

Permission to Take Part in a Human Research Study



University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult consent to participate in a Research Study

Title of research study: "Spit for Buffalo" Saliva Sample Collection Project

Version Date: 2/15/17

Investigator: Richard Gronostajski

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are a patient in the UBMD Practice plan and we are recruiting all UBMD patients to participate.

What should I know about a research study?

- Someone will be available to explain this research to you if you have questions.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at the Genome, Environment and Microbiome (GEM) community at UB (716-829-3890). You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu

if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this project being done? Researchers and patients at UB and around the world are trying to find out why people differ in their health, the diseases they get, their lifespan and how they respond to drugs and other medical treatments. The cells in your body contain Genes, which are made of DNA, that are the blueprints for building us. Each person's Genes contain changes called mutations



IRB Approval Period
HRPP Revision Date: September 17, 2015

Permission to Take Part in a Human Research Study

that may affect a person's health and the diseases they get. The complete list of all of a person's Genes and their mutations is called their Genome. In addition, we each have microorganisms living on and within our bodies that can influence our health. These organisms are referred to as our Microbiome. The purpose of the "Spit for Buffalo" project is to collect saliva (spit) samples that contain cells from you (containing your genome) and your Microbiome so that we can study the Genes and microbes that you have that may influence the diseases that you, or people with the same mutations or Microbiome as you, will get during your lifetime. Participating in this project means that you will contribute to a better understanding of how our Genome and Microbiome affect our lives.

How long will the research last?

We expect that your data will be stored for this project for an undetermined time. The data that you contribute could well outlast your lifetime and help future researchers discover the causes of human diseases.

How many people will be studied?

We hope to get about 100,000 people in this research study over the next several years. Only those patients 18 or older may participate.

What happens if I say yes, I want to be in this research?

We will give you a collection kit for a saliva sample. Please follow the instructions that came with the kit, seal it and return it to the front desk. That is all you need to do. If your sample is used for future studies, we ask you below whether you would agree to be contacted to answer some questions or allow additional samples to be collected. You may choose to agree by checking the box or choose to not check it. If you check it only the bar code that identifies your sample will be given to future investigators and they must obtain independent IRB approval prior to obtaining your name and address to contact you. If you do not check it you will not be contacted again.

WHAT WILL HAPPEN WITH YOUR SAMPLE? We will record the bar code on your sample tube and add it to your electronic health record (EHR) so that we know that we have a sample from someone with your health and medical conditions stored in our collection (the UB BioBank). DNA will be prepared from your sample either right after collection or at some time in the future when a researcher from UB or around the world asks us for Genome or Microbiome data from someone with your health and medical characteristics. Your DNA (and that of your Microbiome) will be sequenced (read) and that data will be stored in computers for analysis of your Genome and Microbiome.

WHAT WILL HAPPEN WITH THE DATA YOU CONTRIBUTE? Your DNA sequence data will be stored in controlled-access databases that meet international security and safety standards. Selected researchers from around the world will be able to search for sequence information on these databases to find people with specific mutations and/or medical conditions listed in your EHR to study. These searches will not contain personal information like your name and address. If you allow us to contact you again we might contact you to ask for more information or another sample. If you do not agree to be contacted in the future, your data will still be stored for future researchers to examine and compare with DNA sequences from patients in Buffalo and around the world.



Permission to Take Part in a Human Research Study

WHO IS BEING ASKED TO PARTICIPATE? We are trying to get as large a group of volunteers who have as many different medical conditions as possible to participate. We hope to eventually have all patients in the UBMD network participate if they choose to do so.

What happens if I do not want to be in this research?

Not participating will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will simply not participate in the research study.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. However, once the barcode has been input into your medical record, the researchers will not have access to remove it and your sample may continue to be used by investigators that have already relied on your permission to conduct research.

Is there any way being in this study could be bad for me?

There are no known risks of contributing saliva samples for analysis. There is an unlikely risk for possible loss of confidentiality. And, in these types of large scale Genomic studies there is always the possibility that your Genome or Microbiome data could somehow be associated with your personal information. All reasonable and legally-required precautions will be taken to prevent this and it is not anticipated. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, your participation may help medical research better understand a variety of medical conditions which may indirectly help you or others in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other



Permission to Take Part in a Human Research Study

representatives of this organization. The results of these studies will be published in scientific and medical literature. When results are published names or personally identifiable information are not used. Your personal genetic information will be protected in confidential databases. We will not be returning any Genome or Microbiome information to patients as this is a research study and not part of your medical treatment.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include loss of your sample, although we will try not to do this.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

The only new health information that will be entered into your health records will be a bar code number associated with the saliva sample you have submitted.

B. Who is authorized to provide or collect this information?

The principal investigator is authorized to place this bar code into your health record. No one is allowed to obtain the bar code unless they receive separate IRB approval to do so.

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

 X Other medical investigators/centers/institutions participating in this research study: Investigators at UB and those participating in genomic studies around the world who have received IRB approval for their work.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your



Permission to Take Part in a Human Research Study

information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization in writing at the time of your office visit where saliva collection occurs. However, once the barcode has been input into your medical record, it will no longer be possible for you to revoke this authorization and the barcode will remain in your medical record. You should know that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s): The UB Genome, Environment & Microbiome community coordinator, 701 Ellicott St. Buffalo, NY, 14203.

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Optional: Permission to be Contacted for Future Research

For most patients we do not anticipate contacting you again. For some patients with specific diseases or genomes we might want to contact you again to obtain more information or ask to collect additional samples. Please check the box on the next page if you will allow us to contact you again in the future for additional information.



Permission to Take Part in a Human Research Study

Please check this box if you agree to be contacted in the future.

☐

Why do I have to sign this document if my name isn't being used?

You are being asked to sign this document to comply with a Federal law to show that you consent to your saliva sample being collected. Your name will not be associated with any genetic data obtained. These data and your electronic health record will be associated only with the bar code on the sample collection tube. This form with your name on it will be stored in a secure location to be made available only as required by Federal law to show that proper consent has been obtained from all patients. **It will never be used to obtain genetic or medical data about you.** If you agreed to be contacted in the future by checking the above box, then that information will only be present in your electronic health record which is secured and available only to qualified medical personnel.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject

Date

Printed name of subject