UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

A randomized, parallel-group (autogenous ex vivo produced oral mucosa equivalent (EVPOME) vs. palatal oral mucosa (POM) efficacy study in subjects requiring additional keratinized oral mucosa for dental rehabilitation with endosseous dental implants or around erupted teeth to restore periodontal health.

IRB# HUM00065554

1.2 Company or agency sponsoring the study:

Department of Defense

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Stephen E. Feinberg, D.D.S., Ph.D., University of Michigan, Professor, Department of Surgery and Dentistry

Robert Eber, D.D.S., M.S., University of Michigan, Clinical Professor, Department of Periodontics and Oral Medicine

Cynthia L. Marcelo, Co-Investigator, Ph.D., University of Michigan Department of Surgery

Shiuyang Kuo, Co-Investigator, Ph.D., University of Michigan Department of Surgery and Dentistry

Myra Kim, Co-Investigator, Sc.D., University of Michigan School of Public Health Biostatistics

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We want to improve the current standard of care for repairing mouth defects. This study allows us to test our *tissue equivalent, Ex-Vivo Produced Oral Mucosa Equivalent or EVPOME,* which is your cells grown on top of a piece of AlloPatch. AlloPatch is freeze dried human cadaver tissue and it is routinely used in reconstructive procedures. The tissue equivalent product is an experimental agent and does not have FDA approval. The tissue equivalent product will be tested against a non-experimental method of grafts to see which works best. The non-experimental method uses a piece of tissue taken from the roof of your mouth (palate) and grafts it in the mouth at the defect site. If you wear an upper denture or upper removable partial denture the tissue will be taken from your lower jaw behind your back teeth. This is one of the standards of care methods for repairing defects or wounds in the mouth. It is also used for widening the band of keratinized mucosa

(firm, pink gum tissue that is like a callous) that is needed to form a good seal around dental implants.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you do not want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. No aspect of your treatment (except the experimental procedures described below) or non-research benefits depends on your enrollment or continued participation in this or any other study.

3.1 Who can take part in this study?

To participate in this study you must meet the following criteria:

(1) Be an adult over 18 years of age.

(2) Must be in need of soft tissue grafting surgery to increase the width of keratinized mucosa (firm, pink gum tissue that is like a callous) The proposed graft area must be suitable for a graft measuring up to approximately 15mm X 10mm X 20mm, which is about 3/4 inch long and 3/8 inch wide. This is referred to in the consent form as the “defect area”.

(3) Be able to understand and provide informed consent for participation in the protocol.

(4) Women of child bearing potential must not be pregnant, testing negative on a urine pregnancy test, and not planning to become pregnant. While we do not expect the EVPOME treatment to harm an unborn child, there may be some risk associated with the anesthesia and pain medication needed during surgery. Therefore, you must agree to abstain from sex during the course of the trial or use a reliable form of contraception during the trial such as oral contraceptive and condom, intra-uterine device (IUD) and condom, or diaphragm with spermicide and condom. If you do become pregnant during the trial, please inform the study doctor immediately. You will be followed to the conclusion of the pregnancy.

You may not participate in this study if any of the following pertain to you:

(1) If you have any liver, kidney, heart, blood, metabolic or systemic disease which may make execution of the protocol or interpretation of the results difficult, you will be excluded.

(2) If you have a history of syphilis, HIV, Hepatitis B or Hepatitis C, you will be excluded.

(3) If you are pregnant or planning to become pregnant during this study, you will be excluded.

(4) If you have a known or suspected allergy to bovine (cow) protein or iodine, you will be excluded.

(5) If you are currently receiving radiation therapy or have a history of radiation therapy treatment to the head and neck region, you will be excluded.

(6) If you are currently smoking or using tobacco products, you will be excluded. Subjects who have quit smoking more than 6 months prior to study enrollment are considered former smokers.

(7) If you have any other medical/physical history the investigator deems unacceptable for participation, or have a history of either alcohol or drug abuse in the past 5 years, you will be excluded.

(8) If you or your authorized representative is unable to provide informed consent, you will be excluded.

(9) If you have participated or plan to participate in another clinical trial within 30 days of entrance

into this study, you will be excluded.

(10) If you are taking medications that can result in gingival enlargement (Cyclosporine, Dilantin, calcium channel blockers), you will be excluded.

(11) If you are taking medication for the treatment of a thyroid disease, you will be excluded.

(12) If you are allergic to any of the following antibiotics Gentamycin, Cefoxitin, Lincomycin, Polymyxin B, Vancomycin, cephalosporins, or clindamycin, you will be excluded.

(13) If you currently use intravenous antiresorptive therapies or have used intravenous antiresorptive therapies in the last 5 years then, you will be excluded.

(14) If you have had a prior successful or attempted graft placement at the study defect site, you will be excluded.

For your safety, it is very important that you provide us with complete and accurate information about your health history/condition.

3.2 How many people (subjects) are expected to take part in this study?

Sixty (60) subjects total will participate in this study. Thirty (30) subjects will receive a graft of palatal mucosa, and 30 subjects will receive an experimental treatment with a graft made from AlloPatch and their own oral mucosal cells, EVPOME.

4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

Standard Care:

There are procedures that would be performed for treatment of your defect whether you were in this study or not. These are as follows:

- Oral examinations and medical history, including an X-ray evaluation of the site, if no x-rays have been taken in the past two years.
- Dental impression of the upper jaw to make a protective plastic stent (cover) to protect the donor site after harvesting of the tissue from the top of your mouth (palate)
- Surgical coverage of defect with palate oral mucosa graft (self-donated tissue). The graft surgery will be performed with local anesthesia in an out-patient clinic.
- Post-surgical follow-up visit, weeks 1-2, and 3-6 months, post-surgery.

Study-related Care:

- Surgical coverage of defect with experimental graft material, the EVPOME
- Tissue biopsies
- Oral photographs (photographs will be taken of oral treated areas only; they will not be identifiable)
- Additional follow-up visits

Measurements taken during visits, including laser Doppler flowmetry (an instrument that non- invasively measures blood flow) and close examination of grafts

Study groups

There are 2 treatment groups to which you may be assigned. The assignment will be made randomly, in a fashion similar to results from tossing of a coin (heads or tails).

Please keep in mind that the EVPOME is tissue that is made in the laboratory from your biopsy tissue. This tissue product is made on top of AlloPatch. AlloPatch is made of donated skin from cadavers. It is taken only from people who have a known "clean" medical history, and, it is then also specially sanitized and processed to protect against transmission of disease or rejection by the body.

- ***Group 1 (Ex-Vivo Produced Oral Mucosa Equivalent [EVPOME] Experimental Group)*:** You will be treated with EVPOME to cover the defect. You will come to the clinic for one extra visit where a 6 mm biopsy will be taken from the top of your mouth (palate) or the lower jaw behind your back teeth. The 6 mm biopsy will be grown into the size of graft needed for coverage of your defect. This process will take approximately 30 days. This grown graft (EVPOME) will be grafted to cover your defect. Media, the fluid that we will grow your EVPOME in at the laboratory, may be kept by the study team and analyzed for proteins or chemicals secreted by your cells. This analysis may help the study team to understand why people have differing graft results.

  At 4 weeks after your surgery, a 2mm circular post-operative biopsy will be taken to determine successful "take" of the graft. This sample will undergo a series of laboratory testing.

- ***Group2 (Palatal Oral Mucosa [POM] Non-experimental Group)*:** You will be treated with palate oral mucosa to cover the defect. You will have a piece of tissue larger than 6mm taken from the roof of your mouth. The tissue taken will depend upon the size of the defect to be covered. The tissue taken from the roof of your mouth will be used to cover the defect.

  At 4 weeks after your surgery, a 2mm circular post-operative biopsy will be taken to determine successful "take" of the graft. This sample will undergo a series of laboratory testing.

<u>Surgical procedures:</u>

Group 1 EVPOME Graft

After being numbed, you will have a small, 6.0 mm (~1/4in.) circular piece of tissue taken from the roof of your mouth or your lower jaw behind your back teeth. At this time the protective plastic stent (cover) we made to protect the donor site may be placed. In the laboratory we will use this piece of tissue to grow a larger piece of gum tissue, EVPOME, for grafting back in your mouth. Once the EVPOME is ready (in approximately 30 days) we will graft it into your mouth, using local anesthesia and customary surgical techniques. We will use sutures to hold the graft in place. At 4 weeks after your surgery, a 2mm circular post-operative biopsy will be taken to determine the success of the graft. This tissue will undergo a series of laboratory testing.

Group 2 Palatal Oral Mucosa Graft

After being numbed, you will have a strip of tissue the approximate size of a postage stamp taken from the roof of your mouth. This palate oral mucosa strip will be grafted into your mouth, using local anesthesia and customary surgical techniques. We will use sutures to hold the graft in place and at this time the protective plastic stent (cover) we made to protect the donor site on the top of your mouth will be placed.

At 4 weeks after your surgery, a 2mm circular post-operative biopsy will be taken to determine the success of the graft. This tissue will undergo a series of laboratory testing.

4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

Intraoral photographs will be taken at all visits.

Visit 1 (Screen) (2 to 3 hours)

The initial appointment includes an oral examination, urine pregnancy test for females, dental impression of the upper jaw (maxilla), patient history, study information and review of the informed consent form. X-ray(s) of the affected area may need to be taken to make sure you are eligible for the surgery. You will have ample time to read over this consent form and discuss it with study staff.

Visit 2 (Harvest biopsy for Group 1 only) (1 to 2 hours)

This visit will consist of an outpatient surgery to obtain a 6 mm punch biopsy from the top of your mouth (palate) or the lower jaw behind your back teeth with local anesthesia. We may place a protective stent (cover) after the biopsy to protect the donor site.

Visit 3 (Baseline/graft placement) (3-4 hours)

This visit will consist of an outpatient surgery to place a graft in your mouth to cover the defect. Group 1 subjects will receive an EVPOME graft, an experimental graft procedure to the defect area. Group 2 subjects will have palate oral mucosa grafts which have been harvested from the roof of the mouth grafted to the defect and placement of an upper jaw protective stent.

POST- OPERATIVE appointments:

Visit 4 (1-2 hours)

Post-operative follow-up visit to take place within 1 week of surgery. Oral examinations and assessments will be performed.

Visit 5 (1-2 hours)

Post-operative follow-up visit to take place within 2 weeks of surgery. Oral examinations and assessments will be performed.

Visit 6 (2-3 hours)

Post-operative follow-up visit to take place within 4 weeks of surgery. Oral examinations and assessments will be performed. A 2mm biopsy of the graft will be taken.

Visit 7 (1-2 hours)

Post-operative follow-up to take place within 8 weeks of surgery. Oral examinations and assessments will be performed.

Visit 8 (End of Study) (2-3 hours)

Post-operative follow-up visit to take place within 24 weeks of surgery. Oral examinations and assessments will be performed.

At nine and twelve months after your engraftment surgery you will receive telephone calls from the study team as follow-up, unless you don't complete the study for any reason.

4.3 When will my participation in the study be over?

Your participation in this study will be over after your 8th study visit which will be about 28 weeks after

your first visit. The total duration of this study is expected to be two years.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

1. Pain, swelling, numbness or discomfort from the biopsy site in the mouth. The research staff will try their best to minimize pain by using good surgical techniques and pain medication. There is a remote possibility that you may have an allergic reaction to the local anesthetic. If you have an allergic reaction, treatment will be provided by the researcher and/or surgeon.

   The x-rays taken are part of your standard care. Although all radiation adds up over your lifetime, small doses for dental x-rays should not be significant. The risk of radiation exposure is minimal and is therefore difficult to compare to everyday risks.

   Even though the radiation dose is low, you should not participate in the study if you are or think you might be pregnant. Female subjects must be postmenopausal for at least 2 years, surgically sterilized, or utilize effective birth control. These risks will be minimized by wearing a lead apron.

2. Adverse experiences can occur as part of the research in the laboratory setting. For example, the cells may not grow or face harsh conditions that are not optimal for use. There is a very slim chance that you may receive adversely affected cells, including a contaminated graft. The researchers will practice good laboratory technique to minimize contamination. Contamination is not a foreseen problem because all of our laboratory work is done under sterile conditions, both the technique and the instruments we use. In addition, at every step of the process tests will be done to assure that the cells and/or grafts are not contaminated. If the cells and/or graft are found to be contaminated the tissue will be discarded and another biopsy will be obtained. In our previous EVPOME trial we did not have any contaminated grafts. If it is found that the graft was contaminated the researchers will contact you and bring you in as soon as possible to evaluate the graft to see if anything needs to be done, such as, removal of the graft and/or treatment with antibiotics. Whatever course is taken you will be followed until the grafted area is completely healed.

3. The experimental laboratory grown graft, EVPOME, might not “take” and thus fail as a graft. It is also possible for the non-experimental palatal oral mucosa graft to not “take” and fail as a graft. We will use standard surgical techniques to try to assure success of the graft. While uncommon, graft failures can occur. If the graft fails, you will be able to discuss necessary standard of care options with your doctor. These standard of care options will occur outside of this study and be billed to you and your insurance.

4. Pain can occur after we take the small 2.0 mm circular, post-surgery, tissue biopsies. The surgeon will provide pain medications after the biopsies are taken.

5. If you are or may become pregnant, this research may involve unforeseeable risks of harm to you, the embryo or the fetus. It will be important to notify us if you are planning to or do become pregnant during this study.

6. Taking part in more than one research study may be harmful to you. If you are already taking part in another study, please let us know. You should not take part in more than one study at the same time, unless you and the investigators agree that you are not likely to be harmed, and the outcome of the studies will not be disturbed. As with any research study, there may be additional

risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in Section 10 of this form.

Please note: It is important that you tell the researchers about any injuries, side effects, or other problems that you experience during this study. You may also need to tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any benefits from being in this study. The grafting procedure usually will result in greater width and volume of keratinized (callous) tissue (gum tissue) at the site of your current or proposed dental implant. Keratinized tissue provides a better seal around implants than non-keratinized tissue and may provide increased resistance to future implant loss. The results of this study could allow the development of an oral tissue substitute that would provide future patients who need soft tissue mouth grafts a means of going through less pain and discomfort. The success of this study may lead to future successes of similar procedures for use to cover larger defects that can occur from physical injuries, i.e. gun shot, explosive, motor vehicle, and/or resulting from cancer surgery. If successful it will also assist in development of more complex tissue for reconstruction of the lips, nose, eyes or urogenital system.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

You may opt to be treated in the usual and customary manner by taking a larger piece of tissue from the top of your mouth or palate, for grafting the defect. Another option is to not have any treatment in the area.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

Although it is advised that you obtain follow-up care from the researchers for your own safety after the graft, you may choose to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

Leaving the study prematurely may result in graft failure. If this occurs the procedure may have to be repeated using another method, such as the palate oral mucosa graft.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

There are many reasons why the researchers may need to end your participation in the study. These include, but are not limited to:

- ✓ In the opinion of the researcher, it is not to your benefit to continue to participate.
- ✓ Your eligibility to participate changes.
- ✓ Your condition changes and you need treatment that is not allowed while you continue to participate in the study.
- ✓ You fail or refuse to follow instructions from the researchers.
- ✓ The study is suspended or cancelled.
- ✓ We were unable to grow your tissue to make a graft outside of your mouth.
- ✓ The graft did not "take" (become attached) during the healing process.
- ✓ The graft became infected such that it was no longer sticking to the reconstructed site and became non-functional.

8. FINANCIAL INFORMATION

8.1 Will taking part in this study cost me anything?

The study will pay for research-related items and services provided in this study. We do not expect you to be billed for the surgery or follow-up visits. If it is necessary for us to prescribe you any medicines, then your medical drug insurance will have to pay for the prescription and you will have to pay the co-pay. If you require sedation for any of the procedures, then you will have to pay for the cost of the sedation. We do not expect that any of the subjects will require sedation. You will have to pay for parking and transportation. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

The study team has given you instruction about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, Call Dr. Feinberg at (734) 763-5963 or Dr. Eber at (734) 255-4282 or the study coordinator, Iwonka Eagle, (734) 763-6102. The doctor will either treat you or send you to another doctor for treatment. You will get free medical care at the UMHS for a complication, injury, or illness caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS will pay for your treatment only if the need for treatment has been caused by the study drug, device or procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care

- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

Oral or intravenous (IV) sedation may also be provided at your request; however, you will assume all costs of sedation.

8.2 Will I be paid or given anything for taking part in this study?

There will be no financial benefit to you for inclusion in this study.

8.3 Who could profit or financially benefit from the study results?

The University of Michigan and the researchers of this study will not receive any financial benefit from the study results.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

University of Michigan policies require that private information about you be protected. This is especially true for your personal health information.

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

We shall put the information collected about you during the study into a research record. This research record will not show your name, but will have ID codes entered in it that will allow the information to be linked to you. However, we shall keep your research record confidential, to the extent provided by federal, state and local law. We will not allow anyone to see your record, other than people who have a right to see it. You will not be identified in any reports on this study. The United States Food and Drug Administration and the company sponsoring this research, Department of Defense, may inspect the research records. If a company would like further information from our records we, the investigators, will review your medical record, and if relevant information is found, make a copy of it, and then replace your name and institutional registration number with just the project-specific code assigned to you (so that you as a person cannot be identified), and then make it available to the company. We will honor the wishes of individual patients (and their parents/guardians) as to whether, when, or how the identity of patients would be disclosed publicly by discussing with them a mutually agreeable course of action prior to release of any information.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care.

Information about you may include information about your health and your medical care before, during, and after the study, even if that information wasn't collected as part of this research study. For example:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your deficiency of oral mucosa or need to have surgical reconstruction, the treatment you have received, and your response to the treatment
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- Medical and research monitors reviewing this study for data quality and safety may see your health information.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Representatives of the U.S. Army Medical Research and Materiel Command are parties to whom private health information may be disclosed.
- Representatives of the U.S. Army Medical Research and Materiel Command (or the DOD) are authorized to review research records for this study.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of

the results. You can search this website at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?

Even after the study is complete or after you decide to withdraw from the study, information about you may be used or disclosed as follows:

- ✓ To preserve the integrity of the other information collected during the study.
- ✓ As part of a data set used for research, educational and other lawful activities that does not include your name, social security number, or other identifying information.
- ✓ To help University and government officials make sure that the study was conducted properly
- ✓ As required by applicable federal or state law. For example, if you withdraw from the study at any time, a record of your withdrawal and the reasons you gave for withdrawing will be kept as part of the study record. In addition, government officials who are responsible for oversight and review of clinical trials may require certain disclosures.
- ✓ In addition, the information may be used to create a database about information on graft success or failure regarding tissue engineered oral mucosa.

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments

- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Dr. Stephen Feinberg
Mailing Address:	1500 E. Medical Ctr. Dr. TC B1-208, Ann Arbor, MI 48109-5018
Telephone:	(734) 763-5963
Study Coordinator:	Iwonka Eagle
Mailing Address:	1011 North University Ave. Room 1360D, Ann Arbor, MI 48109
Telephone:	(734) 763-6102

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Research Subject:
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with Dr. Robert Eber. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Date of Birth (mm/dd/yy): _____

ID Number: _____

Research Subject:
I agree to allow my cells and excess EVPOME device(s) to be maintained and used for future research purposes in the tissue repository HUM00035831. I understand that I am not required to allow my excess tissues to become part of the tissue bank HUM00035831.

☐ Initial this box to allow your tissues to be used for future research in HUM00035831.

☐ Initial this box to decline allowing your tissues to be used for future research in HUM00035831.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee:
I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____