HUMAN RESEARCH PROTECTION

IRB reliance

Number	901	Version Date	20 MAY 2020
Resource type	FAQ		
Author	Erin Venegoni		
Approved by	Jennifer Hart		

Visit the Hennepin Healthcare HRPO webpage for current forms and information:
https://www.hhrinstitute.org/researcher-resources/ohsr/

1) What does "reliance" mean?

Reliance refers to an arrangement (legal arrangement) between two or more institutions to allow for IRB regulatory review and oversight of a study by one institution's IRB for one or more other institutions when multiple IRBs have jurisdiction for the same research protocol. Refer to Appendix A below for more commonly used terms in IRB reliance.

2) What is a reliance agreement?

The Hennepin Healthcare Human Research Protection Program ("HRPP") uses this term to refer to the formal written agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization serving as the IRB of record and the institution relying on that IRB. This term includes: IRB Authorization Agreement (IAA), cooperative agreement, master services agreement ("MSA"), master joint agreement ("MJA"), or umbrella agreement.

Hennepin Healthcare is signed onto the SMART IRB Agreement and frequently uses that agreement for reliance requests.

3) Why are reliance agreements needed?

Every institution is responsible for research conducted by its personnel, regardless of where the research occurs. When Hennepin Healthcare conducts human subjects research, the Hennepin Healthcare IRB must review it unless a reliance arrangement is established and you receive administrative approval to rely on the IRB review of another qualified IRB.

4) What is an external IRB?

An external IRB refers to an IRB that is not affiliated with Hennepin Healthcare. In a reliance arrangement, the External IRB agrees to take on the IRB regulatory review and oversight for a research protocol. An example of an external IRB is an IRB at another institution (e.g. a university's IRB) or an independent IRB (e.g. Advarra). Other terms may include IRB of record, reviewing IRB or central IRB (cIRB), or single IRB (sIRB).

5) When will Hennepin Healthcare consider relying on an external IRB?

Approval to rely on another IRB requires an administrative review by the Hennepin Healthcare IRB office. Requests to rely on an external IRB are reviewed on a case-by-case basis. Various factors are considered in determining eligibility to rely on an external IRB such as whether the study is required to use a single IRB (e.g. a multi-site federally funded study), risk level of study and whether the other institution is accredited. We do **not** rely on an external IRB if the study is determined to be exempt or if Hennepin Healthcare is not engaged in human subject research.

For more information about the single IRB requirement for federally funded research, refer to the 902 FAQ *Single IRB review for federally funded research*.

6) How to I request to rely on an External IRB?

Refer to the 112 Guidance *Relying on an external IRB/single IRB* for more information on submitting a request for reliance.

Use of an external IRB will require that you work with and become familiar with another IRB's submission process and IRB policies and SOPs, if applicable. Depending on the institution and reliance arrangement, you may be working through a designated IRB liaison from the lead study site or coordinating center OR working directly with the external IRB office. Questions on the IRB submission requirements and process for a specific institution should be directed to that institution.

7) What about federally funded research that requires single IRB review?

Refer to 902 FAQ *Single IRB review for federally funded research* for information about the single IRB requirement for federally funded research.

8) Why is a request to rely required if Hennepin Healthcare is not the IRB?

Reliance on an external IRB (i.e. an sIRB) is limited to the IRB regulatory review.

What that means is that you: (1) still need to work with the Hennepin Healthcare IRB office; (2) remain responsible for completion / compliance with any institutional policies and requirements (**including ancillary reviews**); and (3) Hennepin Healthcare retains overall responsibility for conduct of research at Hennepin Healthcare.

9) Is approval for reliance on an external IRB/establishing a reliance agreement the same thing as having IRB approval for the Hennepin Healthcare site?

No. When the Hennepin Healthcare IRB office approves relying on an external IRB, the study team must still obtain IRB approval from the external IRB before beginning any study activities. The study team remains responsible for ensuring all Hennepin Healthcare institutional requirements are met before beginning the research and over the course of the research study. You must receive Hennepin Healthcare IRB office approval for external IRB review before submitting to the external IRB for local site approval. You will receive correspondence via IRBReliance@hhrinstitute.org when approval to pursue external IRB is granted.

10) Will all IRBs agree to serve as the IRB of record?

No. Policies regarding acceptance of IRB oversight are specific to each institution. If you wish to request that an institution's IRB serve in this capacity, you should contact them to confirm their policy before proceeding. At this time the Hennepin Healthcare IRB is not agreeing to serve as the IRB of record on multi-site research.

11) Once I receive HRPP approval for relying on an external IRB, who do I contact for questions about how to submit my study to the IRB of record?

Questions about how to submit your study to the external IRB should be directed to the external IRB or designated coordinating center. Your reliance arrangement may involve standard operating procedures (SOPs) that describe with whom and how to communicate with the external IRB.

12) Who negotiates the terms of the reliance agreement and signs the agreement?

The reliance agreement is negotiated and finalized by the Hennepin Healthcare IRB office. The Hennepin Healthcare IRB office will also coordinate review by legal counsel, as needed. The Institutional Official or designee from each participating institution signs reliance agreements. The Hennepin Healthcare IRB office coordinates the signature process. The Hennepin Healthcare IRB office will also work on any local context form requested by the external IRB.

13) What is SMART IRB – I keep hearing about it?

SMART IRB is NOT an IRB. SMART IRB is the name of a model reliance agreement designed to streamline the reliance process. SMART IRB was developed under an award from the National Center for Advancing Translational Sciences ("NCATS") of the National Institutes of Health ("NIH") to support single IRB review of multi-site human subjects research.

SMART IRB includes:

- An IRB reliance agreement that permits eligible institutions that join it ("Participating

Institutions") to rely on the IRB review and oversight of human subjects research by another Participating Institutions' IRBs; and

- A set of standard operating procedures (SOPs) to guide implementation of the reliance relationship among Participating Institutions.
- Centralized online system to support sign-on and reliance determinations (i.e. Participating Institutions agreeing which institution will serve as the reviewing IRB and whether the other Participating Institutions are willing to rely on review by that IRB). Note: Some SMART IRB Participating Institutions use the online platform but others do not. The alternative to the online system is the SMART IRB Agreement Letter of Acknowledgement/Implementation Checklist. The UMN HRPP Reliance area can help you identify which will be used.

You can find more information about SMART IRB here and here.

14) Is the Hennepin Healthcare signed on to use the SMART IRB Agreement and what does that mean?

Hennepin Healthcare is signed on to the SMART IRB Agreement as a Participating Institution. Using the SMART IRB Agreement means that the institutions collaborating on a project and seeking to utilize single IRB review do not have to establish and execute a reliance agreement. A decision to use the SMART IRB Agreement is made on a study-by-study basis by each Participating Institution. Using SMART IRB does **not** replace or negate the internal process here at Hennepin Healthcare for requesting reliance on an external IRB. You can refer to the information on the IRB website for more information on that process.

15) What do I submit to the Hennepin Healthcare IRB office after my study is approved for reliance on an External IRB?

Even when your research relies on an external IRB, there are ongoing reporting obligations to the Hennepin Healthcare IRB office. Refer to 112 Guidance *Relying on an external IRB/single IRB* and 312 Form *Notification to HRPO for ceded studies*.

APPENDIX A: DEFINITIONS

Engagement of Organizations in Non-Exempt Human Subject Research: An organization is considered engaged in human research when its employees or agents, for the purposes of the research project obtain 1) data about the subjects of the research through intervention or interaction with them; 2) identifiable private information about the subjects of the research; 3) informed consent of human subjects for the research; OR 4) a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by subcontractors (i.e. employees or agents of another organization).

HHS Guidance: Engagement in Human Subjects Research

External IRB: An external IRB refers to an IRB that is not affiliated with Hennepin Healthcare. In a reliance arrangement, the external IRB agrees to take on the IRB regulatory review and oversight for a specific study or set of studies. An example of an external IRB is an IRB at another institution (e.g. a university's IRB) or an independent IRB (e.g. Advarra). Other terms may include IRB of record, reviewing IRB or central IRB (cIRB), or single IRB (sIRB).

Local Context: Knowledge of the institution and community environment in which the research will be conducted. In order for the External IRB to review for another institution, it must have adequate knowledge of that institution's local context sthc as local research policies, state and local laws, and a community's attitude toward research.

Reliance Agreement: the formal written agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization serving as the IRB of record and the institution relying on that IRB. This term includes: IRB Authorization Agreement (IAA), cooperative agreement, master services agreement ("MSA"), master joint agreement ("MJA"), or umbrella agreement.

Relying Institution: The institution that has agreed to rely on the review of another IRB to provide IRB review and oversight for a specific study or set of studies.

Single IRB: The selected IRB of record that conducts the ethical review for participating sites of a multi-site study.