### UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO A NON-UM INSTITUTIONAL IRB

<table>
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<tr>
<th>Do I still need to work with IRBMED?</th>
<th>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. Refer to the Central IRB at University of Michigan Workflow for more information on completing Ceding Applications.</th>
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| **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) |
| **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 from IRBMED. Study teams need to work with the non-UM IRB to determine who is responsible for development of the UM site specific consent form(s) with local boilerplate.  
**NOTE:** Variations from the UM Boilerplate must be approved by IRBMED. |
| **After IRBMED Agrees to Cede IRB Oversight to Non-UM Institutional IRB** | 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, **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. |