

Research Investigator Application for Use of the MHVI Women's Health Research Registry™

Overview

The Women's Health Research Registry™ was developed by the Center for Women's Cardiac Health and Research and supported by the Long Beach Memorial Medical Center Foundation to help facilitate women's health research. MHVI Women's Health Research Registry™ will assist in identifying women who are willing to consider participating in a research study or clinical research trials (CRTs). The Registry contains demographic, personal and family health history information obtained from the Health History Questionnaire completed by each woman either on-line or by paper version. This confidential data base is only accessible by the registry investigators and staff, who will conduct the queries for potential research studies.

Application Procedures

1. Complete the attached application for the Women's Health Research Registry™, assuring that all required fields are completed. If you need any assistance in completing the application, please feel free to contact the registry coordinator at (562) 933-2460.
 - i. NOTE: Investigators conducting feasibility queries of the database are not required to obtain IRB approval. Feasibility queries produce only the number of women meeting study eligibility criteria.
2. Submit the application and all required attachments to: MHVI, Women's Health Research Registry™, located at: Center for Women's Cardiac Health & Research, 2865 Atlantic Ave, Suite 210, Long Beach, CA 90806.
3. Each application will undergo review by the Internal Review Committee. This Committee meets once a month and a response will be made available within 24-48 hours of review.

NOTE: You are required to list the MHVI Women's Health Registry™ as a recruitment tool when applying for IRB approval. If this was not done, please submit an amendment to the IRB application indicating that the Registry will be utilized.

Use of Information

Contact information for the registry participants that have matched eligibility criteria for a study will be provided to the investigator AFTER the participant has been contacted by the MHVI Women's Health Research Registry™ staff, and has agreed to receive additional information from you or your study coordinator regarding the study.

All investigators receiving contact information of matched registry participants will provide to the Registry a participant enrollment list every 2 weeks until the end of the study. This information is necessary in order to document the women participating in studies and to track the frequency of contact for all women in the Registry.

IMPORTANT NOTE: Patient contact information provided by the Registry **must not be retained for use** in another study, and should be destroyed following completion of patient recruitment. The Principal Investigator of the study is responsible for any misuse of these data. Inappropriate use of these data will result in suspension of Registry privileges.

Application for Use of the MHVI Women's Health Research Registry™

I. Applicant Information

Principal Investigator

Last Name:		First Name:	
Academic/Faculty Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:		Email:

Principal Investigator

Last Name:		First Name:	
Academic/Faculty Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:		Email:

Co-Investigator

Last Name:		First Name:	
Academic/Faculty Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:		Email:

Co-Investigator

Last Name:		First Name:	
Academic/Faculty Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:		Email:

Co-Investigator

Last Name:		First Name:	
Academic/Faculty Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:	Email:	

Co-Investigator

Last Name:		First Name:	
Academic/Faculty Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:	Email:	

Study or Recruitment Coordinator

Last Name:		First Name:	
Title:		Department:	
Sponsoring Company/Organization:			
Address:		City/State:	Zip Code:
Phone:	Fax:	Email:	

II. Statement of Understanding / Data Use Agreement

The MHVI Women's Health Registry™ is comprised of women consenting to be contacted for participation in clinical research studies. A woman's inclusion in the Registry does not obligate her to enroll in a clinical study, nor does it constitute her informed consent to a review of any other patient identifiable information held by MHS MemorialCare or Long Beach Memorial Medical Center on her behalf, including, but not limited to, her medical record. Study-specific IRB approved informed consent must be obtained from all women meeting eligibility criteria in order to participate in any clinical study.

Data obtained from the Registry may be used only for the purposes stated in this application and its accompanying IRB approval. Patient contact information

provided by the Registry must not be retained for use in another study, and should be destroyed or returned to the Registry following completion of patient recruitment. The Principal Investigator of this study is responsible for any misuse of these data. Inappropriate use of these data will result in suspension of Registry privileges and notification of the MHS IRB.

I understand and agree to abide by these statements.

Principal Investigator (printed) Signature Date

Principal Investigator (printed) Signature Date

III. Proposal History

1. Title of Proposal:			
Provide brief statement about the purpose, significance and relevance to women's health (50-75 words)			
2. Type of Study:	Clinical Trial: (describe)	Investigator Initiated:	Industry Initiated:
	Survey:	Outcomes Research:	Multi-Center:
3. Characteristics:			
Duration of Study: (mo's or yrs)		Duration of subject participation: (mo's or yrs)	
Expected Enrollment period: (mo/yr-mo/yrs) _____/_____-_____/_____		Total number of subjects by gender:	Male:_____ Female:_____
Source of Funding:		NIH:	
Study Sponsor:			
Expected completion date of Study:(mo/yr-mo/yrs) _____/_____-_____/_____		Number of subjects Desired from Registry: _____	
4. IRB Approval:	Yes	Date:	IRB Project #:
5. The following must be attached:			
<input type="checkbox"/> IRB application		<input type="checkbox"/> IRB Approval letter	

Please attach the following separately:

IV. Proposal Narrative

1. Abstract (250-400 words)

Briefly summarize the objectives and study design.

2. Specific Aims

Briefly outline what the research intends to accomplish. The objectives should be stated as clearly identifiable hypotheses.

3. Protocol synopsis

Two page synopsis outline of the methodology

V. Inclusion/Exclusion Criteria

Identify the parameters for the query of the Registry database. Please use the MHVI Women's Health Registry™ Investigator Query Form to specify up to 3 inclusion/exclusion criteria.