

Participant ID#: \_\_\_\_\_

Louisiana State University Health Sciences Center - New Orleans

## Consent to Participate in Research

**STUDY TITLE:** Molecular Mechanisms in the Treatment of Pyoderma Gangrenosum with Dehydrated Human Amnion/Chorion Membrane

**PRINCIPAL INVESTIGATOR:** Alison A. Smith, MD, PhD

**EMERGENCY CONTACT:** Alison A. Smith, MD, PhD

**STUDY SPONSOR:** N/A

**STUDY SITES:**

UMCNO	Ochsner Baptist
2000 Canal Street	2700 Napoleon Ave
New Orleans, LA 70112	New Orleans, LA 70115

### 1. Invitation to be Part of a Research Study

Alison A. Smith, MD, PhD, and associates from the Department of Surgery at the Louisiana State University Health Sciences Center in New Orleans (LSUHSC-NO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. The research team is asking you to be in this study because you have pyoderma gangrenosum. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, "you" always refers to the participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

### 2. Important Information about this Research Study

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have more details, including contact information for people who can answer any questions or

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concerns you may have. Please take time to read this whole document and ask questions before deciding if you want to take part in this research study.

Things you should know:

- The purpose of the study is to identify genes or groups of genes that are involved in causing pyoderma gangrenosum (PG).
- In order to participate, you must be over age 18 and diagnosed with pyoderma gangrenosum.
- If you choose to participate, you will receive treatment for your PG wounds that involves two surgeries and post-surgery clinic follow-up visits. You will be in the study for 6 months if you decide to stay for the whole study.
- The main risks of being in the study are associated risks with EpiFix which are minimal but may include no increase in wound healing rates, lower overall function or results in a higher complication rate, infection transmission and allergic reactions. Many precautions are taken to make sure the study product is free of contaminants so the risk of contracting an infectious disease is very low. No evidence of graft rejection, infection transmission or allergic reactions has been reported to date.
- You might benefit from being in the study because you suffer from pyoderma gangrenosum. We expect wounds to heal faster and better with our proposed treatment. We hope to reduce the total cost of treatment by reducing the time to heal and reduced rehabilitation time. However, it is possible for you to receive no direct benefit from the proposed treatment. No direct medical benefit can be guaranteed. No promise can be made concerning the study outcome.
- The alternative is not to participate. Treatment alternatives should be discussed with the treating physician as it is dependent on the clinical presentation and patient. You will be provided with standard treatment as prescribed by your physician.
- Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time.

### 3. Why is this study being done?

This is a research study designed to identify genes or groups of genes that are involved in causing pyoderma gangrenosum. Doing this will potentially allow us to identify the genetic cause of pyoderma gangrenosum, which is something that has yet to be determined. Additionally, we are hoping to identify certain genes or genetic pathways that are specifically targeted by treatment of a wound with dehydrated human amnion/chorion membrane (EpiFix). With this data we hope to better understand the method by which EpiFix can specifically heal a wound. Ultimately, all this data will be used to identify specific findings that aid in the diagnosis and treatment of PG.

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This research study will be conducted in the New Orleans area at several local hospitals. Research studies only include people who choose to take part. There will be no penalty for choosing not to join the study. Before agreeing to do this research study it is important you read this consent form, ask any questions you have and understand the answers to your questions. Please ask the research staff to explain any words or sections you do not understand. When you are done and all your questions have been answered, please sign and date the form on the last page if you agree to join the study.

## 4. What will happen if I take part in this study?

### Before you begin the study

Before you begin the study, you will need to have a pre-evaluation including:

- Background and demographic information
- Wound size and severity
- Pain level
- Risk factors
- Medication use
- Photographs of wound

### During the study

If you agree to take part in this study, you will undergo a surgery where the pyoderma gangrenosum wounds are going to be treated with the EpiFix. About a week later, you will then receive another where skin grafts will be placed on the wounds that were treated in the first surgery. In each surgery, samples of your wound will be taken, and genetic information from these samples will be studied to identify the genes that are active before and after treating the wound with EpiFix. You will then have routine post-surgery clinic visits to monitor the healing of your wounds and make sure that no extra medical treatment is needed.

Study staff will evaluate your wound twice a week for the first two weeks, then once a week until 6 weeks. Following this, you will then be followed every 4 weeks up to 22 weeks. These visits to the clinic will include taking wound measurements, taking digital photos, asking about your level of pain and evaluating development of infection. There are no extra study-related laboratory tests required. We anticipate each visit to the clinic to last a maximum of one hour. Based on this schedule, you can expect to be enrolled in our study for approximately 6 months.

With your permission, we would like to take photographs of the wounds for study purposes. Please note that these photographs will be completely de-identified from your personal information. You may review the photographs. You are allowed to request withdrawal of such materials from our study at any point by giving us the request in writing. You may review and edit the media at your discretion. You do not have to agree to audio/video recording in order to participate in the study.

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### **Consent to be Audio/video Recorded**

*I agree to be audio/video recorded. I may withdraw my consent at any time by submitting a request in writing to the researcher.*

YES \_\_\_\_\_ NO \_\_\_\_\_ Initials \_\_\_\_\_

## **5. What should I know about genetic research?**

### **Genetic information and privacy risk**

The samples collected during this research will be used to extract your genetic information. We plan to identify genes or groups of genes that are involved in causing pyoderma gangrenosum using tissue samples taken from your wounds. Doing this will potentially allow us to identify the genetic cause of pyoderma gangrenosum, which is something that has yet to be determined. Additionally, we are hoping to identify certain genes or genetic pathways that are specifically targeted by treatment of a wound with dehydrated human amnion/chorion membrane (EpiFix).

Your genetic information is unique to you. It is possible for someone to use genetic information in research records to identify you even if there are no other identifiers such as your name or address in the records. The researchers believe this risk is very small. However, the risk may increase in the future as people come up with new ways of tracing genetic information.

### **Discrimination based on genetic information**

Health insurance companies, group health plans, and most employers may not treat you differently based on your genetic information. This is because of a federal law called the Genetic Information Nondiscrimination Act. This law protects you in the following ways:

- Health insurance companies and group health plans may not:
  - ask for your genetic information that we get from this research, or
  - use your genetic information when making decisions about your eligibility or premiums.
- Employers with 15 or more workers may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

All health insurance companies, group health plans, and all employers with 15 or more employees must follow this law.

Federal law does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from treating you differently based on your genetic information. It also does not prevent different treatment because of a genetic disease or disorder that you already know about.

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According to Louisiana law, your genetic information is your property. Insurance companies or employers may not get samples containing your genetic information without first getting your written permission. Insurance companies or employers also cannot use your genetic information to treat you differently when you are looking for a job or buying insurance.

## 6. How many people will take part in this study and how long will it last?

In total, 20 people will take part in this study at LSUHSC-NO.

If you complete the entire study, your participation will last 6 months.

## 7. What are the risks of taking part in this study?

### **Known risks and discomforts**

The known risks and discomforts from the study procedures are minimal but may include no increase in wound healing rates, lower overall function or results in a higher complication rate, infection transmission and allergic reactions. Many precautions are taken to make sure the study product is free of contaminants so the risk of contracting an infectious disease is very low. No evidence of graft rejection, infection transmission or allergic reactions has been reported to date. Drawing blood has a small risk of local pain, bruising, infection, swelling and/or bleeding at the needle puncture site.

There are risks with any medical intervention. These risks include but are not limited to allergic reaction, wound complication, pain, infection, amputation, delayed wound-healing and possibly death. Death is listed as a risk to the subject as is customary for any treatment utilizing general anesthesia. Please realize that both described treatments require surgery and the use of general anesthesia within the operating room. General anesthesia is the standard of care for these types of surgery; risks associated with anesthesia will be discussed with you in a separate clinical procedure consent form specific to the hospital where you will have the operation performed. Your wound will be evaluated at follow-up to ensure medical care is provided in the event of an adverse reaction to treatment.

### **Unknown risks and discomforts**

The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about continuing to take part in the study.

## 8. Are there any benefits to participating in this study?

### **Possible benefits to you**

We expect wounds to heal faster and better with our proposed treatment. We hope to reduce the total cost of treatment by reducing the time to heal and reduced rehabilitation time.

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However, it is possible for you to receive no direct benefit from the proposed treatment. No direct medical benefit can be guaranteed. No promise can be made concerning the study outcome.

### **Possible benefits to others or society**

This study will help the researchers learn more about EpiFix. This information may help in the treatment of future patients with pyoderma gangrenosum like yours.

## **9. What other choices do I have if I don't take part in this study?**

The alternative is not to participate. Treatment alternatives should be discussed with the treating physician as it is dependent on the clinical presentation and patient. You will be provided with standard treatment as prescribed by your physician.

## **10. How will my information be kept confidential?**

The researchers will protect your information by making every effort to protect your privacy and keep your data confidential. Your personal information will be stored on a password protected computer that is only accessible by the study personnel. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

- Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
- Other organizations or agencies if required by law.

If any publications and/or presentations result from this study, they will not identify you by name.

## **11. Will my information/specimens be used for future research?**

We will not use or share any of your information and/or samples collected as part of this study for future research, even if identifiers are removed. Any samples obtained for this study will be discarded or destroyed once they have been used for their intended purpose in this study. All related research materials will be destroyed 3 years from study completion.

## **12. Will there be any costs to me for taking part in this study?**

The costs of all drugs, visits, procedures and study-related and unforeseen complications must be met by the subject. Treatment of your medical condition will be billed to your

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insurance in the normal way. You may be responsible for co-payments or deductibles. No costs are covered by this research study. Prior to enrollment in the study, we advise that you check with your insurance company to confirm they will cover the cost of treatment with dehydrated human amnion/chorion membrane (EpiFix). In the event that your insurer does not cover the cost of treatment, the patient will be responsible for meeting the cost of such treatment. If you have any questions about treatment for which you may be responsible for paying, please discuss this with your physician or study staff.

Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar conditions.

### **13. Will I be paid or for taking part in this study?**

You will not receive any type of payment for taking part in this study.

### **14. Who can profit from study results?**

#### **Researcher Financial Interests in this Study**

N/A

#### **Use of My Specimens**

Any specimens (e.g., tissue, blood, urine) obtained for routine lab testing will be discarded or destroyed once they have been used for the purposes described in the protocol.

### **15. What should I do if I get sick or injured during the study?**

If you believe the research procedures have made you sick or caused an injury to you, immediately seek medical advice and/or treatment by:

- Contacting the Principal Investigator and/or the Co-Investigator whose phone numbers are listed in the next section; and/or
- Calling the Research Injury phone number listed in the next section; and/or
- Contacting your regular medical doctor; and/or
- Contacting the treatment center of your choice.

In the event of study-related harm, the principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There are not funds available to pay for any disability that results or for damages such as lost wages, etc.

If the insurance company does pay for the care and treatment of study-related injury, you may be responsible for any co-payments and deductibles.

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## 16. Who can I contact if I have questions about this study?

### **The research team:**

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

#### **Principal Investigator**

Name: Alison A. Smith, MD, PhD  
Address: 1542 Tulane Ave  
Room 751  
New Orleans, LA 70112  
Phone #: 504-903-9009

#### **Co-Investigator**

Name: Frank Lau, MD  
Address: 1542 Tulane Ave  
Room 734  
New Orleans, LA 70112  
Phone #: 504-568-4750

24-Hour Phone #: 412-607-3047

Research Injury Phone #: (504) 940-8407

### **Office of the Chancellor, LSU Health Sciences Center - New Orleans:**

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

- you have questions about your rights while taking part in this study, or
- you have any concerns or suggestions, and
- want to talk to someone other than the researchers about the study.

## 17. What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

- Your safety and welfare are at risk.
- You do not follow instructions.
- You miss scheduled visits.
- You fail to complete study activities.

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

The researcher may stop you from taking part in this study if at any time it is believed to be in your best interest; if you do not follow the study procedures; if the study is stopped. You could

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be taken off the study if your health worsens; if another treatment option appears to be appropriate; or for any other cause which prevents your continuing in the study.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

## 18. Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have. If you want more information about your rights as a research participant, please visit [https://www.lsuhsc.edu/administration/academic/ors/participant\\_information.aspx](https://www.lsuhsc.edu/administration/academic/ors/participant_information.aspx).

If you are a LSUHSC-NO student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. Your decision will not affect your grades or job status at LSUHSC-NO. You will not be offered or receive any special consideration if you take part in this research study.

## 19. Your Consent

By signing this document, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I will receive a copy of the consent form.
- I do not waive any of my legal rights by signing this consent document.
- I can contact the study team or the Chancellor's Office using the contact information provided above if I have any questions or concerns after signing the consent form.

### Signature of Participant:

*I agree to take part in this study.*

Participant Signature

Printed Name

Date

### Signature of Reader & Witness to Consent of Subjects Who Cannot Read:

*The study subject has indicated to me that he/she is unable to read. I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was*

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*given the opportunity to ask questions, and that the subject has indicated his/her consent for participation by completing the signature line above.*

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Reader Signature

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Printed Name

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Date

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Witness Signature

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Printed Name

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Date**Signature of Legally Authorized Representative for Adult:**

*I am a legally authorized representative of the person named below. I agree for this person to take part in this study.*

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Name of Participant (Please print)**Type of LAR (Check applicable box):**

- Court-appointed Guardian
- Health Care Proxy
- Durable Power of Attorney
- Family Member/Next-of-Kin. Relationship: \_\_\_\_\_
- Other: \_\_\_\_\_

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LAR Signature

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Printed Name

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Date**Signature of Person Obtaining Consent:**

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*I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.*

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Signature of Person Obtaining Consent

Printed Name

Date