## Getting Started With NCI CIRB

<table>
<thead>
<tr>
<th>Who Is CIRB?</th>
<th>CIRB is a central IRB that conducts all IRB reviews of selected NCI-sponsored trials.</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do I contact CIRB?</td>
<td>Telephone 888-657-3711  Fax: 301-560-6538  Email: <a href="mailto:ncicirbcontact@emmes.com">ncicirbcontact@emmes.com</a>  Web: <a href="http://www.ncicirb.org">www.ncicirb.org</a></td>
</tr>
</tbody>
</table>
| How do I begin working with CIRB? | • Principal Investigators must be registered with NCI CIRB.  
• Protocols are available for download on the CTSU website. |
| 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, CTSU website. Team members should obtain copies of the following for the Ceding Application:  
• Approved protocol  
• Investigator brochures (if applicable)  
• Approved template consent  
• CIRB approval notice for the study which includes the current approval period (upload in section 44.1 of the eResearch application) |
| What are the requirements for the informed consent document(s)? | U-M specific boilerplate language must be inserted by the U-M Study team into the CIRB approved template document(s). The resulting document(s) become the draft U-M Consent and is submitted as a part of the ceding application to IRBMED. |
| Review by IRBMED | If IRBMED determines Oversight can be ceded to CIRB, an approval with contingencies outcome will be generated. The U-M PI is required to complete and submit the CIRB “Intent to Comply” form. Upon submission, U-M will be added to the review queue for site review. Once CIRB approves U-M as a site, Study team must respond to contingencies, uploading documentation of CIRB site approval in correspondence.  
Once all outstanding IRBMED issues are addressed and CIRB has approved U-M as a site, IRBMED will issue the final Acknowledgement determination. IRBMED will generate the U-M site specific consent documents. |

## After IRBMED Agrees to Cede IRB Oversight to CIRB

| 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.,)**  
  o Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;  
  o RDRC/SHUR: changes in radiation dosing;  
  o CRAO: billing calendar updates, changes that would impact subject injury language in consent  
  o 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 CIRB or Sponsor (e.g: interim analysis or enrollment complete need not be reported)  
• Study Terminations from CIRB  
Once all activity is completed and the team receives permission from CIRB to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission. |