IRB Review of Multi-Site Research

PROCESS FLOWCHART

HCSRN – OVERVIEW OF THE MULTI-SITE RESEARCH APPROVAL PROCESS

Lead PI originates study

Lead PI obtains agreement from his/her institution’s IRB (or another HCSRNR IRB) to serve as the Lead IRB

Lead PI recruits Local PI at institution “A”

Lead PI submits application to IRB at institution “A”

IRB “A” cedes review to Lead IRB**

Lead IRB approves application

Lead IRB assumes ongoing responsibility for those institutions ceding to it

Lead PI submits application to IRB at institution “B”

IRB “B” reviews and approves application

Cede to Lead IRB?

Yes

No

IRB “B” assumes ongoing oversight responsibility for study at its institution

* Assumes that other local reviews (e.g., for scientific merit have been conducted, and that local context issues have been addressed

**AA: Covered by HCSRNR Reciprocal Reliance Agreement, another IRB Authorization Agreement, or is KP-region to KP-region ceding

PLEASE SEE NEXT PAGE
IRB Review of Multi-Site Research

**Lead IRB**
- Reviews the proposed research submitted by the Lead PI
- Accepts responsibility for study oversight from a ceding IRB

**Ceding IRB**
- Reviews proposed research submitted by the Local PI for its institution and cedes responsibility to the Lead IRB

**Reviewing IRB**
- Reviews proposed research submitted by the Local PI for its institution and oversees the study in its institution
-Communicates primarily with the Local PI, and communicates with Lead PI as required

**Lead PI**
- Originates the research protocol
- Oversees the study in its entirety in the HMORN
- Prepares the HMORN Multi-site Research Application Cover Sheet and the IRB application of the Lead IRB
- Recruits Local PIs
- Submits the proposed research to the Lead IRB
- Assists the Local PIs in preparing their research applications, as required
- Communicates with Reviewing IRBs as required

**Local PI**
- Submits the proposed research to the Local IRB
- Ensures that any institutional-specific application requirements are included in the multi-site research application
- Oversees the study at his or her institution and maintains ongoing communication with the Lead PI around project status and any problems