Investigator Responsibilities for Using a GRU-External IRB

I. Policy

The following external IRBs are available for use according to the criteria listed below:

1. Western Institutional Review Board (WIRB®)
   - Externally-sponsored clinical trials which have undergone FDA review.
2. National Cancer Institute Central IRB
   - Cooperative Clinical Oncology Group Protocols
3. University of Georgia
4. Other GRU Approved IRB- request reviewed on a case by case basis

II. Responsibilities

The principal investigator (PI) is responsible for:

- Notifying the GRU IRB Office at EXTERNAL_IRB@gru.edu of their External IRB submission by completing signing, and attaching the GRU-External IRB Form
- Initiating and obtaining all applicable GRU ancillary approvals as indicate by institutional policy
- Complying with the policies of the external IRB and the GRU-IRB.

Please note: A comprehensive list of PI Responsibilities is located in the IRB Policy: Principal Investigator and Sub-Investigator Responsibilities

III. Process

New Study Submission

An email notification should be sent to EXTERNAL_IRB@gru.edu and formatted as listed below:

- Subject Line: NEW STUDY_PI NAME_SELECTED EXTERNAL IRB_IRB EXTERNAL NUMBER
- The completed GRU-IRB Office External IRB form must also be attached to the email
- Documentation of any required ancillary approvals that have been obtained. The required ancillary approvals may include:
  - Institutional Biosafety Committee (IBC)
  - Radiation Safety

The GRU-IRB Office External IRB Administrator will monitor the new study submission to ensure:

- CITI is current and verified for all research team members listed on the GRU IRB External Submission Form

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• GRU boilerplate language requirements for the consent document are met
• Ensuring external IRB approval
• Required ancillary approvals have been obtained and documented

Once all items noted above have been verified and documented, the GRU External IRB Administrator will issue the GRU IRB Office External IRB Release within 3 business days to the PI, study coordinator, pharmacy and DSPA.

**Amendments, Continuing Review, and Reportable Events**

The external IRB will provide the GRU IRB Office access to all IRB actions to include continuing review and reportable events. The GRU IRB Office Compliance staff is responsible for reviewing the reportable events to determine if they require immediate reporting to the GRU IRB Office Director, Institutional Official, and/or Research Administration Leadership.

**GRU IRB Office Administrative Fee Change**

Effective September 1, 2014, the GRU IRB Office administrative one-time fee for external new IRB submissions to Western IRB (WIRB) has increased to $1,500.00. This increase is due to the continuing increase in resources associated with the administrative duties required for external IRB studies. The sponsor will be invoiced for the fee, which is due at the time of submission to WIRB.