

CONSENT AND AUTHORIZATION TO PARTICIPATE IN RESEARCH

Title of Research: University of Texas Southwestern Medical Center Tissue Resource (UTSTR)

Sponsor: Simmons Cancer Center

Primary Investigator: Dr. Cheryl Lewis

214-648-7597

DESCRIPTION AND PURPOSE: The purpose of this study is to compile information and samples from patients evaluated or treated for cancer or other diseases to help us advance our understanding of the disease. Volunteers can participate in this study as healthy controls to provide a comparison group. Samples and information will be made available to researchers who are involved in the study of cancer or other diseases and are attempting to improve upon our ability to prevent, diagnose or treat these conditions. Samples are obtained during the ordinary course of your care, and will include blood, bodily fluids, and tissue removed during treatment or surgery. Normally, these samples are leftover at the end of your treatment, and would otherwise be discarded as medical waste. If no leftover blood sample exists, we would like to have a blood sample drawn for the repository. The amount of blood collected will be 3 tablespoons or less. For some patients, we may ask for up to three blood draws per year (no more than 3 tablespoons each time) so researchers may monitor changes during your treatment. If a sample doesn't exist (e.g. saliva, cheek swab or urine) we will ask your permission to obtain a sample.

You are also being asked permission for repository staff to obtain information from your medical record about your medical history, any treatment you receive, and the result of that treatment. This information will include any treatment you are receiving now, as well as treatment you may receive in the future. Your sample(s) and medical information will be kept in the repository permanently. The repository will be maintained at and by UT Southwestern Medical Center for the purposes of medical and scientific research only. By participating in this research, your tissues will be made available to approved researchers at UT Southwestern and other research institutions. Samples will be marked with a coded identifier and information will not be released in an identifiable way to researchers unless they have been approved by the UTSW Institutional Review Board and the UTSW researchers have been trained in protecting patient privacy. No research results will be released to your insurance provider, employer, family, etc.

POSSIBLE RISKS: The most likely potential risk of participating in the repository is accidental release of your medical information. To limit this risk, any medical record information the repository receives about you will be kept confidential as required by law. The computer database containing your information is protected to prevent unauthorized access.

POSSIBLE BENEFITS: Although participating in the repository will not directly benefit you, it can lead to advances in the research of disease and in the care of patients. The knowledge to be gained from studying samples, tied to the results of treatment received by the people who donated the sample, will provide valuable information for future treatment.

ALTERNATIVES TO PARTICIPATION: You do not have to participate in the repository. If you do not participate, your care will not be affected nor will your relationship with your physicians. If you choose not to participate, simply do not sign this form. Also, participation can be stopped at any time. To discontinue participation at any time, you need to contact the repository in writing at: UT Southwestern Tissue Resource, 5323 Harry Hines, Dallas TX 75390-8517. All samples and documentation in the repository will then be destroyed; however, samples that have been already used for research or their results will not be destroyed.

COSTS AND REIMBURSEMENTS: You will receive no payment for your participation. There will



be no costs to you or your insurance provider/government program. You will not receive any benefit, financial or otherwise, from drugs, treatments, devices or publications resulting from the use of samples and information in the repository.

RESEARCH: DNA is found in almost all cells of the body. DNA contains the hereditary information that makes us who we are. Researchers use DNA to examine genetic factors in disease. We may isolate DNA from samples, and this DNA may be kept forever. Part of your sample may also be grown indefinitely. These cells will be available for future research.

Your genetic and health information may be released, with no direct identifiers, into scientific databases that are accessible on the Internet. 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 collect the results of whole genome studies. The NIH and other data banks will store your genetic information and give it to other qualified researchers to do more studies.

I certify that I have watched the biorepository video. _____initials

YOUR QUESTIONS: Dr. Cheryl Lewis is available to answer questions about the repository at 214-648-7597. The Chairman of the UT Southwestern Institutional Review Board is also available to answer questions about your rights as a participant in research at 214/648-3060.

YOU WILL HAVE A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that identifiable data and samples may be given out to researchers who have been properly trained to protect the information as determined by the IRB.

Signature of Participant (>18)

Printed Name of Participant (>18)

Date and Time

Signature of Legally Authorized Representative

Printed Name of Legally Authorized Representative

Date and Time

NAME OF PERSON OBTAINING CONSENT

Signature

Printed Name

Date and Time

