Carolinas Collaborative Research -- Guidance Document for UNC Researchers

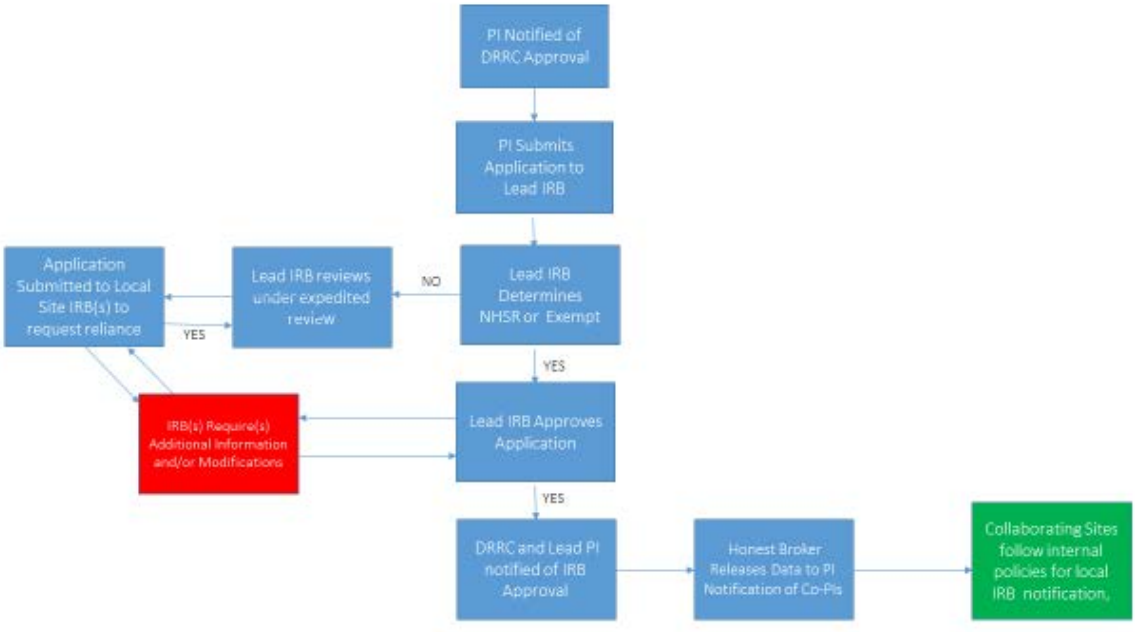
INTRODUCTION

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 study agreement (MSA) 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). See https://carolinascollaborative.org/ for more information.

WORKFLOW DIAGRAM



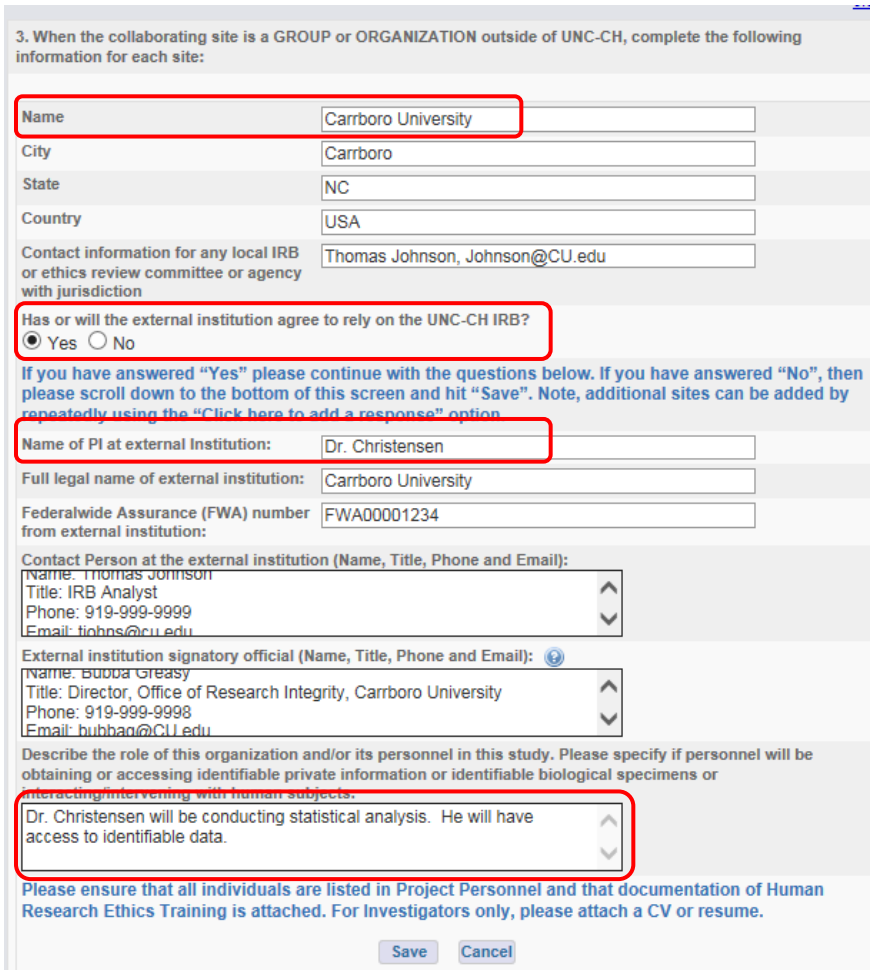
Process overview

1. Lead PI on Carolinas Collaborative project submits request to CC DRRC
2. CC DRRC reviews project
3. Once reviewed, CC DRRC sends a letter to Lead PI to submit to IRB

4. Lead site IRB review:
    a. <u>If project determined to be **exempt or NHSR**</u>: Non-lead sites rely on Lead IRB determination per MSA
    b. <u>If project "**approved**"</u>: Lead site IRB determination shared with non-lead researchers; submitted to local IRB for concurrence. Non-lead IRB may review independently. Additional communication details illustrated above.

How to complete the IRBIS application when UNC researcher is Lead PI (and UNC is the reviewing IRB)

1. List all external collaborators on Project Personnel List. Department name of external collaborators must include the name of the External Institution (e.g., James Rand, Wake Forest-Social Sciences, Co-Investigator)
2. Multi-site Study Question #2 (**Is UNC-CH the lead site or is the lead PI or a UNC-CH employee?**) Select "yes".
3. Multi-site Study Question #3 (**Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH?**) Select "yes".
4. Multi-site Study table (**When a collaborator(s) outside of UNC-CH is (a) exercising authority or responsibility on behalf of a group or organization, (b) performing activities designated by a group or organization, or (c) using the collaboration for scholarly advancement (e.g., promotion, tenure) at a group or organization**) Select "Click here to add group or organization outside of UNC-CH" and enter only:
    - Full Legal Name of External Institution
    - Select "yes" for "**Has or will the external institution agree to rely on the UNC-CH IRB?**"
    - Name of PI at External Institution
    - Describe the role of this organization and/or its personnel in this study.



5. Section C.1.1: What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'): Select: "Medical records in any format" and then check "Carolinas Data Warehouse for Health (CDW-H)" and "Carolinas Collaborative Data Review Committee".

   ☐ Medical records in any format.

   ALERT: You must check both boxes: 1) Medical records in any format and 2) Electronic medical record using Epic, or you/your study team will not be granted access to Epic for research purposes.

   Check all that apply: *

   ☐ **Electronic medical records using Epic, WebCIS or other electronic system**

   ☐ **Carolina Data Warehouse for Health (CDW-H) (for UNC and its affiliates only)**

   ☐ **Carolinas Collaborative Data Review Committee**

   Triggers REQUIRED DOCUMENT: —"*CC DRRC letter*"

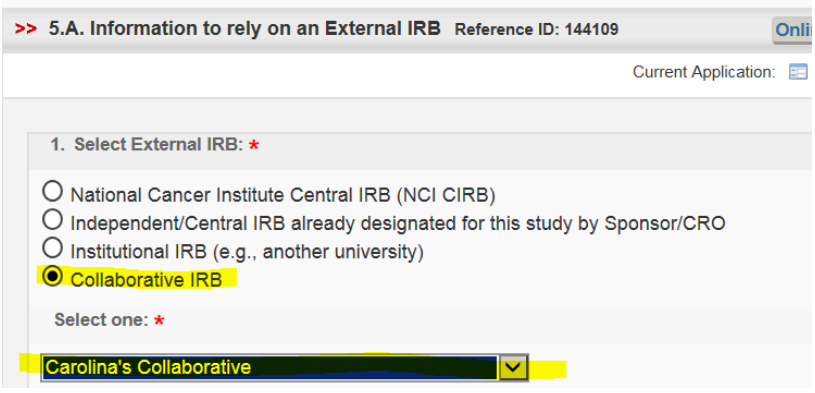
   ☐ **Paper medical records**

6. Attachments: Upload a copy of the CC DRRC letter. The IRB will not approve your research without this letter.

How to complete the IRBIS application when the UNC researcher is *not* the Lead PI and UNC is relying on the external IRB and the external IRB approves the research

*****You *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.*** In these instances, UNC will rely on the Lead IRB via a Master Agreement that is already in place.**

1. List only UNC research personnel on Project Personnel List.
2. Multi-site Study Question #2 (**Is UNC-CH the lead site or is the lead PI a UNC-CH employee?**) Select "no".
3. Multi-site Study Question #3 (**Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH?**) Select "no".
4. Multi-site Study Question #3 (second question) (**Are you requesting that UNC-CH rely on an external IRB for continuing review and approval of this study?**) Select "yes".
5. Obtain a copy of the external IRB's SOP and review them. Then check "I agree to obtain and review the external IRB's policies PRIOR to conducting research."
6. Section 5.A: Information to rely on an External IRB: Select Collaborative IRB and then Choose: "Carolina's Collaborative" from the drop menu.



7. Section C.1.1: What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'): Select "Medical records in any format" and

then check “Carolinas Data Warehouse for Health (CDW-H)” and “Carolinas Collaborative Data Review Committee”.

☐ Medical records in any format

ALERT: You must check both boxes: 1) Medical records in any format and 2) Electronic medical record using Epic, or you/your study team will not be granted access to Epic for research purposes.

Check all that apply: *

☐ **Electronic medical records using Epic, WebCIS or other electronic system**

☐ **Carolina Data Warehouse for Health (CDW-H) (for UNC and its affiliates only)**

☐ **Carolinas Collaborative Data Review Committee**

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