229A – Request to Rely on an External IRB: Primarily used for commercial or central IRB

When you may be able to use an External IRB: External IRB must be accredited!

Agreements in place with WIRB-Copernicus, Quorum and Schulman; Otherwise, ask liz.carroll@mssm.edu if a specific commercial IRB can be relied upon.

- Multicenter trial with a central IRB & and the MSHS site is one of many sites: not overall PI of the study
- Multicenter Consortium project with central IRB

When you can’t:

- Investigator holds IND/IDE
- Investigator-initiated study
- When conditions under Section A do not meet eligibility requirements

What you need to do:

1. Sinai Central: IF#
2. Submit 229A to IRB@mssm.edu (if you know a conflict has been disclosed attach protocol and consent form)
3. Get HSM# and make submission to GCO
4. Once you get go ahead (waiver of IRB jurisdiction form, etc.) from PPHS, make submission to external IRB
5. Once you get IRB approval, submit copy of approval to IRB@mssm.edu with HSM# in subject line so records can be updated

CONTINUATIONS: Copy of IRB approval must be submitted to IRB@mssm.edu with HSM# - External IRB continuation in subject line.

New Information Reporting: Follow policy of external IRB. If there is a serious issue at this site, such as site suspension, FDA/OHRP site audit, SAE at site, PI must notify local IRB Chair with a detailed explanation of the situation, corrective action plan, resolution. DO NOT SUBMIT A HRP-224 to IRB@mssm.edu for projects using another IRB.

229B – Request to use BRANY: REMINDER

Submit 229B to IRB@mssm.edu to register your BRANY study. This is required of all studies going through BRANY.