

## CONSENT TO INVESTIGATIONAL TREATMENT OR PROCEDURE

I, \_\_\_\_\_, hereby authorize or direct \_\_\_\_\_, associates or assistants of his/her choosing, to perform the following treatment or procedure (describe in general terms), Remnant tissue (from the tissue that will be removed during my surgery) will given to Tissue Procurement Services (TPS), which is a part of the Cooperative Human Tissue Network (CHTN), for use in research involving disease mechanisms, diagnosis and therapies. The remnant tissue will be procured and shipped to investigator(s) who are studying this tissue type and who are members of the CHTN. The TPS will uniquely label (code) my tissue so that the investigator(s) receiving the tissue cannot link the tissue to my name. However, if the investigator(s) need further information about my case, TPS will be able to link the tissue back to my name by the code and therefore provide the investigator(s) with the information.

upon \_\_\_\_\_  
(myself or name of subject)

### **The experimental (research) portion of the treatment or procedure is:**

The objective of this research is to operate a highly productive, efficient tissue procurement service at The Ohio State University Medical Center as a part of the Cooperative Human Tissue Network (CHTN) of the National Cancer Institute (NCI). This division provides human normal, diseased, benign, and malignant surgical and autopsy tissue specimens for research investigators in the United States and Canada. This includes solid tissue, blood/sera, ascites fluids and pheresis specimens. Remnant tissues obtained for the CHTN will be examined and selected grossly for further quality controlled microscopically with histological review by a surgical pathologist. Tissues will be procured by investigator-specified guidelines and shipped within 24 hours or in batches according to the investigator's needs. This division works closely with other CHTN divisions to network investigator requests nationally, to educate the research community on the availability of CHTN specimens, to actively participate in the CHTN agendas to improve services and develop CHTN-wide policy and protocols.

### **This is done as part of an investigation entitled:**

National Cancer Institute-Cooperative Human Tissue Network and Tissue Procurement Services

#### **1. Purpose of the procedure or treatment:**

To provide quality remnant human tissue specimens to basic researchers who would otherwise not have access to human tissues for their research

#### **2. Possible appropriate alternative procedures or treatment (not to participate in the study is always and option):**

On the day of my surgery, a nurse or a member of the surgical team will visit me before or after (when appropriate) the procedure to obtain written consent and answer any questions I might have. My medical care will not be altered or compromised by my decision. If I decide to consent for this study, I can withdraw my consent at any time (provided that the tissue has not already

been given to an investigator). My private information will be protected. My signed consent form will be entered into the database to be matched with the procured specimens. A copy of the consent will be left with my hospital chart and the original will be stored in the Tissue Procurement office. If I do not give consent, I may ask to have the remnant tissue destroyed or completely delinked of any identifying information (thus retaining the specimen for use by investigators without any ability to link the tissue back to my medical record for any additional information they may need).

**3. Discomforts and risks reasonably to be expected:**

The tissue collected for this study adds no additional risks to my scheduled operative procedure. There is no risk that my name would become known because the specimens are coded. TPS will keep my coded information in a secured area and in a secured computer system that only authorized individuals have access. It is unlikely, but possible that information could inadvertently be left without being blocked out before giving the tissue to an investigator.

**4. Possible benefits for subjects/society:**

There are no direct benefits to me for participating in this study. However, there may be a general benefit to society from knowledge gained in their research of the tissue specimens. The research may aid in the diagnosis of cancer and/or other diseases and in the prediction of the treatments for specific cancers and/or other diseases.

**5. Anticipated duration of subject's participation (including number of visits):**

The tissue collection for this study adds no additional time to my scheduled operative procedure.

No future contact is required.

I hereby acknowledge that \_\_\_\_\_ has provided information about the procedure described above, about my rights as a subject, and he/she answered all questions to my satisfaction. I understand that I may contact him/her at Phone No. \_\_\_\_\_ should I have additional questions. He/She has explained the risks described above and I understand them; he/she has also offered to explain all possible risks or complications.

I understand that, where appropriate, the U.S. Food and Drug Administration may inspect records pertaining to this study. I understand further that records obtained during my participation in this study may contain my name or other personal identifiers and may be made available to the sponsor of this study. Beyond this, I understand that my participation will remain confidential.

I understand that I am free to withdraw my consent and participation in this project at any time after notifying the project director without prejudicing future care. No guarantee has been given to me concerning this treatment procedure.

I understand in signing this form that, beyond giving consent, I am not waiving any legal rights that I might otherwise have, and I am not releasing the investigator, the sponsor, the institution, or its agents from any legal liability for damages that they might otherwise have.

In the event of injury resulting from participation in this study, I also understand that immediate medical treatment is available at University Hospitals of The Ohio State University and that the costs of such treatment will be at my expense; financial compensation beyond that required by law is not available. Questions about this should be directed to the Office of Research Risks at (614) 688-4792.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM Signed \_\_\_\_\_  
(Subject)

Witness (es) \_\_\_\_\_  
if required (Person Authorized to Consent for Subject if Required)

I certify that I have personally completed all blanks in this form and explained them to the subject or his/her representative before requesting the subject or his/her representative to sign it.

Date: \_\_\_\_\_ Signed: \_\_\_\_\_  
(Signature of Project Director or his/her Authorized Representatives)