Instructions for Relying on Western IRB (WIRB)

WIRB Copernicus Group

The University of South Alabama has an agreement authorizing Western Institutional Review Board (WIRB), an independent commercial IRB, to review and approve selective industry sponsored multi-center clinical trials.

WIRB Contacts

For General Questions: Client Services	USA Contact/Institutional Issues: Elaine J. Azarenko
Telephone: 1-800-562-4789	Telephone: 1-360-252-2446
Email: clientservices@wirb.com	Email: eazarenko@wirb.com
Web: www.wirb.com	Web: www.wirb.com

Eligibility Criteria: WIRB Submission

Studies NOT eligible for WIRB submission:

1. Phase I clinical trials
2. Planned emergency research
3. Single patient emergency use or compassionate use situations
4. Embryonic stem cell or gene therapy research
5. Protocols funded by a Cooperative Oncology Group/NCI sponsored trials
6. Federally funded protocols
7. Investigator initiated research
8. Protocols where the Principal Investigator holds the IND/IDE
9. Research involving prisoners

Studies eligible for WIRB submission:

1. The trial is a phase II, III or IV, multi-centered, industry-sponsored and for a FDA regulated drug or device study.
2. The protocol must be written and designed by the sponsor (not Investigator-initiated)
3. The study must meet the National Institutes (NIH) definition of a clinical trial (A prospective biomedical or behavioral research study of human subjects that are designed to answer specific questions about biomedical or behavioral interventions [drugs, treatments, devices, or new ways of using known drugs, treatments, or devices]).
4. The sponsor of the research must be a for-profit entity/company.
5. The principal investigator must meet USA requirements to serve as PI on a research study.

Working with USA IRB

Research site initiates submission process beginning with USA IRB preliminary review

- Create a New Project in IRBNet
- Submit the following documents for **USA IRB** preliminary review and acknowledgment, to include:
  - USA IRB Part A Application
  - IRB External Review Request Form
  - Sponsor Protocol
  - Sponsor Informed Consent – **To include USA IRB boilerplate language, as applicable to study**
  - PI must electronically sign package 1 for USA IRB local review

All key personnel listed on Part A IRB application should have completed the required applicable human subjects training, ACRP (as applicable), and HIPPA in research.

NOTE: IRB fees should be included in the study budget. There is a one-time USA administrative review fee of $2000 for initial submissions. The contract agreement will include this fee to be paid to USA by the sponsor. WIRB will bill the sponsor directly, if allowed. Include this information on the WIRB Billing Section of the Initial Review Form.

Review Process

- USA IRB will conduct a preliminary review of the request to rely on WIRB as the IRB of record
- USA will provide an acknowledgement letter published in IRBNet upon completion of the preliminary review

ATTENTION! WIRB will **NOT** initiate protocol review until receipt of USA's IRB acknowledgment letter.

	IRB Submission to WIRB
Submission to WIRB	WIRB Copernicus has partnered with IRBNet, so the online submission portal will remain unchanged. **NOTE:** WIRB should be selected from the drop down menu and the WIRB link to the forms menu should be accessed to obtain the appropriate submission forms. Standard Submission Requirements Include: Current WIRB initial review submission form, consent form, PI's current professional license (unless already on file), PI's CV (unless already on file), and site- specific material such as subjects material and advertisements. Instructions on submitting your packet are available from the WIRB website. (Access the WIRB Submission Forms) **INCLUDE USA IRB Acknowledgment Letter!** **NOTE:** WIRB submission/documents must be created as package 2 in IRBNet. DO NOT submit to WIRB until USA IRB preliminary review is complete and acknowledgement letter published.
WIRB Review	- WIRB will issue a tracking number via email upon receipt of submission - WIRB will contact the investigator/contact person directly with questions about the submission, and with determination of approval, modifications, or disapproval - Once approved, all approval documents will be uploaded as published board documents in IRBNet. - Any questions that the PI/contact person may have regarding the WIRB review process should be directed to WIRB Consent Documents: For WIRB approved projects, you must use the WIRB stamped consent document for enrolling subjects. The USA IRB is not the IRB of record for the protocol. **NOTE:** Commencement of project should not begin until all approvals and the clinical trial agreement are in place
Submission to WIRB After Initial Approval	
What documents should be submitted to WIRB after initial approval?	Continuing Review, Amendments, Adverse Events, Protocol Deviations, Closure Notifications, and any other submissions required by WIRB's reporting requirements. **NOTE:** Some sponsors will submit materials on behalf of the USA site (i.e. amendments); otherwise the USA research team is responsible. USA IRB will be notified by WIRB about USA investigator's submission activity, thus there is no requirement to provide copies of these submissions to USA IRB. Approval for these items will be returned through IRBNet.
Submission/Notification to USA IRB After WIRB Initial Approval	
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 WIRB: • 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 Closure • 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 WIRB approval protocols**: WIRB will arrange for monitoring ongoing research, as its policies and procedures require. The USA IRB/ Office of Research Compliance and Assurance may monitor any WIRB approved protocol as part of its quality assurance program. **Record keeping**: You should establish record keeping procedures for your files, and store WIRB documents,

NOTE: See USA IRB 1101: WIRB Initiative for detailed policy and procedures