**RELIANT IRB REVIEW GLOSSARY OF TERMS**

**Lead Principal Investigator (PI):** The PI for the study at the Reviewing IRB institution; the Lead PI coordinates study activity across all sites, to ensure clear communication of study related information, consistent adherence to the protocol, and regulatory compliance.

**Local IRB Number:** The study number assigned by the Reviewing IRB.

**Registration:** Because the HUB is housed on the Metro IRB platform, all key study personnel at each study site must register with the Metro IRB by filling out an online form at the following link: **mhirb.metrohealth.org**. A notice will be sent when the registration has been processed.

**Reliance Request:** A request sent through the HUB from the Reviewing IRB, asking the IRB(s) at the collaborating sites(s) to rely on their review and oversight for a given protocol. The approval letter, protocol, consent form, and other study documents are sent with the request.

**Reliant Review HUB:** An online submission portal housed on the MetroHealth IRB platform to allow communication between participating institutions.

**Reliant Review Number:** The study number assigned and used to reference the study in the HUB.

**Relying Investigator:** The PI at the relying institution(s). The Relying Investigator is responsible for ensuring that all local protocol requirements are met prior to acceptance, and for communicating with the local IRB.

**Relying IRB(s):** The IRB(s) at the collaborating site(s) for the study. The Relying IRB receives the Reliance Request from the Reviewing IRB and administratively reviews the attached documents. The Reliance is *accepted* or *declined*. If accepted, the Relying IRB agrees to accept the Reviewing IRB’s determinations for the duration of the protocol.

**Reviewing IRB:** The IRB at the lead site for an inter-institutional study; responsible for initial *approval* of the research and all subsequent review and oversight. Also sometimes called the IRB of Record.

**RELIANT REVIEW (RR) REVIEWING IRB INVESTIGATOR CHECKLIST**

Study Title: ­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Local IRB#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reliant Review #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lead PI: (Coordinating the study across all sites): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: Depending on the nature of the study, some of the items below may not apply.

1. Identify collaborators at other CTSA institutions

* All Key Study Personnel for each site must be listed for the protocol with the Metro IRB HUB (mhirb.metrohealth.org). Personnel at each site who are to receive notices MUST register with the Metro IRB HUB. [**NOTE**: At minimum the site PI site, an additional study team contact, and IRB administrator are suggested]
* Each site Principal Investigator for the study contact their IRB administration to facilitate Reliant Review (RR) process.
* Provide copies of protocol and consent form to PI at relying site(s) so process for local requirements can begin (coverage analysis, department approval, etc.).
* Provide a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
* Provide a plan to coordinate the collection of reportable events from collaborating sites.

2. Submit for IRB approval, either as a new protocol using RR, or an amendment adding RR sites to an already approved protocol.

* Once approval is received, contact IRB administration to upload documents to the HUB and issue the reliance request.
* Provide names of all the investigator(s) and key personnel for the study at all sites to IRB administration for the reliance request.
* **­­­Provide collaborators at the relying sites with a copy of the reportable event policy for the IRB of Record and instruct them on what needs to be reported under this policy.**
* Disclose information regarding conflict of interest and how it is being managed to the Reviewing [and Relying?] IRB administrator so this information can accompany the reliance request.
* Communicate with collaborators that the protocol is approved and the reliance request has been issued.
* As amendments and continuing reviews are approved, contact IRB administration to ensure that information in the HUB is updated and current.
* Communicate with collaborators as amendments and continuing reviews are submitted so they are aware of changes, new expiration dates, etc.
* **Notify the IRB of Record of any reportable events at any site, per regulations and site specific policies.**
* Notify collaborators of any reportable events and provide appropriate documentation.

Collaborating Site: Personnel:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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IRB admin \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other(s)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Other(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RELIANT REVIEW (RR) RELYING IRB INVESTIGATOR CHECKLIST**

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Local IRB#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reliant Review #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI at the **Relying** IRB:

1. Once you have agreed to collaborate with an investigator at another institution

* Contact the IRB administration at your organization to notify them that a reliance request will be coming.
* Provide IRB administration at your organization with the names of all key study personnel at the lead site.
* Obtain a copy of the protocol and consent form(s) from the lead site PI.
* Obtain a copy of the reportable event reporting policy of the Reviewing IRB.
* **Submit a shell study in the local electronic system, uploading documents received.** From the iRIS home page, select Study Assistant, then Add a New Study. Select Reliant Review form, and complete with requested information.
* Ensure that all local protocol review requirements are met (coverage analysis, department approval, DUA, MTA, etc.).
* Notify IRB administration of any staff changes so they can update the HUB documentation.
* Notify IRB administration and the lead PI of any reportable events, according to regulations and the Reviewing IRB’s policy.

Lead site PI \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Add’l contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB admin \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_