

UNIVERSITY OF MICHIGAN HOSPITALS & HEALTH CENTERS
Request and Consent to
OPTIONAL TISSUE RESEARCH

BIRTHDATE
NAME
Reg No.

Date: _____ Time: _____ A.M./P.M.

- University of Michigan Tissue Procurement Core: IRBMED # 2003-0265, PI=Director, Tissue Procurement Core

Purpose of the Research and Any Research Uses or Disclosures:

The University of Michigan maintains a Tissue Procurement Core ("TPC"). University researchers use tissue and related information gathered by the TPC to learn more about cancer and related medical conditions. We also provide outside researchers with tissue specimens but in those cases do not include name, address, medical record number or other identifiers that link the tissue to you.

Research Procedures:

If you agree to participate in this research project by signing below, you will not have any procedures other than those described on page 3 of the procedure consent form. Only excess tissue will be given to the TPC. Your doctors will not take more tissue from you than they need to diagnose or treat your condition.

Risks and Benefits of the Research:

There are no known risks to participating in the research. If you do participate, the tissue and information you donate to us will be used to help us learn more about cancer and related medical conditions and to help others in the future who may have these conditions. You will not be paid or reimbursed for your participation in the research project, even if it results in commercial developments by the University of Michigan or others.

Information to be Used or Disclosed:

A unique code will link your tissue to your medical record without use of your name. If you agree to participate in this project, information from your medical records - including any information about diagnosis or treatment for mental health, substance abuse, HIV/AIDS, or other communicable diseases - may be collected by the researchers and used for this project. Some of the information will be put into the project database.

People Allowed to Release and Receive the Information:

By signing your name below, you will agree to let the University of Michigan and its health care providers use or disclose your medical records to the TPC and other University of Michigan researchers for this project. Also, University and government officials and others who oversee the research may have access to the records.

Right to Revoke:

You have the right to revoke your authorization at any time by writing to the Tissue Procurement Core at University Hospital, Room 2G332, Ann Arbor, MI, 48109-0054. If you do, only the information that already has been used for a specific research project will continue to be used. However, your information will not be further used or disclosed without your permission unless required by law.

Voluntary Participation/Refusal to Sign:

Participating in this research project is completely voluntary. If you decide not to participate, or if you decide to withdraw (end your participation), you will not suffer any penalty or loss of benefits to which you otherwise would be entitled. Your treatment at the University of Michigan will not be affected by your willingness or refusal to participate.

Duration of Study and Expiration Date or Event:

Unless you revoke your authorization, your permission for us to use your tissue and related information will not expire. This study is expected to continue indefinitely.

Privacy Rights:

If your information is disclosed to individuals outside the University of Michigan, it may no longer be protected by the federal privacy regulations. However, as long as it remains in the University, it will be protected by our own policies and procedures. For more information on our privacy practices, please refer to the University of Michigan Notice of Privacy Practices, available at http://www.med.umich.edu/hipaa/npp_official.htm

Contact Information

To learn more about this study, contact the Tissue Procurement Director at 734-615-3860. For information about your rights as a research subject, write to our institutional review board (IRBMED) at 517 W. William, Argus I, Ann Arbor, MI 48103-4943, call 734-763-4768, or e-mail irbmed@umich.edu. For more information about privacy at the University of Michigan, contact our Privacy Director at (734) 615-4759, or call toll-free, (866)-990-0111.

Signature of Patient or Legally Authorized Representative (If patient is a minor or unable to sign)

Consent Obtained By

Date

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Request and Consent to
Medical, Surgical, Radiological or Other Procedures

BIRTHDATE
NAME
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PLEASE PRINT CLEARLY WHEN COMPLETING THIS SECTION.

1. My diagnoses/conditions are: _____

2. My recommended procedures are: _____

My procedures have been explained by: _____ ID#: _____

My procedures will be performed or supervised by: _____ ID#: _____

3. My risks include: _____

4. I understand the approximate location of my procedure or surgical incision will be marked on my body prior to the procedure unless it is considered to be an excluded site below. For illustrative purposes, the approximate operative site may be marked on the diagrams provided.

I CONSENT TO THE FOLLOWING:

PROCEDURE(S)

I consent to the procedure(s) listed in #2 above including any tissue implants (please initial).

Exceptions (TO BE COMPLETED BY PROVIDER ONLY):

BLOOD OR BLOOD COMPONENT TRANSFUSION(S)

I consent to all transfusions given during my hospitalization or course of treatment (please initial).

Transfusion is not applicable to my operation

Exceptions (TO BE COMPLETED BY PROVIDER ONLY):

I HAVE READ AND UNDERSTAND THE INFORMATION ON THIS FORM AND ON PAGES 1 AND 2 BEFORE I SIGNED BELOW.

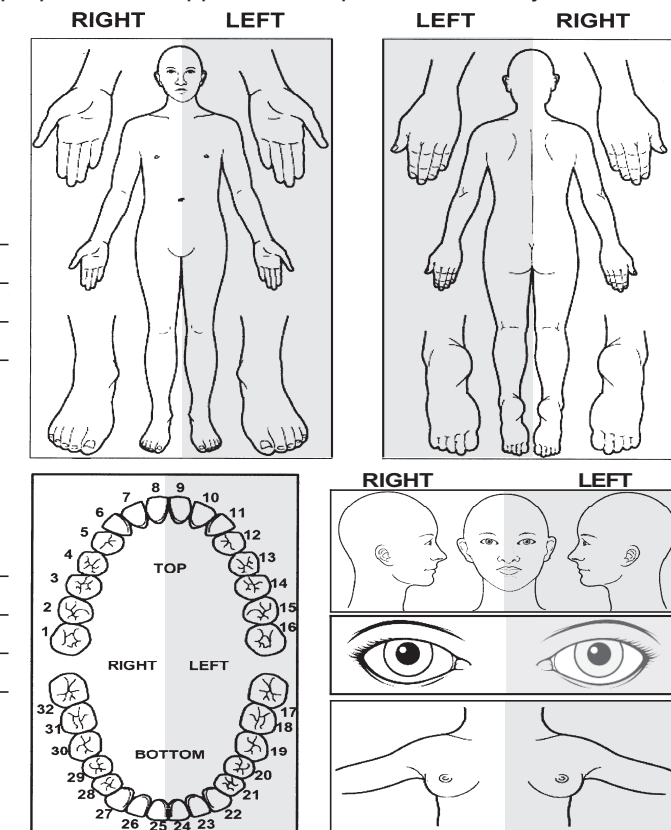
Signature of Patient or Legally Authorized Representative (if patient is a minor or unable to sign)

Printed Name of Legally Authorized Representative (if patient is a minor or unable to sign)

Relationship: Spouse Parent Next-of-Kin Legal Guardian DPOA

Consent Obtained, Explained and Witnessed By:

Date: _____ Time: _____ A.M./P.M.



- Excluded Sites: Check here if the operative site is considered an excluded site. Excluded sites are as follows:
• Mid-line sternotomy for open heart surgery
• Cesarean delivery
• Interventional procedures for which the site of insertion is NOT predetermined, such as cardiac catheterization
• Laparotomy, laparoscopy, transvaginal, transrectal, penile and endoscopic procedures that do NOT involve left/right distinction of the organ
• Breast biopsy with wire localization
• Intra-oral and dental procedures.

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Request and Consent to

Medical, Surgical, Radiological or Other Procedures

1. I have spoken with my doctors. They have explained my diagnosis and condition (listed on page 3).
2. My doctors have recommended the procedures listed on page 3 to diagnose or treat my condition. They have explained the **POTENTIAL BENEFITS** of these procedures. They also have explained the **RISKS OF REFUSING** the procedures.
3. My doctors have explained the **RISKS OF THE PROCEDURES** and I understand them. The major risks are listed on page 3.
4. I understand the planned location of my procedures may be marked on my body before the procedures. It may also be marked on the diagrams on page 3.
5. I understand that if I am given **ANESTHESIA OR SEDATION ANALGESIA**, there will be other risks. These risks include severe blood loss, infection, damage to teeth, mouth, throat, or vocal cords, nerve or eye damage, drug reaction, slowing or stopping of breathing, failure of the anesthetic or sedation analgesia, cardiac arrest, risks that cannot be predicted, permanent disability or even death. There may be other unknown risks. I understand these risks and I consent to the use of any anesthetic or sedation analgesia that my doctors or the anesthesiologists believe is necessary.
6. My doctors have explained the **ALTERNATIVES** to the recommended procedures and their risks. I want to have the recommended procedures.
7. I understand that sometimes during a procedure, or afterwards (for example if I am in an intensive care unit), my doctors may decide that **RELATED OR ADDITIONAL PROCEDURES** are also necessary. I request and authorize the University of Michigan and the providers responsible for my treatment to perform any necessary additional procedures.
8. I **DONATE** and authorize the University of Michigan to own, use, retain, preserve, manipulate, analyze, or dispose of any **excess tissues, specimens, or parts of organs** that are removed from my body during the procedures described above and are not necessary for my diagnosis or treatment. The University of Michigan may use or retransfer these items to any entity for any lawful purpose, including education and retrospective research on anonymous specimens.
9. I request and authorize the University of Michigan and any **doctors, nurses, medical residents and other trainees, technicians, assistants or others** who may be assigned to my case to participate in my diagnosis and treatment. I understand that **representatives of companies** that sell equipment used in my procedures may also be present and participate. I also understand that the University of Michigan is a teaching institution. Medical and other students can and do participate in procedures as part of their education. By signing this form, I agree to allow these students to participate in my procedures. This may include performing **exams under anesthesia** that are relevant to my procedures.
10. I understand that unexpected events may happen before or during surgery or procedure. This may require changing the providers originally scheduled to perform or supervise my procedures.
11. I understand that the practice of medicine, surgery and dentistry is not an exact science. I have been told about the probability of success of the procedures. **NO PROMISES OR GUARANTEES** have been made or can be made to me about the success, outcomes, or side effects of the procedures.
12. I have been given a chance to ask question about the procedures and this form and my questions have been answered.

List any exceptions under the Exceptions section located on page 3.

PERF

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CONSENT FOR USE OF BLOOD OR BLOOD COMPONENTS

1. I understand I may need transfusion during my procedure. Reasons for transfusion will be for one or more reasons that may include: to correct anemia, to increase the oxygen delivery to my body, to treat a blood clot or to prevent bleeding. My provider has told me what a blood transfusion is and how it will be done. The blood products that may be used include:

(1) Red Blood Cells	(3) Plasma/cryoprecipitate	(5) Stem Cells
(2) Platelets	(4) Granulocytes	(6) Mononuclear cells
2. The risks of a transfusion include:
 - (1) **Common Reactions that usually are not dangerous:** bruising, fever, chills, rash or hives.
 - (2) **Less Common But More Serious Reactions, especially if I have heart disease:** kidney failure, heart failure, or shortness of breath (kidney or heart failure may lead to death).
 - (3) **Very Rare But Possibly Life Threatening** (less than 1 in 100,000): getting an infectious disease, like hepatitis or HIV/AIDS, bacterial infection, breakdown of transfused blood by my immune system, lung injury or death.
3. My provider has explained the potential benefits of the a transfusion, and the risks of refusing a transfusion. I understand that there may be alternatives to allogeneic (blood bank) transfusion, depending on my condition and the time involved, and that each of these has its own risks, which have also been explained. These include:
 - (1) **Growth factors or Iron:** these products take days to months to replace or increase blood cells
 - (2) **Autologous blood:** my own blood that I donate before surgery, or that is salvaged during surgery
 - (3) **Directed donors:** blood donated by people I choose (requires at least 3-4 days, and has not been found to be any safer than blood bank donors)
4. UMHHC uses blood obtained from Food and Drug Administration licensed and registered blood establishments, who test for infectious agents. UMHCC does not do its own testing and makes no guarantees about the blood products.
5. I understand the risks and potential benefits of a transfusion and I want to receive any medically necessary transfusions during my course of treatment.

PROVIDER: List any exceptions under the Exceptions section located on page 3.

CONSENT FOR TISSUE IMPLANTS

1. The procedures on page 3 may include replacement of lost or damaged tissue. Tissue might include: bone, ligaments, tendons, fascia, cartilage, cornea and sclera, skin, veins and arteries, heart valves, pericardium, or dura mater.
2. Each of the following options for replacement of lost or damaged tissue has risks. My provider has explained these risks. These include:
 - (1) **Autograft** - tissue from another part of my body for repair. Risks include increased anesthesia time, infection, transfer failure, or two surgical sites
 - (2) **Allograft** - tissue obtained from a human donor. Risks include communicable disease such as hepatitis, HIV/AIDS or CJD (the human form of mad cow disease), infection, or implant failure
 - (3) **Synthetic materials** - artificially prepared human and non-human based. Risks include communicable disease such as hepatitis, HIV/AIDS or CJD (the human form of mad cow disease), infection, possible blood thinning medication, or foreign material rejection.
 - (4) **Xenograft** - animal tissue. Risks include infection, immune rejection, or viral infection.
3. I understand that UMHHC uses tissue obtained from Food and Drug Administration registered tissue establishments which must screen donors and perform testing for communicable disease. UMHHC does not do its own testing and makes no guarantees about the tissue implant.
4. I understand the risks and potential benefits of a tissue implant. I want to receive any medically necessary tissue implants during my course of treatment.

PROVIDER: List any exceptions under the Exceptions section located on page 3.