RESEARCHERS GUIDE: REQUEST to RELY on a COMMERCIAL IRB

The purpose of this guide is to provide basic information on when a researcher can request to use a commercial IRB for the review of a research study, instructions on what to submit, and what the institutional review process is for this type of submission.

A dictionary of commonly used terminology related to this submission type is appended to this document.

In order to request to rely on a commercial IRB, please note: We have Master Agreements with WIRB, Quorum, Chesapeake, and Schulman. If the commercial IRB you want to use is not one of these, contact the PPHS to see if a specific commercial IRB can be relied upon.

WHEN CAN YOU REQUEST TO RELY ON A COMMERCIAL IRB?

- Conducting an Industry-Sponsored, Multi-Center clinical trial using a commercial IRB & and the MSHS site is one of many sites. The MSHS site PI is not the overall Principal Investigator (PI) of the study.
- Conducting a Multicenter NIH-Consortium/Network project using a commercial IRB.

WHEN CAN’T YOU USE A COMMERCIAL IRB – EVEN THOUGH THE STUDY IS MULTI-CENTER?

- A Mount Sinai Investigator holds the IND/IDE
- The study is Investigator-Initiated
- The study is a Phase I (first- in-human) study

WHAT DO YOU NEED TO SUBMIT FOR INTERNAL PROCESSING?

1. Investigator Forms (IF): Log-in to Sinai Central at https://sinaicentral.mssm.edu and create an IF and have all members of the research team complete their disclosures of financial interest related to the research study. Make a note of the IF# as you will need to include it in your submission to PPHS and GCO. The Conflict of Interest (COI) Committee will review the investigator form.
   - If any potential conflicts are identified, PPHS contacts FCOI for their evaluation.
   - If any conflicts are identified and require management, FCOI will send the management plan to the PI.
   - A copy of the management plan signed by the conflicted Researchers/PI needs to be uploaded under the Attachments tab in Ideate.

2. Ideate submission: Submit an application Request to Rely on an External IRB through Ideate.
• Upload under Attachments all study materials including protocol, Investigator Brochure (IB)/package inserts, device information, consent documents, and institutional waiver form completed with study information.

3. InfoEd submission: Make a Grants and Contracts Office (GCO) submission through InfoEd at https://eresearch.mssm.edu/. You can contact the GCO at 212-824-8300 for assistance.

4. Once all offices associated with the project [i.e. Investigational Drug Services (IDS), Radiation Safety Committee (RSC), Financial Administration of Clinical Trials Services (FACTS), Clinical Research Unit (CRU), Institutional Biosafety Committee (IBC) and PPHS] have approved their component of the research, PPHS will sign the waiver form and upload under Attachments/PPHS Uploads (available from the Live List) and you will receive a Response Required to Secure Approval in Ideate with a general comment indicating that you may proceed with submission to the external IRB.

5. Once you receive a signed waiver form or Quorum Cover Sheet from PPHS, make the submission to the commercial IRB.

**Submission to commercial IRB must include:**

• Institutional waiver or (for Quorum only) Cover Sheet. Quorum cover sheet includes information required to customize the HIPAA authorization section of the ICF/HIPAA authorization for ISMMS.

• RSC: Include any required language from the RSC in your submission for inclusion in the consent document.

• FCOI: Include any management plans and disclosures that are required by the ISMMS FCOI committee.

• For Schulman or Chesapeake – customized Consent/HIPAA authorization including ISMMS required language. For WIRB - Do not customize the consent document, WIRB has ISMMS required language on file and will complete this.

6. Once you receive commercial IRB approval, log in to Ideate, find the submission on your To-Do list (or re-assign to yourself to put it on your To-Do list) and click on it. Upload the IRB Approval documents under the attachment tabs and make a note of the IRB approval dates in the response, and submit (the PI must complete this step). Once the IRB approval letter has been received, PPHS will update InfoEd with IRB approval dates and will make the study active in Ideate once PPHS receives confirmation that the contract has been signed.

7. You will get the contract signed through FACTS/GCO or MSIP (the office negotiating the study specific contract)

**NOTE:** Start the process of negotiating budgets and consent language with the Sponsor/CRO early so you will be ready to make your submission to the Commercial IRB once you receive the signed waiver of IRB jurisdiction form from the PPHS.
OTHER INSTITUTIONAL REVIEWS, IF APPLICABLE:

If the study requires IT security risk assessment, begin this process as soon as possible by contacting ITSecurityRisk@mountsinai.org to Request a Risk Consultation or Risk Assessment.

If the study will require Biomedical Engineering or other device clearance, begin this process as soon as possible.

WHAT DOES THE PPHS EVALUATE FOR STUDIES THAT REQUEST TO USE A COMMERCIAL IRB?

PPHS verifies that:
1. Education requirements have been fulfilled—Basic Human Subjects Research course/Refresher HIPAA and Data Security HIPAA for Research Update GCP
2. A submission has been made in InfoEd for GCO;
3. The study meets the criteria for Commercial IRB review;
4. All required attachments are uploaded; and
5. All members of the study team have made their Conflict of Interest Disclosures under the IF#.

If prerequisites listed above are not met, the Ideate submission will be returned to the PI.

WHAT IS THE EXPECTED TIMELINE FOR A REQUEST TO USE A COMMERCIAL IRB?

Following a submission for a Friday deadline, the review should be completed by RSC, FACTS, CRU, IBC and PPHS within 5 days.

If a conflict of interest must be evaluated, PPHS will alert the Financial Conflict of Interest committee who will review within 5 business days of notification. Permission to proceed with submission to the Commercial IRB cannot be granted until the FCOI evaluation is complete, and if required, a management plan signed by the PI is uploaded to Ideate and disclosure language inserted into the consent document.

WHAT ELSE DO I NEED TO SUBMIT ONCE MY STUDY HAS BEEN APPROVED?

CONTINUING REVIEW OF STUDIES UTILIZING COMMERCIAL IRBS: For requests made through Ideate, create a continuing review application and upload the current IRB approval documents.

If the initial request was made outside of Ideate, a copy of IRB approval must be submitted to IRB@mssm.edu with HSM# - Commercial IRB continuation in subject line. Financial conflict of interest disclosures in Sinai Central (a new IF#) and submission to the GCO in InfoEd are required each year for continuation.

REPORTABLE INFORMATION REPORTING FOR STUDIES RELYING ON COMMERCIAL IRBS: Follow the policy of the commercial IRB. If there is a serious issue at this site, such as site suspension, FDA/OHRP site audit, SAE at site, PI must notify the PPHS office with a detailed explanation of the situation, corrective action plan and/or resolution.
### Appendix A - Commonly Used Terminology:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BRANY</strong></td>
<td>The Biomedical Research Alliance of New York. BRANY was founded by participating institutions in NYC to encourage Industry Sponsors to conduct their clinical trials at these institutions through the opportunity to have BRANY IRB review the research for all participating institutions. BRANY agrees to follow institutional policies.</td>
</tr>
<tr>
<td><strong>Central IRB</strong></td>
<td>An IRB that is reviewing for multiple sites (can be independent or an institution’s IRB)</td>
</tr>
<tr>
<td><strong>Commercial IRB</strong></td>
<td>An independent (not based at an institution) IRB</td>
</tr>
<tr>
<td><strong>External IRB</strong></td>
<td>Any IRB that is external to the Institution</td>
</tr>
<tr>
<td><strong>Inter-Institutional IRB Agreement (IIA)</strong></td>
<td>Another term for an IRB Reliance Agreement</td>
</tr>
<tr>
<td><strong>IRB Reliance Agreement</strong></td>
<td>An Agreement entered into between two institutions indicating that one will serve as the Reviewing IRB and the other will Rely on their review of the research</td>
</tr>
<tr>
<td><strong>Master Agreement</strong></td>
<td>A Master Agreement is an agreement that is designed to cover a class of research, rather than one specific research project</td>
</tr>
<tr>
<td><strong>Single IRB (sIRB)</strong></td>
<td>A term used by NIH to describe a study that will use one IRB to review all sites (used like the term Central IRB)</td>
</tr>
<tr>
<td><strong>SMART IRB</strong></td>
<td>An initiative from NIH NCATS that provides a universal IRB Reliance Agreement and set of common Standard Operating Procedures. This platform does not provide project management support/assistance and is not an IRB or IRB review mechanism.</td>
</tr>
<tr>
<td><strong>Waiver of Jurisdiction Form</strong></td>
<td>When a Master Agreement is in place, the Waiver of Jurisdiction Form is used to indicate that a specific research project falls under the terms of the Master Agreement and is required for each study</td>
</tr>
</tbody>
</table>
**APPENDIX B**

**WIRB-COPERNICUS GROUP CLARIFICATION:** ISMMS has a Master Service Agreement in place with WIRB and requires WIRB to customize the consent document per our template they have on file, etc. ISMMS doesn’t have an Agreement with Copernicus Group IRB so studies requesting to use Copernicus are permitted to go through WIRB.

WIRB and Copernicus Group are both part of a larger entity and so they have a special relationship. Copernicus Group IRB reviews overall studies for a sponsor. WIRB reviews the institutional sites. WIRB and Copernicus Group have an arrangement that makes this possible.

**BELOW IS AN EXPLANATION OF HOW THIS WORKS FROM WIRB AND CAN BE SHARED WITH A SPONSOR/CRO IF NEEDED:**

As you know, under SRS, though study-level reviews occur at CGIRB (with input from WIRB Board members), the sponsor agrees that institutional site submissions come to WIRB, so Icahn School of Medicine at Mount Sinai would be processed at WIRB as long as the institution agrees to outsource the study. There are several important reasons why institutional sites are processed at WIRB, which I’ll explain below.

Under SRS, I look at the WIRB sites as “quasi-central” in nature. For example, under SRS, institutional sites are grafted into study-level reviews --- when a study approval or amendment is made at the study-level (through CGIRB), all WIRB and CGIRB sites are automatically approved for the study-level action, and sponsors/CROs can manage and control submissions for all SRS-participating sites through Connexus.

But **more importantly,** Icahn has a contract with WIRB that requires WIRB to perform certain tasks during its review that more or less mirrors a local review. WIRB has proprietary software that enables flexible review of institutions, but CGIRB does **not** have these institutional requirements/preferences built into its workflow. This can lead to delays and unwanted inconsistencies if the review occurs at CGIRB. This is a primary reason that WIRB serves as IRB of record for institutional sites.

Therefore, even if an institutional site tells the sponsor/CRO they can work with the “Central IRB,” the institutional site will be processed at WIRB (rather than CGIRB) in order for WIRB-Copernicus Group (WCG) to best serve the needs and preferences of the institution under its contract.