**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 [Single IRB of Record](#) webpage 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:

- Non UM- IRB Approved protocol
- Investigator brochures (if applicable)
- Non UM IRB Approved template consent
- Approval notice for the overall 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)

**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
- A copy of section 25-1 only from eResearch application. **(Note: Required only if Non-UM IRB is responsible for development of UM Site Specific consent document(s)).**

After obtaining approval from the non-UM Institutional IRB for U-M as a performance site, attach the following in the eResearch activity called Upload Non-UM IRB Approval Documents:

- 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.