Department Chair Responsibilities

I. Purpose
The policy defines the roles and responsibilities of a Department Chair (to include Service Line Chief and Center Chair) or designated department approver, for human subjects research conducted at Georgia Regents University.

II. Definition(s) and Responsibilities
a. The Department Chair is responsible for promoting the ethical conduct and maintaining awareness of human subjects research activities conducted within their departments. The Department Chair is responsible for reviewing each new human use protocol submitted by faculty within their department. This duty may be delegated to a designee or a departmental committee; however, the Department Chair will remain responsible for studies conducted completely, or partially, by personnel within their department.

b. Designated Department Approvers are required to provide scientific review (Research conducted by a principal investigator whose signatory official does not have sufficient expertise to ensure the above statements should also be reviewed and certified by an official or committee with the necessary expertise to determine the merits and probable success of the research. [38 CFR 16; 45 CFR 46; 21 CFR 56; VHA 1200.5 7]) and approve each new protocol submitted by a faculty member within their department. This term is used in the eIRB system for the Department Chair and/or their designated Department Approver. In the event the protocol is submitted by a student, the assigned Department Approver for the Faculty Advisor’s department is required to review and approve the study after approval by the Faculty Advisor.

III. Responsibilities of the Department Chair
a. Prior to IRB Review
i. Approve the conduct of human subjects research within the department via eIRB according to the Department Approver Manual.
   • Approval authority may be delegated at any time to an appropriate faculty member within the department. Please notify OHRP at IRB@gru.edu if the department approver needs to be re-assigned.
   • The Department Chair/designated department approver will approve or request changes to the protocol via eIRB. This is expected within 2 business days of receiving an approval notification from eIRB. However, an IRB Specialist may notify the
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department chair (or designated approver) via email to obtain department approval if not issued in eIRB within the 2 business days.

- Ensure the Principal Investigator has departmental support and adequate resources to conduct the study appropriately
- Disclose any real or apparent conflict of interest (COI) associated with the department approver, study and/or study team, per the GRU COI policy
- Ensure the research has scientific merit and that:
  - The research uses procedures consistent with sound research design
  - The research is designed to answer the proposed question
  - The knowledge reasonably expected to result from the research is important
  - Sufficient resources, facilities and staff to conduct the research are available

b. Post IRB Submission
   i. Notify the GRU OHRP and Institutional Official immediately upon knowledge of:
   - Potential non-compliance
   - Potential unanticipated problem involving subjects or others
   - Potential research misconduct
   - Review the GRU OHRP audit reports emailed to the Department Chair
     a. Audit reports indicating critical findings will be forwarded to the Department Chair of the Principal Investigator’s primary department.
   ii. Collaborate with the GRU OHRP and IRB regarding a “for cause” audit of a protocol or investigator within their department.

IV. Ongoing Responsibilities of the Chair and Designees
   i. Collaborate with the GRU OHRP to provide training as needed for research faculty and staff within the department
   ii. Identify areas of risk and work with the GRU OHRP to mitigate the risks appropriately
iii. Ensure research records for faculty who leave the institution are stored according to the GRU IRB Research Record Retention policy.

iv. Promote the conduct of research within the department in compliance with federal regulations, applicable state law, and institution policies and procedures.

V. Resource:
   1. eIRB Department Approver’s User Manual