Title: **Responsibilities of the Research Team**	*Applicable to: **Beaumont Health**	Effective Date: **04/04/2018**
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Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **Clinical Research SOP's, Research Institute**

***For This Document, Beaumont Health Includes**:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE:

This standard operating procedure (SOP) defines the general responsibilities of key research personnel and research support staff.

II. SCOPE:

This SOP applies to all key research personnel and research support staff involved in supervising, managing, conducting or supporting Beaumont study-related activities.

III. RESPONSIBILITY:

It is the responsibility of all key research personnel to be knowledgeable about their specific job duties.

IV. PROCEDURES:

General responsibilities of key research personnel and research support staff:

1. Conduct clinical studies according to federal regulations, guidelines governing human participant research, Beaumont Health (BH) policies and procedures, Research Institute (RI) policies and procedures and policies of the Institutional Review Board (IRB) record, which may be the Beaumont IRB or an approved external IRB.

2. Fulfill job responsibilities specific to their job title according to RI job Weighted Job Questionnaires (WJQs), staff qualifications, licensure and Beaumont policies.
3. Complete and maintain all RI and protocol specific educational requirements in accordance with Training and Education for Individuals Involved in the Conduct of Clinical Research.
4. Comply with federal regulations and Beaumont Research Institute (BRI) policies governing disclosure of personal, professional or financial interests in a research study that may impact upon its conduct, evaluation or outcome.
5. Participate as appropriate in the hiring and training of individuals recruited as members of the research department.
6. Assure trained individuals, including Research Nurse Clinicians/Coordinators/Assistants or non-Research Institute staff (with appropriate approval), manage each planned or ongoing clinical study.
7. Develop organizational aids and checklists to facilitate patient recruitment and enrollment as well as the collection of complete and accurate study data.
8. Enroll participants in studies and manage their participation according to ethical, regulatory, and protocol-specific requirements.
9. Maintain the regulatory and study files for each research project.
10. Participate in quality assurance activities such as monitoring visits, internal audits, sponsor audits, and inspections by external regulators, e.g. Food and Drug Administration (FDA).
11. Assure the Principal Investigator (PI) is informed in a timely manner of all study-related activities through meetings, memos, electronic mail and voice mail.
12. Assure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and test articles.
13. Manage the business aspects of studies, including developing and negotiating study budgets and contracts.
14. Communicate with the IRB or record as appropriate.

IV. ETHICAL OBLIGATIONS AND EXPECTATIONS:

As components of the human research protection program (HRPP), IRB members and staff (both Beaumont IRB and approved external IRBs), investigators, research staff, other employees and students bear ethical obligations and expectations. Jointly they are responsible for supporting an institutional culture of respect and conscience with an emphasis on respect for and protection of human participants in research at Beaumont. In promoting this culture, the Beaumont and approved external IRB chairs and vice chairs are directly responsible for overseeing the protection of research participants by ensuring the proper review, approval, disapproval or determination of exemption from further review of research projects. IRB members actively participate on the IRB, a federally mandated committee charged with the responsibility of

reviewing research, to ensure the rights of research participants are protected and risk of harm is minimized. The Beaumont IRB manager and staff provide administrative support to facilitate IRB processes, providing guidance, remaining current about regulatory changes, and ensuring compliance with federal, state, local and institutional policies in order to protect human participants. Beaumont investigators, research staff, other employees and students are responsible for ensuring research is conducted ethically and with integrity, while ensuring participant safety.

To assure Beaumont research is conducted ethically and with the utmost integrity, it is the responsibility of all employees, medical staff members, investigators/key research personnel and IRB members and staff to report any incidents of undue influence or allegations of non-compliance to any of the following:

1. Their supervisor
2. The Vice President of Research/Institutional Official
3. The RI Administrative Director
4. The RI Compliance Coordinator
5. The Chairperson of the IRB of record
6. The Corporate Compliance Office
7. Legal Affairs
8. Beaumont Corporate Compliance Line

V. APPLICABLE REGULATIONS AND GUIDELINES:

21 CFR 312.53 Selecting investigators and monitors
21 CFR 312.60 General responsibilities of investigators
21 CFR 312.61 Control of the investigational drug
21 CFR 312.62 Investigator recordkeeping and record
21 CFR 312.64 Investigator reports
21 CFR 312.66 Assurance of IRB review
21 CFR 312.68 Inspection of investigator's records and reports
21 CFR 312.69 Handling of controlled substances
21 CFR 54 Financial Disclosure by clinical investigators
January 1988 Guidelines for the monitoring of clinical investigations
FDA Information Sheets October 1998 - Frequently Asked Questions, Continuing Review After Study Approval, Recruiting Study Subjects, Payment to Research Subjects, Screening Tests Prior to Study Enrollment, A Guide to Informed Consent, Sponsor-Investigator- IRB Interrelationship

May 1997 - International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
Beaumont Research Institute WJQs - All current research key personnel and research support staff job descriptions

VI. REFERENCES TO OTHER APPLICABLE SOPs:

Research Administration policy *Research Administration Oversight*
Research Administration policy *Responsibilities of the Principal Investigator*
All current Beaumont Research Institute policies and procedures

CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.