

## **Informed Consent Form and HIPAA Authorization**

**Study Title:** [Title of Biorepository]

**Version Date:** [Date]

|  |  |  |
| --- | --- | --- |
| **Principal Investigator:** | [Investigator Name] | Telephone: [(xxx) xxx-xxxx] |

[NOTE: This consent form provides a basic structure that must be edited to conform to the details outlined in the biorepository protocol (procedures, subject population(s), etc.). It is not intended to be used without modification.

Include certificate of confidentiality language if applicable. Delete all sections that don’t apply, including the instructions highlighted in yellow.

* Add concise explanation and additional information where necessary.
* If the risks of sample collection are greater than minimal, injury compensation language must be added as well as emergency contact information.
* If this form is being used to ask a parent to give permission for a child to join a biorepository change language in text and headings accordingly (You 🡺 Your child). If collecting data from both the parent and the child this must be made clear throughout the explanation of the study.
* If you are creating a databank that would not accurately be labelled a biorepository, you should change this term throughout, edit the language about types of information being collected and possible future uses, and remove HIPAA language if appropriate.]

# Key points you show know

You are being asked to contribute to a research biorepository called [insert name of biorepository here]. You are being asked to join the biorepository because [describe the disease or reason the subject was chosen or delete if this does not apply]. A biorepository contains samples of blood, tissue, and other information from many different people. Researchers can take samples and information from the biorepository and use them for their own studies.

This biorepository is a research project. It is not part of your health care and will not directly help you. It is designed to help us learn about health and disease for the benefit of all people. Participating in this project is completely up to you. You can say no if you do not want to join the biorepository.

If you decide not to participate in this project, it will not affect your health care treatment or any relationship you have with UTRGV or the researchers. You will not lose any rights or benefits to witch you are entitled.

This type of research involves various types of genetic testing. Genetic testing looks at pieces of DNA called genes. Genes provide the instructions needed to make our bodies work. Some of the research done with your samples could include whole genome sequencing. Whole genome sequencing is when a researcher determines all your DNA at one time. [NOTE: You can delete the previous sentence if it does not apply but you and/or other researchers will not be able to use these data for whole genome sequencing in the future if this statement is not included; therefore, the IRB recommends you leave this in if there is any doubt.] Because the field of genetic testing is advancing rapidly, we can’t predict all of the tests that will be done.

Your samples will be used to create cell lines that will be used for XXXX (if applicable). The data we get from the information and samples you provide may also be used for studies on a whole range of topics such diabetes, heart disease, HIV, sexually transmitted diseases, or mental health disorders. This does not mean we believe you have any of these conditions but we want you to know that the research we and others may do can cover many different topics.

By signing this form, you are giving the biorepository your permission to share your samples and collected information with researchers anywhere, including those in other countries and those working for companies. The biorepository will follow all regulatory standards before releasing samples or information.

You are giving your permission for researchers to use your samples and health information to study any disease or health condition. You will not be told about the purpose or the specifics of the studies being conducted. It is possible that you might have chosen not to consent to some of these studies. [NOTE: DO NOT DELETE THE LAST SENTENCE].

Researchers may contact you again to ask for more samples or information; you will not be told what is found out about your individual sample [NOTE: Secondary research will not qualify for exempt status if results are returned to subjects; you may edit/change this sentence but keep this caveat in mind]. Many genetic tests are experimental, and the meaning of the test results is not known.

# What is involved in the study?

If you agree to take part in the study, you will come to UTRGV for 1 study visit.

The samples and information in the biorepository will be stored and used indefinitely.

The study involves the following:

Medical History: [Explain how the information will be obtained]. Information (data) will be collected from your medical records and from a brief interview (if applicable). The information will include your diagnosis, treatments, and medications (and whatever else). OR You will be asked to complete a short survey about your health.

Blood Samples: Up to XXXX Tablespoons of blood will be taken and stored in the biorepository. We will take this blood by inserting a needle into your arm.

Other Specimens: [Include an entry for each type of specimen]. We will also request a urine sample, saliva sample, or cheek cell sample (whatever is applicable). [Describe how the sample will be collected for each type of specimen, i.e., *Collecting cheek cells involves rubbing a cotton swab on the inside of the cheek for about 10 seconds.*]

# How will my sample be protected?

[NOTE: DELETE THIS SECTION IF IT DOES NOT APPLY OR DELETE/MODIFY STATEMENTS BELOW IF THEY ARE NOT CORRECT.]

Whenever possible, donated samples and your health information will be stored with a code instead of identifiers (such as name, date of birth, medical record number, social security number). However, some types of research may require the use of identifying information (such as your birthdate) the more information about you that is combined together, the more likely it is you could be identified.

All information used by this project will be protected so that it can only be accessed by authorized people. Still, no one can guarantee that computer security will be perfect.

No published scientific reports will identify you directly.

[NOTE: The figure below is an example only. It is applicable for when the investigators won’t have the key to the code. Delete if not applicable.]

###

# Are there any risks to taking part in this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to the study doctor.

[NOTE: DELETE IRRELEVANT SECTIONS BELOW OR ADD ADDITIONAL RISKS REVELANT TO YOUR STUDY.]

**Risks associated with collection of blood:** Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

**Risks associated with collection of urine, saliva and cheek cell samples:** The physical risks of these procedures are all minimal. A cheek swab could include irritation of the cheek where the sample was taken.

**Risks associated with collection of leftover tissue:** Only tissue that is leftover and that would normally be thrown away will be used for the research. There are no additional risks from the collection of these samples.

**Risks to your personal privacy and confidentiality:** Research that uses health information and that involves genetic testing can affect your privacy. [NOTE: MODIFY THE FOLLOWING STATEMENTS IF NEEDED] Your participation in this research will be held strictly confidential and only a code number will be used to identify your stored samples and data. However, because there will be a link between the code and your identity, confidentiality cannot be guaranteed.

**Risks associated with genetic testing:** Since future research studies will involve genetic analyses, potential risks include stigmatization of individuals or groups of individuals. It could also affect your insurability. [NOTE: MODIFY OR DELETE THE FOLLOWING SENTENCE IF THIS IS NOT TRUE.] The protections in place (described above) minimize those risks. Only coded samples and data will be stored and used for future research.

There is also a Federal law, called the Genetic Information Nondiscrimination Act (GINA), which 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 may 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.

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

There may be other risks that are not known at this time. Tell the study investigator or study staff right away if you have any problems.

# Are there any benefits to taking part in this study?

There will be no direct benefit to you from participating in this study. We hope that the information and samples in the biorepository will help researchers and physicians better understand how to identify, prevent, and treat various diseases.

The samples stored as part of this study could lead to discoveries or inventions in the future that may be of value to UTRGV or to other organizations. You will not receive any money or other compensation that may come from products that are developed from research samples.

# What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. [NOTE: MODIFY THE FOLLOWING STATEMENT IF YOU ARE NOT COLLECTING INFORMATION FROM MEDICAL RECORDS.] This will include information from your medical records and samples. No research laboratory test results will appear in your medical records. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

* Members of the research team and other authorized staff at
UTRGV.
* People from agencies and organizations that perform independent accreditation and/or oversight of research, such as the Department of Health and Human Services, Office for Human Research Protections.

[NOTE: Include the following ONLY if applicable (i.e., receiving or using identifiable information)]

* Representatives of XXXX who is the study sponsor funding this research.
* (Labs analyzing identifiable samples) Laboratories who will test your blood/urine/tissue sample(s) for the study, such as (List lab names who receive identifiable specimens.)
* (Labs analyzing coded samples) Your samples/data will be shared with outside laboratories including XXXX, YYYY and ZZZZ, who will analyze (and store, if applicable) your samples. Your samples/data will be labeled with a XXXX (include whatever is appropriate e.g. study number, date when they were obtained, your initials). The outside laboratories will not know who you are. Private information such as your name, birth date or medical record number will not be shared with them (if applicable).
* The Data Coordinating Center at XXXX (multi-center research studies).
* Groups monitoring the safety of this study (e.g. DSMB)
* The National Institutes of Health (or other funding agencies) who is sponsoring this research;
* The Food and Drug Administration (FDA); (if applicable)
* Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. (if applicable: sexually transmitted diseases, HIV, AIDS, child abuse, etc.)

By law, UTRGV is required to protect your health information. By signing this document, you are authorizing UTRGV to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

# Can you leave the biorepository?

Even if you decide to participate now, you can leave the project any time without penalty by contacting:

Dr. XXXX
The University of Texas Rio Grande Valley
Division/Department

INSERT STREET AND CITY, STATE, AND ZIP CODE AND PHONE NUMBER

Keep in mind that we will not be able to get back your information or samples if they have already shared them with other researchers or if we can no longer identify them as having come from you.

# What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. XXXX at (xxx)-xxx-xxxx.

The Institutional Review Board (IRB) at The University of Texas Rio Grande Valley has reviewed and approved this research. The IRB looks at research studies like these and makes sure research subjects’ rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB at 956.665.3598 or irb@utrgv.edu.

• When a study is approved under §46.406 then both parents/guardians need to sign the consent document. Modify signature page.

• If the study will only enroll adults, edit the paragraph starting with “By signing this form…” to remove references to the parent and to only refer to the subject.

• If the study involves both the child and one or both of the child’s parents, the paragraph must make clear that the parent(s) is consenting for both their own participation as well as the participation of their child.

DELETE THIS ENTIRE BOX BEFORE SUBMITTING THIS FORM TO THE IRB.

# Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Consent |  | Signature of Person Obtaining Consent |
|  |  | Date: |

By signing this form, you are indicating that you have had your questions answered, you agree to take part [allow your child to take part] in this research study, and if you are the parent of a child participant, you are legally authorized to consent to your child’s participation. You are also agreeing to let UTRGV use and share the health information collected as part of this research as explained above. If you don’t agree to the collection, use and sharing of the health information, you (or the child participant) cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child’s participation.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Subject |  |  |
|  |  |  |
| Signature of Subject (18 years or older) |  | Date |
|  |  |  |
| Name of Authorized Representative (if different than subject) |  | Relation to subject:[ ]  Parent [ ]  Legal Guardian |
|  |  |  |
| Signature of Authorized Representative |  | Date |
|  |

[NOTE: If only children will take part, don’t include a signature line for the subject and remove the “(if different than subject)” from the Name of Authorized Representative line.

Be sure that the paragraph includes all subjects (e.g. parent AND child, vs just child).]

## Child Assent to Take Part in this Research Study

### For children capable of providing assent:

I have explained this study and the procedures involved to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in terms he/she could understand and that he/she freely assented to take part in this study.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Obtaining Assent |  | Date |

This study has been explained to me and I agree to take part.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Subject (optional) |  | Date |

[NOTE: Delete the following if all subjects will assent.]

### For children unable to assent:

I certify that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Responsible for Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Responsible |  | Date |

**[NOTE:**

1) Delete assent lines if none of the children will be old enough to assent (e.g., neonates) or if the study only involves subjects capable of consenting for themselves.

2) If some may be old enough and some not, include both statements so that the investigator can document on the Assent page, why a particular subject was unable to assent.]