HealthPartners, Inc.
Consent to Participate in a Research Study

Study Title	Early Administration of Insulin Glargine in Patients with DKA
Study Investigator	Bjorn Westgard, MD Emergency Department (651) 254-9900 Adis Keric, PharmD Pharmacy – Emergency Department (651) 254-9900
Study Team Coordinators	Regions Research Staff (651) 254-9900 (24/7 contact number) CCRCresearch@healthpartners.com

Introduction

You are invited to participate in a research study. You are eligible because you have been diagnosed with diabetic ketoacidosis, or DKA, at Regions Hospital, and need intravenous (IV) insulin to treat it. Taking part in this research study is voluntary.

To make reading this consent form easier, please note that the word "you" refers either to you if you are the patient (research participant), or to the patient (research participant) if you are his/her family member.

Important Information about the Research Study

Things you should know:

- There are two types of insulin used to treat DKA. Short-acting insulin is started right away to return your blood sugar to normal. Long-acting insulin is used to prevent DKA from happening again.
- The purpose of the study is to determine whether getting both types of insulin (short-acting and long-acting) early on in your treatment can help your DKA to resolve more quickly than getting short-acting insulin early and long-acting insulin only after your blood sugar has returned to normal.
- If you choose to take part, your care team will continue to treat your DKA as they normally would. You will be randomized into one of two study groups. Depending on which group you are in, your care team may or may not give you long-acting insulin ***earlier*** than they would if you were not in the study. You will get long-acting insulin regardless of which study group you are in.
- Risks and discomforts from this research include blood sugar that is too low.

- The study could benefit you by helping your DKA to resolve more quickly than it otherwise would. It is also possible that there will be no direct benefit to you.
- Taking part in this research project is voluntary. You don't have to participate, and you can stop at any time.
- If you decide to not be in the study, you would continue to receive standard treatment for DKA. This could mean that you will receive long-acting insulin later than you would if you were not in the study. This is normal practice for Regions Hospital.

Please take time to read this form and ask questions before deciding whether to take part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you decide to take part in this study, you will be asked to sign and date this form and will be given a copy of the signed and dated consent form.

Why am I being asked to participate?

You are being asked whether you would like to participate in a research study about insulin because you came to the hospital with diabetic ketoacidosis (DKA) and need intravenous (IV) insulin to treat it. DKA is diagnosed by a blood test you get when you arrive to the hospital. All patients are diagnosed with DKA at Regions Hospital get short-acting insulin through an IV.

What is the purpose of this study?

In this study, we want to find out whether giving patients two types of insulin (short-acting and long-acting) early on in their hospital stay helps DKA to resolve faster than if long-acting insulin is given later.

Where will this study take place?

This study will take place at Regions Hospital. We expect to enroll about 132 subjects.

What is involved if I take part?

If you agree to take part in this study, you will be asked to sign this consent form before any study-related procedures are performed. The investigator and research team will ask you questions to see if you qualify to be in the study.

If you meet all criteria to be in this study, you will be randomized to one of two groups. Randomization means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 50% chance of being assigned to each group.

- Study group one, or the "control group", will receive standard of care. If you are in the control group, you will receive the same treatment for your DKA as you would receive if you were not in the study. You will be given an IV of short-acting insulin until your blood sugar returns to

normal. At that point, you will receive shots of long-acting insulin when your doctor determines you need them.

- Study group two, or the "experimental group" will be given an IV of short-acting insulin, as you would get if you were not in the study. You will receive a shot of long-acting insulin within two hours of the start of your IV. This is earlier than you would receive long-acting insulin if you were not in the study. After you receive your first dose of long-acting insulin, you will receive the same treatment for your DKA as you would receive if you were not in the study. You will continue to receive shots of long-acting insulin when your doctor determines you need them.

You cannot choose which group you will be in, but you will know which group you are in.

As a subject, you will be responsible for:

- telling the investigator if you are feeling bad or worse than before
- following the directions of the investigator and research team

Are there any risks to me?

There may be risks, side effects and discomforts if you choose to participate in this study. These can be physical, emotional, financial or social. The ones we know about are listed below.

There may be side effects from getting long-acting insulin earlier than you normally would. Many side effects go away, but sometimes they can be serious, long-lasting, or may never go away. There may be other side effects that we don't know about yet, so be sure to tell the investigator about any unusual symptoms.

Risks of long-acting insulin when used at the same time as short-acting insulin:

- Patients in the experimental group may be at increased risk of blood sugar that is too low (hypoglycemia).
- Symptoms of low blood sugar may include feeling sweaty, shaky, hungry, or faint. It may cause you to have a fast or irregular heartbeat. In severe cases, low blood sugar could cause confusion or disorientation, or even coma.
- No study that has looked at using long-acting and short-acting insulin at the same time has shown an increased risk of low blood sugar. However, there is still a chance it could happen.

Other risks:

- There is also the risk of the loss of the confidentiality of your health information, but the study team will take measures to prevent this from happening.

Are there any benefits to me?

You may or may not benefit from being in this study. Your DKA could resolve more quickly than it would if you were not in the study. It is also possible that your DKA could stay the same or even get worse. We hope the information learned will help other patients with DKA in the future.

How much will it cost to participate?

There is no additional cost to participate in this study. You will have to pay for any insurance copays and deductibles for your hospital visit and medications, the same as you would if you were not in the study.

Will I be paid to participate?

You will not be paid to participate in this study.

How long will I be in the study?

You will be in the study until you are discharged from the hospital.

The study may be stopped early by the FDA or the investigator. You could be asked to stop being in the study for any of the following reasons:

- for your safety
- if you do not follow our directions for this study

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before discharging from the hospital, let the investigator know. There may be special procedures to follow for your safety.

If you don't want to be in this study, your other options include receiving standard of care treatment for your DKA. This means you will receive short-acting insulin through an IV, and shots of long-acting insulin when your blood sugar returns to normal. You may get other labs, imaging, and treatments for your DKA as determined by your doctor.

What if I am harmed from being in the study?

If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible.

Will my records be kept confidential?

Your study records will be kept as confidential as possible. This is further described in the HIPAA Authorization. Please know that at any time, your study records may be reviewed by the United States Food and Drug Administration (FDA), the HealthPartners IRB, or the study team.
Any information we collect on you for this study, even if identifiers are removed, will not be used or distributed for future research studies.

All tests, assessments, and procedures done as part your hospital stay (other than your use of the study drug, if applicable) will be done as part of your treatment for DKA and not solely for research. If you would like to know the results of any tests performed during your hospital stay, consult with your care provider.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

Who oversees this study?

HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	**You should contact**	**Contact information**
You are harmed by the research or have questions about clinical procedures in the study	Bjorn Westgard, MD Adis Keric, PharmD	651-254-9900
You have questions about your rights as a research subject	IRB office	952-967-5025

Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for HealthPartners to use and disclose your personal health information as described below.

The following are examples of personal health information that may be collected for this study:

- results of tests and procedures
- information about your medical conditions and history

The collected information may contain your name, address, telephone number, social security number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

Who will see my protected health information?

By signing this Authorization, you allow the research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at HealthPartners/or Dental Clinic) to the following:

Who may have access:	**Purpose:**
HealthPartners consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For HealthPartners to remain accredited

Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves HealthPartners, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed.

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the HealthPartners IRB office at 952-967-5025.

If you withdraw permission for us to use your personal health information:

- you can't continue in the research study
- we will stop collecting health information from you
- we will still use and disclose any information that we gathered while you were a subject
- there will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?

You can see your study records at any time.

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date

_____

Witness signature (if applicable*) Date

**Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

Representative signature Date

Relationship to Subject:_____

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research
- I have explained and discussed potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent Date