

POLICIES/PROCEDURES

LONG BEACH MEMORIAL MEDICAL CENTER
MHVI - CENTER FOR WOMEN'S CARDIAC HEALTH
Department Specific Procedure

SUBJECT:

Women's Health Research Registry—Investigators Contact Procedures

PURPOSE:

The MHVI Women's Health Research Registry™, an MHS Research Council (IRB)-approved program, will provide research investigators the opportunity to recruit interested women from the community within their specific protocols and provide ease in enrollment for gender-specific research by allowing access to the Research Registry database.

SCOPE AND RESPONSIBILITY:

- A. Scope: All potential investigators whom approach the Research Registry with an approved Memorial Health Services, Institutional Review Board (IRB) protocol, whom wish to seek potential subjects for study enrollment, will abide by this policy.
- B. Responsibility: The Center for Women's Cardiac Health and Research administrative team.

PROCEDURE:

I. UTILIZING THE RESEARCH REGISTRY

- A. An investigator will request use of the research database by providing an MHS IRB approved research protocol. An internal review team will review the protocol for approval based on scientific merit, relevance and ethical propriety.
 - a. The team will be comprised of the Principal Investigators of the Research Registry, Drs. Peggy Kalowes RN, PhD, Jagat Narula, MD, FACC and an independent LBMMC investigator to be appointed on an annual basis.
 - i. Protocol review will take place once a month or as needed, based on the number of protocols received.
- B. After review and approval of the protocol, the research registry coordinator will utilize the inclusion/exclusion criteria of the protocol for key searches of the registry database. Contact will be initiated and maintained with the research study coordinator for answers to pertinent questions and for feedback.
- C. When the registry database has produced the results of the inquiry, the registry research coordinator will contact the names of the participants matched through the database.
 - a. A letter with the research investigator's information as well as the description of the study will be mailed to the participant.
 - b. A self-addressed, stamped envelope will be provided for the participants ease in replying.

- c. Each participant will have the option to accept or decline being approached for consent for participation in that particular study.
 - i. If participants have questions regarding the specific study, they may contact the MHVI Research Registry office for more information, or they may be referred to the study research coordinator.
- d. If the participant elects to be sent more information from the investigator regarding the research study, they may either call the research registry coordinator, or reply via the self-addressed stamped envelope provided.
 - i. If the participant decides to consider participation in the study, they will allow the Registry office to release their name, address and phone number to the principal investigator (PI) or investigator's designee (usually a co-investigator).
- e. A wait period of 2 weeks will be allowed for response from the selected participants. After this time, the research registry coordinator will phone the participants that have not responded by mail or phone, and ascertain their interest at that time. This contact and response will be documented.
- f. After all potential subjects have been contacted the research registry coordinator will contact the PI/or study coordinator and provide the names and contact information of the participants who have elected to consider participation in the study. Further contact with the study subjects will be through the PI/study coordinator of the specific protocol.
- g. The study PI will provide to the research registry the names of the subjects who have been **enrolled** or who were **ineligible** to participate in the study.
 - i. If a participant is enrolled in a research study, their database information will be placed on hold for the duration of the study period, so the participant will not be contacted during this time for other research opportunities.
 - ii. For those participants who were ineligible, or who chose not to participate in this study, their names will be released from hold status and they will again be available to database queries for other research studies, unless they decide to withdraw from the registry itself.

REFERENCES:

1. Smith Y, Johnson A, Newman L, Greene A, Johnson T, Rogers J. Perceptions of clinical research participation among African American women. *J Womens Health*. 2007;16.
2. Vidaver RM, Lafleur B, Tong C, Bradshaw R, SA. M. Women subjects in NIH-funded clinical research literature: Lack of progress in both representation and analysis by sex. *J Womens Health Gend Based Med*. 2000;9.

REVIEWED/APPROVED BY:

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| Department of Cardiology Committee | December, 2009 |
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