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Tegarderm® Placement for Bag Mask Ventilation in the Bearded Patient

Study Consent Document
Document Date: February 11, 2020

Approved by the
Human Research Review Committee
at the University of New Mexico Health Sciences Center
on: February 12, 2020

Note: "Template Version" date of 2/7/2019 in the document footer refers to the consent document template form only, and not its contents

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Tegaderm and Beards Study

We are inviting you to join a research study about a way that might help people with beards breathe better when they are going under anesthesia.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

We're doing this study to learn if a covering on beards helps breathing masks have a better seal and then work better. If you join, you would be in this study for about five or ten minutes.

Our goal is to find out if a special bandage ("Tegaderm"; it's like plastic wrap for food, but one side is slightly sticky or tacky) covering your beard gives a better seal for the mask we use to help you breathe before surgery, when removed the covering when removed the covering will not pull out any facial hair. Tegaderm bandages are FDA-approved, and we are using them in a way similar to the labeling indications.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

With your help, we hope to learn more about helping the air mask work better for bearded patients having surgery. For a complete description of benefits, refer to the Detailed Consent that starts on the next page.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR IT?

The main risks are mild irritation from the bandage or a minor allergic reaction to its adhesive. Irritation is uncommon and allergic reactions are very rare. For a complete description of the risks, refer to the Detailed Consent. You should not volunteer if you are allergic to Tegaderm.

DO YOU HAVE TO BE IN THIS STUDY?

If you decide to join our study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Neal Gerstein of the Department of Anesthesiology & Critical Care Medicine in the University of New Mexico - School of Medicine. If you have questions, suggestions, or concerns about this study or if you want to withdraw from it, his office phone number is 505-272-2610.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) during business hours (8AM – 5PM Mountain Time), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version February 11, 2020

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

- If you have heart disease
- If you have a medical problem that affects your breathing
- If a doctor has told you that you have a "difficult airway"
- If you are allergic to Tegaderm

WHERE IS THE STUDY GOING TO HAPPEN, AND HOW LONG WILL IT LAST?

The research procedures will happen here, today, at the UNM Hospital operating room. The total amount of time you will be asked to volunteer for this study is about five minutes.

WHAT WILL YOU BE ASKED TO DO?

If you join our study, we'll get you ready for surgery just like normal. Then these things will happen:

1. We'll have you breathe oxygen through a mask for a little while (about a minute or two).
2. We'll give you anesthesia (you'll be "asleep").
3. We'll put a hole in the Tegaderm bandage so that you can always breathe, and then we'll put it over your beard.
4. We'll measure how well the mask seals against your face without the bandage (our usual way), and with the bandage to form a smooth covering over your beard. The one we do first will be chosen randomly, like tossing a coin.
5. Then your surgery will happen, just like usual.
6. We'll remove the bandage before you "wake up" from anesthesia.
7. We'll record some information about you like your age, height, weight, length of your beard, and how well the breathing mask worked with and without the bandage.

The only things that are special for our study are the Tegaderm bandage (#3 and #6), measuring how well the mask seals (#4), and recording information for research purposes (#7).

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is an occasional risk that the bandage may cause mild irritation on your skin, and a rare risk of allergic reaction to its adhesive (the sticky part). These reactions usually go away on their own, or they can be treated with medicine here in the hospital.

Being in our study means that you will get air through a mask for an extra 2 minutes or so before we place your breathing tube. There is a tiny risk that participants could inhale stomach contents or be injured if too much air accidentally goes into the stomach, but we cannot be sure that this risk really is higher than if you were not in our study.

There is always a chance that any medical treatment can harm you. The research treatments and procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from being in this study. However, if you join it, the information we learn may help us improve care for other people with beards in the future.

WHAT WILL IT COST YOU TO PARTICIPATE?

Being in our study will not cost you anything.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of your care even if you do not join this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the study results, we will write about the combined results instead of focusing on individual people in it. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. We will store your name only temporarily, in a locked cabinet in a secure office. Then we will transfer it to secure computer storage.

You should know there could be some times when we would have to show your information to other people to follow the law. Here are some examples:

- The law requires us to share your information with authorities if you tell us about a child being abused, or if you pose a danger to yourself or someone else.
- A court or other state agencies, if you have a reportable disease or condition.
- The FDA, for oversight of our study.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

Yes. You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

We may remove you from the study at any time if:

- You are not able to follow directions.
- Your doctors decide that your participation in the study is more risk than benefit to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You can take part in this study if you are currently involved in another research study. It is important to let your doctor know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Gerstein at 505-272-2610 during normal business hours. Outside business hours, you can call the Operating Room front desk at 272-2626.

A doctor will decide what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be charged to you and/or your insurance company, Medicare, or Medicaid as appropriate.

WILL YOU BE PAID FOR PARTICIPATING IN THIS STUDY?

No, you will not receive any rewards or payment for being in the study.

WHAT ELSE DO YOU NEED TO KNOW?

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. 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.

If you volunteer to take part in this study, you will be one of about 25 people to do so.

If significant new findings develop during the course of this study you will be provided with this information.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name or medical record number.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI).

As part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes your age, weight, height, race, whether you have obstructive sleep apnea, how widely you can open your mouth, the length of your beard, and information about how well the breathing mask worked with and without the Tegaderm bandage.

In addition to researchers and staff at UNMH and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no

longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study does not expire unless you cancel it. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time if you notify the UNM investigators in writing. To do this, please send a letter asking for withdrawal to:

Dr. Neal Gerstein
Anesthesiology Department, MSC10-6000
1 University of New Mexico
Albuquerque, NM 87131

Please be aware that the research team does not have to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or use your health information (revoke the Authorization). If you revoke the authorization:

- You must send a written letter to the address above to tell us about your decision.
- We may use and release your health information already collected for this research study.
- Your protected health information may still be used and released if you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the hospital's Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer during business hours (8 – 5 Mountain Time, Monday-Friday) at 505-272-1493.

INFORMED CONSENT SIGNATURE PAGE

You are deciding if you want to participate in this research study. This consent document includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

PARTICIPANT'S SIGNATURE

_____ _____

Signature of research subject **Date**

_____

Printed name of research subject

INVESTIGATOR'S SIGNATURE

_____ _____

Signature of investigator obtaining informed consent/HIPAA Authorization Date

_____

Printed name of investigator obtaining informed consent/HIPAA Authorization

if necessary, WITNESS (TRANSLATOR)'S SIGNATURE

_____ _____

Signature of witness (translator) Date

_____

Printed name of witness (translator)