Department of Veterans Affairs | VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. **VAMC:** North Florida/South Georgia Veterans Health System

UF Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM

to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Subject Name: _____ Date _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. VAMC: North Florida/South Georgia Veterans Health System

3. Who can you call if you have questionsconcerns, or complaints about this research study?

Principal Investigator:

Andrew Franck, PharmD

Malcom Randall VA Medical Center 1601 SW Archer Road (111D) Gainesville, FL

During normal business hours, dial 352-376-1611 x 105771 for Principal

Investigator.

4. Who is paying for this research study?

The sponsor of this study is DexCom, Inc.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board **(IRB) office at (352) 273-9600** or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this study is to compare the use of continuous glucose monitoring (CGM) versus point-of-care (POC) glucose monitoring in the critical care setting for differences in glycemic control and other important ICU outcomes. You will be in the research study for up to 10 days or until you leave the intensive care unit, whichever is shorter.

What is involved with your participation, and what are the procedures to be followed in the research?

You will have your blood sugar monitored with a continuous glucose monitor. The continuous blood glucose monitor is worn at all times during your treatment. You may also have your blood sugar monitored with point-of-care or blood sample

monitoring. If you decide to take part in this study, you will be randomly assigned (much like the flip of a coin) to either group 1 or group 2. Group 1 will wear a continuous glucose monitor, but the study team will be blinded to the glucose readings. This means they will not monitor your blood glucose levels from the continuous glucose monitor, but rather from the point-of-care finger sticks you usually receive. Group 2 will wear a continuous glucose monitor and the study team will be unblinded. This means your blood glucose readings will be monitored by the continuous glucose monitor and you will not receive point-of-care finger sticks. If you are assigned to group 1, you will not receive the benefits of continuous glucose monitoring, if there are any. Also, you will have a 50% chance of being assigned to group 1 and a 50% chance of being assigned to group 2. You will also be asked to complete a questionnaire.

b) What are the likely risks or discomforts to you?

Continuous glucose monitors (CGMs) are minimally invasive but could cause some patients mild physical pain or discomfort. Another risk is inaccurate measurement of blood glucose which could lead to hypo- and hyperglycemia.

c) What are the likely benefits to you or to others from the research;

The use of CGMs may lead to the benefit of increased patient comfort by decreasing point-of-care finger sticks. It may also lead to the reduction of serious hypoglycemia and other adverse events.

d) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

You do not need to participate in this study to receive treatment for your condition.

You have the option of not participating in the study and you will receive the same care and treatments that you normally would receive.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Website at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

You will receive the same clinical care and treatment for your conditions. Your blood sugar will be monitored only with point-of-care ('fingerstick') blood glucose measurements or with a blood sample.

7. What will be done only because you are in this research study?

At the start of this the study you will have a continuous glucose monitor placed on your skin, with a sensor that goes into the subcutaneous tissue (under the skin). This monitor will be worn the entire time you are enrolled in the study, up to 10 days.
You will have your blood sugar monitored with this continuous glucose monitor. The continuous blood glucose monitor remains on your body during your treatment in the ICU. You may also have your blood sugar monitored with point-of-care or blood sample monitoring.

If you decide to take part in this study, you will be randomly assigned (much like the flip of a coin) to either group 1 or group 2. Group 1 will wear a continuous glucose monitor, but the study team will be blinded to the glucose readings. This means they will not monitor your blood glucose levels from the continuous glucose monitor, but rather from the point-of-care finger sticks you usually receive. Group 2 will wear a continuous glucose monitor and the study team will be unblinded. This means your blood glucose readings will be monitored by the continuous glucose monitor and you will not receive point-of-care finger sticks. If you are assigned to group 1, you will not receive the benefits of continuous glucose monitoring, if there are any. Also, you will have a 50% chance of being assigned to group 1 and a 50% chance of being assigned to group 2. All other aspects of your care will be the same as if you had chosen not to participate in this study.

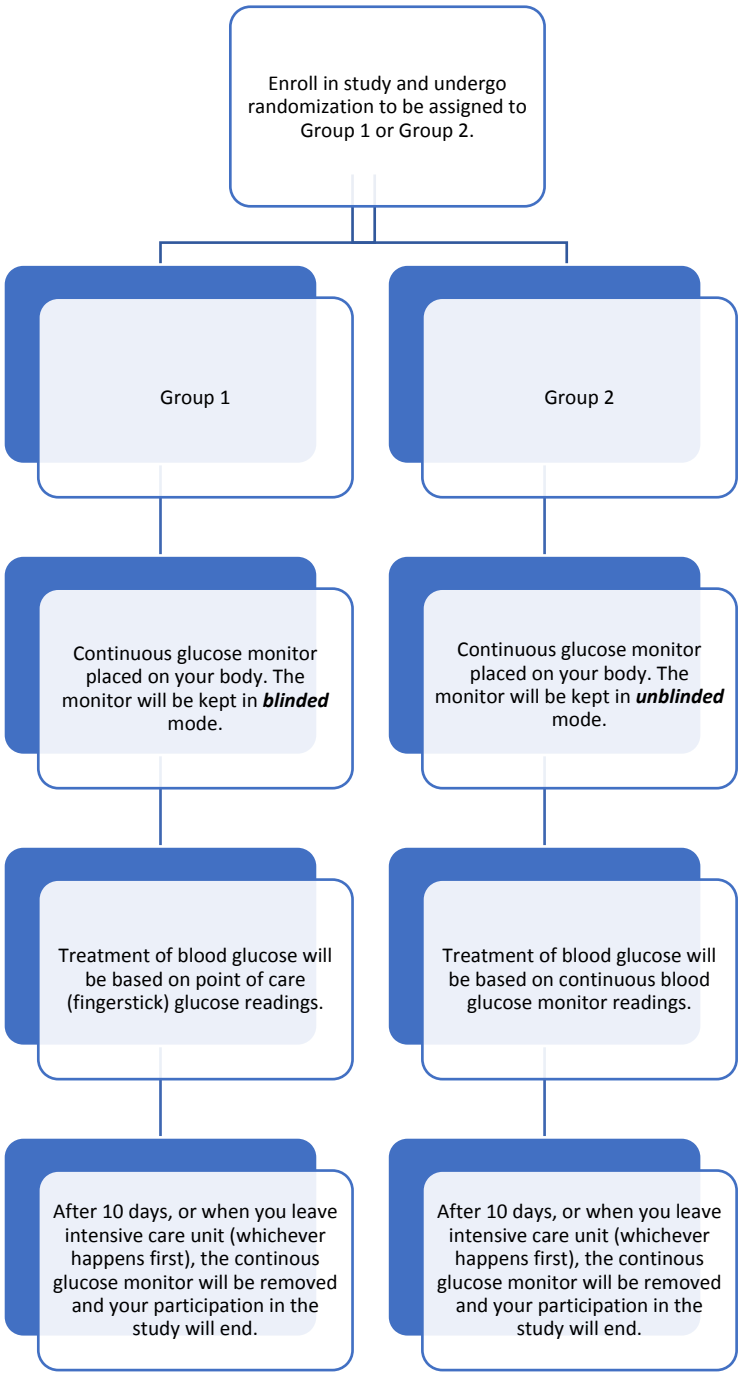
Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. **VAMC:** North Florida/South Georgia Veterans Health System



Subject Name: _____ Date _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. VAMC: North Florida/South Georgia Veterans Health System

At the end of this study you will be asked to complete a questionnaire about your experience.

If any identifiable information was collected as part of this research, it is possible that your research information, with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. How long will you be in this research study?

You will be in the research study for up to 10 days or until you leave the intensive care unit, whichever is shorter.

9. How many people are expected to take part in this research study?

We will enroll patients for a maximum of 2 years or a maximum of 300 patients.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Continuous glucose monitors (CGMs) are minimally invasive but could cause some patients mild physical pain,discomfort, or other adverse effects.

The product manufacturer states, that while uncommon, inserting the sensor can cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin. Only a few patients in the G6 clinical studies got slight redness and swelling. No sensor wires broke in the clinical studies; however, there is a remote chance a sensor wire could break or detach and remain under your skin. Sterile broken sensor wires usually don't pose a significant medical risk.

Another risk is inaccurate measurement of blood glucose which could lead to hypo- and hyperglycemia.Hypoglycemia may cause symptoms including tremor, palpitations, anxiety, sweating, hunger, paresthesias ("pins and needles" feeling),

Subject Name: _____ Date _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. VAMC: North Florida/South Georgia Veterans Health System

dizziness, weakness, drowsiness, delirium, and confusion that persists until treated. In very rare cases, severe and prolonged hypoglycemia can result in seizure, coma, or death. Hyperglycemia may lead to increased thirst, hunger, weakness, increase urination, blurred vision. Hyperglycemia may potentially increase the risk for infection, need to prolong ICU stay, and death.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study ?

Taking part in this research may or may not benefit you. The use of CGMs results in less point-of-care finger sticks. This may lead to increased comfort for you. With the use of CGMs your glucose levels can be monitored more carefully. This may lead to less cases of hypoglycemia.

11b. How could others possibly benefit from this study?

Subject Name: _____ Date _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. VAMC: North Florida/South Georgia Veterans Health System

Information gained from this study may help patients in the future.The use of CGMs may lead to the benefit of increased patient comfort by decreasing point-of-care finger sticks. It may also lead to the reduction of serious hypoglycemia and other adverse events.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

You have the option of not participating in the study and you will receive the same care and treatments that you normally would receive.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- If you no longer meet the requirements for inclusion based on the study criteria

Subject Name: _____ **Date** _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. **VAMC:** North Florida/South Georgia Veterans Health System

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.

15. Will you be paid for taking part in this study?

No, you will not be paid for taking part in this study.

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

Subject Name: _____ Date _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. VAMC: North Florida/South Georgia Veterans Health System

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day and <insert phone number> after business hours. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Continuous Glucose Monitoring for Hyperglycemia in Critically Ill Patients

Principal Investigator: Andrew Franck, Pharm.D. **VAMC:** North Florida/South Georgia Veterans Health System

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date