IRB Reliance Agreements
CREST

May 14, 2015

Institutional authorization agreement (IAA)

• For multi-site, non-exempt research with engaged external sites, arrangements may be made for institutions to rely on one-another for IRB review
• MSU may enter into a written agreement (IAA or IRB reliance agreement) to rely on another institution’s IRB review or to allow another institution to rely on MSU’s IRB review
• Each IAA is situation and context-dependent
• The MSU Institutional Official retains final authority to determine whether MSU may enter into an IAA
MSU as the IRB of Record

- Determine relying IRB’s requirements for requesting review by the MSU IRB.
- Complete questions 10 and 11 of the initial MSU IRB application to indicate relying institutions or submit a revision application to the MSU IRB to add relying institution(s) for already approved projects.

Institutional Reliance Agreements with MSU

- Allegiance Health
- Borgess
- Bronson
- Covenant HealthCare System
- Marquette General Health System
- McLaren Health Care
- Memorial Healthcare
- Mercy Health
- Michigan Department of Community Health
- Michigan Public Health Institute
- Munson Medical Center
- Pine Rest Christian Mental Health Services
- Sparrow Health Systems
- Spectrum Health System
- Van Andel Research Institute
To Request Review by a Non-MSU IRB

• Contact the MSU IRB
• Submit a Reliance Application along with the following documentation:
  • All funding agreements
  • Reviewing IRB application
  • Reviewing IRB approval letter
  • Reviewing IRB approved consent forms
  • Protocol

PI Reporting Responsibilities to MSU HRPP

• Any audit (e.g. NIH or FDA)
• Potential unanticipated problem involving risks to subjects or others (UIRPSO)
• Potential subject complaint
• Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRBs
• Suspension or termination of IRB approval
• Reviewing IRB determination/continuing review (including renewals, revisions, protocol deviations, closures, etc.)
Use of the WIRB

• Study that involves human subjects and is designed to evaluate prospectively the safety and/or effectiveness of new drugs or devices or behavioral intervention
• Protocol for the research study was designed and written by the sponsor
• Sponsor holds all INDs/IDEs for the protocol
• Only sponsor of the research is a for-profit entity/company
• National multi-site protocol where the protocol has already been reviewed by the WIRB at other sites
• MSU investigator has not previously submitted the study to a MSU IRB