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

Study Title:	Effectiveness of a diabetes focused discharge order set among poorly controlled hospitalized patients transitioning to glargine U300 insulin
Principal Investigator:	Kathleen Dungan, M.D.
Sponsor:	The Ohio State University

- **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.

1. Why is this study being done?

You are being asked to participate in this study because you are hospitalized and have type 2 diabetes with high blood sugar or blood glucose levels. High blood glucose levels can increase the risk for diabetes complications, repeat hospitalizations, and even death. Therefore, it is important to control high blood glucose levels with medication after you are discharged or leave the hospital. This study will evaluate how the instructions you receive when discharged affect your blood glucose control and diabetes outcomes.

Insulin is a hormone that removes glucose from the blood and insulin therapy is considered to be one of the most effective therapies for lowering blood glucose. Insulin therapy involves injection

of insulin at certain times, which helps lower your blood glucose. Insulin therapy can require additional education and support compared to other therapies.

If you agree to participate in this study, you will be randomly assigned, like the toss of a coin, to one of two groups. Both groups will receive insulin therapy with an FDA-approved drug called TOUJEO® (Glargine U300). The insulin dose will be adjusted as long as needed to keep your blood glucose controlled. If you are assigned to Group 1, you will receive certain care instructions for managing your diabetes and the study team will contact you to adjust your insulin. If you are assigned to Group 2, you will receive a standard set of care instructions for managing your diabetes and the insulin adjustments will be managed by your usual providers.

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

Approximately 222 patients will take part in this study at The Ohio State University.

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

Enrollment Visit (Visit 0)
If you agree to participate in this study, you will be asked to sign this consent form at an enrollment visit during your hospitalization. After signing the consent form, the enrollment visit will include the following procedures, which are expected to last about 1 hour:

- **Data collection**: The study team will collect your demographic information, such as age and gender, and ask you questions about your marital status, education, employment and home ownership. The study team will request your contact information, including an email address, the contact information of two emergency contacts, and the contact information of your primary care physician. The study team will collect information about your hospitalization, the reason for your admission, your medical background, the medications you are taking, and laboratory test results.
- **Pregnancy test**: If you are a woman of childbearing potential, you will be asked to complete a urine pregnancy test if not already performed. You will not be allowed to participate in this study if you are pregnant.
- **Questionnaires**: You will be asked to complete questionnaires that will help assess your diabetes education needs, the amount of support you have from other people to manage your diabetes, and your level of empowerment to manage your diabetes.
- **Blood tests**: As part of your normal care, you may have approximately 1 tablespoon of blood drawn to test your HbA1c levels, a measure of long-term glucose control. As part of the research study, you will also have a small amount of blood (less than a teaspoon) collected by fingerstick to measure your fasting blood glucose. You must abstain from eating or drinking within 8 hours prior to the fasting blood glucose test. However, you are allowed to drink water.
- **Glucose monitoring:** You will be asked to check your glucose levels as part of routine care recommended by your healthcare team.
- **Diary & Education:** You will receive a diary and be given instruction for recording daily medications and blood glucose readings in a diary. You will be asked to record your

medications and blood glucose reading for the next 24 weeks. You will receive education on how to manage your diabetes at home.

- **Medication dispensation:** You will receive an FDA-approved insulin therapy called TOUJEO® (Glargine U300) and instructions for taking the medication.
- **Randomization & Discharge Instructions:** You will be randomly assigned, like the toss of a coin, to one of two groups. You will not be allowed to choose your group assignment. **If you are assigned to Group 1,** you will receive a specific set of care instructions called the discharge order set (DOS). Subjects assigned to Group 1 will also receive additional nurse support to help you make adjustments to your insulin therapy after you leave the hospital**. If you are assigned to Group 2,** you will receive different care instructions called the enhanced standard care (ESC), which include instructions for taking your insulin and managing your diabetes at home.

Phone Call Visits (Visits 1 & 2)
The study team will contact you by phone 2 weeks (Visit 1) and 6 weeks (Visit 2) after you are discharged from the hospital to determine how you are doing with your diabetes and review your diary records. Any specific medical concerns reported during any call will be forwarded to your primary care provider. If you are in Group 1, the nurse will call you to assist with adjustment of your insulin dose. If you are in Group 2, your hospital team will determine the best follow-up strategy for you. The phone call visits are expected to last about 30 minutes.

Clinic Visits (Visits 3 & 4)
You will be asked to return to the clinic(at Carepoint East or McCampbell Hall) 12 weeks (Visit 3) and 24 weeks (Visit 4) after you are discharged from the hospital. Visit 3 and Visit 4 are expected to last about 1 hour each.

You will be asked to attend Visit 3 and Visit 4 in fasting conditions. This means that you must abstain from eating or drinking within 8 hours prior to the visit. However, you are allowed to drink water.

At these clinic visits, the following procedures will occur:

- **Questionnaire**: You will be asked to complete a questionnaire at Visit 3 and at Visit 4 that will assess your level of empowerment to manage your diabetes.
- **Blood tests**: At Visit 3 and Visit 4, you will have a small amount of blood (less than a teaspoon) collected through a fingerstick to check your HbA1c, a measure of long-term glucose control, and your fasting blood glucose.
- **Diary & Medications Review:** At Visit 3 and Visit 4, the study team will review your diary with you and make note of any events where your blood glucose became too high (hyperglycemia) or too low (hypoglycemia). The study team will also review your medications and examine how you used TOUJEO®. If you are in Group 1, the nurse will assist with adjustment of your insulin dose if needed. If you are in Group 2, your hospital team will determine the best follow-up strategy for you.
- **Medication dispensation:** At Visit 3, you will receive an FDA-approved insulin therapy called TOUJEO® (Glargine U300).

A summary of study procedures is illustrated below:

Visit number	0	1	2	3	4
Time of Visit	Enrollment	2 week	6 week	12 week	24 week
Type of visit	In-person	Phone	Phone	In-person	In-person
Informed Consent	x				
Randomization	x				
Demographics/Socioeconomics	x				
Medical History	x				
Medications Review	x				
Pregnancy Test	x			x	x
Questionnaires	x			x	x
Dispense TOUJEO®	x			x	
Administer/Review Diary	x	x	x	x	x
Review Insulin Adherence & Hypoglycemic/Hyperglycemic Events		x	x	x	x
Nurse counselling **(Group 1 Only)**		x	x	x	x
Blood tests	x			x	x

4. How long will I be in the study?

Your participation in this study will last for 24 weeks after you have been discharged from the hospital and will include two phone calls and two clinical visits. At the end of your study participation, you should consult with your primary care physician for continued care.

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?

TOUJEO® (Glargine U300) has received approval by the U.S. Food and Drug Administration for use in treating adults with diabetes mellitus. Side effects and discomforts associated with TOUJEO® include hypoglycemia (low blood glucose) and weight gain - the risk is similar to or less than that reported for other insulins. Allergic or injection site reactions and low potassium levels are rare but have been reported. If you experience any side effects, you should notify your study doctor.

Since you require insulin, there is a risk of developing low blood glucose (hypoglycemia). The risk of severe low blood glucose is very small because of the dose adjustment plans being used. High blood glucose (hyperglycemia) emergencies are also possible. The risk of low or high blood glucose levels are expected to be similar whether or not you choose to participate in the study. However, some data suggest that the risk of low blood glucose is lower with TOUJEO® compared to some other insulin therapies. Recognizing hyperglycemic and hypoglycemic symptoms and careful and frequent monitoring of blood glucose levels can help to manage your blood glucose and prevent it from getting too high or too low. You will need to notify the study team if you develop significant low or high blood glucose.

Physical injury or discomfort is possible with blood draws. The risks associated with blood draws include bleeding, infection, bruising, and pain; these risks are minimal and will typically not be greater than usual care since we will aim to use samples from other medically required blood draws. Your blood will be drawn by trained professionals.

The pregnancy test may provide unwanted or unexpected information that could complicate your care. If a pregnancy test is positive we will inform you and your medical team and you will not be enrolled in the study.

Certain questions on the questionnaires may make you feel uncomfortable. You do not need to answer any questions that make you feel uncomfortable.

As part of this study you are at risk for a breach in confidentiality of your protected health information (PHI). We will protect your PHI by storing your data in a secure database and using a special code; however, you are still at risk for a breach in confidentiality.

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

As a participant in this study, you may achieve better control of your blood glucose from more frequent interaction with the study staff. The results of this study may lead to improved treatment of diabetes for future diabetes patients as well.

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. You will continue to receive medical care for your condition if you do not participate. If you do not participate, your doctor may still offer you treatment routinely provided for type 2 diabetes, including insulin therapy to regulate your blood glucose, and may still recommend that you monitor your blood glucose regularly.

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

There will be no costs to participants outside of costs incurred through standard of care procedures. TOUJEO® is provided free of charge, as are laboratory HbA1c tests. However, the study does not cover other glucose lowering medications (if you need it) or glucose testing supplies.

10. Will I be paid for taking part in this study?

You will receive $60 for Visit 3 at 12 weeks after your discharge and $60 for Visit 4 at 24 weeks after your discharge. You will be paid through ClinCard, a debit card that will be loaded with payment after each visit is complete. If you do not complete the study, you will only be paid for the visits you have completed.

By law, payments to subjects are considered taxable income.

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 participants in research.

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

Only study investigators will have access to your study information. Your identity will not be revealed in any study publication. You will be assigned a special number or code that will be used for identification purposes so that your name can be removed from study files where possible. Your study number will be kept separately from your name and personal information and password protected. Your consent and data forms will be stored in locked files in a locked office when not in use. Your computer data will be password-protected on a secure server. Your social security number will not be recorded for the study. Furthermore, we will not collect other sensitive information such as psychiatric conditions, drug use, or social security numbers.

Intensive 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.

14. 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;

- Records about your study visits;
- 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 and other test results
  Diaries and questionnaires
- Records about any study drug you received;

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;

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.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study or if you feel you have been harmed or injured as a result of study participation, you may contact:

Kathleen Dungan, M.D.
1581 Dodd Dr
5th Floor McCampbell Hall
Columbus, OH 43210
(614) 685-3333

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Officer
600 Ackerman Rd
Suite E2140
Columbus, OH 43201

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:

Ms. Sandra Meadows
Office of Responsible Research Practices
1-800-678-6251

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