Title: **Vulnerable Populations: Enrollment of Employees, Students or Trainees**	*Applicable to: **Beaumont Health**	Effective Date: **04/03/2018** Last Periodic Review Date: **04/03/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, 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 policy provides guidelines for the recruitment of employees, students, and trainees as participants in research conducted within Beaumont Health (BH), in order to ensure issues surrounding voluntariness, undue inducement, and confidentiality are addressed. **The Beaumont Health (Beaumont) IRB serves as the primary Institutional Review Board for human participant research conducted at Beaumont (for information about the use of external IRB's, see policy *Review by an External Institutional Review Board*).**

II. SCOPE:

The policy applies to principal investigators, research staff, institutional review board (IRB) members and staff, physicians, administrators and employees of BH and students or trainees in recognized educational programs or activities at BH.

III. BACKGROUND:

Federal regulations governing human participant research do not provide specific guidance concerning the inclusion of employees, students or trainees as research participants in research conducted by the institution where they are employed or active as a student or trainee. The Office of Human Research Protections (OHRP) discusses employees under the heading of "Special

Classes of Subjects" in its IRB Guidebook. OHRP advises attention be given to *voluntariness, undue inducement,* and *confidentiality* and recommends avoiding individual solicitations to participate in research.

A. **Ethical Considerations -** The central ethical concern with respect to employees, students or trainees participating in human research is the individual, under certain circumstances, may not feel free to decline. Employees, students or trainees may volunteer to participate out of a belief they will gain favor with physicians, administrators, supervisors or faculty (e.g., better work assignments, grades, recommendations, position, etc.), or failure to participate will negatively affect their relationships (i.e., seen as uncooperative, not committed to department goals, not part of the scientific community). The pressure may be subtle, for example, when a culture of expectations emerges in a work group that reinforces and encourages employees to participate in research. Alternatively, the pressure may be more overt, with individuals fearing their employment may be adversely affected if they do not participate.

   Another ethical concern is employees, students and trainees may be more at risk of invasion of privacy or loss of confidentiality than other research participants. Co-workers of employees, students or trainees participating in research may have access to research data and may obtain and share personal information about research participants inappropriately. Research involving the collection of data on sensitive participants such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to participants of which they should be made aware and from which they should be protected, to the greatest extent possible.

IV. DEFINITIONS:

Employee - For purposes of this policy, "employee" refers to an individual employed by BH or serving as a volunteer/intern/observer at BH.

A. **Student -** For purposes of this policy, "student" refers to an individual who is approved to participate in activities at Beaumont Health (Beaumont) as part of a formal and recognized educational affiliation.
B. **Trainee -** For purposes of this policy, "trainee" refers to an individual in the process of being formally trained by a Beaumont mentor.

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V. POLICY:

Under no circumstances may a Beaumont researcher or administrator coerce or impose undue influence on an employee, student or trainee to participate in research.

All Beaumont employees, students, and trainees enrolled as participants in research will be treated in a manner commensurate with their special status. Such individuals are vulnerable to coercion. Additional safeguards must be implemented to protect their rights and welfare (45 CFR 46.111(b) and 21 CFR 56.111(b)), as described below.

A. **Prohibition on Required Enrollment -** An employee may not be required to enroll in employer-initiated research as a condition of employment. Similarly, a student may not be required to enroll in Beaumont research as part of a course requirement.

B. **Enrollment Solicitation -** Employees may not be *directly* (i.e., in person, via direct email or telephone) solicited by their direct supervisor to enroll in Beaumont research, regardless of the level of risk. Alternate acceptable recruitment methods may include the posting of IRB-approved flyers and the placement of IRB-approved advertisements may be used. Direct solicitations increase the likelihood participation will be the result of undue influence, either because of the relationship between the recruiter and the prospective participant, or methods of communication employed by the recruiter which may act to persuade prospective participants to participate, thus compromising the voluntariness of the agreement to participate.

   In the event an employee, student or trainee asks their supervisor, who is also the researcher, about research opportunities within their own department, the supervisor may provide the information requested. The supervisor will be responsible to provide objective and complete information about the research and be especially careful not to influence the decision of the employee, student or trainee.

   Consent providers may not enroll employees, students or trainees who report directly to them. In the event an employee, student or trainee responds to an indirect solicitation to participate, someone other than a direct supervisor should administer the informed consent to limit the opportunity for coercion (intended or unintended). When research is both non-therapeutic (unlikely to produce a diagnostic, preventive, or therapeutic benefit to current participants) and "more-than-minimal risk", Beaumont employees, students or trainees may not participate *IF* they are directly supervised by an investigator of the research.

C. **Confidentiality -** Whenever employees, students or trainees are the targeted research participants, regardless of level of risk or prospect of direct medical benefit, investigators must

provide the IRB with specific plans for ensuring the privacy of these vulnerable populations will be respected. These plans must take into account and adequately address the special concerns raised by the workplace context.

D. **Participation Incentives -** The use of monetary incentives for soliciting employee, student or trainee participation in research is only permissible when consistent with what other participants are offered and within the requirements of IRB Policy 220 *Compensation and Incentives Offered to Research Participants*.

E. **Investigator Guidelines -** Investigators enrolling employees, students or trainees in research must:
   1. Engage in recruitment and consent activities outside of the presence of the employee, student or trainee's supervisor(s), faculty or advisors whenever possible.
   2. Ensure the employee, student or trainee understands they may choose not to participate in the research and their decision will not affect their employment, grade or performance evaluation.
   3. Outline procedures to ensure the employee, student or trainee will not be participant to undue influence or coercion and to ensure each employee, student or trainee's privacy will be respected.
   4. Ensure steps are taken to avoid informing supervisors, administrators or faculty of individuals who decline participation.
   5. Conduct the research procedures out of sight of other employees, students or trainees whenever possible. For example, surveys or questionnaires could be given to employee, student or trainee participants to complete at home and mail back to the investigators instead of asking the individual(s) to convene in a room on-site, which could identify them as research participants to their superiors, instructors, co-workers or fellow students or trainees.
   6. Ensure all data given to the employer or faculty (when applicable) is either in the aggregate or is stripped of all identifiers so the employee, student or trainee participant's identity is protected.

F. **Additional Guidance for Student Participants -** Investigators enrolling the institutions' students or trainees in research must:
   1. Ensure students understand they may choose not to participate in the research and their decision will not affect their grade/class standing.
   2. Avoid using class time to recruit or engage in the research.
   3. Outline procedures in the research protocol to ensure the students will not be subject to undue influence or coercion and to ensure the student's privacy will be respected.

G. **Students or Employees as Participants of non-Beaumont Research**
External investigators conducting research projects that do not involve Beaumont investigators but involve recruitment targeted specifically at members of the Beaumont community as a defined group must obtain approval from the appropriate official responsible for the group to be recruited. Review by the Beaumont IRB is not required when Beaumont is determined not be engaged in the research as defined in IRB Policy *Institutional Engagement in Research*.

H. **Recruitment of non-Beaumont Students or Employees –** When promotional material names Beaumont, references a Beaumont department (e.g., Urology Research), Beaumont physician, or provides a Beaumont phone number, Marketing approval is required. If the promotional material is targeted towards enrollment of employees, students or trainees, particular attention must be paid to ensure the materials are not coercive in nature. Requirements set forth in the *Clinical Research Study Promotion* policy and the *Compensation and Incentives Offered to Research Participants* policy must be followed. Prospective IRB review and approval of all promotional materials related to clinical research activities is required.

Beaumont investigators targeting students or employees from another institution for participation in Beaumont research must respect the institution's policies or practices with regard to such recruitment and seek appropriate institutional permission before initiating recruitment activities.

VI. APPLICABLE REGULATIONS:

45 CFR 46 HHS: Protection of Human Subjects
21 CFR 50 FDA: Informed Consent
21 CFR 56 FDA: IRB Review and Approval

VII. REFERENCES:

OHRP IRB Guidebook "Special Classes of Subjects"
RI Policy *Institutional Engagement in Research*
IRB Policy *Compensation and Incentives Offered to Research Participants*
IRB Policy *Informed Consent and Authorization in Research*
IRB Policy *Review by an External Institutional Review Board*
IRB Policy *Clinical Research Study Promotion*
IRB Policy *Recruiting Human Participants for Clinical Research*

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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.