

	<p>Human Research Protection Program Institutional Review Board</p> <p>Maine Medical Center BioBank Authorization to Participate in a Research Project and Permission to use or Release Protected Health Information (PHI)</p>	
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PROJECT TITLE: Maine Medical Center BioBank

PROTOCOL NUMBER: 2526

CONSENT VERSION DATE: July 31, 2014

HOSPITAL OR INSTITUTION: Maine Medical Center

INVESTIGATOR: Anne C. Breggia, Ph.D., Director, Maine Medical Center BioBank

CO-INVESTIGATOR: Michael A. Jones, M.D., Chief, MMC Pathology Department

SUBJECT'S NAME (printed): _____

The Maine Medical Center BioBank (MMC BioBank) would like to be able to store excess tissue removed during your clinical care along with some of your health information. The tissue samples would then be available for researchers to use in scientific research to learn about various health problems.

You can decide to take part in this storage program or not. This consent form gives information to help you decide. Please read it carefully and take all the time you need to make your choice. Be sure to ask as many questions as you want. Everyone who takes part in research should know that:

- Taking part is voluntary. If you choose to take part, you can quit at any time.
- No matter what you decide, now or in the future, it will not affect your medical care.
- Taking part may involve some risks as described on page 3.

WHAT IS THE PURPOSE OF THIS PROGRAM?

The purpose of this program is to collect tissue samples, other bodily fluid samples (blood, urine, sputum, etc.) and health information from many people. These samples and information will be stored so they can be used for research now and in the future. Researchers who would use your tissue samples and health information are trying to learn about various health problems. Some of these studies may be about how genes affect health and disease, or how genes affect response to treatment. Some of them may lead to new products, such as drugs or tests for diseases. Through these studies, researchers hope to find new ways to detect, treat and maybe prevent or cure health problems. Researchers can do more powerful studies when they share information with each other. They share this information with each other by putting this information in scientific

databases. There is no limit on the length of time the MMC BioBank and associated researchers will store and use your samples and information. They may keep using your tissue for research indefinitely unless you decide to withdraw from (leave) the program. How to withdraw from the program will be explained later in this form.

WHAT IS INVOLVED?

Your signature on this form means that you have received the information about this program and that you are giving Maine Medical Center permission to:

1. Collect and store de-identified excess tissue and body fluids that would normally be discarded for use in research:
Some tissue may be removed from your body during a procedure that is needed for your clinical care. After your care is complete, there may be some tissue and body fluids (urine, sputum, etc) left over. The tissue and body fluids could be discarded or destroyed because they are not necessary for your care; or you may choose to let them be used for research. Your care is the first priority and your doctor will not take more tissue than what would normally be taken for your care. Sometimes left over specimens are stored in the laboratory prior to being discarded. Your permission would include use of any specimens that may be in the laboratory related to a past surgical procedure.
2. Collect and store de-identified information about you and your health for use in research:
The MMC BioBank may collect basic information such as your name, age, sex, and race or ethnic group, or family history. They may also collect information from your medical record that is related to your health and/or disease history. Some examples include results of tests, medical procedures, images (such as X-rays), and medications you take. They will look at your medical record from time to time to update this information. This will take place for as long as your sample is stored in the MMC BioBank, which may be years, unless you tell us you no longer wish to participate in the MMC BioBank program. **Information that could directly identify you, such as your name, birth date, or social security number are removed and never sent to researchers.**
3. Allow researchers to use the materials and health information stored in the MMC BioBank for approved studies:
Researchers from Maine Medical Center, other institutions, the government, and commercial, drug- or health-related companies can apply to use the materials.
4. Send some of your de-identified genetic and health information to scientific databases:
Your information, along with that from many other people may be compiled in scientific databases, including internet-connected electronic databases with restricted public access. **Information that could directly identify you will never be included.**
5. Collect and store blood: Researchers may need blood (up to 40 milliliters, approximately two and a half tablespoons) to be drawn specifically for the MMC BioBank to be used in future research. Please be aware that you can participate in the BioBank Program even if you refuse to allow blood to be drawn.



WHAT ARE THE POSSIBLE BENEFITS?

There will be no direct benefit to you, financial or otherwise, for participating in this program. By participating, you may help researchers make discoveries that might help people in the future.

WHAT ARE THE POSSIBLE RISKS?

There is no discomfort to you as a result of storing leftover tissue. If a blood sample is collected, you may feel brief pain or have some bruising from the needle. There is also a small risk of infection, light-headedness, and fainting.

Although the MMC BioBank will take many measures to protect your personal information, there is a small risk that someone could get access to the data stored about you. There are laws against the misuse of genetic information, but they may not give full protection. The MMC BioBank believes the chance these things will happen is very small, but cannot be 100% guaranteed.

HOW WILL THE MMC BIOBANK RESPECT MY PRIVACY AND CONFIDENTIALITY?

Your privacy is very important to us and the MMC BioBank will make every effort to protect it. Here are just a few of the important steps they will take:

- Your samples will be stored in locked freezers in a secured building and information about you and your samples will be stored in a secure database, on computers that have restricted access and many additional layers of protection.
- Your name and other identifiers will be removed from both your sample and from your personal information and replaced with a unique coded number. Only a few people at Maine Medical Center will be able to link this code to your name. The link between this code and your name will also be stored on a secure, password-protected computer (and/or a locked file cabinet) at Maine Medical Center.
- Research records are separate from medical records. The MMC BioBank will not place any information from this program in your medical record.
- Researchers who study your sample will not know who you are. The MMC BioBank will give researchers only the unique code number and will not give them any information that directly identifies you. Your name will not be used in any publication resulting from studies done on your tissue or in any publication related to the MMC BioBank.
- The MMC BioBank will not give your information to anyone, except if required by law. To further protect your privacy, they have obtained a Certificate of Confidentiality from the National Institutes of Health. Information that is shared outside of Maine Medical Center may no longer be protected by the federal privacy law called "HIPAA", however, it will be protected as described in this form and potentially by other privacy laws.

WHO WILL USE THE SAMPLES AND INFORMATION IN THE BIOBANK?

The samples and health information collected and stored at Maine Medical Center may be made available to researchers at Maine Medical Center, other medical centers, universities, or other academic or commercial companies doing research in the United States or around the world.

Researchers will need to obtain approval to use samples and information from the MMC BioBank. Researchers will also have to obtain approval from the Institutional Review Board (IRB). The IRB is a group of people who are responsible for ensuring that any risks are minimized and that your rights and welfare are protected at all times.

HOW WILL MY SAMPLES AND INFORMATION BE USED?

Researchers will use your samples and information to study various diseases such as cancer, diabetes, and other health issues now and in the future.

Some examples of what scientific researchers may use the samples and information for include:

- Genetic research: this allows researchers to look at some or all of your genetic traits. Studying genes along with health information will help us to better understand what causes certain diseases.
- Animal research. The growth of cells in live animals may be very helpful in understanding human disease.
- To create a cell line: This means that they would treat the cells from your sample in a way that allows the cells to grow in a laboratory. This is done so that researchers can have an unlimited supply of cells for research for a long time, maybe forever.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance company for your participation. You will not be paid for your participation. If research leads to the development of commercial products such as new tests or drugs, you will not share in any profits. In the unlikely event that you become injured as a result of taking part in the MMC Biobank program, no reimbursement, compensation, or free medical care is offered by Maine Medical Center or the academic and commercial institutes that receive your tissues and information for research.

WILL I FIND OUT ANY OF THE RESULTS OF THIS PROGRAM?

You, your family, and your personal healthcare providers will not receive personal or aggregate results from research done using your samples.

WHAT ARE MY OPTIONS?

Taking part in the MMC BioBank is your choice. You can choose to take part or not take part.

WHAT IF I CHANGE MY MIND?

If you leave the program, and do not wish to have any more of your personal data collected, you must notify us in writing. You may also call the MMC BioBank at telephone number (207) 662-3515 and your request to stop collecting information will be honored, but you must also notify us in writing.



To notify us in writing, send your request to:

Anne C. Breggia, PhD, Program Director
Maine Medical Center BioBank
Attn: Laurie Hibbard
22 Bramhall St., G6152
Portland, ME 04102

If there are any samples remaining from your surgery that have not been distributed for use they will be discarded. Likewise, any medical information that has been collected will be discarded. Since your name is not linked to samples and related medical information sent to researchers, you will no longer be able to withdraw them once they have been distributed.

PERMISSION TO USE OR RELEASE IDENTIFIABLE HEALTH INFORMATION
FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this program without your written permission. If you sign this form, it will provide that permission. This section of the consent document is intended to inform you about how your health information will be used or disclosed in this program. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law.

WHY AM I BEING ASKED TO RELEASE THIS INFORMATION?

As part of this program, you are being asked to allow the MMC BioBank to collect health information about yourself. This information will be collected, entered into the MMC BioBank database and shared with investigators who are trying to learn more about various health problems.

WHAT AM I BEING ASKED TO RELEASE?

For this program, the following information may be collected:

- Your past medical history
- Your family background
- Your weight, blood pressure, temperature and the results of your physical examination from each visit
- All medication you are currently taking
- All past surgeries
- Summaries of your past hospitalizations
- Laboratory and pathology reports

WHO WILL SEE THIS INFORMATION?

Study data and medical records may be reviewed, monitored or audited at the study site by the study sponsor, its agent, independent ethics committees, the Maine Medical Center Institutional Review Board (IRB), personnel from the Office of Human Research Protection or appropriate regulatory and government agencies. Representatives from these groups may need to look at your medical records to ensure that the data on the study forms is correct or that the study was



conducted properly. This type of review will take place at the study site where the medical records are stored. The information collected is the property of investigator, and you will not be able to get it back. In the event of any publication regarding this program, your identity will not be disclosed (made known). Your research program information, which does not personally identify you, and which is sent to a researcher might be further disclosed to others. If disclosed by them, the information is no longer covered by the federal privacy regulations.

WILL THE INFORMATION COLLECTED AS PART OF THIS PROGRAM BE DESTROYED WHEN IT IS NO LONGER NEEDED?

It is difficult for investigator to know how long your information will be kept at least until the end of the research program, but most likely it will be stored in a database at a researcher's office for an indefinite (unknown) length of time. We do not know when your information will no longer be used, and there is no expiration date after which it will be discarded (thrown out).

WHAT IF I DO NOT AUTHORIZE YOU TO COLLECT AND RELEASE MY HEALTH INFORMATION?

If you agree to be in have your specimens banked, you are authorizing the release of your health information as well. If you do not want to release your health information, you may not take part in banking your specimens for future research.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about your rights as a research participant, contact the Maine Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 396-8183.



I have read, or have had read to me, the above information before signing this consent form. I agree to participate in this research program. I also authorize use or disclosure of my personal health information for the purpose of future research. I have been offered ample opportunity to ask questions and have received answers that fully satisfy those questions.

I agree to provide my excess tissue, body fluids (urine, sputum, etc.) and medical information.

Yes No _____ **Initial**

I agree to provide up to 40 milliliters of blood.

Yes No _____ **Initial**

Signature of Patient or Authorized Representative

Date/24 hour time

Printed Name of Patient or Authorized Representative

Signature of the Person Obtaining Consent

Date/24 hour time

Signature of Witness

Date/24 hour time

Witness to Consent of Subjects Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation (check one box as applicable):

Making his/her mark above

Other means _____
(fill in above)

Witness for adults unable to read or write

Date 24 hour time



Child's Assent

This research study has been explained to me, including the 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 and my questions have been answered. I agree to take part in this research study. I know that I do not have to be in this study, being in this study is up to me and my researcher won't be mad at me if I don't join. I can change my mind later and stop being in the study. My researcher, parent or guardian may take me out of the study at any time.

Signature of Subject (child)

Date 24 hour time

Printed Name of Subject (child)

If the patient is too young, the patient refuses to sign, or the provider/parent/guardian/s request that the child not sign, indicate the reason:

Parent(s)/Guardian(s) giving permission for the child's participation.

Parent(s) Signature

Date 24 hour time

Parent(s) Signature

Date 24 hour time

Person Obtaining Consent (required section for all studies)

Study representative statement

I have fully explained in terms understandable to the subject all of the following: the purpose of this research, the study procedures, the possible risks and discomforts and the possible benefits. I have answered all of the subjects and his/her authorized representative(s) question to the best of my ability. I will inform the subject of any changes in the procedure or the risks and benefits if any should occur during or after the course of the study.

Signature of the Person Obtaining Consent

Date 24 hour time

Printed Name of the Person Obtaining Consent

A signed copy of this consent form must be given to each subject entering the study.