

CONSENT FORM

Title of this Research Study

Comparison of Porcine Collagen Membrane (Mucograft Seal) and Bovine Collagen Wound Dressing (HeliPlug) in Atraumatic Extraction Sites with DFDBA Bone Particulate Graft: A Randomized Controlled Trial

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

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Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

The study will help to understand healing after a tooth extraction and bone graft.

You have a tooth that needs to be removed. A 3D xray will be taken prior to removal of the tooth. Numbing medicine will be given and the tooth will be taken out. A bone graft and cover will be placed to prepare the area for an implant. Stitches will be put in the area and you will be taught how to keep the area clean. Two weeks later, you will return to the clinic to have the stitches taken out.

If you decide to take part in this study, the following things will also be done. Before the tooth removal, the study investigator will take a digital impression of your teeth and some measurements of your gum. Two weeks later you will return to the clinic to have the stitches taken out and the same measurements taken. Six weeks after the

tooth is taken out we will take a very small piece of gum from the area. This will not affect how you heal. After three months, you will come back to the clinic and have a 3D xray taken to plan your dental implant.

Risks of being in this study could include temporary soreness, bleeding and swelling of the area where the tooth was taken out.

There are no benefits to being in this study. You can proceed with tooth removal and implant planning without being a part of this study.

Why are you being asked to be in this research study?

You are being asked to be in this research study because you are a healthy adult, aged 19-75 years old, need to have a bicuspид or front tooth removed and are planning to get an implant. Up to 24 people will be in this study.

What is the reason for doing this research study?

The study will help us learn more about healing after a tooth extraction.

What will be done during this research study?

This study will start by taking measurements of the gums around the tooth to be removed and a digital impression of your teeth. A small piece of paper will be used to soak up a small amount of liquid around your tooth. These paper pieces will be frozen and the liquid analyzed at a later time. You will also have a 3D xray taken. Numbing medicine will be given to the tooth and it will be removed. A bone graft and type of cover will be placed to prepare the area for a dental implant. Your investigator will not know which type of cover you will be getting until right before it is placed. You will not be told which cover you're receiving, but both options are suitable materials. Stitches will be placed at the area and you will be sent home.

Two weeks after the tooth removal, you will return to the College of Dentistry. At that appointment, stitches will be removed and another digital scan will be taken.

Six weeks after the tooth removal, you will return to the College of Dentistry. At that appointment, a very small piece of gum will be removed. The gum sample will be looked at by a scientist to measure how it healed. That scientist will not know which patient the gum sample is from. The removal and analysis of this gum sample is different from the usual care of a removed tooth.

Three months later, you will return to the College of Dentistry for a final appointment. At that time, another digital scan will be taken, as well as a final 3D xray.

There are no plans to perform any genetic tests (including whole genome

sequencing) on your samples.

The sample(s) we collect will not be used for other research studies by us, or by any other investigator after this research is over.

What are the possible risks of being in this research study?

The risks of being in this study include minor soreness, bleeding and slight swelling at the site where the tooth was extracted.

The gum and liquid samples will not be labeled with your name or any identifying personal information.

What are the possible benefits to you?

You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?

Possible benefits to society include a better understanding of wound healing in the mouth.

What are the alternatives to being in this research study?

Instead of being in this research study, you can choose not to take part. The usual care of having your tooth extracted and grafted, and implant planning will be available to you whether or not you choose to participate in the study.

What will being in this research study cost you?

There will be no additional costs to you for being in this study.

You will have to pay any insurance deductibles and co-payments for usual care. If you want to speak with someone about your insurance, just tell us.

Will you be paid for being in this research study?

You will not be paid to be in this research study.

Who is paying for this research?

This research is funded by the Graduate Periodontics Department.

What should you do if you are injured or have a medical problem during this research study?

Your health and safety is our main concern. If you are injured or have a medical problem or some other kind of problem because of the study call someone listed at the end of this consent form.

How will information about you be protected?

In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.

The information will not be used for other research by us, or by any other researcher.

Who can see information about you?

We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

You are letting us use and share your PHI for as long as the research is going on. The Privacy Rule may not apply to all these groups. Once disclosed outside of UNMC federal privacy laws may no longer protect your PHI. Ask the investigator (or contact the Office of Regulatory Affairs at IRBORA@unmc.edu) if you have questions.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly

confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: UNMC College of Dentistry, 4000 Easter Campus Loop South, Lincoln, NE 68583-0740

What will happen if you decide not to be in this research study?

You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?

You can stop being in this research (withdraw) at any time. If you decide to stop being in the research, please let us know.

If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?

We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?

We gave you a copy of "*What Do I Need to Know Before Being in a Research Study?*"

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?

You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
 - Telephone: (402) 559-6463.

- Email: IRBORA@unmc.edu
- Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
 - Telephone: (402) 559-6941
 - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____ Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature _____ of _____ Person _____ Obtaining
Consent _____ Date _____

Authorized Study Personnel

Principal

* Killeen, Amy
phone: 402-472-7848
alt #: 402-472-7848
degree: DDS

Secondary

* Reinhardt, Rick (Rick)
phone: 402-472-1287

alt #: 402-472-1287

degree: DDS

Participating Personnel

* Czechner, Otto

phone: 402-472-3249

alt #: 402-472-3249

degree: DDS

* Davis, Richard

phone: 402-472-3249

alt #: 402-472-3249

degree: DDS

* Ingalsbe, Greg (Greg)

phone: 402-472-1311

alt #: 402-472-3249

degree: DMD

* Lee, Joyce

alt #: 402-472-3249

degree: DDS

* Scanlan, Christine

phone: 402-472-1311

alt #: 402-472-3249

degree: DDS

* Schlemmer, Paula

phone: 402-472-3249

alt #: 402-472-3249

degree: DDS

Lead Coordinator

Christiansen, Megan (Megan)

phone: 402-472-6770

alt #: 402-472-1441

degree: BS, RDH

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.