

NOVEMBER 2, 2022

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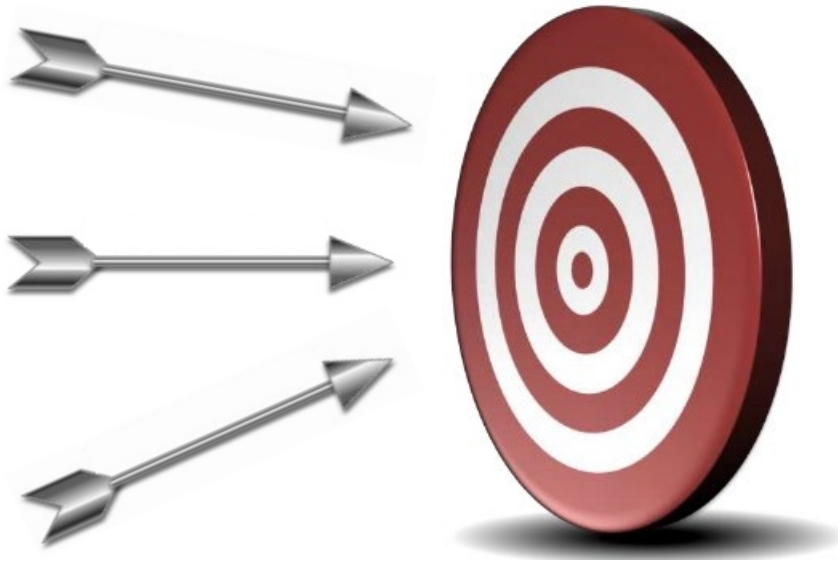
Slides adapted from "What you need to know about Single IRB" presentation by Donna Silver, Director, RPO on November 22, 2019

Aims of this Presentation

- Review the Single IRB regulatory requirement, then vs. now
- Look at experiences with single IRB at UVM since 2019
- Explore current UVM Policy and scenarios for reliance at UVM



What is Single IRB Review?

- **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 the research 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.

Why Is Single IRB Required?

- **NIH Single IRB Policy**: Use of a Single IRB for NIH-funded, multi-site research was required as of January 25, 2018
- **Revised Common Rule's cooperative research Single IRB mandate**: Use of a Single IRB for multi-site research supported or conducted by HHS where each site will conduct the same protocol was required as of January 20, 2020

COMMON RULE sIRB APPLIES TO:	DOES NOT APPLY TO:
Human Subjects Research	Exempt & "Research Not Requiring IRB Review" protocols
Federally-funded research	Industry, Foundation, or Internally funded protocols
Career Development (K) awards	International protocols (i.e. GDPR)
Fellowship (F) awards	Training (T) awards
	Research that must be reviewed by more than one IRB by law (i.e. tribal law)
	Research for which the supporting Federal department/agency determines & documents that use of sIRB is not appropriate

What Is UVM's Current sIRB Policy?

- **UVM as the Relying Site**: UVM will allow UVM/UVMHN researchers to rely on an External IRB for multicenter, domestic, non-Exempt human subjects protocols with federal funding.
  - UVM is currently the IRB of record for UVMMC (including UHC, satellite sites) and CVMC
- **UVM as the Reviewing IRB**: Currently, the UVM IRB will not act as the Reviewing IRB except under certain, rare circumstances.
  - If a UVM PI is the lead, they may choose to have one of the collaborating sites be the Reviewing IRB or enlist the services of WCG IRB.
  - We have allowed collaborative partners to rely on UVM for a very small number of rural, community projects

- Find more information in Section 13 of the UVM RPO Policies and Procedures page

UVM as the Relying Site

- UVM may enter into individual reliance agreements with Reviewing IRBs
- UVM has the following master reliance agreements in place:
  - **Master reliance agreements** allow UVM to rely on an External IRB repeatedly without having to renegotiate an agreement for each individual project.

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SMART IRB

wcg IRB

What is SMART IRB

- "SMART IRB (the Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform) is designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants."
- The **SMART IRB is not a single IRB** that will review collaborative research. It is a platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) allowing institutions and their investigators to initiate, track, and document study-specific reliance agreements.

As of November 2022, there are **1039** participating institutions!!

Process to Rely on External IRB

Step 1. UVM PI or designee requests reliance by creating a new External IRB protocol in UVMClick following UVM RPO Policies & Procedures, Section 13.3

- ✓ Required documents include: Protocol, Consent template (approved by External IRB), local Consent with required local content, separate HIPAA Authorization if sIRB is not Privacy Board, DMSP, Request to Rely form, Reliance Agreements requiring Institutional Official signature (if not using Master Agreement), Study/Lead Site approval memo from External IRB
- ✓ Reviewing IRB may request local context information from UVM study team and/or IRB.

Step 2. UVM IRB Reliance Administrator reviews submission, and clarifications are requested if applicable

- ✓ Simultaneously, a reliance agreement is negotiated between the two IRBs.
- ✓ Simultaneously, required local Ancillary Reviews are being conducted.
- ✓ If the research is more than minimal risk, a facilitated review is conducted by an IRB Chair or designee.

Step 3. Single IRB meeting between UVM IRB Reliance Administrator and study team

Process to Rely on External IRB

Step 4. UVM study team submits materials to the reviewing IRB

- ✓ Submission platforms include: Huron Exchange, WCG IRB Connexus, NCI IRB Manager, IREx, REDCap, email

Step 5. Receipt of site approval from reviewing IRB by study team

Step 6. Reviewing IRB-approved materials (approved local ICF, site approval memo) are submitted to the UVM IRB. UVM IRB conducts final check of all required items and grants formal permission to begin work at UVM.

Work Begins

UVM as the Lead Site in Collaborative Research

- UVM has subcontracted with WCG IRB (formerly Western IRB aka WIRB) for single IRB services where UVM researchers wish to be the lead single IRB for their federally funded proposals.
- Contact information is located on our website at https://www.uvm.edu/rpo/wcg-irb
- Grant proposals should include the use of WCG IRB as the IRB of record for the UVM PI's multi-site research activities. Budgets must be developed to include the expense for the use of this commercial IRB.

UVM as the Reviewing IRB

- In rare instances, the UVM IRB has agreed to be the IRB of Record for federally-funded, non-Exempt, multi-site studies where UVM is the lead site (not our current policy).
- UVM, Maine Medical Center (MMC), and Dartmouth Hitchcock Medical Center are collaborating organizations in the Northern New England Clinical and Translational Research Network (NNE-CTR)
  - The NNE-CTR aims to improve the infrastructure and support for clinical and translational research in Maine, New Hampshire, and Vermont
- Projects funded through NNE-CTR are required to use a single IRB. The institutions have agreed that the lead institution will be the Reviewing IRB and Relying Sites will cede their review under the current SMART IRB Master Reliance Agreement. See Policies & Procedures Manual, Section 13.8, for more information.

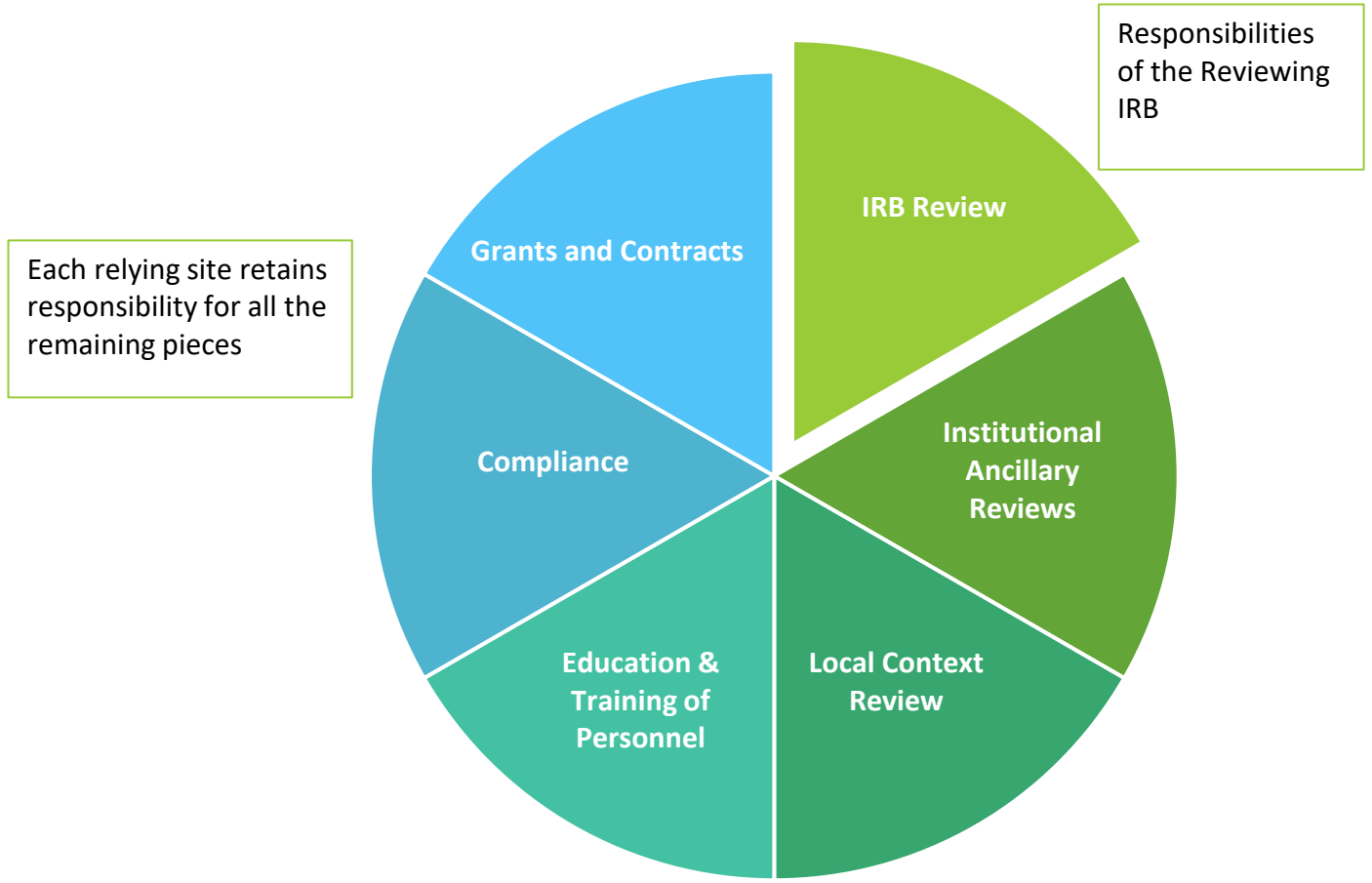
UVM as the Reviewing IRB

- The VT Agency of Human Services (AHS) and the University of Vermont (UVM) IRB have a reliance agreement in place that allows the AHS IRB to rely on the UVM IRB for collaborative projects led by a researcher at UVM if:
  - The UVM researcher has signed a scope of work with AHS, or
  - AHS has provided financial support, or
  - the project requests access to data or resources from one of the State member departments
- If a protocol fits one of these scenarios, the PI should contact the AHS IRB to determine if they wish to review the protocol or rely on the UVM IRB. The UVM IRB is required to review and approve regardless of the AHS IRB's decision to review. When both IRBs review the protocol, research activities may not begin until both the AHS and UVM IRB approvals have been obtained. See Policies and Procedures manual, Section 13.9 for more.

Process for UVM to be the Reviewing IRB

Contact the IRB Reliance Administrator at UVM to determine feasibility

Single IRB Review Does not Equal Single Institutional Review



What is a relying site responsible for?

- **Institutional Ancillary 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, Privacy Board review, etc.].
- **Local Context Review:** Communicate to the Reviewing IRB the requirements of any local laws (i.e. age of majority), ancillary reviews, etc. and provide any required site-specific language 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, approved protocol/ICF/DMSP, and all applicable local laws/institutional requirements.
- **Grants/Contracts:** Negotiating and maintaining sub-awards, clinical trial agreements, data use agreements.

UVM PI Responsibilities to the Reviewing IRB

- Communication with the lead PI and Reviewing IRB are crucial
- UVM PI and staff must 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

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

UVM PI Responsibilities to UVM IRB

- Communicate with the IRB Reliance Administrator 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 protocol changes affecting the locally required consent form language, changes in PI or key personnel, reportable events, noncompliance, protocol closure
- Contact UVM IRB if you receive notification of any reviews or audits by the Reviewing IRB, regulators, or others related to the study

What We Have Learned

January 25, 2018 – November 2019	November 2019 – November 2022
UVM relied on 8 External IRBs for 143 studies (NCI CIRB = 135; 7 other IRBs = 8)	UVM relied on 23 External IRBs for 181 studies (in Click) 60 PI's have submitted External IRB studies
Each sIRB requests different info and order of events is out of our control	Perhaps the dust has settled
Jury still out on whether less vs. different work	Consensus is… different work. External IRB studies can still be very time consuming for the Relying PI and IRB
UVM PI's aren't reaching out to UVM IRB; often it's the Reviewing IRB/Site	More PI's and research coordinators are reaching out prior to requesting reliance
All Reviewing IRBs (except NCI CIRB) have used the SMART Reliance Agreement	We have seen use of new Master Agreements (StrokeNet, WCG IRB), addenda to Master Agreements per study, and individual Reliance Agreements

What We Have Learned

November 2019 – November 2022
UVM has had 29 requests to rely through SMART IRB, and reached reliance on 17
PI's have had to learn new submission platforms (and sometimes, so have we!)
We needed a new position to increase the capacity for Single IRB research at UVM = IRB Reliance Administrator and Health Network Liaison
Communication between the Reviewing and Relying IRBs could be better
Facilitated reviews can be helpful to ensure local feasibility
We may consider requesting more updates from UVM PI's to ensure adequate local oversight
Single IRB can get complicated for certain funding sources, such as the Department of Defense
More and more alternate funding sources/sponsors are requesting Single IRB

What's the Future of sIRB at UVM?

- UVMClick Version 9: December 2022
  - One, STUDY record (SITE record is gone!) to streamline submission
  - New "How to Request Reliance on an External IRB" user guide will be published on the UVM RPO website
- Using metrics, assess current sIRB portfolio to determine needs of the UVM/UVMHN research community and the Research Protections Office
  - Reliance on External IRB
  - Reliance on UVM IRB
- Establish robust post-approval monitoring of Single IRB protocols
- Revisit UVM RPO Policies & Procedures regarding Cooperative Research
- Provide more educational resources for UVM/UVMHN investigators

Resources

- Procedures for Relying on External IRB for Federally Funded Research (UVM P&P Manual Section 13.3)
- UVM Forms and Data Entry Instructions for Requesting Reliance
- WCG IRB Information specific to UVM
- SMART IRB
- NIH FAQs
- NIH Single IRB for Multi-Site or Cooperative Research website
- Secretary's Advisory Committee on Human Research Protections – Single IRB Points to Consider
- UVM RPO: IRB Reliance Administrator & Health Network Liaison can be reached at:
  - jen.dulin@uvm.edu
  - Jen Dulin on Microsoft Teams

Questions?

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