A Randomized Trial of Blinded vs Unblinded Sepsis Biomarker Monitoring in Burn Patients

NCT ID not yet assigned

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This consent form is not valid without a TTUHSC IRB stamp in the lower left corner of each page

CONSENT TO TAKE PART IN A SOCIO-BEHAVIORAL RESEARCH STUDY

This is a research study for people who **voluntarily** choose to take part. Please **take your time** to make a decision, and discuss the study with anyone you think could help you with your decision. If you decide not to take part you will not lose access to benefits you would normally get.

STUDY TITLE: A Randomized Trial of Blinded vs Unblinded Sepsis Biomarker Monitoring in Burn Patients

INVESTIGATOR(S): Brian Schneider, MD

CONTACT TELEPHONE NUMBER(S): 806-743-2370
(You may contact the investigator(s) at the number(s) listed above if you have any concerns or unexpected complications.)

INSTITUTION(S: TTUHSC Lubbock and UMC Lubbock

OVERVIEW

What you need to know:
- Infections can make recovering from a burn injury more complicated.
- Some infections can cause organs to stop working the way they should. This is called sepsis.

What you will be asked to do while in the research study:
- Allow your care team to collect blood for infection monitoring

Most common risks from blood draw include:
- Bruising
- Soreness
- Minor bleeding

If you are interested in learning more about the study and participation, the rest of this form will be reviewed and discussed with you.

DETAILED INFORMATION

1. What is the purpose of this study?

Because some infections can make burn recovery more complicated, we want to determine if monitoring blood daily for signs of infection can help us identify and treat these infections sooner.

120 patients will be included from TTUHSC/UMC.

2. How long will I be in this study?

The maximum time you will be in the study is 45 days.

3. What will happen in this study that is different than my usual care?
A daily blood draw is being done for research purposes.
This will start on the first day in the burn unit and continue until you leave the burn unit. hese should be listed with the timing when they occur in the study. Your results from these blood tests will not be disclosed to you.

When the study is done,
we will keep your unidentifiable recorded medical information to use in our future research, or in research done by our colleagues. If your unidentifiable medical information is used in future studies, we will not ask for your consent again before using it. You will not know when or if the data are used for research, and no one will be able to tell you any results of research that used your data.

It is possible that this data will be used in research that could profit the researchers or others. If the data is used in that way, you will not share in any of the potential profit.

4. What about confidentiality and the privacy of my records?
We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center (TTUHSC) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

Study results that are used in publications or presentations will not use your name.

The sponsor of the study, Abionic, can also review the study records, but the sponsor is not allowed to remove or copy information that identifies you by name, with one exception. If you receive Medicare benefits, the Sponsor, Abionic, is required by law to report payments made to you for treatment, complications, and injuries that arise from this Study. Information that you are taking part in the Study, medical treatments received, Medicare claims, and other personal information about you such as your name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

5. What are my choices if I decide not to take part in this study?
If you decide not to participate in this study, nothing will change about your care.

6. What risks are expected based on what we know now?
There are no other known risks beyond what is stated in the Overview at the beginning of this form.

7. What happens if I am injured because I take part in this study?

Texas Tech University Health Sciences Center and UMC do not/does not offer to pay for or cover the cost research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

8. Are there any benefits to me?

There is no guaranteed benefit to you. However, the blood test may have information to support the rapid diagnosis of sepsis, which could lead to earlier treatment. This could potentially result in improved management but no guarantees are being made.

For future burn patients, the findings from this study could improve care and recovery.

9. Will I receive anything for taking part in this study?

You will not be paid for participating in this study.

10. Will it cost me anything to take part in this study?

There are no costs to you for participating in this study.

11. Does anyone on the research staff have a personal financial interest in this study?

No one on the research staff has a financial interest in this study.

12. If I decide to take part in this study can I stop later?

Yes, your participation is voluntary. You can decide to stop taking part in the study at any time, however, any data about you that has been collected up to that point in time cannot be removed.

If you decide to stop, let your researcher know as soon as possible so we can assure your needs related to this research are met. It's important that you stop safely. If you decide to withdraw from the study you can decide if you want to keep letting the researcher know how you are doing or if you want to completely withdraw from participation.

Your researcher will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

13. Are there any other reasons why my participation might end?

Yes. The researchers may take you off the study if:

- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by Institutional Review Board (a committee that reviews and approves research) or study sponsor, Abionic.

14. What if I have questions?

For questions about this study, contact the Investigator, Brian Schneider, MD. 806-743-2370.

In the event you believe an emergency may affect your participation in this study, contact the investigator.

If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTUHSC EthicsPoint Hotline: 1-866-294-9352, or you can file an EthicsPoint report online: https://secure.ethicspoint.com/domain/media/en/gui/12958/index.html. Please choose the "Regulatory Compliance" option when making an online report.

[SIGNATURE PAGE FOLLOWS]

You will be given a signed and dated copy of this form.

_____
Printed Name of Subject

_____
Signature of Subject Date

_____
Signature of Guardian/Authorized Representative Date

I have discussed this research study with the subject and his or her authorized representative, using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

_____
Signature of authorized research personnel who conducted the informed consent discussion Date

[THIS SPACE HAS BEEN LEFT INTENTIONALLY BLANK]

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

AUTHORIZATION TO USE AND/OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION for a RESEARCH STUDY

STUDY TITLE: A Randomized Trial of Blinded vs Unblinded Sepsis Biomarker Monitoring in Burn Patients

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information** (PHI) if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.

2. If you choose to cancel this Authorization, please give notice in writing to:
   Institutional Privacy Officer
   Office of Institutional Compliance
   3601 4th St MS 8165
   Lubbock TX 79430

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

• hospital records and reports • admission history, and physical examination • X-ray films and reports; operative reports	• immunizations • allergy reports • prescriptions

• laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS) • any other Protected Health Information needed by the research personnel listed above	• consultations • clinic notes • mental health records • alcohol/substance abuse records

For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC Institutional Review Board, TTUHSC compliance reviews, the US Food and Drug Administration (FDA) or governmental agencies in other countries. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

_____
Printed Name

_____
Signature of Individual or Authorized Representative Date

_____
If applicable, Relationship of Authorized Representative or Authority to Sign Date