# UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO A Non-UM Institutional IRB

## Do I still need to work with IRBMED?
Yes, study team members must complete an eResearch application to fulfill additional U-M research obligations (e.g., ancillary committee reviews). Select application type "Requesting Review by a Non-UM IRB (Ceding Application)" in section 1-1.1. Refer to the Central IRB at University of Michigan Workflow for more information on completing Ceding Applications.

## Working With IRBMED

### What documents do I need for the U-M Ceding application?
Study teams must obtain the approved versions of project documents from study Sponsor. Team members should obtain copies of the following and upload in the Ceding Application:

- Approved protocol
- Investigator brochures (if applicable)
- Approved template consent
- Approval notice for the study which includes the current approval period. The type of letter may vary depending on when UM joins as a site, but it **MUST** contain the most recent approval interval for the proposed non-UM Institutional IRB. (upload in section 44 of the eResearch application)
- Coversheet for the Non-UM IRB (if applicable)

### What are the requirements for the informed consent document(s)?
IRBMED has developed boilerplate language that must be inserted into consent and assent templates as applicable. This language is available for download on the IRBMED website. This boilerplate language is inserted into the sponsor template consent and becomes the Draft UM consent and is submitted as a part of the packet to the Non-UM Institutional IRB. NOTE: Variations from the UM Boilerplate must be approved by IRBMED.

Study teams need to work with the non-UM IRB to determine who is responsible for development of the consent form(s) with local boilerplate. In the event the non-UM IRB will be developing consent(s), study teams will upload the template consent(s) in 10-6 of the eResearch application.

## After IRBMED Agrees to Cede IRB Oversight to Non-UM Institutional IRB

### U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to a Non-UM IRB. Now what?
Study Team will send the following to the Non-UM Institutional IRB:

- Copy of IRBMED Acknowledgement letter agreeing to cede IRB oversight
- Draft U-M consent
- A copy of section 25-1 only from eResearch application. (Required only if Non-UM IRB is responsible for development of final consent document(s))

After obtaining approval from the non-UM Institutional IRB for U-M as a performance site, **post correspondence** in eResearch and attach:

- Approval notice from non-UM Institutional IRB for U-M as a site
- All approved consent and/or assent document(s) for U-M

These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by non-UM IRB to begin research activities.

### What are my continuing obligations to IRBMED and U-M?
Study teams **must submit the following events and information** occurring at U-M via the Ceding Application in eResearch using standard submission formats:

- Amendments to the study that impact U-M ancillary committees (i.e.,
  - Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;
  - RDRC/SHUR: changes in radiation dosing;
  - CRAO: billing calendar updates, changes that would impact subject injury language in consent;
  - COI: addition/removal of study team members)
- Scheduled Continuing Reviews
- Serious Adverse Events that are related to the research per IRBMED guidance
- Unanticipated Problems
- Protocol deviations that may represent a systematic problem requiring local evaluation by IRBMED to determine that sufficient local resources are available for safe conduct of the study
- Reports of Continuing and/or Serious Non-Compliance
- Study holds or suspensions that are not built into the study design from Non-UM Institutional IRB or Study Sponsor (eg: interim analysis or enrollment complete need not be reported)
- Study Terminations from Non-UM Institutional IRB

Once all activity is completed and the team receives permission from the Non-UM Institutional IRB to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.