Carolinas Collaborative Projects
IRB Reliance Agreement Guidance (SOP)

INTRODUCTION

The members of the Carolinas Collaborative (CC) have agreed to rely on each of the other institutions' IRB(s) to review collaborative projects. This master agreement is limited to research conducted as part of the CC and concerns the IRB review of studies involving the sharing of data among the collaborating institutions. Research involving prospective enrollment for interventions or other direct participation of human subjects is **not** covered by this agreement. The IRB reliance and cooperative IRB review allows the CC institutions to cooperate in research studies, while avoiding duplication of effort with respect to IRB reviews.

IRB reliance agreements allow one IRB to conduct a review (Primary IRB) with the other site IRBs requesting to rely on the Primary IRB for review. Only minimal paperwork on the local level is required with a request to rely on another IRB. In general, reliance agreements do not apply to research that is determined by an IRB to be either Not Human Subjects Research (NHSR) or Exempt; however, the IRBs involved in the CC Master Agreement have made an exception and will allow this type of research to be covered under this agreement and will not require IRB review on a local level.

Prior to seeking IRB approval for the use of shared data, investigators must obtain the approval of the CC Data Request Review Committee (DRRC).

PROCESS WORKFLOW FOR IRB SUBMISSION

1. The Primary (reviewing) IRB shall be the IRB of the Lead Investigator's home institution.

2. The Lead Investigator submits request for shared data to the CC DRRC.

3. Upon receiving approval from the CC DRRC, the Lead Investigator submits an application for approval to the IRB of his/her home institution. The IRB application should include the following:
    a. CC DRRC approval letter/form
    b. Statement in the IRB application indicating that the research is being conducted under the "Carolina's Collaborative IRB Authorization Agreement."
    c. Listing of names and institutions of co-investigators that will be relying on Primary IRB.

4. Upon receiving IRB approval or a determination by the lead site IRB, the Lead Investigator provides a copy of the IRB letter to the DRRC and to co-investigators at collaborating institutions.

5. The result of the lead site review (exempt, NHSR, or approved) determines the next steps for co-investigators. The co-investigator(s) follow internal policies for local IRB notification, concurrence, or review.
    a. <u>If project determined to be **exempt or NHSR**</u>: Non-lead sites rely on Lead IRB determination per Carolinas Collaborative Master Agreement. With these types of

determinations, non-lead site investigators typically do not need to submit an application to or notify their local IRBs. *

b. <u>If project "**approved**"</u>: Lead site IRB approval letter is shared with non-lead researchers. Non-lead researchers submit application to local IRB for concurrence (request reliance on lead site IRB for IRB review). Non-lead IRB has option to conduct full review independently.
c. If requested, collaborating site co-investigators submit copies of local IRB approval (or concurrence with Primary IRB) to lead Investigator and CC DRRC.

***** Policies may vary from institution to institution; therefore, the local IRB should be consulted regarding notification and documentation of IRB review (e.g., Carolina Collaborative investigators *do not* need to submit an application to the UNC IRB if the Lead IRB made a "not human subjects research" (NHSR) or "exempt" determination).

WORKFLOW DIAGRAM