Subject Identification

"Short" Tissue Repository Version Date: January 2015

Protocol Title: The Cardiovascular Biorepository (CVBio) in collaboration with the Partners HealthCare Biobank (Partners Biobank)

Principal Investigator: Christopher Newton-Cheh, MD, MPH

Site Principal Investigator: same

Description of Subject Population: Individuals seen at Massachusetts General Hospital and the MGH Heart Center

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

We are asking you to participate in two related projects:

- 1) The Cardiovascular Biorepository or "CVBio"
- 2) Partners HealthCare Biobank or the "Partners Biobank"

Researchers at Partners HealthCare System (Brigham & Women's Hospital, Massachusetts General Hospital, and other Partners institutions) are studying how genes and other factors affect people's health and contribute to human disease, such as heart and vascular disease, stroke, and other health conditions. To perform this research, we are asking Partners patients to allow us to store their health information and biological samples in the Partners Biobank and the Institute Biorepository.

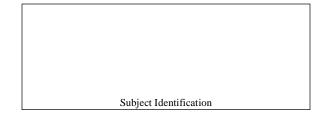
Taking part in these biorepositories is up to you. Your decision to participate will not affect your clinical care in any way. Your participation can help us better understand, treat, and even prevent diseases that affect your loved ones, your family's future generations, and the larger community.

Collection of Samples and Health Information for Research

1. What is the purpose of this research?

The purpose of this research tissue bank is to collect, process, and store blood until researchers need them to do research. Tissue samples in this bank will be used mainly for research on how genes and other factors affect people's health and contribute to human disease, such as heart and

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other health conditions. There is also an attached "Fact Sheet" that expands on the consent form to provide definitions and additional information.

Taking part in this research study is up to you. Your decision won't change the medical care you receive within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

If you have any questions before you sign this consent form or after you join the study, you can contact the CVBio staff at 617-643-1699 from Monday - Friday 9 am – 5pm. The person in charge of the tissue bank is Christopher Newton–Cheh, MD, MPH. Or you can contact the Partners Biobank staff at 617-525-6700 from Monday - Friday 9a – 5p. The person in charge of the Partners HealthCare Biobank is Scott T. Weiss, MD.

If you want to speak with someone **not** directly involved in the study, contact the Partners Human Research Committee at 617-424-4100. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

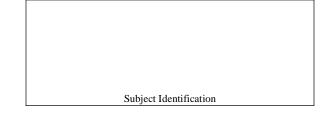
2. What will happen in this study?

- We will draw a blood sample from you, about 3 tablespoons
- We may also use blood, urine or tissue samples collected as part of your clinical care now or in the future that would otherwise be thrown away.
- We will also look at your medical records now and in the future to update your health information. We will store some of your health information in the study database.
- We may ask you to complete questionnaires about your health.
- We may contact you via telephone to get follow-up information in the study database.
- We may contact you in the future to get additional information and ask if you are interested in joining other research studies.

3. For what type of research will my samples be used?

- We may create a "cell line" from your sample that will allow researchers to have an unlimited supply of your cells for future research.
- We may use your cells to create pluripotent stem cells. This type of cell can be used to create different types of tissue, for example, heart, muscle, or lung cells. Your cells might be used in research that alters genes in the cells in order to study different diseases and normal

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healthy processes. Your cells might be mixed with other human cells, animal cells, or grown in lab animals like mice.

- We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links between various factors of health and disease.
- We may share your samples and any cell lines that are created, your DNA sequence
 information, your health information, and results from research with other central tissue or
 data banks, such as those sponsored by the National Institutes of Health, so that researchers
 from around the world can use them to study many conditions. The samples and data will be
 sent with only your code number attached, not your name.
- It is not possible to list every research project. Also, we cannot predict all of the research questions that will be important over the next years.

4. Will I get results of research done using my samples?

- Generally, we will not return individual results from research using your samples and
 data to you or your doctor. Research using your sample is just a stepping stone in
 learning about health and disease. Most of the findings that come from studying your
 sample will not be relevant to your personal health. However, in the future, this may
 change.
- It is important to remember that research results are not always meaningful and are not the same as clinical tests. While you should not expect to receive any results from your participation in this research, if experts from the Bank decide that research results from your sample are of high medical importance, we will attempt to contact you. In some situations, follow up testing might be needed in a certified clinical lab. You and your medical insurer may be responsible for the costs of these tests and any follow up care, including deductibles and co-payments.
- It is possible that you will never be contacted with individual research results. This does not mean that you don't have or won't develop an important health problem.
- In the future, when research results are published, they may show that certain groups (for example, racial, ethnic, or men/women) have genes that are associated with increased risk of a disease. If this happens, you or others may learn that you are at increased risk of developing a disease or condition.

5. What are the benefits to me? Will I be paid for my samples?

You will not directly benefit from research conducted on your samples stored in the tissue bank. We hope that research using the samples and information will help us understand, prevent, treat, or cure diseases.

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You will not receive payment for your samples.

6. What are the costs to me to take part in the research tissue bank?

There are no costs to you to participate in this tissue bank.

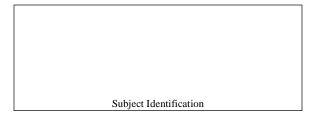
7. How are my samples and health information stored in the bank?

Staff at the bank will assign a code number to your samples and health information. Your name, medical record number, or other information that easily identifies you will not be stored with your samples or health information. The key to the code that connects your name to your samples and information will be stored securely in a separate file.

8. Which researchers can use my samples and what information about me can they have?

- Your coded samples and health information may be shared with researchers at Partners institutions. They may also be shared with researchers at non-Partners institutions or with for-profit companies that are working with Partners researchers. Your samples will not be sold for profit. We may use your samples and information to develop a new product or medical test to be sold. The hospital and researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.
- We will only share information that identifies you with researchers within Partners who
 have approval of the Partners ethics board. We will not share information that identifies
 you with researchers outside Partners.
- In order to allow researchers to share research results, agencies such as the National Institutes of Health (NIH) have developed secure banks that collect and store research samples and/or data from genetic studies. These central banks may store samples and results from research done using CVBio and Partners BioBank samples and health information. The central banks may share these samples or information with other qualified and approved researchers to do more studies. Results or samples given to the central banks will not contain information that directly identifies you. There are many safeguards in place at these banks to protect your privacy.
- As part of your participation in the study, a unique subject number will be assigned to you that will allow researchers to see if you have been involved in more than one research study or database for patients with heart disease. If you have participated in more than one study or database, this unique subject number will help connect

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information across studies. This subject number will also allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number and not your personal identifiable information will be accessible to other investigators. This unique subject number may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you.

9. How long will the bank keep my samples and information?

We will store your samples and information indefinitely.

10. Can I stop allowing my samples and information to be stored and used for research?

Yes. You can withdraw your permission at any time. If you do, your samples and your information will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers. If you decide to withdraw please contact the tissue bank staff in writing.

Partners HealthCare Biobank	Phone: 617-525-6700
422-EBRC, 221 Longwood Ave.	FAX: 617-264-6898
Boston, MA 02115	Email: biorepository@partners.org

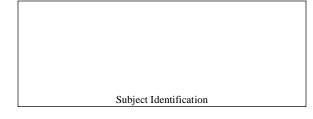
You may also contact CVBio to withdraw your permission:

Cardiovascular Biorepository	Office: 617-643-1699
Research Study Staff	Fax: 617-643-9303
32 Fruit Street, Yawkey 5-800	Email: CVBIO@partners.org
Massachusetts General Hospital	
Boston, MA 02114	

11. What are the risks to me?

- The main risk of allowing us to use your samples and health information for research is a potential loss of privacy. We protect your privacy by coding your samples and health information.
- There is a risk that information about taking part in genetic research may influence insurance companies and/or employers regarding your health.

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- We do not think that there will be further risks to your privacy by sharing your samples and/or whole genome information with other researchers; however we cannot predict how genetic information could be used in the future.
- There is a very small risk of bruising, infection, or fainting from drawing blood.

12. If I take part in the bank, how will you protect my privacy?

In general, health information that identifies you is private under federal law. However, you should know that in addition to Partners researchers the following people or groups may be able to see, use, and share your identifiable health information from the research and why they may need to do so:

- Any sponsor(s) of this bank and the people or groups it hires to help with the bank
- The Partners ethics board that oversees the project and the Partners research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)

We share your identifiable health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

You have the right <u>not</u> to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

Informed Consent and Authorization for Collection of Samples and Health Information for Research

Statement of Person Giving Informed Consent and Authorization

I have read this consent form.

Sponsor Amendment No: N/A

Partners HealthCare System Research Consent Form Subject Identification "Short" Tissue Repository **Version Date: January 2015** This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study. I have had the opportunity to ask questions. I understand the information given to me. **Signature of Subject:** I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above. Subject Date Time (optional) **Signature of Study Doctor or Person Obtaining Consent: Statement of Study Doctor or Person Obtaining Consent** • I have explained the research to the study subject. • I have answered all questions about this research study to the best of my ability. Study Doctor or Person Obtaining Consent Time (optional) Date Signature of Guardian or Authorized Representative for Adult: I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above. Print Name (check applicable box below) Court-appointed Guardian Health Care Proxy **Durable Power of Attorney**

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Family Member/Next-of-Kin

Partners HealthCare System Research Consent Form	
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Signature	Date/Time
Relationship to Subject:	
Consent of Non-English Speaking Subjects Usin Spoken Language	ng the "Short Form" in the Subject's
Statement of Hospital Medical Interpreter	
As someone who understands both English and the in the subject's language, the researcher's presentat was given the opportunity to ask questions.	
Hospital Medical Interpreter	Date/Time
OR	
Statement of Other Individual (Non-Interprete	r)
As someone who understands both English and the that the English version of the consent form was prown language, and that the subject was given the consent form was prown language.	resented orally to the subject in the subject's
Name	Date/Time

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