Study Title	Expanding use of continuous glucose monitoring beyond COVID in critical care: Impact on nurse work patterns and patient outcomes
NCT Number	N/A
Document Description	Informed Consent From

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Expanding use of continuous glucose monitoring beyond COVID in critical care: Impact on nurse work patterns and patient outcomes

Principal Investigator: Eileen Faulds, PhD, MS, RN, FNP-BC, CDCES

Sponsor: Dexcom, Inc.

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

- This study is to determine if it is safe, effective, and practical to use continuous blood glucose monitoring (CGM) devices in hospital settings.

- These devices are commonly used outside the hospital for people with diabetes but their use inside the hospital has not been approved and is therefore investigational.
- Individuals in the intensive care unit are very ill and we have not fully investigated how illness could affect device accuracy.
- The use of these monitors could reduce the number of finger stick blood sugar checks for patients, avoid low blood sugars and give more accurate insulin dosing for patients.
- Using these monitors could also make the workload of hospital staff more manageable, resulting in better overall care for all patients.
- You would not need to do anything other than agree to wear the monitor while in the hospital.

1. Why is this study being done?

This study is to determine if the use of continuous glucose monitors (CGM) in hospital settings will benefit patients and/or staff and can be safely used as a replacement for some traditional fingerstick glucose testing.

2. How many people will take part in this study?

There will be approximately 100 patients who take part in this study.

3. What will happen if I take part in this study?

If you decide to take part in this study, you will be asked to wear a continuous glucose monitor (CGM) while you are in the Intensive Care Unit. The monitor will be placed on your arm by hospital staff. The monitor is replaced every 10 days. If you are still in the hospital after 10 days, the CGM may be replaced. You will be given finger stick blood sugar tests every 4 hours to test the accuracy of the monitors. Finger stick monitoring will be done more frequently if your clinical condition changes and if you were to become more severely ill, the CGM would remain in place to collect information but would not be used to monitor your glucose. If you are not on CGM you would have your glucose checked by a fingerstick 4 to 24 times a day depending on what kind of insulin you are on.

If you choose to be in this study, then some of your medical information will be taken from your electronic medical record to compare to patients who did not wear the continuous monitor.

4. How long will I be in the study?

You will continue to wear the monitor as long as you are in the Intensive Care Unit (ICU).

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are

otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There is a risk that the CGM system may fail to detect either high glucose (hyperglycemia) or low glucose (hypoglycemia). Failure to accurately detect a high or low glucose could result inappropriate insulin dosing or failure to give insulin and could lead to injury or even death. We will reduce this risk by continuing to perform finger stick tests to check the accuracy of the CGM system throughout the study. There may be some discomfort or pain when the continuous monitor is attached to your skin. There is very minimal risk of infection during installation. The finger stick tests are used to protect against the monitor being inaccurate or failing.

7. What benefits can I expect from being in the study?

There will be no direct benefits to you if you participate in the study.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs to you for taking part in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

Future Research Use:

With your permission, Dexcom, the study funder, would like to store your de-identifiable information for future research purposes, and as part of such future research purposes, your de-identifiable information may be disclosed to people or entities not listed above, such as researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research.

You do not have to agree to use of your de-identified data for future research in order to be in this study, and your decision will not affect the care you receive at The Ohio State University.

I agree to allow my de-identified data to be stored and used for future research as described above: (initial)

____ YES ____ NO

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.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 the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about laboratory, x-ray, and other test results;
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: Dexcom, Inc.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. 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.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Eileen Faulds at (614) 293-0477 or Eileen.faulds@osumc.edu.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Mary Beth Happ at (614) 292-8336 or happ.3@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Eileen Faulds at (614) 293-0477 or Eileen.faulds@osumc.edu.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time