# Instructions for Relying on NCI CIRB (CIRB)

| Getting Started With NCI CIRB | |
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| Who Is  | CIRB is a central IRB that conducts all IRB reviews of selected NCI-sponsored trials.<br>The University of South Alabama has an agreement authorizing NCI to review and approve selected NCI sponsored trials. |
| How do I contact CIRB? | Telephone 888-657-3711 Fax: 301-560-6538<br>Email: ncicirbcontact@emmes.com<br>Web: www.ncicirb.org |
| What is required before working with NCI CIRB? | • Principal Investigators must be registered with NCI CIRB.<br>• All Investigators and Staff must have a CTEP ID #<br>• 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:<br>• IRB External Request Review Form<br>• USA IRB Application Part A (On-line Wizard in IRBNet)<br>• NCI CIRB Approved protocol<br>• NCI CIRB Approved model consent/assent document(s) – **To include USA IRB- NCI CIRB boilerplate language, as applicable to study.**<br>• CIRB approval notice for the **overall study** which includes the current approval period<br><br>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.<br><br>USA IRB will provide an acknowledgement letter published in IRBNet upon completion of the preliminary review.<br><br>**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.<br><br>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:<br><br>• 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<br>• 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)<br>• Study Terminations from CIRB or sponsor<br>• Subject complaints<br>• Conflict of interest updates<br>• Breach of confidentiality/ HIPAA privacy or security violations<br>• Amendment to change PI or key personnel (**NOTE: IRB Application Part A must be updated to reflect personnel changes)**<br>• Completion of annual check-in form (USA IRB – IRBNet email notification will be generated)<br><br>**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.<br><br>**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 for detailed policy and procedures**