Title: **Inclusion of Women and Minorities in Clinical Research**	*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:

The purpose of this policy is to provide guidelines for researchers at Beaumont Health regarding the inclusion of women and minorities in clinical research. **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:

This policy applies to investigators, research staff, key research personnel, Institutional Review Board (IRB) members and IRB staff.

III. BACKGROUND:

A. Clinical studies should be designed so the participant population is representative of the clinical population affected by the condition being studied. Demographic factors such as gender must be considered and included as appropriate. Beaumont research policies related to the inclusion of women, men, and minorities in clinical research are important both to ensure the benefits of research are shared and to prevent a disproportionate burden among the

groups. By including the appropriate participant population, the study findings will be valid and generalizable to the larger clinical population.

B. Federal regulation as described in the Civil Rights Act of 1964 makes it illegal to discriminate against individuals on the basis of gender or race. Thus, any automatic exclusion of women or minorities from research protocols without a compelling scientific rationale is discriminatory.

C. Food & Drug Administration (FDA) and Public Health Services/National Institutes of Health (PHS/NIH) guidelines: *FDA Research, Policy, and Workshops on Women in Clinical Trials* and *Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page* also address the inclusion of women and minorities in clinical research, requiring investigators to assess the theoretical and/or scientific links between sex/gender, race/ethnicity and their identified topic of study. A minority group is a readily identifiable subset of the U.S. population distinguished by racial, ethnic and/or cultural heritage. The categories of race and ethnicity recognized by the IRB mirror those used by the U.S. Office of Management and Budget. These include five categories for race: American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American and White, and two categories for ethnicity, "Hispanic or Latino" or "Not Hispanic or Latino."

IV. POLICY:

Researchers must actively recruit women and minorities into clinical trials to assure adequate representation with the potential to support valid data analysis based on gender, race or ethnicity, when appropriate. The investigator must determine how to actively recruit women and minorities, especially in Phase III trials. Outreach programs are recommended and cost is not an acceptable reason to exclude underrepresented groups.

Exclusion is permissible, when based solely on sound scientific rationale which clearly demonstrates inclusion is inappropriate with respect to the health of the participant or the purpose of the research (e.g., prostate studies).

A. **Inclusion of Women** - The IRB requires clinical research protocols include adequate representation of women. There should be approximately equal numbers of both sexes in populations at risk unless different proportions are appropriate for the given protocol due to documented prevalence, incidence, morbidity, mortality rates, or expected intervention

effect. Any exception must be described in the protocol and IRB application as part of the justification for any disproportionate representation of one gender over the other. The rationale must be scientifically based.

B. **Inclusion of Minorities -** The IRB requires clinical research protocols include adequate representation of minorities, including their sub-populations. The inclusion of minorities must be considered in all stages of research design. Special consideration should be placed on data collection from groups for whom knowledge gaps still exist, the disease or condition is disproportionately prevalent, or where the test article operates in a notably different manner. Investigators should be aware of concurrent research addressing specific minority populations as well as areas where it would be appropriate to study a single minority group.

From a practical perspective, there is a theoretical limit to the number of subgroups which can be studied in detail in any given protocol. The investigator should clearly address and justify the scientific rationale for the inclusion or exclusion of minorities and their subgroups in terms of the research objectives. In geographic locations where limited numbers of racial/ethnic populations are available, the investigator must address this issue in terms of the research purpose, study size, relevant characteristics of the disease, disorder, or condition being studied and feasible methods to include minority groups. The development of appropriate outreach plans is highly recommended.

When promotional material mentions Beaumont, references a Beaumont department (e.g., Cardiology Research) or physician, or provides a Beaumont phone number, Marketing approval is required. If the promotional material is targeted towards children, the marketing must be age appropriate for the study populations' understanding. Additionally, the requirements of *Clinical Research Study* Promotion IRB policy and *Compensation and Incentives Offered to Research Participants* IRB policy must be followed and prospective IRB approval in place, prior to use in a study.

V. PROCEDURE:

A. **IRB Review of Protocols -** Each protocol will be individually reviewed to determine if plans for inclusion of women and minorities are appropriate and/or adequate. The automatic exclusion of women or minorities without scientific justification will not be accepted. The IRB will ensure the investigator has provided a detailed explanation supporting their targeted enrollment plan. The IRB will evaluate the proposed plan for the inclusion of minorities and both genders for appropriate representation or assess the proposed justification

if representation is limited or absent. The IRB will also evaluate plans for recruitment/outreach for study participants.

At the time of Continuing Review, the enrollment of gender, race and ethnicity will be reported to the IRB on the Progress Report form. Inequitable distribution will require justification by the investigator. If the inequity cannot be justified, the investigator will be required to state what actions will be taken during future enrollment to address this issue.

VI. REFERENCES:

21 CFR 50.3 Definitions
45 CFR 102 Definitions
21 CFR 56.108 (b) IRB Functions and Operations
45 CFR 46.108(b) IRB Functions and Operations
45 CFR 46.111 Criteria for IRB Approval of Research
21 CFR 56.111 Criteria for IRB Approval of Research
Coded Private Information or Specimens Use in Research, Guidance

VII. ASSOCIATED POLICIES:

IRB Policy *Continuing Review and Renewal of a Protocol*
IRB Policy *Expedited Review of Research*
IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *Review by an External Institutional Review Board*
IRB Policy *Compensation and Incentives Offered to Research Participants*
IRB Policy *Clinical Research Study Promotion*
IRB Policy *Recruiting Human Participants for Clinical Research*

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.