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| Title: Institutional Authority | *Applicable to: Beaumont Health | Effective Date: 03/16/2018 |
| Policy Owner: Administrative Director | Document Type: Policy | Last Periodic Review Date: 03/16/2018 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:

The purpose of this policy is to establish the authority under which the Institutional Review Board (IRB) at Beaumont Health is empowered. According to the Bylaws of the Research Institute, the IRB operates under the authority of the Beaumont Board of Directors.

II. SCOPE:

This policy applies to all physicians, staff and employees of Beaumont, and all clinical research conducted at Beaumont facilities or under the auspices of the IRB. Beaumont research encompasses all laboratory based, translational and clinical research conducted at Beaumont utilizing Beaumont facilities/equipment, patients or staff, unless Beaumont is determined not to be engaged in the research, per Research policy [*Institutional Engagement in Research*](#). Any investigation involving human participants at Beaumont, utilizing Beaumont facilities, patients or staff (including retrospective studies of specimens or medical records) requires prior review and approval by the IRB. This includes but is not limited to:

1. Clinical research conducted at Beaumont facilities.
2. Outcomes studies where data collection is taking place in the private practice, but surgical procedure being assessed took place at Beaumont.
3. Studies based on a medical, clinical or other record or report which is initiated at Beaumont.
4. Registry studies where data is being collected in the private practice, but the intervention took place at Beaumont.

Disclaimer: User must ensure that any printed copies of this policy/procedure are current by checking the online version of the policy/procedure before use.

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5. The investigator or key personnel are Beaumont employees, residents or fellows.

III. GENERAL:

The mission of Beaumont is to provide all patients with the highest quality health care. The participation of Beaumont physicians and staff in conducting clinical research is important to the mission. The IRB is organized based on regulatory and ethical necessity to protect the rights and welfare of human research participants. The IRB shall maintain compliance with specific regulatory and ethical requirements to provide initial and continuing review of research involving human participants at Beaumont facilities, in accordance with federal regulations, hospital policy and Research Institute Bylaws. The IRB may elect to cede authority to an external IRB for a subset of studies which meet requirements described in Research policy [*Review by an External Institutional Review Board.*](#)

At the request of the principal investigator (PI) the IRB will review protocols in accordance with International Conference on Harmonization Good Clinical Practice Consolidated Guidelines (ICH GCP).

A. **Ethical Principles Governing Human Participant Research**

The primary ethical principles applied to research overseen by the IRB, including protocols “exempt” under federal regulations pertaining to human participant research, are those set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* (Belmont Report). The three main principles are:

1. Respect for persons (e.g., applied by obtaining informed consent, giving consideration to privacy and confidentiality, and adding protections for vulnerable populations)
2. Beneficence (e.g., applied by weighing risks and benefits)
3. Justice (e.g., applied by the equitable selection of subjects).

Studies conducted under ICH-GCP are also conducted in accordance with the ethical principles which have their origins in the Declaration of Helsinki and are consistent with good clinical practice and the applicable regulatory requirements.

All parties involved in the conduct of research are expected to also adhere to the principles of expertise (“competent to do the work”) and integrity (“faithfully adhere to professional principles”).

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IV. POLICY:

The Chairperson of the IRB shall make regular reports, at least annually, to the VP of Research. The IRB will either agree to cede authority to an Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredited IRB or be the final approving authority of research involving human participants at Beaumont and facilities. For the purpose of this research oversight committee, biomedical research or clinical investigation includes:

- A. Any study/experiment which involves a test article and one or more human participants, regulated by the Food and Drug Administration under section 505 (i), 507 (d), and 520 (g) of the Federal Food, Drug and Cosmetic Act as amended.
- B. Biomedical research or clinical investigations which support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.
- C. Systematic investigations, including research development, testing and evaluation, involving human participants or identifiable information, for the purpose of increasing generalizable knowledge.

The organization grants the IRB the authority to:

- A. Approve, require modification to secure approval, or disapprove all clinical research activities.
- B. To suspend or terminate approval of research not being conducted in accordance with IRB requirements or which has been associated with unexpected serious harm to participants.
- C. To observe, or have a third party observe, the consent process and or the conduct of the research.

The VP of Research or the Administrative Director of Research serves as the Institutional Official for the IRB, and signs the Federal Wide Assurance on behalf of the institution to comply with 45 CFR 46 for human participant research. The VP of Research is authorized to review and sign a Department of Defense Addendum. Approval by the IRB does not prevent Beaumont, under the direction of the Institutional Official, consistent with federal regulations, from suspending, terminating, or otherwise stopping a research study considered inappropriate,

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objectionable or contrary to the mission of Beaumont. However, officials of Beaumont may not approve research involving human participants or their data which has not first received the review and approval of the IRB.

The IRB shall conduct its' operations in accordance with written policies and procedures.

V. ASSOCIATED POLICY AND PROCEDURES:

Beaumont Health System, Research Institute Bylaws
 Research Policy [Research Administration Oversight](#)
 Research Policy [Institutional Engagement in Research](#)
 Research Policy [Review by an External Institutional Review Board](#)

VI. REFERENCES:

21 CFR 50 Protection of Human Subjects
 21 CFR 56 Institutional Review Boards
 45 CFR 46 Protection of Human Subjects
 ICH E6 Part 3 Institutional Review Board/Independent Ethics Committee

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.