SUBJECT: RESEARCH OVERSIGHT COMMITTEE	POLICY NO. I.34
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Memorial Hospital at Gulfport
Leadership Manual

I. PURPOSE:

To provide guidelines regarding investigational, clinical, or observational research trials to protect the safety of patients by ensuring that these activities are adequately controlled and supported. The Research Oversight Committee (ROC) shall focus on the protection of human subjects, determine whether resources are available in the organization to support the study, and shall ensure corporate compliance, billing, finance, conflict of interest and HIPAA have been addressed.

The responsibility of the ROC in the evaluation of biomedical research is to help safeguard the dignity, rights, safety, and wellbeing of all current and potential research subjects. All studies that will occur at MHG or utilize MHG patients are required to be reviewed and approved by the ROC prior to any research activities occurring.

II. POLICY:

A. This Committee is responsible for the review of all proposed research study applications. The ROC may approve, request changes, or deny the application based on their review.

B. The ROC will meet as frequently as necessary to accomplish its purpose.

C. All records shall be kept by the Principal Investigator in a secure location for at least three (3) years, or as long as required by the associated IRB.

D. Members of the medical staff, current employees, and affiliates of Memorial may submit an application to the Research Oversight Committee for review.

III. PROCEDURE:

A. The Principal Investigator (PI) planning a research activity involving human subjects will obtain an application packet from the MHG Home Page for any new Research Study, found under Departments/Risk Management/Clinical Research, or by emailing the ROC Secretary at clinicalresearch@mhg.com.

B. Any research performed by students at Memorial must be approved by the appropriate Department Administrator prior to submission of application to ROC. Studies to be performed by Medical Residents are to be reviewed and approved by Graduate Medical Education (GME) Faculty and also approved by the designated outside IRB, prior to submission to ROC. (Attachment A)

C. The PI is to complete the Proposed Research Study Application and submit it to the ROC Secretary. The application is to include the MHG ROC Application form (Attachment A), copy of the proposed Protocol, proposed Informed Consent Form (ICF), IRB Authorization Agreement documenting the IRB of record, and brief Summary of the Study. These may be sent electronically to clinicalresearch@mhg.com.

D. New Research Study Applications may be submitted at any time during the year. There are two types of review either by the full convened ROC or by the expedited/exempt process. Exempt/Expedited ROC review is assessed by the ROC Secretary and submissions are reviewed by ROC Co-Chairs and can occur independently of scheduled ROC meetings. Fully Convened ROC review will apply to all studies that do not meet the criteria for expedited review.

E. The Proposed study summary, Protocol, ICF and completed application packet will be distributed to the membership prior to the scheduled meeting for review.

F. The PI (or designee) is required to attend the ROC meeting to present the proposed research study for approval and field any questions. Within one week of the review, the PI will be notified in writing of the ROC action. If the ROC denies permission, a response will be provided in writing. The PI will be afforded the opportunity to appeal.

G. If a particular study is proposed to the ROC that necessitates "specialty input" to evaluate the proposal, the committee will invite appropriate "experts" to speak to the topic at hand.

H. PIs must apply for Annual Renewal in order to continue the research at Memorial Hospital by completing the "Continuing Review Form" found on the Home page (Departments/Risk Management/Clinical Research). (Attachment C)

I. The PI (or designee) is responsible for notifying the ROC of any changes in the IRB approval, informed consent, any significant adverse event, significant protocol amendment or to close the study.

J. Study Closure submission occurs when the study will no longer recruit from or perform study procedures at MHG. A summary of the Study activities should be provided that indicates how many subjects were enrolled and completed the study, any serious adverse events, and PIs evaluation of the Research to date. (Attachment C)

K. If no subjects are recruited within 12 months of approval, written justification for continued approval will be required.

IV. MEMBERSHIP:

Membership of the ROC will include a Chairperson, Co-Chair, and Secretary as well as other clinical disciplines and operational support necessary to ensure subject safety and feasibility of effectively performing the proposed studies. The Co-Chairs will include designated Hospital representatives and a member of the Memorial Medical Staff. The chairpersons shall appoint the membership in consultation with Administration and Medical Staff Leadership. Chairpersons are appointed by the Chief Medical Officer. Additional membership may include, but is not limited to, Pharmacy, Billing, Privacy Officer, Compliance Officer, Risk Management, Chief Medical Officer, Clinical Leadership and others as needed. It is expected that the membership will review the Proposed Study, Protocol, and ICF prior to the ROC meeting in which a Study is presented.

A quorum (2/3) of committee membership must be present either in person or by conference call for a vote to take place. Only appointed members of the ROC are eligible to vote on a Study. A study is approved with a simple majority. Each voting member will complete and sign a form validating the Criteria for approval. (Attachment B). Expedited studies can be reviewed and approved by the two Chairpersons, with reporting to the Committee at large at the subsequent meeting.

V. COMPLIANCE WITH HHS REGULATIONS

A. Memorial Hospital is responsible for and maintains compliance with Department of Health and Human Services (HHS) on the Protection of Human Subjects.

B. All Memorial Hospital's sites and locations may share information for the purpose of treatment, payment, or health operations. Research is considered treatment. For disclosure of trial participants' protected information outside of directly affiliated locations, the study participant must authorize this disclosure and use by means of written consent, usually contained in the ICF.

EFFECTIVE:

President/CEO — Date: 11-19-20

Chief Medical Officer — Date: 11/19/2020

Chief of Staff — Date 11/30/20

Senior Vice President, Patient Care Services, CNO — Date 11-20-2020

Compliance Officer — Date 11/19/2020

Designated Institutional Official (DIO) for Graduate Medical Education — Date 11/23/2020

ATTACHMENTS:

A. ROC Application Form
B. Criteria for ROC Approval of Research
C. Continuing Review Form (Includes Study Closure)

COVERAGE: Employees. Contract/agency staff, and others as identified in this policy

FOR INTERPRETATION: Administration