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

CONSENT TO TAKE PART IN A MEDICAL 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: Starvation in the Treatment of Diabetic Ketoacidosis: Is there enough evidence to support this practice?

INVESTIGATOR(S): Kenneth Iwuji, MD (Principal Investigator)
Kenneth Nugent, MD
Sierra Sullivan, MD
Jesus Davalos, MD
Abbie Evans, MD

CONTACT TELEPHONE NUMBER(S): Kenneth Iwuji, MD (806)-743-3150
(You may contact the investigator(s) at the number(s) listed above if you have any concerns or unexpected complications.)

INSTITUTION(S):
Texas Tech University Health Sciences Center
3601 4th Street
Lubbock, TX 79430

University Medical Center
602 Indiana Ave
Lubbock, TX 79415

OVERVIEW

What you need to know:

- This study aims to learn more about the role of diet in treating diabetic ketoacidosis (DKA).
- You are being asked to take part because you are in the MICU to treat DKA.

What you will be asked to do while in the research study:

- You will be asked to allow researchers to access your medical records.
- You will be randomly chosen to receive one of two diets while in the MICU.
- Some people will not eat until a certain test value improves (usual care).
- Other people will receive food (liquid and/or solid) from the start.

Most common risks include:

- Loss of privacy is possible with all research. Steps will be taken to prevent this.
- Other risks are possible, including high blood sugar and a longer amount of time spent in DKA. However, we will try to prevent this risk by checking hourly blood glucose levels as is standard in the treatment of all DKA. Should your health condition change

or participation in this study would not be in your best interest, you will be removed.

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?**
   This study aims to better understand how eating while in the MICU affects patient results. It is common for doctors to keep DKA patients off food for until certain tests improve. It is not known whether this is helpful or not.

   At least 88 people will take part.

2. **How long will I be in this study?**
   You will only take part until you are released from the hospital.

3. **What will happen in this study that is different than my usual care?**
   If you agree to take part, info from your medical charts and blood tests will be used. You will be randomly put in one of two groups. You will either receive food from the start, or receive food after a certain test value is better. You will not be told the results of the study.

   When the study is done, we will properly dispose of your recorded medical information and it will not be used in future studies.

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.

5. **What are my choices if I decide not to take part in this study?**
   Your choice to participate will not affect your care. You will still be treated for DKA and have your blood monitored regularly.

6. **What risks are expected based on what we know now?**
   Your blood sugar could be raised by eating sooner. It is also possible that DKA could last

longer. Your blood will be checked every hour to lower this risk. Should your health condition change or participation in this study would not be in your best interest, you will be removed.

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

Texas Tech University Health Sciences Center and UMC do not offer to pay for or cover the cost of medical treatment for 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?

You may not benefit from taking part. However, this study may help to provide better care to DKA patients in the future.

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/study doctor 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 stop the study intervention(s), 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/study doctor 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 I might stop being in the study?

Yes. The researcher/study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.

- 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 the Food and Drug Administration.

14. What if I have questions?

For questions about this study, contact the Investigator, Kenneth Iwuji, MD (806)-743-3150.

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

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

_____Subject was unable to read and understand the written consent.

The elements of informed consent required by 45 CFR 46.116 and 21 CFR 50 have been presented orally to the subject or the subject's authorized representative in a language understandable to the subject or representative.

Signature of Witness to Oral Presentation Date

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TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
AUTHORIZATION TO USE AND/OR DISCLOSE
YOUR PROTECTED HEALTH INFORMATION for a RESEARCH STUDY

STUDY TITLE: Starvation in the Treatment of Diabetic Ketoacidosis: Is there enough evidence to support this practice?

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	• immunizations • allergy reports

• X-ray films and reports; operative reports • 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 *(*use separate form for disclosure of psychotherapy notes)*	• prescriptions • 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 of Subject

_____
Signature of Individual or Authorized Representative Date

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