Document Title: Ceding Application - What, When, and How

A. INTRODUCTION

The purpose of this guidance document is to provide the study team with an overview of the specifics of the Ceding application type. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

For the purpose of this document, both IRBs are referred to as University of Michigan IRBs [U-M IRBs].

B. WHAT

The Ceding application registers and documents that a University of Michigan IRB will rely on another IRB of Record for the purpose of IRB Regulatory determinations for specific Human Subjects Research projects.

C. WHEN

The Ceding application should be filled out when an external IRB, other than the U-M IRBs, will be the IRB of record for a Multi-Site Research project. A Ceding application may be needed due to a study's requirement to follow a single IRB mandate (the NIH sIRB mandate or the Common Rule sIRB mandate) or the Sponsor and/or lead site requesting the model be followed for the specific study.

D. HOW

Initial Application-Request:

1. Complete a new Ceding application in eResearch.
    a. Select **Human Subjects Study Application** under **Create New**.
    b. Complete all required fields marked with a red asterisk (*).
        i. Only study team members affiliated with the University of Michigan should be added to Ceding applications; contact IRB staff before including an external study team member.

c. In section 1-1.1 Application Type, select: “Requesting Review by a Non-UM IRB”. This provides an abbreviated application.
d. Section 4-3
    i. Fill out the IRB of record information.
        1. Naming conventions for Master Reliance agreements with the University of Michigan.
            a. WCG IRB - this includes Western IRB, Copernicus IRB
            b. Advarra IRB - this includes Cheasapeake, Schulman
            c. NCI CIRB - National Cancer Institute Central IRB
            d. Salus IRB - this includes Ethical & Independent Review Services

NOTE: Any supporting documents provided in the ceding application must match the version number/date as documented on the IRB of Record approval letter.

Follow IRB-specific instructions below for completing the Ceding application.

<u>IRB-HSBS</u>

1. Section 4-3.6: Upload supporting documents. Documents may include:
    a. Protocol
    b. Informed consent
    c. Surveys
    d. Overall Study IRB of Record approval letter
    e. IRB Reliance agreement document and local context form(s)
2. HSIP Subject Incentives: If a study involves incentives the following two steps will be needed:
    a. Section 1.8 - add a note detailing the incentive that will be offered as part of the study.
    b. Manually move to section 13 via the left-hand application section menu. Fill out this section to trigger HSIP support.
3. When the application is complete and there are no errors, the local PI can submit the application to the IRB.

<u>IRBMED</u>

1. Section 7: Fill out this section based on protocol design
    a. This section routes the application to any applicable local Ancillary committees. Ancillary committee reviews are required as part of the local review even when ceding to an external IRB of Record.
2. Supporting documents and sections:
    a. Protocol - sections 1-6.1 (Cancer Center) or 5-4.1
    b. Consent - section 10-6.1
        i. Ensure that the informed consent template, uploaded in section 10-6.1, has all locally required language present for review. (The locally required language is available on the IRBMED single IRB website.)
    c. Overall Study IRB of record approval letter - section 44.1
    d. IRB agreement and local context documents - section 44.1
3. When the application is complete and there are no errors, the local PI can submit the application. The application will then route through any necessary local Ancillary committee based on study design.

IRB Office processing:

1. After the application is received by the IRB office, IRB staff will review it for local context considerations and consistency between the application and supporting documents. IRB staff will request changes, if needed.
2. After any necessary changes are made, the application will be assigned for local review.
    a. Local review involves evaluating:
        i. Study team expertise
        ii. Study team training
        iii. Potential COI and management plans
        iv. Study design compared to local law/regulations related to Human Subjects Research
        v. The IRB of Record for accreditation standings and/or IRB roster for expertise
        vi. The changes required by local ancillary committees and the plan for informing the IRB of Record.
3. After the local review is complete:

a. IRB-HSBS: Any required agreement or local context form(s) will be filled out and provided by IRB staff. Prior to receiving full U-M acknowledgement of the Ceding application, the fully executed Reliance Agreement must be uploaded.
b. IRBMED: the application will receive the U-M acknowledgement that documents U-M is willing to cede IRB oversight to the IRB of Record. Any required IRB Reliance Agreement and local context forms will be filled out by IRB staff.

Continued reporting after initial review:

1. After the initial U-M IRB acknowledgment of the ceding application, for the study funds to be released by ORSP, the study team or IRB staff must upload the site activation approval obtained from the IRB of Record. To complete this process, utilize the activity in eResearch called "Upload Non-UM IRB Approval Documents".

2. Other types of continued reporting that must be submitted in eResearch after initial review:
    a. Amendments to the study that impact the study team and/or any applicable UM ancillary committees
        i. Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;
        ii. RDRC/SHUR: changes in radiation dosing;
        iii. COI: addition/removal of study team members
        iv. NOTE - CRAO billing calendar updates or study calendar updates are to be completed in OnCore
    b. Scheduled Continuing Reviews (if applicable)
    c. Serious Adverse Events and Unanticipated Problems that are related to the research per AE guidance:
        i. IRB-HSBS: AE Guidance
        ii. IRBMED: AE Guidance
    d. Other Reportable Information or Occurrence(s) as outlined in the ORIO guidance.
        i. IRB-HSBS: ORIO Guidance
        ii. IRBMED: ORIO Guidance

e. U-M Site Terminations from IRB of Record: Once all activity is completed and the team receives permission from the IRB of Record to terminate the U-M as a performance site, the team must terminate the eResearch application via a continuing review/Termination submission.

Who to contact with questions:

- IRB-HSBS study teams: irb.hsbs.reliance@umich.edu
- IRBMED study teams: IRBMEDCentralIRB@umich.edu