SUNY Upstate Medical University External IRB Submission Overview Guide

When is it a requirement to use single IRB (sIRB) for multi-site research studies?

- ✓NIH funded multi-site research
- ✓revised Common Rule (rCR) cooperative research provision for multi-site research
- ✓Industry sponsor – often a requirement for participation. Upstate encourages use of Sponsors selected sIRB
- ✓FDA regulated multi-site research for investigational drugs, devices and biologics - *coming soon!*

- Investigator compliance with both the external IRB requirements and Upstate policies is required, in addition to all applicable regulations

Reliance Request

- Send an email to Nikki Mason, mason@upstate.edu with the Reliance Agreement requesting to rely on an external IRB
- Once Reliance Agreement is fully signed include in IRBNet submission package
- Read in IRBNet Forms & Templates library for Researchers "Instructions – Using a Central External IRB" for submission and ongoing reporting requirements

Submit in IRBNet

- Submit the research study in IRBNet indicating review by an External IRB.
- Ancillary and Upstate IRB administrative reviews conducted, approval to submit to External IRB letter issued.

Submit to External IRB

- Follow External IRB process for submission.
- If Protocol and Consent Forms are modified by External IRB submit approved versions to Upstate IRB in IRBNet

Post Approval