# Instructions for Relying on NCI CIRB (CIRB)

## 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. The University of South Alabama has an agreement authorizing NCI to review and approve selected NCI sponsored trials.</th>
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<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>
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| What is required before working with NCI CIRB? | • Principal Investigators must be registered with NCI CIRB.  
• All Investigators and Staff must have a CTEP ID #  
• Protocols are available for download on the CTSU website. |
| Do I still need to work with USA IRB? | Yes- research sites must submit to the USA IRB an IRB External Request Review form via IRBNet, in addition to the documents outlined below in the section “Working With USA IRB.” |

## Working With USA IRB

| What documents do I need to submit to USA IRB? | Research site must obtain the approved versions of project documents from study Sponsor, CTSU website. The following documents should be submitted to USA IRB for preliminary review:  
• IRB External Request Review Form  
• USA IRB Application Part A (On-line Wizard in IRBNet)  
• NCI CIRB Approved protocol  
• NCI CIRB Approved model consent/assent document(s) – To include USA IRB- NCI CIRB boilerplate language, as applicable to study.  
• CIRB approval notice for the overall study which includes the current approval period  
PI must electronically sign package 1 for USA IRB preliminary review |
| Review Process | USA IRB will conduct a preliminary review of the request to rely on NCI CIRB as the IRB of record. USA IRB will provide an acknowledgement letter published in IRBNet upon completion of the preliminary review.  
**ATTENTION!** The research site cannot begin submit to NCI CIRB until they have received an acknowledgement letter from USA IRB confirming reliance to NCI CIRB as IRB of record.  
**SEE USA IRB SOP 1102: NCI CIRB** section 4.0 “Obtaining NCI CIRB Approval to Conduct a Study” for additional information to request/submit a new study to NCI CIRB. |

## After USA IRB Agrees to Rely on NCI CIRB as IRB of Record

| What are my continuing obligations to USA IRB? | To ensure adequate institutional oversight of research activities, the research site must notify the USA IRB of the following occurrences related to protocols overseen by the NCI CIRB:  
• Protocol deviations that may represent a systematic problem requiring local evaluation by USA IRB to determine that sufficient local resources are available for safe conduct of the study  
• Study holds or suspensions that are not built into the study design from CIRB or Sponsor (eg: interim analysis or enrollment complete need not be reported)  
• Study Terminations from CIRB or sponsor  
• Subject complaints  
• Conflict of interest updates  
• Breach of confidentiality/ HIPAA privacy or security violations  
• Amendment to change PI or key personnel **(NOTE: IRB Application Part A must be updated to reflect personnel changes)**  
• Completion of annual check-in form (USA IRB – IRBNet email notification will be generated) |
| Monitoring of NCI CIRB approval protocols | CIRB will arrange for monitoring ongoing research, as its policies and procedures require. The USA IRB/ Office of Research Compliance and Assurance may monitor any NCI CIRB approved protocol as part of its quality assurance program. |
| Record keeping | Record keeping procedures for all files must be established, and NCI CIRB documents, e-mail notifications, and other correspondence must be stored / filed as previously maintained through normal USA IRB approval. |

**NOTE:** See [USA IRB SOP 1102: NCI CIRB](http://www.ncicirb.org) for detailed policy and procedures