MAYO CLINIC

Name and Clinic Number

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A pilot study: evaluating the safety and feasibility of using Stromal Vascular Fraction (SVF) for the treatment of aerodigestive fistulae in adults

IRB#: 17-003774

Principal Investigator: Dr. Timothy Woodward and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Timothy Woodward **Study Team Contact:** Natalie Fares	**Phone:** (904) 953-2000 **Phone:** (904) 953-2000 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Rd. Jacksonville, FL 32224	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Florida:** (904) 953-7058	▪ Billing or insurance related to this research study

1. Why are you being asked to take part in this research study?

You are being asked to participate in this study because you have an aero-digestive fistula. An aero-digestive fistula refers to an abnormal communication between the respiratory and digestive tracts.

The plan is to have about 10 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this research study is to see if using your own cells taken from fat in your stomach or hips can help heal your fistula. The procedure to obtain the fat from your stomach or hips is call lipoaspiration. The cells we will use are called stromal vascular fraction (SVF).

3. Information you should know

Who is Funding the Study?

Mayo Clinic Center for Regenerative Medicine is funding this study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

It will take you about 5 years to complete this research study. During this time, we will ask you to make 12 study visits to Mayo Clinic.

5. What will happen to you while you are in this research study?

Before beginning any research activities you will be asked to sign this informed consent form. If you agree to be in the study, you will be asked to participate in the following:

The Screening Visit will take about 1 hour. During this visit, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. You may not be eligible if your fistula measures greater than 15 mm. If you aren't eligible for this study, the Principal Investigator will inform you.

At this visit we will:

- Review you current medications
- Record your medical history
- Physical exam
- Vital signs, including temperature height, weight and blood pressure
- Clinical assessment of your fistula
- Fistula assessment via imaging if clinically necessary
- Patient education. Education will involve discussion about your fistula and possible treatments

Visit 2 will take about 5 hours. At this visit we will:

- Review any changes to your current medications
- Review your medical history
- Physical exam
- Vital signs, including height, weight and blood pressure.
- Clinical assessment of your fistula

- Fistula assessment via imaging if clinically necessary, as part of standard of care
- Lipoaspiration
- Administer SVF during endoscopy
- Ask you about health problems since your last visit
- Patient education

Approximately 80-100 mL of fat will be taken from your stomach through lipoaspiration. SVF will be taken from your stomach fat and mixed with a sealant called TISEEL then injected into the fistula during your endoscopy. The procedure is expected to take less than 4 hours.

As standard practice, during your endoscopy the investigator would like to takes pictures of your fistula. These pictures will help the investigator assess your fistula as part of your normal standard of care.

Do you agree to have pictures of your fistula taken during the endoscopy? Please check your answer.

☐ Yes ☐ No Please initial here: _____Date: _____

If clinically indicated, a stent may be placed covering the fistulous tract after the administration of the SVF as part of your normal standard of care.

You will be allowed to eat low residue meals 8 hours after the procedure.

After your procedure: Visits 3 (1 month), 4 (4 months), 5 (7 months), 6 (10 Month), 7 (1 Year) will take about 1 hour. At this visit we will:

- Vital sign (temperature)
- Clinical assessment of your fistula
- Ask you about side effects or health problems since your last visit
- Assess your fistula using one of the following: barium swallow x ray, MRI or CT scan as part of standard of care. Imaging of your fistula may be done at other visits if clinically necessary as part of standard of care.
- Patient education

Yearly follow up Visits (Year 1, Year 2, Year 3, Year 4, and Year 5) will take about 1 hour. At this visit we will:

- Physical exam
- Vital signs including temperature height, weight and blood pressure
- Clinical assessment of your fistula

- Assess your fistula using one of the following: barium swallow x ray, MRI or CT scan if clinically necessary as part of standard of care.
- Ask you about side effects or health problems since your last visit
- Patient education

6. What are the possible risks or discomforts from being in this research study?

Taking part in this research study may lead to added costs to you. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance company to see what services will be covered and what you will be responsible to pay.

An endoscopy is a very safe procedure. Rare complications include:
-Bleeding. Your risk of bleeding complications after an endoscopy is increased if the procedure involves removing a piece of tissue for testing (biopsy) or treating a digestive system problem. In rare cases, such bleeding may require a blood transfusion.
-Infection. Most endoscopies consist of an examination and biopsy, and risk of infection is low. The risk of infection increases when additional procedures are performed as part of your endoscopy. Most infections are minor and can be treated with antibiotics. Your doctor may give you preventive antibiotics before your procedure if you are at higher risk of infection.
-Tearing of the gastrointestinal tract. A tear in your esophagus or another part of your upper digestive tract may require hospitalization, and sometimes surgery to repair it. The risk of this complication is very low — it occurs in an estimated 1 of every 2,500 to 11,000 diagnostic upper endoscopies. The risk increases if additional procedures, such as dilation to widen your esophagus, are performed.
You can reduce your risk of complications by carefully following your doctor's instructions for preparing for an endoscopy, such as fasting and stopping certain medications.

Risks of lipoaspiration include an allergic reaction to the Hunstad solution. Hunstad solution is used to reduce discomfort during lipoaspiration. Additional risks include bleeding, infection and bruising at the lipoaspiration site.

Risks of the TISEEL and stem cell sealant include formation of a blood clot or allergic reaction.

Pregnant and nursing women will not be allowed to participate in this study. Please tell your study doctor if you are pregnant or think you might be pregnant. If you are a woman of child bearing potential, you must use birth control for the duration of the study. Your study doctor will tell you which birth control methods should be used during this study.

There may be unknown side effects may ranging from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

Your doctor will discuss the risks of the MRI, CT, barium swallow x ray, and endoscopic intervention for your fistula, as these tests and procedures are part of your standard clinical care.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest
- if you don't follow the study procedures
- if the study is stopped

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

This study may not make your health better. However, the condition of your fistula may improve.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include the endoscopy with administration of the TISEEL sealant without stem cells. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Fat collection by lipoaspiration
- SVF administration

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- Physical Exams
- Endoscopy or Bronchoscopy
- Barium swallow x ray, CT, MRI

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Research Billing at the telephone number provided in the Contact Information section of this form.

12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. What will happen to your samples?

Your samples will be used for this study. When the study is done, they will be destroyed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Hard copy data such as consent forms will be stored in locked file cabinets; electronic data will be stored in secure web-based database. The database has built in system for control of access, data integrity and audit trails. Access and confidentiality are controlled in a manner similar to other institutional systems.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.

- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature