# BIOREPOSITORY Informed consent

**Department of**

## Title of Study:

## Investigator(s):

For questions or concerns about the study, you may contact       at      .

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the UNLV Office of Research Integrity – Human Subjects at 702-895-0020 or via email at IRB@unlv.edu.

*\*\*For studies that ONLY involve children, revise the consent form to refer to the participant as “your child...."\*\**

## Purpose of the Study

A biorepository contains samples of blood, tissue, and information from many different people that are stored for future research use. Researchers can take samples and information from the biorepository and use them in their own studies. You are invited to participate in a research biorepository called       *(insert name of biorepository).* The       *(insert name of biorepository)* will support research studies about       *(describe the types of research that may use these data and specimens)*

## Participants

You are being asked to participate in the biorepository because you are a subject in a UNLV research study where private information and/or specimens are being collected.

## Procedures

Research using private information and/or specimens is an important way to try to understand human health and medical conditions. You are being given this information because the investigators want to save your private information and/or specimens for future research.

If you volunteer to participate in this biorepository, you will be asked to consent to allow storage and sharing of your *(insert what private information and/or biological specimens, e.g. saliva, blood, DNA, hair, teeth, etc. will be stored in the biorepository)* for future research use.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

In the future, a researcher may wish to conduct research that requires human specimens such as yours. That researcher would then ask the biorepository for a sample and yours might be provided for the research. The specimens will be used primarily by researchers at UNLV. However, there may also be collaborative efforts with other universities, the government, and private companies.

Your specimens will be maintained by UNLV for such research purposes, as long as allowed by the law or until UNLV decides to discontinue your donated sample or discontinue the biorepository.

Your biospecimens will be stored *(insert how specimens will be stored - and if appropriate how specimens will be linked, e.g., under diagnosis and medical record or code number and unlinked.)*

*If unlinked (if applicable):* Because your specimens will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the specimens after they are taken.

*If specimens will be sent out of UNLV for analysis, include a statement:* Your specimens will be sent outside of UNLV for analysis.

*If specimens could be part of, or lead to the development of a commercially valuable product, include the following:* Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, UNLV, and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

*Include the following language if future research on specimens will include genetic testing:* As part of the analysis on your specimens, the investigators *(Choose one: may/will)* do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

*A statement on whether whole genome sequencing will occur (include for all research involving specimens):* The process of determining all or nearly all of your DNA sequence is called whole genome sequencing.It is different from genetic testing that does not involve whole genome sequencing because it provides a much more detailed snapshot of your genome.This research *(Choose one:* *will/might/will not)* include whole genome sequencing.

*If investigators will not share the research results with the participant, the following language can be added:* The results of the study of your specimens from this project will be used for research purposes only, and you will not be told the results of the tests.

## Benefits of Participation

There may not be direct benefits to you as a participant in the biorepository. However, we hope to learn      .

## Risks of Participation

There are risks involved in all research studies. You may feel uncomfortable allowing your data and specimens to be stored and shared. While every effort will be made to protect your identity and health information, there is a small risk of loss of privacy.

## Cost /Compensation

There may not be financial cost to you to participate in this biorepository. The biorepository will take no additional time for you. You will not be compensated for your consent to data storage and sharing.

## Confidentiality

Research that uses private information and/or specimens can affect your privacy. No reference will be made in written or oral materials that could link you to this biorepository. All records will be stored in a locked facility at UNLV for       years after completion of the study. After the storage time the information gathered will be      .

*If specimens will be linked/coded, please include:* Your participation in this research will be confidential and only a code number will be used to identify your stored data and specimens. However, because there will be a link between the code and your identity, confidentiality cannot be guaranteed.

## Voluntary Participation

Your participation in this biorepository is voluntary. You may refuse to participate in this study. You may withdraw at any time without prejudice to your relations with UNLV. You are encouraged to ask questions about this study at the beginning or any time.

## Participant Consent:

I have read the above information and agree to participate. I have been able to ask questions about the biorepository. I am at least 18 years of age. A copy of this form has been given to me.

Signature of Participant Date

Participant Name (Please Print)

*If your study includes the use of HIPAA protected health information, please include the following*:

**Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study**

If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at [name of covered entity or entities] to use or disclose (release) your health information that identifies you for the research study described above.

The health information that we may use or disclose (release) for this research includes [complete as appropriate]:

[Provide a description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.]

The health information listed above may be used by and/or disclosed (released) to:

[Name or class of persons involved in the research; i.e., researchers and their staff[\*\*](https://privacyruleandresearch.nih.gov/authorization.asp#FOOTNOTE2)]

[Name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that [include the appropriate statement below]:

You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.
**(When the research involves treatment and is conducted by the covered entity or when the covered entity provides health care solely for the purpose of creating protected health information to disclose to a researcher)**

OR

[Name of covered entity] may not condition (withhold or refuse) treating you on whether you sign this Authorization.
**(When the research does not involve research-related treatment by the covered entity or when the covered entity is not providing health care solely for the purpose of creating protected health information to disclose to a researcher)**

Please note that *[include the appropriate statement]:*

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that [name of covered entity(ies)] has already acted based on this Authorization. To revoke this Authorization, you must write to: [name of the covered entity(ies) and contact information].
**(Where the research study is conducted by an entity other than the covered entity)**

OR

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, [name or class of persons at the covered entity involved in the research] may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to: [name of the covered entity(ies) and contact information].
**(Where the research study is conducted by the covered entity)**

This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as "end of the research study."]

Signature of participant or participant’s Date

personal representative

Printed name of participant or participant’s If applicable, a description of the personal

personal representative representative’s authority to sign for the participant

## OPTIONAL ELEMENTS:

Examples of optional elements that may be relevant to the recipient of the protected health information:

* Your health information will be used or disclosed when required by law.
* Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.
* No publication or public presentation about the research described above will reveal your identity without another authorization from you.
* If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.
* **When the research for which the use or disclosure is made involves treatment and is conducted by a covered entity:** To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that [name of the covered entity] maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at [name of the covered entity] to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by [name of covered entity]. If it is necessary for your care, your health information will be provided to you or your physician.
* If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.