

Henry M. Goldman School of Dental Medicine Clinical Research Policy

- I. Purpose: To promote the conduct and ensure the quality of human subjects research conducted by GSDM faculty and residents and students by providing resources to researchers, training requirements and a School-based oversight structure to support researchers.

- II. Scope: This policy supplements the University-wide policies on the conduct of research and covers all human subjects research conducted by GSDM faculty and residents, including clinical trials, epidemiological and behavioral studies; outcomes research; and health services research.

- III. Policy/procedure:
 - A. Departmental Oversight of Clinical Research
 1. Department Chairs are responsible for oversight of all research conducted in their departments and for ensuring the requirements of this policy are implemented and followed in their departments.
 2. Each Department Chair shall appoint a departmental Research Director, with ½ day per week of protected time for research and whose duties shall include.
 - a. Promote and facilitate research by the department's faculty and residents;
 - b. Serve as a Faculty Research Mentor to resident researchers;
 - c. Serve as a resource to other Faculty Research Mentors in the department;
 - d. Ensure a Self-Assessment Review is performed twice per year for each departmental research project;
 - e. Ensure the GSDM Research Database contains complete and accurate information for all research projects in the department; and
 - f. Other related duties as assigned by the Department Chair.
 - B. Principal Investigators: GSDM residents may not serve as Principal Investigator on IRB protocols. Every research study must have a faculty member as Principal Investigator.
 - C. Faculty Researchers

Any faculty member conducting a clinical research project must complete the following training:

 - a. CITI human subjects protection and HIPAA training, as mandated by the BU-BMC IRB.
 - b. Clinical Research Resources Office (CRRO) training on "The Principal Investigator Role: What Every New and Seasoned PI Needs to Know about the Conduct and Oversight of Clinical Research".
 - D. Faculty Research Mentors
 1. Qualifications: Any willing faculty member may serve as a Research Mentor to a resident researcher following completion of the following training:
 - a. CITI human subjects protection and HIPAA training, as mandated by the BU-BMC IRB.
 - b. Clinical Research Resources Office (CRRO) training on "The Principal Investigator Role: What Every New and Seasoned PI Needs to Know about the Conduct and Oversight of Clinical Research".
 - c. Training on the GSDM Research Study Design Worksheet.

2. Responsibilities:
 - a. Ensure resident researchers participate in required research training, as specified below.
 - b. Meet with residents concerning their research projects.
 - c. Assess and advise on the feasibility of residents' proposed research projects.
 - d. Review and approve resident researcher Research Study Design Worksheets.
 - e. Coordinate the development of faculty-led umbrella projects to allow residents in shorter programs to participate in an aspect of a continuing study.
 - f. Ensure that a Self-Assessment Review is conducted twice per year for each research project and delivered promptly to the GSDM Research Database.
- E. Resident Researcher Training Requirements
 1. Have completed or be enrolled in class lectures on research study design and human subject research (OB 830 or a similar department-specific research course).
 2. CITI human subjects protection and HIPAA training, as mandated by the BU Medical Campus-BMC IRB.
 3. "Clinical Research Training –Residents" offered by the CRRO.
 4. Training on the GSDM Research Study Design Worksheet.
 5. For studies involving clinical trials, Good Clinical Practice training.
- F. Required Steps when Proposing Research: All resident researchers must take the following steps:
 1. Work with Faculty Research Mentor and statistician to complete GSDM Research Study Design Worksheet.
 2. Receive Faculty Research Mentor and statistical consultant approval.
 3. Be familiar with and utilize GSDM and University research resources, including Protocol Builder, and use them as needed.
- G. Office of the Associate Dean for Research Role
 1. Create and maintain an electronic GSDM Research Database of all active research projects in all departments of GSDM, which shall be accessible by department chairs, Faculty Research Mentors and faculty researchers.
 2. Facilitate training opportunities for GSDM researchers.
 3. Maintain a Blackboard page providing clinical research resources for the GSDM research community.
 4. Identify existing GSDM repositories and work with their Principal Investigators to facilitate access by members of the GSDM research community.
 5. Identify and catalog other large data sources *e.g.* NHANES, SEER, the Cancer Genome Atlas; maintain information on accessing these in a well-publicized, easily accessible location.
 6. Identify and facilitate access to additional repositories of research data collected at GSDM.
 7. Annually provide a report to the Dean/Executive Committee to include:
 - a. Number of active clinical research projects.
 - b. Median number of rounds for all submissions to the IRB.
 - c. Median rounds for different categories (Full Board, Expedited, Exempt, Not Human Subjects Research).
 - d. Number of incomplete protocols submitted to the IRB.
 - e. Median number of days in IRB.

- f. Findings from GSDM quality assurance self-assessments, including number of minor and major deviations.
 - g. Findings from official Office of Human Research Affairs audits, including number of minor and major deviations.
 - h. Number of trainings completed in compliance with requirements.
 - i. Such other measures as the Dean/Executive Committee may request.
- IV. Regulations, references, forms
- BU Clinical Research Resources Office (“CRRO”) <http://www.bumc.bu.edu/crro/>
 - Boston University Research Policies <https://www.bu.edu/policies/research-scholarly-activities/>
 - GSDM Research Study Design Worksheet <http://www.bu.edu/dental-research/student-research/>