Instructions for Relying on WCG (Formerly WIRB)

<table>
<tr><th colspan="3">WIRB Copernicus Group
(WCG)</th></tr>
<tr><td></td><td colspan="2">As of July 12, 2017 the University of South Alabama (USA) has entered into an agreement with the WIRB Copernicus Group (WCG) to become the IRB of record for eligible studies.</td></tr>
<tr><td>WCG Contacts</td><td>WCG Client Services
Telephone: (800) 562-4789
Email: clientservices@wirb.com
Web: www.wcgirb.com</td><td>USA Contact/Institutional Issues: Deena Horowitz, CIP
Telephone: (360) 252-2442
Email: dhorowitz@wirb.com
Web: www.wcgirb.com</td></tr>
<tr><td rowspan="2">Eligibility Criteria:
WCG Submission</td><td colspan="2">Studies <u>NOT</u> eligible for WCG 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
10. Other studies to be determined by the local IRB, such as COVID-19 trials</td></tr>
<tr><td colspan="2">Studies eligible for WCG 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.
6. The research has not previously been submitted to the USA IRB for review.
7. The sponsor holds all INDs/IDEs.</td></tr>
<tr><th colspan="3">Working with USA IRB</th></tr>
<tr><td>Research site initiates submission process beginning with USA IRB preliminary review</td><td colspan="2">- Create a New Project in IRBNet
- Submit the following documents for USA IRB preliminary review and acknowledgment, to include:
o USA IRB Part A Application
o IRB External Review Request Form (located in IRBNet)
o WCG Boilerplate Consent checklist (ensure the sponsor specific additions to the USA IRB Consent language is noted
o Consent form with track changes is only needed if the consent template has NEVER been reviewed by WCG
o Documentation of consent language approval, generally an email, from the sponsor
o Sponsor Protocol

- 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. WCG will bill the sponsor directly, if allowed. Include this information on the WCG Billing Section of the Initial Review Form.</td></tr>
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Review Process	- USA IRB will conduct a preliminary review of the request to rely on WCG as the IRB of record - USA will provide an acknowledgement letter published in IRBNet upon completion of the preliminary review **ATTENTION!** WCG will **NOT** initiate protocol review until receipt of USA's IRB acknowledgment letter.
	IRB Submission to WCG
Submission to WCG	WCG Copernicus has partnered with IRBNet, so the online submission portal will remain unchanged. **NOTE:** WCG should be selected from the drop down menu and the WCG link to the forms menu should be accessed to obtain the appropriate submission forms. Create a New Package, package 2, in IRBNet under the same project. Standard Submission Requirements Include: • Current WCG initial review submission form (**Note: WCG Institution #87329**) • PI's current professional license (unless already on file) • PI's CV (unless already on file) • The USA IRB Acknowledgment Letter (from package 1 in IRBnet) • Signed WCG Boilerplate Checklist (from package 1 in IRBnet) • Correspondence, such as an email, that the sponsor approves the consent language • site specific documents such as subject material and advertisements • If the study has never been reviewed by WCG then include: • Consent form with track changes • Protocol • Investigator's Brochure (if applicable) Instructions on submitting your project are available from the WCG website. (Access the WCG Submission Forms)
WCG Review	What happens after you submit Package 2 to WCG? - An IRBNet submission notification is generated and located in IRBNet Messages and Alerts - WCG will unlock package 2 if there are questions about the submission. Attach / drag updated documents into package 2 and select mark revisions complete. This will notify WCG that the requested revisions are ready for additional review. - Once the submission has been reviewed, WCG will issue an IRBNet email notification of Board Action / Multiple Board Documents Published when the review has been completed. All approval documents will be published in IRBNet, and located under Reviews when the title of the project has been selected. - Any questions that the PI/contact person may have regarding the WCG review process should be directed to WCG Consent Documents: For WCG approved projects, you must use the WCG 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 WCG After Initial Approval	
What documents should be submitted to WCG after initial approval?	Continuing Review, Amendments, Adverse Events, Protocol Deviations, Closure Notifications, and any other submissions required by WCG'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 WCG 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 WCG 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 WCG: • 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 WCG or Sponsor (eg: interim analysis or enrollment complete need not be reported) • Study Closure • Study Terminations from WCG 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 WCG approval protocols**: WCG will arrange for monitoring ongoing research, as its policies and procedures require. The USA IRB/ Office of Research Compliance and Assurance may monitor any WCG approved protocol as part of its quality assurance program. **Record keeping**: You should establish record keeping procedures for your files, and store WCG documents,