1.0 INTRODUCTION

Pursuant to the federal regulations on human subjects research (45 CFR 46, the Common Rule), the Institutional Review Board (IRB) was created. Greenville Hospital System (GHS) maintains a Federalwide Assurance (FWA) with the Department of Health and Human Services (DHHS), which requires that all human subjects research, whether funded or not, be conducted at or on behalf of the institution be reviewed and approved by an IRB prior to initiating a research study.

As an alternative model of IRB review, proposed research protocols which will be conducted at GHS and meet specified criteria may be submitted to the Western Institutional Review Board (WIRB) for review and approval. GHS will be responsible for selecting which industry sponsored studies will be submitted to the WIRB. A negotiated Agreement between GHS and WIRB is on record, and GHS is assured that WIRB is qualified to review local research pursuant to the “Program by Greenville Hospital System and Western Institutional Review Board to Assure WIRB Knowledge of Local Research Context” found in Exhibit A of the Agreement.

2.0 OBJECTIVES

The objective of this SOP is:

2.1 Describe the documentation requirements and submission procedures for eligible proposed research protocols requesting that WIRB serve as the IRB of record for research involving human subjects.

2.2 Outline the process of approval for submission to WIRB by the Office of Research Compliance and Administration (ORCA).

2.3 Identify the documentation and review responsibilities of the GHS for WIRB-approved protocols.

3.0 SCOPE

These policies and procedures apply to principal investigators conducting human subjects who have requested centralized IRB review by WIRB.

4.0 POLICIES AND ASSOCIATED PROCEDURES

4.1 Eligibility Requirements of Proposed Research Protocols

4.1.1 In order to utilize the WIRB services, the proposed research protocol must meet several criteria:

4.1.1.1 The protocol must meet the NIH definition of a clinical trial.

4.1.1.2 The protocol must be industry-sponsored and must have been
designed and written by the industry sponsor.

4.1.3 The industry sponsor must hold all INDs/IDEs for the protocol, where applicable.

4.1.4 The protocol must be a Phase II/III/IV clinical trial designed to evaluate prospectively the safety and/or effectiveness of new drugs, devices, or biologics.

4.1.5 The GHS investigator has not previously submitted the study to a GHS IRB.

4.1.6 The GHS IRB charges a one-time fee of $1000.00 for the processing of industry-sponsored protocols submitted to the Western IRB for review. The contract agreement will include this fee to be paid to the GHS by the sponsor.

4.1.2 The following protocols are not eligible for review by WIRB:

4.1.2.1 Investigator-initiated clinical trials regardless of funding;

4.1.2.2 Protocols receiving funds from a federal or other not-for-profit funding agency;

4.1.2.3 Protocols with industry sponsors who refuse to pay commercial and local IRB fees;

4.1.2.4 Studies involving special local, social, economic, political, or cultural concerns, including but not limited to xenotransplantation, gene transfer, and/or embryonic stem cells;

4.1.2.5 Protocols requiring emergency use/review;

4.1.2.6 Protocols involving medical devices, including those subject to HUD/IDE regulations;

4.1.2.7 Protocols requiring review and approval by the GHS Biosafety Committee (e.g. the study involves recombinant DNA);

4.1.2.8 Research requesting waivers of informed consent and authorization; or

4.1.2.9 Research involving children.

4.2 Division of Responsibilities Between the GHS IRB and WIRB

4.2.1 The following division of responsibilities is based on the premise that the
WIRB’s primary function is initial and continuing review of human subject research protocols and that the GHS IRB’s primary function is determination of eligibility for submission to WIRB and limited local oversight.

4.2.2 The responsibilities of the WIRB are to:

4.2.2.1 Perform initial reviews of proposed research protocols, identify and discuss any issues, and make a final decision of approval or disapproval of the protocol.

4.2.2.2 Carry out continuing reviews and reviews of serious adverse events, protocol amendments, DSMB reports, subject complaints/allegations, and any other documents submitted by the PI for all GHS protocols reviewed by WIRB.

4.2.2.3 Notify the GHS IRB that WIRB has accepted review of proposed research protocols, and provide the GHS IRB with copies of all approvals and denials, including initial reviews, continuing reviews, and reviews of serious adverse events, protocol amendments, DSMB reports, subject complaints/allegations, and any other documents submitted by the PI.

4.2.2.4 Maintain relevant communication with the PI regarding all approvals and denials regarding the protocol.

4.2.2.5 Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CFR 56 and provides special expertise as needed from Board members or consultants to adequately assess all aspects of each protocol including local context issues.

4.2.3 The responsibilities of the GHS IRB are to:

4.2.3.1 Determine eligibility of proposed research protocols for review by WIRB based on the criteria listed in Section 4.1 above.

4.2.3.2 Submit initial submission documents for all eligible protocols to WIRB for review and approval.

4.2.3.3 Ensure that all investigators and staff are properly qualified and meeting GHS IRB standards for eligibility to conduct research, including but not limited to human subjects protection training and collection and maintenance of conflict of interest disclosure forms.

4.2.3.4 Review all WIRB decisions regarding approvals and denials, continuing reviews, adverse events, protocol amendments, and all other reviews for local considerations, and take any necessary actions to address those local considerations.
4.3 **Review and Approval Process**

4.3.1 The local institution PI or designee will complete all required IRB documentation from the GHS IRB website. The local institution PI or designee will then submit all required documentation related to the protocol for review to the Office of Research Compliance and Administration (ORCA) via electronic submission.

4.3.1.1 Documentation should include, but is not limited to:

4.3.1.1.1 GHS Application for Protocol Review by WIRB;
4.3.1.1.2 GHS Request for Submission Form to WIRB;
4.3.2.1.3 WIRB Initial Submission Form or Investigator Submission Form for Multi-Center Protocols;
4.3.1.1.4 Curriculum vitae (CVs) for all investigators
4.3.2.1.5 IRB application materials including but not limited to research protocol, informed consent statement, authorization form, drug brochure, advertisements and solicitation scripts, if applicable;
4.3.2.1.6 Verification that the protocol has been approved by the Scientific Review Committee, Radiation Safety Committee, as applicable; and /or
4.3.2.1.7 Documentation of completion of all GHS IRB requirements (e.g., the passing of CITI training; co-investigator acknowledgements and PI eligibility).

4.3.1.2 The PI and research staff should note that the informed consent form(s) which are submitted with the protocol must conform to GHS IRB and WIRB approved language and standard statements.

4.3.1.2.1 Local additions to the informed consent template dealing with contact information shall be added.

4.3.1.2.2 WIRB may also request substitutions or additions in the informed consent template, particularly to facilitate comprehension by the local population, as long as the proposed changes do not alter the meaning of the content.

4.3.2 Upon receipt of required documentation, GHS IRB staff will review the application for eligibility of review by WIRB.

4.3.3 Notification of WIRB review eligibility will be communicated to the PI within 3 business days of initial submission.
4.3.3.1 If eligibility is denied, GHS IRB staff will notify the PI and request that the study be resubmitted via the formal GHS IRB process.

4.3.3.2 If eligibility is approved, the GHS IRB staff will submit the initial submission documentation to WIRB via the WIRB online submission process.

4.3.3.3 After submission to WIRB, all protocol correspondence will take place directly between WIRB and the PI.

4.3.3.4 Upon notification of approval from WIRB, the protocol investigators and staff will utilize only WIRB-approved documents.

4.3.4 For any WIRB protocol, regardless of its disposition, the GHS IRB will maintain an electronic copy of the protocol file, via the eIRB, including documentation regarding any subsequent reviews and other WIRB documentation provided by WIRB. These documents shall be retained in accordance with GHS ORCA Policies and Procedures and federal requirements.

4.3.5 WIRB will conduct continuing review and reviews of serious adverse events, unanticipated problems, data safety monitoring board reports, protocol amendments, and recruiting reports. The GHS IRB will receive outcomes of these reviews and will take any necessary action regarding local considerations.

4.3.6 GHS IRB may not approve research which has been disapproved by WIRB; however, GHS IRB may disapprove any study approved by WIRB. Despite this right, the GHS IRB will use its best efforts to ensure that clinical research will be performed in accordance with WIRB decisions.

Medical Director, Office of Research Compliance & Administration

Greenville Hospital System Institutional Official

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