

Partners HealthCare System Research Consent Form

Subject Identification

Research Tissue Bank
Version Date: July 2009

Protocol Title: Saliva sample collection in GUTS

Principal Investigator: S. Bryn Austin, ScD

Site Principal Investigator:

Description of Subject Population: GUTS participants

Collection of Samples and Health Information for Research

About this consent form

Please read this form carefully. It tells you important information about the collection and storage of tissue samples for research. A member of our research team will be available by phone to answer any questions you have about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form. If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to give your permission. You should keep one copy of this form and return the signed copy with the rest of your package.

What is the purpose of this research tissue bank?

We are asking you to participate in this tissue bank because you are a participant in the Growing Up Today Study (GUTS). The purpose of this research tissue bank is to collect, process, and store samples until researchers need them to do research. Tissue samples in this bank will be used for research on the effects of stress on health and hormones, such as the effect of early violence and gender differences on hormone levels. We are also collecting DNA for future use in genetic studies of health and disease. Research tissue banks collect and store many types of samples, such as blood, urine or other bodily material.

Our research tissue bank is located at Channing Laboratory, Brigham and Women’s Hospital, Boston, MA. There is no set limit to the number of individuals who provide samples to this bank. The more samples and health information that we can collect, the more useful the tissue bank will be for research.

The National Institute of Health (NIH) is paying to have your samples processed and stored in this tissue bank.

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What will I have to do to give samples to the tissue bank?

As part of this research we will collect saliva samples from you by mail. The instructions on how to collect these samples are enclosed with this form along with a brief questionnaire that you should fill out if you decide to participate. Briefly, there are several tubes enclosed in this package: if you decide to participate you should follow the enclosed instructions describing how and when to spit into these tubes. Also you will fill out the enclosed forms with the specific information about your sample collection. If you decide to participate you will collect these samples over the course of one day.

If you agree, the samples will be frozen and sent to the bank. We are using an alias or fake ID number on all supplies for this project. Once the GUTS specimen bank receives the samples, we will link them to your original ID for conducting scientific research. Some samples will be used to measure hormones including cortisol, dehydroepiandrosterone (DHEA) and alpha amylase in your saliva over the course of one day. These samples will also be used in future research to assess hormones, other biomarkers, and genetic patterns potentially related to risk of cancer, cardiovascular disease, and other diseases. As always, an annual GUTS newsletter will be mailed to you, which will include general information about results. No individual information will be provided to you or reported in the newsletter or any other publication.

The other sample you collect will be used to collect your DNA from cells in the saliva. We are also asking for your permission to store some of your health information that we have collected as part of your participation in GUTS with your samples so that your samples will be more useful for research.

We would also like your permission for the tissue bank staff to contact you in the future. This could be by phone to get updated information about your medical condition(s) or health status.

How are my samples stored?

Staff at the bank will assign your sample a code number and store it in a freezer. They will not keep your name or other information that could identify you with your sample. They will use the code number to connect your sample to your health information that is stored in a computer database. The computer database is protected with a password. Only selected staff at the bank will know the password.

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

Your samples will be made available to researchers at HSPH and BWH and our academic collaborators. Very occasionally, your samples may be shared with for profit companies that are working with MGH, BWH or other Partners researchers on a specific research project. Your samples will not be sold to anyone either for profit or not for profit.

When providing samples to researchers, the specimen bank will provide limited information such that you cannot be identified (for example, your age in five year categories and year of diagnosis). All projects will be approved by the specimen bank's advisory board, which includes the Principal Investigator of this study and of the Growing Up Today Study.

- As described above, all of the samples stored in the bank are labeled with a code number that connects the sample to medical information related to the sample. The key to the code that links the samples and information to a specific individual will only be available to the tissue bank staff, and will be securely stored. Information from questionnaires that you or your mother filled out for the GUTS study will be linked to your specimen by this code. In addition, all studies using the specimen bank must have been approved by the hospital ethics board as well as by the specimen bank advisory board. The ethics board is a group that independently reviews and watches over all research studies involving people. The board follows state and federal laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected
- Researchers outside of HSPH and BWH will never be given the key to the code that links your sample and medical information to your name or other identifiers.

For what type of research will my samples be used?

Your samples and information will be used to find out how stress influences hormone levels and health. Specifically, we will examine the effect of early violence and gender differences on hormone levels. The genetics samples will be stored for future research on health and disease. 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. As we learn more, new types of research and new research questions related to stress and health may be done.

We plan to do genetic research on the DNA in your tissue sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain

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the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

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 to many diseases or conditions. These data will be carefully protected and no identifying information will be linked with genetic data. We may use these DNA samples to see if certain genes are associated with increased risk for diseases like cancer, obesity and other conditions.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other identifiable information will never be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease, which could include conditions such as HIV/AIDS, cancer, asthma, mental illness, and others.

Any information we send to this database is completely devoid of any personal identifiers (e.g., your date of birth, address, or zip code). NIH also restricts access only to qualified researchers who can show an appropriate scientific use for the data, and who commit to maintaining the confidentiality of the de-identified data. If you have questions about these NIH/GWAS studies, or wish to withdraw from them in future, please write to us at GUTS NIH/GWAS Studies, 181 Longwood Ave, Boston, MA 02115, or email guts@channing.harvard.edu. One of our researchers can answer any questions you may have.

How long will my samples and information be kept?

There is no scheduled date on which your samples and information in the bank will be destroyed. Your samples may be stored for research until they are “used up.”

The code linking your samples to your medical record may be kept indefinitely so that your samples and updated health information may be used for research in the future.

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

Yes. You have a right to 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 your permission, you should contact the tissue bank's staff in writing [Laura Anatale- Tardiff GUTS Study Coordinator, 181 Longwood Ave Boston, MA 02115].

Will I get results of research done using my samples?

No. The research we are doing is only a stepping stone in understanding how stress affects health. Therefore, information from this research will not be returned to you or your doctor. In addition, we use research, not clinical, assays in our research. Tests done for research using your samples will not be useful in directing your medical treatment. This information will not be placed in your medical records. However, you will continue to get the GUTS newsletter that will tell you about the research studies we are doing. This newsletter will not announce your results or anyone else's, but it will tell you what we are learning about. We will also publish what we learn in medical journals.

What are the risks to me?

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. We will protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password protected database.

Information that could be used to identify you will only be shared with study staff or collaborators at HSPH or BWH who have approval of the Partners ethics board. Information that likely could be used to identify you will never be shared with researchers outside of HSPH and BWH.

Genetic information that results from this study does not have medical or treatment importance at this time. Since we will not share information that could be used to identify you (e.g., your date of birth, address, or zip code) to outside entities, there is only an extremely small risk that information from taking part in a genetic study may influence insurance companies and/or employers regarding your health.

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As mentioned above, to further safeguard your privacy, genetic information obtained in this study will be labeled only with a code, and the key that links this code with your identifying information will be kept in a password protected database that only certain individuals who need to link the information for this research will have access to.

Taking part in a genetic study may also have a negative impact on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected with your samples and will be stored, used, and shared with researchers as explained above. **In the rest of this section, we refer to this simply as “health information.”** The statement below covers all possible disclosures, but in the Growing Up Today Study, only disclosure to government agencies who fund the research, groups that we hire to assist with the specimen collection, a group that oversees the data (study information) and safety of this research, and people or groups that we hire to do certain work for us related to the research, such as data storage companies are applicable.

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your health information and other identifying information from the research. With the Certificate, we cannot be forced (for example by court order or subpoena) to disclose your health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate’s stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about yourself or your involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in

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this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as overseeing the quality of care or research). Your information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your information:

- Within our Partners research team, and with the following others, to do the research described above (if a box is not checked , it means sharing with that group is not planned for this research study):
 - The sponsor(s) of the research study, and people or groups it hires to help perform this research study
 - Other researchers and medical centers that are part of this research study
 - A group that oversees the data (study information) and safety of this research study
- With people or groups that we hire to do certain work for us related to the research, such as data storage companies, our insurers, or our lawyers
- With federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that set hospital standards, to make sure we do the research according to standards set by ethics and law, and by quality groups. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- With a public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to you or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information. You should know that the recipients of these reports may use this information as they see fit, and may end up sharing the information with other government agencies. We may also voluntarily disclose information in other situations where you or others are at risk.
- Within Partners and outside of Partners, for treatment, payment, or health care operations. In order to minimize disclosures for these purposes, information from this research study will not be placed in your medical record.

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Occasionally we share research related information with outside researchers or groups as part of collaborative studies or pooling projects. When this occurs we do not send personal identifiers (e.g., your date of birth, address, or zip code) and we sign an agreement with the outside person/group to determine how the data will be used and protected. Specifically we use fake identification codes on your biological specimens and data that are different from our internal codes, and we only send the minimum amount of data needed for the research. Despite this, it is possible that such persons or groups outside Partners who get your health information or other identifying information from the research might not have to follow the same privacy rules that we follow. Therefore, we share your 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.

▪ Time Period During Which Your Health Information Might Be Used or Shared with Others

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research for as long as our researchers keep the information.

Your Privacy Rights

- You have the right **not** to sign this form permitting us to use and share your health information for research. If you don't sign this form, you can't take part in this research study. However, you will remain a valued member of the Growing Up Today Study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality. The Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research that our researchers keep.

If you withdraw your permission, you cannot continue to take part in this research study.

For more information about how HSPH and BWH protect the confidentiality of medical information, please see the Partners Notice for Use and Sharing of Protected Health Information (http://www.partners.org/privacy_notice_engl.pdf).

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What are the benefits to me?

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

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

There is no cost to you to have your samples in the bank or for the research using your samples. We will provide all necessary sample collection materials, including a return courier pack. Shipping will be automatically charged to our account.

Will I be paid for my samples?

We will pay you \$25.00 to allow us to store your samples and to allow research to be done with your samples. There are no plans to pay you if research done with your samples and information results in the development or sale of any product or technology.

What happens if I am injured as a result of taking part in this research study?

If you are injured during and as a direct result of sample collection, you should seek medical care as appropriate. Please also contact us at the number provided.

Whom do I call to answer questions about the research tissue bank?

You may ask more questions about the tissue bank at any time. The tissue bank staff are available to answer your questions or concerns. They can be contacted at 617-525-0353 [M-F 9-5]. Frequently asked questions also are addressed on our GUTS Stress Study Page, <http://www.gutsblog.com/stress/faq.html>.

The person in charge of the study is Dr. Bryn Austin. You can call her at 617-355-8194 [M-F 9-5].

Whom do I call if I have concerns about my rights as a research subject?

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If you want to speak with someone **not** directly involved in the tissue bank project, please contact the ethics board office (Partners Human Research Committee). You can call them at 617-424-4100.

You can talk to them about:

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

Also, if you feel pressured to take part in the research tissue bank, or to continue with it, they want to know and can help.

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.
- I can talk to the study team by telephone if I have any questions about the study.
- 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

Consent Form Version Date: 12/1/11