"Tomorrow's Cures Today"

Consent to Participate in Research

The University of Arizona Biorepository

Principal Investigator: David T Harris, Ph.D.

Sponsor: Arizona Health Sciences Center

This is a form for your consent to participate in a research project. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

1. Why is this study being done?

The purpose of this project is to permit your blood, tissues, and fluids ("samples") to be obtained and stored in a biorepository. A biorepository is a collection of samples and health information that can be used by researchers for future studies. Studies may be done to understand the biology and treatment of human diseases (example: cancer, diabetes, asthma, genetic disorders, biomarkers, animal studies, etc.). Your samples will be linked in an anonymous fashion to your health information. There is the possibility that the anonymous data could be used by itself without further consent.

Researchers inside and outside of the University of Arizona may have access to the samples and the linked anonymous health information for research purposes, including but not limited to the Banner University Medical Center health network and the National Institutes of Health. Studies may be in any medical area. The scope of future research projects has not yet been determined. Future studies may be about how genes affect health or respond to treatment. Studies may require genetic testing. We may also collaborate with industry or provide samples to industry. All studies will be conducted in an anonymous fashion.

2. What will happen if I take part in this study?

Samples (such as blood, urine, tissue, etc.) will be collected by your doctor to take care of you. Some samples may also be collected for another research study. We would like to keep the samples after they have been used by your doctor or the research study in the biorepository. If you are scheduled for future procedures, signing this consent will allow the collection of samples from these additional procedures or treatments. Signing the consent will also allow us to anonymously link your medical information to the sample now as well as in the future.

3. How long will I be in the study?

Your samples will be used and stored indefinitely. There is no limit to the length of time your information will be stored for future research.

4. Can I stop being in the study?

Once samples are in the repository they cannot be withdrawn or destroyed. You can choose to not have future samples added to the repository.

5. What risks can I expect from being in the study?

The only risk of participation in the biorepository is accidental disclosure of your medical information. This may result in loss of your privacy. However, when you sign the consent your sample and health information will be given a code. The code will only be used to track your samples. The code will only be known to people who run the repository. We believe the chance these things will happen is extremely small, but we cannot make absolute guarantees. Your privacy and the confidentiality of your data and biological samples are very important to us, and we will make every effort to protect it.

6. What are the benefits of participating?

There is no direct benefit to you from your participation. You will not be informed of any medical results discovered through research. However, your participation may help researchers discover new treatments that may help other people in the future.

7. What other choices do I have if I do not take part in the study?

Your participation in the repository is voluntary. You may choose not to participate. If you choose not to participate you will still receive treatment from your doctor. There will be no penalty or loss of benefits to which you are otherwise entitled.

8. Will my study-related information be kept confidential?

Yes, your samples and health information will be kept confidential. Information will not be shared with researchers that can directly identify you. Your samples and health information will have a code. Researchers will not have access to the key to the code.

There is a small risk of health insurance discrimination based on genetic testing; however, per the Genetic Information Nondiscrimination Act of 2008 (GINA), group and individual health insurers may not use your genetic information to set insurance eligibility, premiums, or contribution amounts, nor can they request or require that you take a genetic test. In addition, employers with 15 or more employees may not use your genetic information to make decisions regarding hiring, firing, job assignments, or promotions, nor can they request, require, or purchase your genetic information. In Ohio, there is a similar state law that also provides some protection for private health insurance plans. GINA does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

There may be times when information about you must be released. For example, information may be disclosed if required by state law. Also, your information may be

reviewed by regulatory offices, such as the Office of Human Research Protections, the Institutional Review Board, and study sponsors.

9. Will there be any costs to me?

There will be no costs to you for participating in this study.

10. Will I be paid for taking part in this study?

There is no financial or other form of compensation to you as a result of your participation. We will use your samples and data for research purposes only. We will not sell them. However, your samples may be used to develop drugs or tests that could be sold by companies. You will not receive any compensation from these activities.

11. What are my rights if I take part in this study?

By signing this form, you do not give up any legal rights.

12. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the Biorepository Director, David T Harris, Ph.D. 520- 626-5127.

For questions about your rights as a participant in this biorepository or to discuss complaints with someone who is not part of the biorepository team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://orcr.arizona.edu/hspp.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

There may be times when it would be beneficial to re-contact you to obtain more information or another biosample. Any re-contact would be done by the original person(s) who consented you, not the biorepository. If you would object to being re-contacted at some time in the future please initial here. _____