UNIVERSITY OF SOUTH ALABAMA

WIRB Pre-Submission and Authorization Form

Refer to WIRB Submission Instructions for details on the submission process

Studies Eligible for WIRB Submission:

Please call USA IRB staff at 460-6308 or email irb@southalabama.edu if further assistance is needed regarding eligibility.

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 trial must be a eligible (See exclusion criteria on last page)
3. The protocol must be written and designed by the sponsor
4. The study must meet the National Institutes (NIH) definition of a clinical trial (A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions [drugs, treatments, devices, or new ways of using known drugs, treatments, or devices]).
5. The principal investigator must meet USA requirements to serve as PI on a research study.

1. Protocol Information

Principal Investigator (PI):	
PI Department:	Contact person:
PI telephone #:	Contact person telephone #:
PI email address:	Contact person email address:
Sponsor (Company) Name:	Sponsor's Protocol Number:
Protocol Title **AND** www.ClinicalTrials.Gov Number:	

List of Research Team Members *NIH human subjects training, ACRP and HIPPA in research training, if applicable, must be completed*	**Individual's Role** (e.g., PI, Co-PI, coordinator)	**Duties** (see table below for code #)

PLEASE NOTE: If more space is needed to list research team members, please attach an additional sheet of paper.

Assigned Study Duties (In Column 3 in above table, enter as many numbers as appropriate to describe study duties. For clarification, you may further describe duties within the IRB protocol as needed.)		
1. Recruitment	**2.** Obtains consent	**3.** Determine Subject Eligibility for Accrual
4. **a**) Subject Physical Examinations or **b**) Follow-up Visits including physical assessments	**5.** Perform study procedures or Specimen Collection	**6.** **a**) Administer or Dispense Study Drugs, Biologics or Devices (must be licensed) or **b**) Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7. Subject Randomization or Registry	**8.** Collection of Subject Data	**9.** Report Data (CRFs, e-CRFs, Spreadsheets)
10. Data Analysis	**11.** **a)** Review Adverse Events **b)** Treat and Classify Adverse Events	**12.** Other (Please insert explanation in column 3 after the number. You may further describe within the protocol)

2. Other Regulatory Committees:

Please indicate if your study requires approval from any of the following regulatory committee, or involved the use of regulated materials *(check all that apply)*:

- ☐ Institutional Biosafety Committee
- ☐ Institutional Animal Care and Use Committee
- ☐ Human Gene Transfer/Recombinant DNA Research
- ☐ Radiation Safety Committee

3. Hospital: Staff/Resources/Facilities:

a. Will this protocol use hospital staff, resources, or facilities? ☐ NO ☐ YES (if yes, complete below)

- ☐ Infusion Center
- ☐ Respiratory
- ☐ Cardiology (ECG, ECHO)
- ☐ Cyberknife
- ☐ GI Lab
- ☐ Laboratory
- ☐ Radiology
- ☐ Pharmacy
- ☐ Neurology (EMG, ABER, SSER)
- ☐ Other (specify):

b. Who will financially be responsible for hospital charges incurred as part of the study? Is there separate funding or is the patient's insurance responsible?

c. Who will provide staff education regarding the pharmaceutical drugs and / or hospital procedures? *(Include the information that will be covered)*

d. List the Hospital resources that will be utilized that are research related; and how often the tests and procedures will occur or be performed:

4. Billing for WIRB Services:

- Study teams are asked to complete the WIRB Billing Information section of the WIRB Initial Review Form, in accordance with Clinical Trial Agreement/Study Contract
- WIRB sends an invoice to sponsor listed on the WIRB Billing Information Sheet.
- There is a one-time USA IRB administrative review fee of $2000 for initial submissions. Sponsors will be billed separately by the University.

5. Principal Investigator's Commitment:

By electronically signing the IRBNet package, the PI certifies that the information provided in this application is complete and accurate, and that this study meets the USA IRB criteria for review by a central IRB. I also understand that the Institution reserves the right to disapprove any study approved by a central IRB.

The PI has ultimate responsibility for the conduct of the research study, its ethical performance, and the protection of the rights and welfare of human subjects. PI agrees to conduct this research study in accordance with all applicable federal and state regulations and USA IRB policies and practices governing human subject research.

PI understands that no research involving human subjects will convene until central IRB approval and all necessary USA approvals are in place. The PI will ensure that if members of the USA research team access protected health information from a USA covered entity in order to seek consent/authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without authorization or an approved waiver.

6. Exclusion Criteria:

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 and federally funded protocols
6. Investigator-initiated research
7. Protocols where the Principal Investigator holds the IND/IDE
8. Research involving prisoners.

7. List of WIRB Industry Partnerships*

Abbott
Actelion
Alcon
Allergan
Amylin
AstraZenca
Bayer
Biogen Idec
Biotronik
Bristol-Myers Squibb
Boston Scientific
Celgene
Covance
Daiichi
Esai
Forest Laboratories
Genetech
Gilead
GlaxoSmithKline
Hoffman-La Roche
Incyte
Johnson & Johnson
Lilly
Merck
Medtronic
Medimmune
Millennium
Novartis
Novella
Novo Nordisk
Pfizer
Purdue
Quintiles
Regeneron
Sanofi
Shire
UCB
United Therapeutics
Vertex

* *Please confirm WIRB submission is permissible by sponsor, if not included in the list above*