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PURPOSE

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

SCOPE

This policy applies to investigators, key research personnel, Human Investigation Committee (HIC) members and HIC staff.

BACKGROUND

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. BH 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.

In addition to promoting sound scientific design, 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.

FDA and NIH guidelines (http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm131731.htm and http://grants.nih.gov/grants/funding/women_min/women_min.htm) 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. Based upon these guidelines, the investigator must determine how to actively recruit women and minorities into their clinical research to assure adequate representation and valid analyses of differences to occur, 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.

Clinical research, as defined by the NIH, is patient-oriented biomedical or behavioral research which involves human participants or material of human origin such as tissues, specimens, and cognitive phenomena. 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 HIC 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

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categories for ethnicity, "Hispanic or Latino" or "Not Hispanic or Latino."

POLICY

All 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, if appropriate.

Inclusion of Women

The HIC requires all 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 *HIC Application* as part of the justification for any disproportionate representation of one gender over the other. The rationale must be scientifically based.

Inclusion of Minorities

The HIC requires all 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.

PROCEDURE

HIC 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 HIC will ensure the investigator has provided a detailed explanation supporting their targeted enrollment plan. The HIC 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 HIC 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 HIC on the *Progress Report Form.* Inequitable distribution will require justification by the investigator. If

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the inequity cannot be justified, the investigator will be required to state what actions will be taken during future enrollment to address this issue.

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
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens
http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm

ASSOCIATED POLICIES

HIC Policy # 205 *Continuing Review of a Protocol*
HIC Policy # 213 *Expedited Review of Research*
HIC Policy # 216 *HIC Initial Reivew of Research*

☐ Original ☒ Revision or Review

Research Institute Compliance Committee Review Date: _____

Corporate Administration Approval: _____ Date: _____
V.P. of Research or Chief Medical Officer

Research Institute Board Approval: _____ Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director