Protocol Language Example

Sample Description

We propose to perform this study on 10 TAAD cases and 10 age, sex and ancestry-matched healthy controls from the Cardiovascular Health Improvement Project (CHIP) biorepository (PI, Cristen Willer). Recently, phenotypic information, family history, DNA, plasma, serum and aortic tissue samples (when available, ~10%) from > 1,500 individuals with aortic aneurysm treated at the University of Michigan Frankel cardiovascular Center have been collected for the CHIP biorepository. We will select TAAD cases based on the following inclusion criteria: i.aortic tissue available, ii. European ancestry, iii.the onset of aneurysm or dissection was prior to age 59, iv. the research subject has a first degree relative with aortic disease.

Boilerplate Language for Grants, Manuscripts, and IRB applications

Cardiovascular Health Improvement Project (CHIP) Biorepository

The goal of the University of Michigan Cardiovascular Health Improvement Project (CHIP) is to create a world-class biorepository aiming to elucidate genetic and environmental causes of cardiovascular disease through the collection of DNA, plasma, serum, clinical and family history information, and lifestyle outcomes.

CHIP Summary

CHIP is a biorepository of DNA, plasma, serum, and aortic tissue samples as well as an extensive clinical database of medical and family history information. CHIP biorepository is an institutional resource serving as a catalyst for scientific discovery with the amassed biospecimens and clinical information.

The CHIP biorepository is led by Dr. Cristen Willer (Principal Investigator) and Dr. Whitney Hornsby (Project Manager) in close collaboration with CHIP directors Dr. Jonathan Eliason and Dr. Himanshu Patel. Governance is provided by the CHIP Steering, Access and Medical Findings committees.

The CHIP team presently occupies space at the Frankel Cardiovascular Center and in the Biomedical Science Research Building on the University of Michigan Medical Campus. All CHIP samples are stored at the University of Michigan Central Biorepository (CBR). The CBR provides a world-class, accredited, standardized, safe and monitored environment for the

processing, storage and distribution of high-quality biospecimens with associated clinical and laboratory data.

Confidentiality of all subject data is key for the CHIP Biorepository. All data is de-identified and indirectly linked with a master list. The master list is maintained by a data broker and has controlled access. Individuals without access to the master list do not have the capability to access the patient's identifiable information.

CHIP Services

Plasma and serum is processed from whole blood at the University of Michigan, Michigan Clinical Research Unit (MCRU).

DNA is isolated from whole blood at the University of Michigan, Michigan Central Biorepository (CBR).

Samples are stored at the University of Michigan Central Biorepository (CBR), which provides a world-class, accredited, standardized, safe and monitored environment for the processing, storage and distribution of high-quality biospecimens annotated with detailed clinical and laboratory data. (freezers, alarms, and DNA isolation equipment is also available)

Sample Inventory monitoring and tracking of sample chain of custody is achieved through the use of a dedicated Laboratory Information Management System (LIMS) called LabVantage

GWAS genotyping

Genotyping was performed on a combined set of 498,075 genome-wide association scan (GWAS) variants, including 217,957 protein-altering variants, using a GWAS+exome chip array (Illumina Human CoreExome).

Methods

We [collected / utilized] [plasma, serum, or DNA] from consented individuals with [disease] from the Frankel Cardiovascular Center at the University of Michigan as part of the University of Michigan Cardiovascular Health Improvement Project (CHIP). Patients were typically seen for [specify cardiovascular disease]. Diagnoses were made by [cardiac surgeons, cardiologist, vascular surgeon] upon [specify mode of diagnosis]. Exclusion criteria included [list criteria]. [DNA] was isolated from peripheral blood lymphocytes.

Acknowledgements

We thank all participants and the collection team of the Cardiovascular Health Improvement Project (CHIP) at the University of Michigan. The collection of samples for University of Michigan Health System – Cardiovascular Health Improvement Project was supported by the Frankel Cardiovascular Center. We appreciate the Aikens Fund for Aortic Research and McKay research award for supporting this project.

CHIP Recruitment and Enrollment Procedures

Eligible subjects for the CHIP study include any patient over the age of 18 willing to give informed consent (or assent and parental consent for patients under the age of 18) with any valve disorder, Marfan's syndrom, Aortic Valve Regurgitation, Aortic Valve Stenosis, Aortic Dissection, Bicuspid Aortic Valve or Abdominal Aortic Aneurysm or other cardiovascular conditions.

CHIP subjects are recruited from the UMHS.

For subjects recruited prior to a planned surgical procedure or from the clinic,the potential subject is greeted by the biobank clinical research coordinator and/or research assistant after they have completed registration activities for their clinical visit or procedure. The purpose of the study is explained and the consent form is explained. Any questions that the potential subject has are thoroughly answered. Several levels of participation are offered:

1. Consent to use information provided in their medical questionnaitre for IRB-approved future researh studies
2. Consent to permit collection of a blood sample for use in IRB-approved future research studies
3. Consent for storage of excess tissue specimens that would normally be discarded during a surgical procedure
4. Consent to contact the subject to gauge interest and potentially to invite for participation in additional studies for which they may qualify based on their health profile

Enrollment into the registry is open-ended and all identified eligible individuals will be offered participation. Potential subjects are excluded only if they are not willing or able to sign informed consent.

CHIP Participation Overview

Since project launch in August 2013, CHIP has amassed over 2000 and over 300 tissue samples. Sample demographics stratified by Disease type, Age, Gender, Race, Ethnicity, Geographic area are available upon request because this will always be changing weekly.

Clinical data, including a study specific 4-question physical exam, is collected upon enrollment and then annually by chart review or by collection via IPAD application (on a password protected device) and kept in a password protected database accessible only to authorized individuals. Electronic files are backed up onto encrypted password protected hard drives to ensure safe and confidential handling of all data. Signed informed consents and source documents are maintained in a binder in a locked cabinet within a locked office. The subject is linked to the CHIP study in their medical record so that providers and staff may identify which studies the subject has agreed to participate in. A subject specific study identification number (CHIP ID) is created and written on each page of the informed consent.