Reliant Review

A General Overview of the Reliant Review process from the perspective of the Investigator

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What Is Reliant Review (RR)

- Reliant Review allows one IRB to be responsible for reviewing, approving and monitoring a study across its life cycle. That IRB acts as the IRB of Record.
- Collaborating IRBs can agree to rely on the IRB acting as the IRB of Record.
- Amendments, continuing reviews, reportable events, and other information are reported to relying IRBs using an electronic HUB and email notices.
- Reliant Review is a work in progress, RR continues to improve through collaboration and feedback.
Benefits of Reliant Review

- RR promotes collaboration among investigators with similar research interests.
- RR has the potential to expand recruitment and increase enrollment in studies.
- Only one IRB submission and review is needed for initial study, amendments, continuing reviews and reportable events.
- IRB staff do all “heavy lifting” with reliant review process, entering information into the HUB and updating the HUB with new or revised documents.
Benefits continued:

- Communication - Relying IRBs and investigators are notified via HUB of updates to protocol or documents.
- One consent used at all sites with a site specific Appendix for relying review sites. (set language 1-2 pages who to contact and subject injury language.)
- Only one expiration date to track
When Can One Use Reliant Review?

- Most studies can be considered for RR but investigators need to talk to the IRB first. Each IRB gets to decide if they want to act as the IRB of Record or if they are willing to rely on another IRB.
- Can’t use if the study was originally approved with a central 3rd party IRB (Western, etc.)
- Chart Reviews registries need to keep HIPAA regulations in mind. Limited data sets require DUA to leave an institution. Direct identifiers can’t leave at all!
Collaborating Institutions

The following institutions signed a legal agreement which permits Reliant Review to be utilized by their IRBs:

• University Hospitals Case Medical Center
• MetroHealth Medical Center
• The Ohio State University
• Case Western Reserve University
• Nationwide Children’s Hospital
• University of Cincinnati
• Cincinnati Children’s Hospital Medical Center
Terminology

- **IRB of Record**
  - The IRB that initially reviews and approves the protocol.
  - This IRB has all IRB oversight. IRB questions should be directed to them.

- **Relying IRB**
  - The IRB from which you are requesting a Reliant Review.
  - Relying IRBs may have institutional requirements for EMR, data, pharmacy, etc.
  - Communicate with them early and often.
Terminology (Cont.)

- **HUB** - An electronic document and process review system for *Reliant Review*

- **IRB Administrators** – A person(s) at each IRB responsible for doing all the work in the HUB.
  - IRB of Record Administrator
  - Relying IRB Administrator

- **Relying IRB Reviewer** - Person other than the Relying IRB Administrator who gives final approval (e.g. the Chair, IRB Director). Not all IRBs require this level of review, some IRBs will allow an administrator to approve an RR request.
Tips for Investigators when considering Reliant Review

- Collaborate and agree on protocol with other PIs first
- Communicate with other institutional offices early (CRU, business office, other committees)
- Start communication with involved IRBs prior to original submission if possible.
- Have plan for staff at all sites to regularly communicate.
- Direct questions to IRB of Record first.
- Communicate!
Tips (Cont.)

- Tell PIs/staff at all sites to register with MHS eIRB at [https://mhirb.metrohealth.org/irb](https://mhirb.metrohealth.org/irb) if there are a large number of study staff send a list to the IRB administrator at your IRB with names, telephone numbers and emails addresses and the HUB administrator will register the entire group.
- HUB is not linked electronically to electronic IRB systems at each institution.
- Check with Relying IRBs if they have additional submission requirements early.
PIs at all sites agree on protocol and to use RR

PIs Contact Relaying IRBs

Communicate

Contact IRB of Record

Other Institutional Issues- Biosafety, CRU, Radiation, HIPAA, etc.

Submit study for initial approval at IRB of Record or amend currently approved study.
IRB of Record uploads documents to HUB

IRB of Record sends notice to Relying IRBs

Relying IRBs accept/approve (one at a time)

All future modifications, CRs, etc. done by staff at site of IRB of Record
Entering the HUB

Click here to enter the Reliant Review HUB.

DON’ T CLICK THIS.
Study Summary Page

Relying IRBs yet to approve

Relying IRBs who have approved.

Approved Documents
Pitfalls

- Lack of early collaboration among PIs and non-IRB entities.
- Original approved study does not account for need for HIPAA requirements for data sharing. Plan ahead.
Contact Information

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