Brief Title: Feasibility Trial Using an Inpatient Insulin Dosing Calculator
NCT Number: NCT06206525
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UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

APPLICATION
IRB Protocol

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with **[DETERMINATION]** For example **1.1.** **[DETERMINATION]** must be answered. Do not upload consent materials for determinations in ***Zipline*** as HSD does not review or approve them.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.
- **NOTE: Do not convert this Word document to PDF.** The ability to use "tracked changes" is required in order to modify your study and respond to screening requests

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1. OVERVIEW

Study Title: Clinical trial using an insulin doing calculator on hospital admission

1.1. [DETERMINATION] Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers them to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP Use of the UW IRB**.*

University of Washington Medical Center

1.2. [DETERMINATION] Consultation history. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

☒ **No**

☐ **Yes →** Briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

Click or tap here to enter text.

1.3. [DETERMINATION] Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

☐ **No**

☒ **Yes →** Briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

STUDY00015475: inpatient initial insulin requirements, lead researcher Hou-Hsien Chiang.
This prior study built up the insulin dosing calculator that will be used in this current clinical trial.

1.4. [DETERMINATION] Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

☒ **No**

☐ **Yes →** Briefly describe the urgency or deadline as well as the reason for it.

Click or tap here to enter text.

1.5. [DETERMINATION] **Objectives**. Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

Patients with hyperglycemia have heterogenous physiologies and their insulin requirements are highly varied. The currently available algorithms cannot preciously predict their initial insulin doses. More importantly, there is no algorithm so far that is supported by evidence.
We hypothesize that standardized algorithms using multiple factors can more precisely predict patients' individual insulin requirements on hospital admission. Our prospective study (STUDY00015475) at the University of Washington (UW) built an insulin calculator for patients with T2DM on home insulin and adequate oral intake peri-admission (sample size 140). Using multivariable regression models, our predicted daily insulin doses have a correlation factor of 0.793 with their actual insulin requirements. No outlier that would be severely overdosed was noted in our observational cohort.
The factors used to predict insulin requirement are patients' oral intake plan, home insulin dose, first blood glucose value on presentation, inpatient glucocorticoid dose, systemic inflammatory response syndrome (SIRS), dose and timing of last long-acting insulin prior to admission. Our online calculator (https://inpatientinsulin.com) will be used to calculate the initial insulin dosing regimen.
Our calculator is based on observational studies, so it remains unclear whether it can help clinicians achieve recommended glycemic targets. We propose using these calculators can achieve inpatient glycemic goal of 100-180 mg/dL (American Diabetes Associations guidelines 2023) faster than the standard of care with less manual adjustments. Before we perform a study of a large sample size, it is important to test whether using this calculator in the clinical setting is safe. This study is a feasibility trial to mainly investigate its safety (no excessive hypoglycemia). We will also examine whether using this calculator decreases hyperglycemia. The trial will provide opportunities to adjust the algorithms before the randomized controlled trial.
The specific outcomes that will be measured are hypoglycemia (< 54 mg/dL), mean BG during the first 24 hours of hospitalization, and severe hyperglycemia (≥ 300 mg/dL). Hypoglycemia (< 54 mg/dL) cannot be 3% higher than the UW observational cohort (explained in section 5.1). Independent two-sample t test will be used to analyze mean BG and Pearson's chi-squared test will be used to analyze the occurrence of hyperglycemia (≥ 300 mg/dL), compared to the UW observational cohort (STUDY00015475). We plan to work with hospitalists at UW hospitals to use this calculator on hospital admissions for patients with T2DM on home insulin.

There is lack of large interventional studies to demonstrate whether improving inpatient glycemic control changes patients' clinical outcomes. The randomized controlled study we planned after this feasibility trial will explore whether using this calculator improves clinical outcomes.

1.6. [DETERMINATION] **Study design**. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This is a clinical trial that uses the insulin dosing calculator for patients who are admitted to the UW hospitals

1.7. [DETERMINATION] **Intent**. Check all the descriptors that apply to your study. You must check at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

Check all that apply	Descriptor
☐	Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	Part of an institution, organization, or program's own internal operational monitoring.
☐	Improve the quality of service provided by a specific institution, organization, or program.
☒	Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to apply to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☒	A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.

Check all that apply	Descriptor
☒	Preliminary, exploratory or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire).
☐	Expanded access use of a drug or device not yet approved for this purpose.
☐	Use of a Humanitarian Use Device.
☐	Other. Explain:

Click or tap here to enter text.

1.8. Background, experience, and preliminary work. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1.8.a. Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page or refer to an attached document with background information that is no more than three pages long.

The current practice of inpatient glycemic management relies heavily on daily adjustments of insulin doses based on inpatient blood glucose values. However, the real-world glycemic data analysis in the US consistently showed suboptimal results of hyperglycemia and hypoglycemia [1].
Patients with hyperglycemia have heterogenous physiologies and their insulin requirements are highly varied. The currently available algorithms cannot preciously predict their initial insulin doses [2,3]. More importantly, there is no algorithm so far that is supported by evidence. Therefore, evidence-based algorithms that can preciously predict patients' individual insulin requirements are of benefit.
1. Bersoux S, Cook CB, Kongable GL, Shu J, Zito DR. Benchmarking glycemic control in u.s. Hospitals. Endocr Pract. 2014 Sep;20(9):876-83.
2. Umpierrez GE, Hellman R, Korytkowski MT, Kosiborod M, Maynard GA, Montori VM, Seley JJ, Van den Berghe G; Endocrine Society. Management of hyperglycemia in hospitalized patients in non-critical care setting: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2012 Jan;97(1):16-38.
3. Chiang HH, Kahn SE, Hirsch IB. Marked variability of starting insulin algorithms for noncritical illness—A survey of 32 academic hospitals in the United States. 83rd American Diabetes Association Scientific Sessions oral abstract presentation (168-OR). 2023 Jun 24, San Diego.

1.8.b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all the discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

Our proof-of-concept study at UC Davis identified several factors associated with initial insulin requirements for patients with history of diabetes mellitus (DM) and any BG value ≥ 180 mg/dL during the first 24 hours of hospitalization [1]. Then our prospective study at the University of Washington (UW) built insulin calculators for patients with different types of DM. For the study population of this trial, patients with T2DM or steroid-induced DM who take insulin prior to admission, our predicted daily insulin dose has a correlation factor of 0.795 with their actual insulin requirements. In addition, we excluded outliers (who have low oral intake before or after admission) so the rest of patients show no severe overdose in our cohort.

1. Chiang HH, Surampudi P, Sood A. Determinants of initial insulin therapy for hospitalized patients with diabetes mellitus. J Diabetes Complications. 2022 Oct;36(10):108307.

1.8.c. Subject matter expertise. Is the study a clinical trial and/or does the study involve use of a drug, biologic, botanical, nutritional supplement and/or is the study otherwise considered to be greater than minimal risk to subjects?

☐ **No** → Answering this question is optional.
☒ **Yes** → Provide the name, degree(s), and contact information (e.g., email, phone number) of someone with appropriate expertise in the subject matter described in the objectives and design of this study. The individual should be unaffiliated with the study and have no other apparent conflict of interest. The individual may be associated with the UW or external to the University. Ensure the individual is aware they may be contacted by HSD.

*Provision of this information is **required** for all clinical trials, for studies involving the use of a drug, biologic, botanical, nutritional supplement and for studies involving greater than minimal risk. For all other studies, the information is optional, though HSD reserves the right to request researcher assistance in providing a consultant if necessary to complete review of the study.*
For the consultant, the request involves a brief email or phone call with targeted questions that usually can be responded to in 30 minutes or less.

Arthi Thirumalai MD, email: arthidoc@uw.edu

1.9. Supplements. Check all boxes that apply, to identify relevant SUPPLEMENTS that should be completed and uploaded to ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all that apply	Type of Research	Supplement Name and Link
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	SUPPLEMENT Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research.	SUPPLEMENT Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk.	SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified.	SUPPLEMENT Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved.	SUPPLEMENT Devices
☐	**Multi-site or collaborative study** The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	SUPPLEMENT Multi-site or Collaborative Research
☐	**Non-UW Individual Investigators** The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	SUPPLEMENT Non-UW Individual Investigators
☐	**Other REDCap Installation Attestation for Electronic Consent** The research will use a non-UW installation of REDCap for conducting and/or documenting informed consent.	SUPPLEMENT Other REDCap Installation
☒	None of the above.	

2. PARTICIPANTS

2.1. [DETERMINATION] **Participants**. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

We plan to recruit adult patients who are admitted to UW Montlake, Harborview and Northwest hospitals with history of type 2 diabetes mellitus on insulin therapy prior to admission. Because we work with the internal medicine hospitalist group, these patients are admitted for various non-critical acute illnesses from the emergency room. They can also be non-emergent admissions from the clinics.
The obstetrics ward tends to use a different glycemic goal than other inpatient populations, so we exclude patients admitted to obstetrics ward. Our prior observation cohort did not include patients admitted for elective surgery or procedure, so our calculator has not been validated in this population.

2.2. [DETERMINATION] **Inclusion and exclusion criteria.**

2.2.a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

1. Patients who are admitted to University of Washington Medical Center – Montlake, Harborview and Northwest hospitals
2. Aged ≥ 18 years
3. With history of type 2 or steroid-induced diabetes mellitus
4. Receiving insulin therapy prior to admission

2.2.b. Exclusion criteria. Describe the specific criteria that will be used to decide which of the subjects who meet the inclusion criteria listed above will be excluded from the research. Define any technical terms in lay language.

1. Patients who are admitted to ICU or obstetrics ward
2. Patients who are admitted for elective surgery or procedure
3. Patients who present with diabetic ketone acidosis, hyperosmolar hyperglycemic state or need IV insulin infusion
4. Patients who have no meal intake for 24 hours prior to admission, planned nothing per oral (NPO) during the first 24 hours after admission
5. Patients who report low appetite (25% or less) on admission or have a significantly decreased level of consciousness that study team does not think they are going to eat right after admission
6. Patients who receive enteral feeding after admission
7. Patients who develop severe acute kidney injury needing dialysis therapy

2.3. [DETERMINATION] **Prisoners**. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

Is the research likely to have subjects who become prisoners while participating in the study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

☒ **No**
☐ **Yes** → If a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?
☐ **No**

☐ **Yes →** Describe the procedures and/or data collection that will continue with prisoner subjects.

Click or tap here to enter text.

2.4. **[DETERMINATION]** Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". Review the guidance on Prisoners for the definition of "prisoner", which is not necessarily tied to the type of facility in which a person is residing.

☒ **No**
☐ **Yes →** Answer the following questions (**2.4.a.** – **2.4.d.)**

2.4.a. Describe the type of prisoners, and their locations(s).

Click or tap here to enter text.

2.4.b. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

Click or tap here to enter text.

2.4.c. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

Click or tap here to enter text.

2.4.d. If the research is funded by one of these federal departments and agencies (Health & Human Services; Energy; Defense; Homeland Security; CIA; Social Security Administration), and/or will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole or pardon decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole or pardon.

☐ **Confirmed**

2.5. **[DETERMINATION]** **Protected populations.** IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the populations is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Check all that apply	Population	Worksheet Name and Link
☐	Fetuses in utero	WORKSHEET Pregnant Women
☐	Neonates of uncertain viability	WORKSHEET Neonates
☐	Non-viable neonates	WORKSHEET Neonates
☐	Pregnant women	WORKSHEET Pregnant Women

2.5.a. If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

Click or tap here to enter text.

2.6. [DETERMINATION] **Native Americans or non-U.S. indigenous populations**. Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering.

☒ **No**

☐ **Yes →** Name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

Click or tap here to enter text.

2.7. [DETERMINATION] **UW Medicine and UW Dentistry residents and fellows.** Will the research involve UW Medicine or UW Dentistry residents or fellows as study subjects?

If it will → **(1)** Describe in the Recruiting section (4.1) and Risks section (10.1) how you will ensure that residents and fellows feel free to truly make a voluntary decision about participation (i.e., no negative consequences from supervisors for saying "no") and how you will ensure that any research data will not be used in the residents' and fellows' supervisor or program evaluation of them; **AND**

(2) You must inform the UW HR Labor Relations representative who negotiates with the resident's and fellows' union about the study before beginning it. This is currently Jennifer Mallahan mallaj@uw.edu .

2.8. [DETERMINATION] **Third party subjects.** Will the research collect private identifiable information about individuals *other than* the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are

asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

☒ **No**

☐ **Yes →** These individuals are considered human subjects in the study. Describe them and what data will be collected about them.

Click or tap here to enter text.

2.9. Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group, and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

☐ **No →** Provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.

Click or tap here to enter text.

☒ **Yes →** For each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number or individuals (or other subject unit) who will complete the research *Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*
All patients who meet inclusion/exclusion criteria (single-arm study)	85

Group name/description	Maximum desired number or individuals (or other subject unit) who will complete the research *Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*
Click or tap here to enter text.	Click or tap here to enter text.
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Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.

3. NON-UW RESEARCH SETTINGS

Complete this section only if UW investigators and people named in the SUPPLEMENT Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1. [DETERMINATION] **Research locations and rationale**. Identify the locations where the research will be conducted and include a description of the reason(s) for choosing the locations. If the research will be conducted internationally, be sure to list all the countries where the research will take place.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is Justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

Click or tap here to enter text.

3.2. [DETERMINATION] **Local context**. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements: http://www.hhs.gov/ohrp/international/index.html

Click or tap here to enter text.

3.3. [DETERMINATION] **Location-specific laws.** Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and countries.

- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states have laws that are similar to the federal HIPAA law but that have additional requirements.

Click or tap here to enter text.

3.4. [DETERMINATION] **Location specific administrative or ethical requirements**. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

Click or tap here to enter text.

3.5. [DETERMINATION] **If the PI is a student: Does the research involve traveling outside of the U.S.?**

☐ **No**

☐ **Yes** → Confirm by checking the box that (1) you will register with the UW Office of Global Affairs before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

4. RECRUITING AND SCREENING PARTICIPANTS

4.1. [DETERMINATION] **Recruiting and screening**. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Note: Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes. Additionally, researchers may not use UW Medicine's Epic Care Everywhere data for research purposes unless the clinical data is necessary for patient/participant safety activities. This means Care Everywhere data cannot be used for recruitment, data abstraction, or any research activities other than those necessary for patient/participant safety.

We plan to work with the internal medicine hospitalist group (part of our research team) to conduct this study. There will be two lead hospitalists of contact at Montlake, Harborview and Northwest each. The screening hospitalists screen patients who need to be admitted to the hospital as their regular practice. In the meantime, they will screen eligible subjects who meet our inclusion/exclusion criteria.
Once eligible subjects are identified, screening hospitalists or admitting hospitalists will explain the rationales of this study and obtain informed consent. This process will be part of the standard admission interview which happens within one hour of admission. The interview happens either in the emergency room or hospital room, depending on whether a hospital room is immediately available.
An alternative way of recruitment is that PI: Hou-Hsien Chiang screens eligible subjects and obtains informed consents

4.2. Recruitment materials.

4.2.a. What materials (if any) will be used to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Screening hospitalists will screen eligible subjects when they screen patients who need to be admitted to the hospital.

4.2.b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter. The text of these letters and emails must be uploaded to ***Zipline*** (i.e., a description will not suffice).

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3. [DETERMINATION] **Relationship with participant population**. Do any members of the study team have an existing relationship with the study population(s)?

Example: a study team member may have a dual role with the study population such as being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for their research.

☒ **No**
☐ **Yes →** Describe the nature of the relationship.

Click or tap here to enter text.

4.4. Payment to participants. The IRB must evaluate subject payment for the possibility that it will unduly influence subjects to participate. Refer to the guidance on Subject Payment when designing subject payment plans. Provide the following information about your plans for paying research subjects in the text box below or note that the information can be found in the consent form.

- The total amount/value of the payment
- Schedule/timing of the payment [i.e., when will subjects receive the payment(s)]
- Purpose of the payment [e.g., reimbursement, compensation, incentive]
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include all of the above-listed information about payment, including the number and amount of payments, and especially when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Researchers should review current UW Financial Management requirements about when Social Security Numbers must be collected, and when research payment must be reported to the UW Tax Office and the IRS: https://finance.uw.edu/ps/how-pay/research-subjects.

If your study involves the use of Amazon's Mechanical Turk (MTurk), you must comply with the UW Procurement Services policy that no UW employee, family member, or student directly involved in the research will participate as a subject. The policy requires adding a qualifying question that asks whether the subject is a UW employee or family member, or UW student who is directly involved in the research. If they answer yes, they must be disqualified from MTurk activities.

none

4.5. [DETERMINATION] **Non-monetary compensation**. Describe any non-monetary compensation that will be provided. Example; extra credit for students; a toy for a child.

none

4.5.a. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research. If you will offer class credit, describe the alternative non-research method by which students can earn that same course credit, including who will provide the alternative (e.g., a student subject pool; the course instructor).

Click or tap here to enter text.

4.6. [DETERMINATION] **Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?**

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

☐ **No →** Skip the rest of this section; go to question **5.1.**

☒ **Yes →** Describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

Data will be accessed (but not obtained or recorded) by the screening hospitalists. The screening hospitalists screen patients who need to be admitted to the hospital as their regular practice, so no extra data will be accessed beyond their regular practice.

4.7. Consent for recruiting and screening. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

☒ **No →** Skip the rest of this section; go to question **5.1.**
☐ **Yes →** Describe the consent process.

Click or tap here to enter text.

4.7.a. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the recruiting and screening procedures?

☐ **No →** Describe the information that will be provided during the consent process and for which procedures.

Click or tap here to enter text.

☐ **Yes, written →** If yes and a written signature will be used to document consent:

- Upload the consent form to ***Zipline***.

☐ **Yes, electronic →** If yes and an electronic signature will be used to document consent:

- Upload the consent form to ***Zipline***.
- **If the eSignature process or method for recruiting and screening is different than for the main study procedures**, use the questions about electronic consent in Sections 8.3. and 8.4. to differentiate between recruiting/screening and main study electronic consent. **If electronic consent will be used for recruiting/screening but not main study consent**, use 8.3. and 8.4. to describe e-consent and note that it is only for recruiting/screening.

5. PROCEDURES

5.1. [DETERMINATION] **Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention, or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

For studies comparing standards of care: It is important to accurately identify the research procedures. Review the section titled, "When to describe risks for studies evaluating medically recognized standards of care" in the Identifying and Describing Reasonably Foreseeable Risks in Research guidance and the draft guidance from the federal Office of Human Research Protections, "Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care"; October 20, 2014.

Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** *on the Seattle Children's IRB website.*

We plan to work with the internal medicine hospitalist group to conduct this study. There will be two lead hospitalists of contact at Montlake, Harborview and Northwest each. The screening hospitalists screen patients who need to be admitted to the hospital as their regular practice. In the meantime, they will screen eligible subjects who meet our inclusion/exclusion criteria.

Once eligible subjects are identified, screening hospitalists or admitting hospitalists will explain the rationales of this study and obtain informed consent. This process will be part of the standard admission interview which happens within one hour of admission. The interview happens either in the emergency room or hospital room, depending on whether a hospital room is immediately available.

This feasibility trial is designed as single-arm and mainly to investigate safety (no excessive hypoglycemia compared to standard of care). We will examine hyperglycemia as a secondary endpoint. We do not include a control arm in this study for comparison. The reason is it takes too many subjects to have enough power to detect potential excessive hypoglycemia (we plan a randomized study of a larger sample size after this feasibility trial to further exam the glycemic and clinical outcomes). For a feasibility trial, we would like to know if it is safe by testing on a small number of subjects.

This consent process will be part of the admission interview which happens either in the emergency room or hospital room. If subjects are not able to consent, the hospitalists will obtain consent from their legally authorized representatives' (LAR) in person or on the phone.

Patients who report low appetite 25% or less, NPO for 24 hours before admission, or planned NPO for 24 hours after admission will be excluded because they have risk to be overdosed by our predicted insulin doses. If patients had a significantly decreased level of consciousness that the study team does not think they are going to eat right after admission, they will also be excluded from this trial.

Hospitalists that are going to enroll subjects will join a one-hour launch meeting when the PI will introduce the study procedure and how to use the online calculator. There will be a session of questions and answers. At the end of the meeting, we will assess whether the hospitalists feel comfortable to start enrolling patients. If they do not feel ready, we will plan further meetings before they start the enrollment.

Hospitalist Enrollment

If subjects agree to join this trial, hospitalists will go to our online calculator to calculate the initial insulin dosing regimen (https://inpatientinsulin.com). The questions in the online calculator will be asked during the interview with the subjects. Some information required in the calculator may be obtained from a caregiver rather than the subject if the caregiver knows the information better. In this case, the hospitalists will obtain consent from the subject or LAR before receiving health information from a caregiver. Hospitalists will confirm whether the caregiver knows the required information well, as the standard of care. If hospitalists could not obtain reliable information within 20% range (plus minus 10%), this subject will not be enrolled. For example, if a subject's home daily insulin dose cannot be confidently narrowed within the 36 - 44 units range, This subject will not be enrolled using home daily insulin dose of 40 units in the calculator.

Resident Enrollment

If patients are admitted to the teaching service (residents' service), attending hospitalists will obtain informed consents and calculate the initial insulin doses personally. Attending hospitalists will work with residents closely to do standard insulin adjustments. When changing shifts, attending hospitalists will sign out to the next attendings.

PI Enrollment

An alternative way of enrollment is that PI: Hou-Hsien Chiang obtains informed consents and calculates the initial insulin doses. The PI will call the attending hospitalist (and the resident if admitted to teaching service) assigned to the patient to confirm that the hospitalist (and resident) will remain on-shift until the insulin order is placed. The PI

will inform the hospitalist (or resident) that the PI will be recruiting and consenting their patient for a study. They will discuss whether the PI or the hospitalist (or resident) will be placing the order.

After the dosage is calculated by the PI using the calculator, the PI will text the dosage to the hospitalist (and resident) using Epic chat and confirm that the PI or the hospitalist (or resident) will place the order, whoever was agreed upon in the earlier phone call. If the hospitalist (or resident) places the order, the PI will check the order was placed correctly. If the PI places the order and the hospitalist (or resident) has already placed it, the PI will delete the existing order. After the initial dose, the hospitalist (or resident) will continue care as usual (under the supervision of a hospitalist if a resident).

Standard Care

After admission, primary providers will monitor their point-of-care capillary (POC) blood glucose (BG) and laboratory venous BG. After the first dose (by the calculator) is given, providers will continue adjusting insulin doses as the current standard of care. As the current standard of care, POC-BG are checked at least before 3 meals, at bedtime, and 2-3AM, so subjects will get their blood glucose checked within 5-6 hours after the first calculator-determined insulin dose. This is the same time frame as for patients given standard of care insulin doses. The 2-3AM blood glucose check is in the UW order set and will be ordered for all subjects in this trial. The rest of patient care will be no different from standard of care.

Other Procedures

We plan to extract data from the inpatient Electronic Medical Record (EMR), including demographic characteristics (age, gender, race, weight, height), diabetes history (diabetes type, home antidiabetic medications), vital signs, laboratory measurements (POC BG and laboratory venous BG, latest hemoglobin A1c, renal function), interventions (inpatient insulin dose and modality, glucocorticoid, pain medication, surgery or procedure), nutrition status (oral intake, tube feed, intravenous dextrose), and hospital admission/discharge dates.

Our UW observational cohort (STUDY00015475) has 1/140 patients (0.7%) who had hypoglycemia < 54 mg/dL during the first 24 hours of hospitalization. We think (and from prior inpatient glycemic trials) 3% increase (which means 3.7%) is considered clinically significant increase, so among these 85 subjects there cannot be more than 85 x 3.7% = 3.15 subjects that develop hypoglycemia < 54 mg/dL. So, if we find more than 3.15 patients (round to 4) who develop BG < 54 during the recruitment, that is more than 3% increase. Because this is the first feasibility trial to apply the calculator on patients, we plan to enroll 10 subjects first, to demonstrate the calculator dose does not cause hypoglycemia (≤54 mg/dL). After these 10 participants are recruited, we will review and analyze these data. Then we will apply for a modification to increase the sample size.

To examine the feasibility, the specific outcomes that will be measured are hypoglycemia (< 54 mg/dL), mean BG during the first 24 hours of hospitalization, and hyperglycemia (≥ 300 mg/dL), compared to our UW observational cohort (STUDY00015475).

The International Hypoglycemia Study Group defined three levels of hypoglycemia for the purpose of standardized reporting: BG < 70 mg/dL (level 1), < 54 mg/dL (level 2), < 40 mg/dL (level 3) [1]. Centers for Medicare & Medicaid Services (CMS) use the same definition to capture hospital glycemic data [2]. BG < 54 mg/dL was defined as clinically significant hypoglycemia and used in prior inpatient glycemic trials [3].

For statistical analyses, trial subjects (single-arm study with utilization of the insulin calculator) will be compared with the UW observational cohort (STUDY00015475) where standard of care was used (mostly by physicians' experience). The primary endpoint is hypoglycemia < 54 mg/dL. The secondary endpoint is mean BG during the first 24 hours of hospitalization and hyperglycemia (≥ 300 mg/dL).

Reference

1. International Hypoglycemia Study Group. Glucose concentrations of less than 3.0 mmol/l (54 mg/dl) should be reported in clinical trials: a joint position statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetologia. 2017 Jan;60(1):3-6.
2. https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS816v0.html
3. Cruz P. Inpatient Hypoglycemia: The Challenge Remains. J Diabetes Sci Technol. 2020 May;14(3):560-566.

5.2. [DETERMINATION] **Recordings**. Does the research involve creating audio or video recordings?

☒ **No →** Go to question **5.3.**
☐ **Yes →** Verify that you have described what will be recorded in the answer to question **5.1.**, and answer question the question below**.**

5.2.a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?
☐ **No →** Email hsdinfo@uw.edu before submitting this application in ***Zipline***. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.
☐ **Yes**

5.3. [DETERMINATION] **MRI scans**. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

☒ **No →** Go to question **5.4.**
☐ **Yes →** Answer questions **5.3.a** through **5.3.c.**

5.3.a. Describe the MRI scan(s). Specifically:
- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

Click or tap here to enter text.

5.3.b. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
☐ CHN Center for Human Neuroscience MRI Center (Arts & Sciences research facility)
☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
☐ Northwest Diagnostic Imaging
☐ Other: identify in the text box below:

Click or tap here to enter text.

5.3.c. Personnel. For MRI scans that will be conducted at the DISC, CHN or BMIC research facilities: Indicate who will be responsible for operating the MRI scanner by checking all that apply.

☐ MRI technician who is formally qualified
☐ Researcher who has completed scanner operator training provided by a qualified MRI operator

5.4. [DETERMINATION] **Data variables**. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

The factors used to predict insulin requirement are patients' oral intake plan, home insulin dose, first blood glucose value on presentation, inpatient glucocorticoid dose, systemic inflammatory response syndrome (SIRS), dose and timing of last long-acting insulin prior to admission. Our online calculator (https://inpatientinsulin.com) will be used to calculate the initial insulin dosing regimen.
On hospital admission, hospitalists will obtain the above data to calculate initial insulin doses: patient's current appetite and meal plan, daily insulin dose prior to admission, first blood glucose value on hospital presentation, glucocorticoid dose before and after hospital presentation, vital signs and white blood cell count, dose and timing of the last long-acting insulin prior to admission.
Data extracted from the inpatient Electronic Medical Record (EMR): demographic characteristics (age, gender, race, weight, height), diabetes history (diabetes type, home antidiabetic medications), vital signs, laboratory measurements (POC BG and laboratory venous BG, latest hemoglobin A1c, renal function), interventions (inpatient insulin dose and modality, glucocorticoid, pain medication, surgery or procedure), nutrition status (oral intake, tube feed, intravenous dextrose), and hospital admission/discharge dates.

5.5. [DETERMINATION] **Data sources**. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

As the above answer

5.6. [DETERMINATION] **Identifiability of data and specimens.** Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. Consider, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from accessing, which means to view or perceive data.*

5.6.a. Will you or any members of you team have access to any direct or indirect identifiers?

☒ **Yes →** Describe which identifiers and for which data/specimens.

name, date of birth, medical record number (MRN)

☐ **No →** Select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

☐ There will be no identifiers
☐ Identifiers or the key have been (or will have been) destroyed before access.
☐ There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

Click or tap here to enter text.

5.6.b. Will you or any study team members obtain any direct or indirect identifiers?

☒ **Yes →** Describe which identifiers and for which data/specimens.

name, date of birth, medical record number (MRN)

☐ **No →** Select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.
☐ Identifiers or the key have been (or will have been) destroyed before access.
☐ There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

Click or tap here to enter text.

5.6.c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOT: Do not describe the data security plan here, that information is requested in question **9.6**.

☐ Identifiers will be stored with the data. Describe the data to which this applies:

Click or tap here to enter text.

☒ Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

For all data variables described in **5.4.**

☐ Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

Click or tap here to enter text.

5.6.d. Research collaboration. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

Click or tap here to enter text.

5.7. [DETERMINATION] **Protected Health Information (PHI).** Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

For information about what constitutes the UW Covered Entity, review UW Medicine Compliance Patient Information Privacy Policy 101 and diagram of the healthcare components.

☐ **No →** Skip the rest of this question; go to question **5.8**.
☒ **Yes →** Answer all of the questions below (**5.7.a.** through **5.7.f.**)

5.7.a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

We need access to patient's name to interview them in the hospital. (will not obtain or use it after the interview)
We need patient's birthday to calculate their age when they are admitted to the hospital.
We need patient's MRN to access their electronic medical charts to obtain data.

5.7.b. Is any of the PHI located in Washington State?

☐ **No**
☒ **Yes**

5.7.c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

Through the UW inpatient Electronic Medical Record system (Epic)

5.7.d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

name, date of birth, medical record number (MRN)

Confirm by checking the box that UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access obtain, use, or disclose any UW Medicine PHI.

☒ **Confirmed**

5.7.e. Will you obtain any HIPAA authorizations electronically (i.e., e-signature)?

☒ **No**
☐ **Yes** → Confirm by checking the box that you have read and understand the *Electronic Documentation of Consent* section of the worksheet on Consent Requirements and Waivers the guidance on Documentation of Consent for information regarding the use of electronic signatures and HIPAA authorizations.

☐ **Confirmed**

5.7.f. For which PHI will HIPAA authorization NOT be obtained from the subjects?

All screening data

Provide the following assurances by checking the boxes.

☒ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☒ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
☒ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. Review UW Medicine Compliance Policy #104.
☒ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8. [DETERMINATION] **Genomic data sharing**. Will the research obtain or generate genomic data?

☒ **No**
☐ **Yes →** Answer the question below.

5.8.a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes →** Complete the supplement for Genomic Data Sharing and upload it to ***Zipline***.

5.9. Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☒ **No**
☐ **Yes**

5.10. [DETERMINATION] **Cannabis (marijuana), hemp, and related compounds**. These questions are about: cannabis (any part of the plant in any form), hemp, cannabidiol (CBD), delta-8-THC, any product derived from cannabis or hemp, and related synthesized compounds. All UW research must comply with federal laws about cannabis because of conditions associated with the federal money that UW receives. Answer the questions below so that HSD can determine whether the federal laws apply to your specific situation. Review the UW Guidance on Research Involving Marijuana for additional information.

5.10.a. Does your research involve any of the following? Check all that apply.
☐ Study staff will obtain or handle any of the above items
☐ Study will provide money to the participants to obtain any of the above items
☐ Study participants will use or consume any of the above items on campus or in any UW-owned or leased facility
☐ None of the above

5.10.b. If you checked any box except "None of the above", provide the following information about each cannabis and related item your research will involve: Name of the item, how you will obtain it, the source, and whether it contains ≥0.3% THC (tetrahydrocannabinol).

Click or tap here to enter text.

5.11. [DETERMINATION] **Possible secondary use or sharing of information, specimens, or subject contact information.** Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time).

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): analyzing data using machine learning models; informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third-party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

5.11.a Is this research funded by an NIH funding application submitted on or after January 25, 2023.

☒ **No →** Continue to next question.
☐ **Yes →** NIH Data Management and Sharing Policy applies to this research. Complete the rest of this section accordingly. If the policy applies and data will not be shared, provide the justification in response to **5.11.d** and write **NA** in response to the other questions.

5.11.b. Does this research involve analyzing UW patient health information using machine learning outside of UW IT systems (e.g., ChatGPT or other external language models)?

☒ **No →** Continue to next question.
☐ **Yes →** A security review of the research is required by UW Medicine. Please check the box to confirm that this review has been completed and upload a copy of the approval letter to *Zipline.*

Note: Your IRB application cannot be approved without documentation that the security review has been completed. For more information about the security review, contact Sally Beahan, Senior Director, UW Medicine Enterprise Records & Health Information at sbeahan@uw.edu .

☐ **Confirmed**

Answer all of the questions below. If sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing per question **5.8**., write **NA** in remaining response boxes.

5.11.c. Describe what will be stored for future use, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

Indirect identifiers will be stored along with all the corresponding data described in 5.4. The key that links direct and indirect identifiers will be stored separately.

5.11.d. Describe what will be shared with other researchers or with a repository/database/registry/machine learning platform, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens. If shared through a repository, specify if it is unrestricted access (i.e., publicly accessible).

No direct identifiers (name, date of birth, MRN) will be shared. Otherwise, all the data described in **5.4.** will be shared.

5.11.e. Who will oversee and/or manage the sharing?

Hou-Hsien Tony Chiang

5.11.f. Describe the possible future uses, and any limitations or restrictions on future uses or users.

Examples of limitations:

- *Consent prohibits or limits the scope of sharing and use (e.g., consent states that data will be used only for cardiovascular research)*
- *Privacy or safety or research participants would be compromised (e.g., there is risk of reidentification and/or harm)*
- *Explicit federal, state, or local, or Tribal law, regulation, or policy prohibits disclosure*
- *Restrictions imposed by existing or anticipated agreements (e.g., with third party funders, partners, with repositories, medical centers providing health information under a data use agreement)*

Data will be used for endocrinology/glycemic research.

5.11.g. **Consent.** Will consent be obtained now from subjects for the secondary use, banking, and/or future sharing?

☐ **No**
☒ **Yes →** Be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent question in Section 8.

5.11.h. **Withdrawal.** Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

☐ **No**
☒ **Yes →** Describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

Data can be withdrawn from the repository but cannot be retrieved after they are released.

5.11.i. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them.

☒ **Confirmed**

5.12. Communication with subjects during the study. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Screening hospitalists or admitting hospitalists will obtain informed consent. If subjects agree to join this trial, hospitalists will go to our online calculator to calculate the initial insulin dosing regimen. The rest of patient care will be no different from standard of care.
Our intervention will be only the initial insulin doses on admission. During the first few hours after hospitalization, subjects will have direct communications with their admitting hospitalists who are our research team. If subjects still have questions after talking to the admitting hospitalists, admitting hospitalists will contact PI: Hou-Hsien Chiang to address subjects' questions as soon as possible during work hours. During the rest of the hospitalization and after hospital discharge, subjects will have PI: Hou-Hsien Chiang's office contact on the HIPPA form.

5.13. **Future contact with subjects**. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

☒ **No**
☐ **Yes →** Describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Click or tap here to enter text.

5.14. Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

☐ **No**
☒ **Yes →** Describe the alternatives.

The currently available algorithms cannot preciously predict patients' initial insulin requirements. They are not supported by evidence either. Therefore, there is no standard alternative to participation. The current practice is hospitalists initiate insulin doses mostly by their own experience.

5.15. Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE****: Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*

- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (Review the **NOTE** bullet point in the instructions above.)

If subjects agree to join this trial, hospitalists will go to our online calculator (https://inpatientinsulin.com, password: uwmedicine) to calculate the initial insulin dosing regimen. The questions in the online calculator will be asked during the interview with the subjects.

6. CHILDREN (MINORS) AND PARENTAL PERMISSION

6.1. [DETERMINATION] **Involvement of minors**. Does the research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

☒ **No →** Go to Section 8.

☐ **Yes →** Provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

Click or tap here to enter text.

☐ **Don't know →** This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

6.2. Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

6.2.a. Will parental permission be obtained for:

☐ All of the research procedures → Go to question **6.2.b**.
☐ None of the research procedures → Use the table below to provide justification and skip question **6.2.b.**
☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3]	
			YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

6.2.b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If both are checked explain:

Click or tap here to enter text.

6.3. Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**
☐ **Yes** → An advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

Click or tap here to enter text.

6.4. UW Office of the Youth Protection Coordinator. If the project involves interaction (in-person or remotely) with individuals under the age of 18, researchers must comply with UW Administrative Policy Statement 10.13 and the requirements listed at this website. This includes activities that are deemed to be Not Research or Exempt. It does not apply to third-party led research (i.e., research conducted by a non-UW PI). Information and FAQs for researchers are available.

This point is advisory only; there is no need to provide a response.

7. ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

When designing assent processes and forms, researchers should first review the guidance on *Protected and Vulnerable Populations* and tipsheet on *Assent and Legally Authorized Representative*.

7.1. Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then verbally expressing whether they want to participate. They may also provide a written assent if they are older. Review the guidance on *Protected and Vulnerable Populations* and the worksheet on **Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

7.1.a. Will assent be obtained for:

- ☐ All research procedures and child groups → Go to question **7.2**.
- ☐ None of the research procedures and child groups → Use the table below to provide justification, then skip to question **7.6**.
- ☐ Some of your research procedures and child groups → Use the table below to identify the procedures for which assent will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will not be obtained	Reason why assent will not be obtained
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will not be obtained	Reason why assent will not be obtained
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.2. Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

Click or tap here to enter text.

7.3. Dissent or resistance. Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

Click or tap here to enter text.

7.4. E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

Click or tap here to enter text.

7.5. Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups → Use the table below to provide justification, then go to question **7.5.b.**

☐ All of the research procedures and child groups → Go to question **7.5.a**., do not complete the table.

☐ Some of the research procedures and/or child groups → Complete the table below and then go to question **7.5.a.**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented
Click or tap here to enter text.	Click or tap here to enter text.

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.5.a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

Click or tap here to enter text.

7.5.b. Upload all assent materials (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6. Children who reach the legal age of consent during participation in longitudinal research.

When children are enrolled at a young age and continue for many years, it is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).

When children reach the legal age of consent, informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

7.6.a. Describe the plans (if any) to re-obtain assent from children.

Click or tap here to enter text.

7.6.b. Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not be obtained or will not be possible, explain why.

Click or tap here to enter text.

7.7. Other regulatory requirements. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

We provide researchers with many resources for designing the consent process and form(s).

- The general Consent guidance provides a broad overview of all consent-related topics. Researchers are strongly encouraged to review HSD's Consent Overview and the section on Key Information before designing consent process/form.
- The guidance on Designing the Consent Process lists the general requirements for consent, required elements of consent, and the criteria for waivers of consent and documentation of consent. This guidance can be used with, or independent of, our Consent Templates.
- Information about parental permission can be found in the guidance on *Protected and Vulnerable Populations.*

Review the following definitions before answering the questions in this section.

Consent is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.

Parental permission is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.

Consent form is a document that provides details about the research so that subjects can make an informed decision about whether they want to participate.

General requirements for consent are the qualities of the consent process as a whole and can be found in the guidance on Designing the Consent Process.

Elements of consent are specific information that is required to be provided to subjects and can be found in the guidance on Designing the Consent Process.

Consent documentation refers to how a subject's decision to participate in the research is documented. This is usually obtained by having the subject sign a consent form.

Short form consent is an alternative way of obtaining written documentation of consent for the unanticipated enrollment of individuals with low literacy or whose language is one for which translated consent forms are not available.

Waiver of consent means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **Note** if you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).

Waiver of documentation of consent means that there is IRB approval for not obtaining written documentation of consent.

8.1. Groups. Identify the groups to which the answers in this section apply:

☒ **Adult** subjects
☐ **Parents** who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2. The consent process and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening, and, if yes, how.

The issue of consent for recruiting and screening activities is address in question 4.7. You do not need to repeat your answer to question 4.7.

8.2.a. Are there any procedures for which consent will not be obtained?

☒ **No**
☐ **Yes** → Use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures of data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? (Check Yes or No)	
			YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Table footnotes
1. If the answer is the same for all groups, collapse your answer across the groups and/or procedures.

8.2.b. Describe the consent process, if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation.*

The screening hospitalists (part of our research team) screen patients who need to be admitted to the hospital as their regular practice. In the meantime, they will screen eligible subjects who meet our inclusion/exclusion criteria. Once eligible subjects are identified, screening hospitalists or admitting hospitalists will explain the rationales of this study and obtain informed consent. This process will be part of the admission interview which happens either in the emergency room or hospital room.
At the emergency room at Montlake and Northwest hospitals, each patient has their own room, so the consent interview will be conducted in a private room. At the emergency room at Harborview hospital, patients may be only separated by curtains. The hospitalists will ask if they prefer to do the consent interview in a private room.
Some subjects do not have decision-making capacity on hospital admission. If subjects are not able to consent, the hospitalists will obtain consent from their legally authorized representatives' (LAR) in person or on the phone. The hospitalists will obtain consent from the subject or LAR before receiving health information from a caregiver, if needed.
If hospitalists obtain consent on the phone, LAR will provide e-signature through the UW ITHS REDCap e-consent framework. If the subjects regain decision-making capacity during the hospitalization, our research team (hospitalists or PI: Hou-Hsien Chiang) will inform subjects that they were enrolled in this research study and obtain verbal consent to obtain medical record data. In this scenario we will use a short consent form for just the medical records review, which includes a description of the procedures, research team contact information, and HSD's contact information.
An alternative way of recruitment is that PI: Hou-Hsien Chiang screens eligible subjects and obtains informed consents from subjects or LAR.

8.2.c. Comprehension. Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

Teach-back method (by asking patients to state in their own words) will be used to ensure subjects understand the information during the consent process.

8.2.d. Influence. Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research; study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

☐ **No**

☒ **Yes** → Describe what will be done to reduce any effect of the setting or relationship on the participation decision.

Examples: a study coordinator will obtain consent instead of the subject's physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

Subjects are recruited at the time of hospital admission when they may still be physically in the emergency room. They may feel under pressure to consent in this situation. We mitigate this effect

by making the consent process/form concise. The consent interview is not expected to be more than 5-10 minutes and it is combined with the standard admission interview when hospitalists admit them to the hospital. We will make it clear that subjects are free to choose standard of care rather than using this new calculator.

8.2.e. Information provided is tailored to the needs of the subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member* of the *subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information present in that section is that which is *most likely* to assist the selected subject population with making a decision. Review the guidance on Key Information and examples of Key Information.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

I had a meeting with the IRB team A with Malaika Schwartz and Galen Basse who advised me to use a short consent form because of limited time during hospital admission. I took reference from our UW consent form example and templates to tailor to what a reasonable member of the subject population would want to know. (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.washington.edu/research/wp-content/uploads/EXAMPLE_Consent_Expedited_FullBoard_v1.0_2023.06.01.pdf). My supervisor Irl Hirsch, who is an experienced clinical researcher, read and approved the content of our consent form.

8.2.f. Ongoing process, new information, and reconsent.

For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

Throughout the course of the study, subjects may need to be notified about new information. This might take the form of a verbal or written communication or may require subjects to provide reconsent. When a modification is submitted in which subjects need to be informed about new information, describe the method and process the research team will use to provide this information.

Review the tipsheet on Reconsent and Ongoing Subject Communication and guidance on Reconsent and Ongoing Subject Communication for details.

The intervention of this study occurs in the initial insulin dosing on hospital admission. The rest of patient care will be no different from standard of care. During the first few hours after hospitalization, subjects will have direct communications with their admitting hospitalists who are our research team. If subjects still have questions after talking to the admitting hospitalists, admitting hospitalists will contact PI: Hou-Hsien Chiang to address subjects' questions as soon as possible during work hours. After that, there is no ongoing interaction with subjects.
Some subjects do not have decision-making capacity on hospital admission and consent will be obtained from their LARs. If the subjects regain decision-making capacity during the hospitalization, our research team (hospitalists or PI: Hou-Hsien Chiang) will inform subjects that they were enrolled in this research study and obtain verbal consent to obtain medical record data. In this scenario we will use a short consent form for just the medical records review, which includes a description of the procedures, research team contact information, and HSD's contact information.

8.3. **Electronic presentation of consent information**. Will any part of the consent-related information be provided electronically for some, or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. Review the guidance on Electronic Consent and Documentation of Consent for information about electronic consent requirements at UW.

☐ **No →** Skip to question **8.4.**

☒ **Yes →** Answer questions **8.3.a.** through **8.3.e.**

8.3.a. Describe the electronic consent methodology and the information that will be provided.

All information materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

If hospitalists or PI obtain consent on the phone, LAR will provide e-signature through the UW ITHS REDCap e-consent framework. The consent form, which is the same as the paper consent form we attached, will be sent by text or email.

8.3.b. Describe how the information can be navigated (if relevant).

For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?

In the REDCAp e-consent system, LARs are able to proceed forward and backward, and provide e-signature at the bottom of the consent form. A read only copy of the consent can be generated that LARs can review, download, and/or print (https://www.washington.edu/research/hsd/guidance/consent/econsent/).

8.3.c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

Our consent form has only 4 pages, including 3 pages of information and one page of signature. Hospitalists or PI will let LARs read the consent form for about 10 minutes. Then hospitalists or PI will call LARs again to answers their questions.

8.3.d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

This is a time sensitive trial in which we need to give subjects insulin therapy in a timely manner. If the LARs do not have access to the electronic device to perform e-consent, we will have to exclude these subjects.

8.3.e. How will the research team ensure continued accessibility of consent materials and information during the study?

The copy of the e-consent will be maintained in REDCap.

8.3.f. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information). If this is not an issue, explain why.

The intervention of this trial (initial insulin doses) will be done at the time of hospital admission. We do not expect there will be significant new findings that might change subjects' willing to participate in this trial.

8.4. Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question **4.7**.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent.

8.4.a. Is written documentation being obtained for:

☐ **None** of the research procedures → Use the following table to provide justification then go to question **8.5.**

☒ **All** of the research procedures → Do not complete the following table, go to question **8.4.b.**

☐ **Some** of the research procedures → Use the following table to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? (Check Yes or No)	
		YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? (Check Yes or No)	
		YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Table footnotes

1. If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.

8.4.b. Electronic consent signature. For studies in which documentation of consent will be obtained, will subjects use an electronic method to provide their consent signature?

- Review the guidance on *Documentation of Consent* and *UW E-Signature Tools* for information about options (including ***REDCap*** e-signature and the ***DocuSign*** system) and any associated requirements.
- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☐ **No**

☒ **Yes** → Indicate which methodology will be used

☒ **UW ITHS REDCap** (excludes REDCap Mobile application, which is a separate software application for use with a mobile device for consent when internet service is absent or unreliable)

☐ **Other REDCap installation** → Please name the institutional version you will be using (e.g., Vanderbilt, Univ. of Cincinnati) in the following field and provide a completed supplement **Other REDCap Installation** with your submission.

Click or tap here to enter text.

☐ **UW DocuSign**

☐ **Other** → Please describe in the following field and provide a signed **Other E-signature Attestation Letter** with your submission.

Click or tap here to enter text.

8.4.b.1. Is this method legally valid in the jurisdiction where the research will occur?

NOTE: UW ITHS REDCap (excludes REDCap Mobile application) and UW DocuSign have been vetted for compliance with Washington State and federal laws regarding electronic signatures.

☐ **No**

☒ **Yes →** What is the source of information about legal validity?

UW ITHS REDCap (excludes REDCap Mobile application) has been vetted for compliance with Washington State and federal laws regarding electronic signatures.

8.4.b.2. Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

Review the guidance Documentation of Consent for information and examples

☐ **No →** Provide the rationale for why this is not required or necessary to protect subjects or the integrity of the research. Also, what would be the risks to the actual subject if somebody other than the intended signatory provides the consent signature?

Click or tap here to enter text.

☒ **Yes →** Describe how subject identity will be verified, providing a non-technical description that the reviewer will understand.

Subject identity will be verified by full name, date of birth and medical record number (U number).

8.4.b.3. How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

Copy of the e-consent information will be sent to LARs by text or email through UW ITHS REDCap. The copy will also be maintained in REDCap.

8.4.c. Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

8.4.c.1. Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form).

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

Hospitalists or PI can read the form to the person before they sign it.

8.5. Non-English-speaking or-reading adult subjects. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☐ **No**

☒ **Yes →** Describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

Hospitalists or PI will use UW Interpreter Services to interview subjects whose primary language is not English.

8.5.a. Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) - for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research related vocabulary in English and the target language.

Hospitalists or PI will use UW Interpreter Services to interview subjects during the admission interview (which is a standard of care). The interpretation could be by phone/video/in-person.

8.5.b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the local in which they will be used.

☒ Check this box to confirm that before using them with subjects, you will upload in *Zipline* all translated consent materials that will be provided to subjects in written or electronic form (per **HSD policy**).

If the IRB determines that your study is greater than minimal risk, or otherwise determines it is required, you will need to work with your translator to provide a Translation Attestation. If the attestation is required, you will be informed by the IRB during the course of the review.

We will get our consent form translated by an independent certified translation service recommended by the HSD (https://www.washington.edu/research/hsd/guidance/consent/#8a2), once the English consent form is approved by the IRB.

8.6. [DETERMINATION] **Deception**. Will information be deliberately withheld, or will false information be provided, to any of the subjects?

NOTE: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subjects to an intervention or about the purpose of the procedure(s) is deception.

☒ **No**
☐ **Yes →** Describe what information and why.

Example: it may be necessary to deceive subjects about the purpose of the study (describe why).

Click or tap here to enter text.

8.6.a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

☐ **No**
☐ **Yes**

8.6.b. Will subjects be debriefed later? (Note: this is not necessarily required.)

☐ **No →** Provide your reasoning for not debriefing subjects.

Click or tap here to enter text.

☐ **Yes →** Describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

Click or tap here to enter text.

8.7. [DETERMINATION] **Cognitively impaired adults, and other adults unable to consent**. Will such individuals be included in the research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

☐ **No →** Go to question **8.8.**
☒ **Yes →** Answer the following question.

8.7.a. Rationale. Provide the rationale for including this population.

A certain percentage of inpatients are initially confused or have altered mental status on admission. Like patients who are alert and oriented, they can also have elevated blood glucose that need to be managed by accurate insulin doses. Excluding these populations will make the calculators not applicable to them. In this case, the hospitalists or PI will ask whether patient's legally authorized representative is willing to consent for the patient.

8.7.b. Capacity for consent/decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

Evaluating capacity for consent/making medical decisions is part of the admission interview by hospitalists. PI will also evaluate subjects' capacity for consent/making medical decisions.

8.7.b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase of diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

The intervention of this study occurs in the initial insulin dosing on hospital admission. The rest of patient care will be no different from standard of care. After hospital discharge, there is no ongoing interaction with subjects.

8.7.c. Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate-consent") from a legally authorized representative (LAR).

For research conducted in Washington State, review the guidance on Diminished and Fluctuating Consent Capacity and Use of a Legally Authorized Representative (LAR) to learn which individuals meet the state definition of "legally authorized representative".

If subjects are not able to consent for themselves, the hospitalists or PI will ask patient's legally authorized representative (LAR) to if he/she is willing to consent for the patient.

8.7.d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

We will not obtain assent for the study procedure from subjects if they do not have the decision capacity to provide consent themselves.

8.7.e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

Being in the study is voluntary. If potential subjects tell the hospitalists or PI that they do not want to participate, we will not include them in the study.

8.8. Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
☐ Participation in the research will not affect the method of abortion.
☐ No enticements, benefits or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the woman and the person who obtains the informed consent.

8.9. Consent-related materials. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's Local Site Documents page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: it may be appropriate to combine parental permission with consent if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participants. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered text; licensed and restricted standardized tests.*

9. PRIVACY AND CONFIDENTIALITY

9.1. [DETERMINATION] **Privacy protections.** Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold contact" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g., details about sexual behavior) may feel like an invasion of privacy to some individuals.*

To protect privacy, identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data.
The consent interview may happen in the emergency or hospital room. At the emergency room at Montlake and Northwest hospitals, each patient has their own room, so the consent interview will be conducted in a private room. At the emergency room at Harborview hospital, patients may be only separated by curtains. The hospitalists or PI will ask if they prefer to do the consent interview in a private room.

9.2. [DETERMINATION] **Identification of individuals in publications and presentations.** Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

☒ **No**
☐ **Yes** → Will subject consent be obtained for this use?

☐ **Yes**
☐ **No** → Describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

Click or tap here to enter text.

9.3. [DETERMINATION] **State mandatory reporting**. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

☒ **No**
☐ **Yes** → The UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

Click or tap here to enter text.

9.4. [DETERMINATION] **Records retention requirements.** Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g., Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state that identifying information will be destroyed at the end of the study or after the records retention period required by state and/or federal law.

Review the "Research Data" and "Personal Identifiers" sections of the following website for UW Records management for the Washington State research records retention schedules that apply in general to the UW (not involving UW Medicine data): ***http://f2.washington.edu/fm/recmgt/gs/research?title=R; https://finance.uw.edu/recmgt/gs/research?title=P.***

Review the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

☒ **Confirm**

9.5. [DETERMINATION] **Certificates of Confidentiality.** Will a federal Certificate of Confidentiality be obtained for the research data? *NOTE: Answer "No" if the study is funded by NIH or the CDC, because most NIH-funded and CDC-funded studies automatically have a Certificate.*

☒ **No**

☐ **Yes**

9.6. [DETERMINATION] **Data and specimen security protections**. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the guidance on Data and Security Protections for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

9.6.a. Choose the level(s) of protections that will be applied to the data and specimens. If more than one level will be used, use the text box to describe which level will apply to which data and which specimens and at which sites.

☐ **Level 1:** Very low risk of harm if disclosed
☐ **Level 2:** Some risk of minor harm if disclosed
☒ **Level 3:** Could cause risk of material harm if disclosed
☐ **Level 4:** Would likely cause serious harm to individuals if disclosed
☐ **Level 5:** Extremely sensitive; could cause severe harm to individuals if disclosed

We believe the study data are level 3: non-sensitive personal health information. But we plan to store the study data separately from the identifier, which can make the data de-identified (level 1: very low risk of harm if disclosed).
We plan to store study data and the link (between direct and indirect identifier) separately in REDcap. Only the study members (PI Dr. Hou-Hsien Tony Chiang and supervising faculty Dr. Irl Hirsch) have access to the database.

9.6.b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. **HSD allows researchers to request exceptions to data security requirements, if the exception is necessary and does not significantly increase risk to participants**. If there are any protections within the level listed in 9.6.a which will not be followed, list those here, including identifying the sites where this exception will apply. For example, if you intend to store subject identifiers with study data (not permitted under requirement U9 for Risk Levels 3-5), then indicate this in the box below (e.g., "We will not adhere to requirement U9 for screening data").

Click or tap here to enter text.

10. RISK / BENEFIT ASSESSMENT

10.1. [DETERMINATION] **Anticipated risks.** Describe the anticipated risks of harm, discomforts, and hazards to the subjects and others of the research procedures.

For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in question **9.6.**

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement, or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*

- *Ensure applicable risk information from any Investigator Brochures, Drug Package Inserts, and/or Device Manuals is included in your description.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; taking blood samples to monitor something that indicates drug toxicity.*
- *Review the guidance on Identifying and Describing Reasonably Foreseeable Risks in Research for information about which risks should be described in the consent process/form.*
- *As with all questions on this application, you may refer to uploaded documents.*

There is theoretical risk of hypoglycemia when using our initial insulin dosing calculator. But the same risk exists in the standard of care as well.
Our UW observational cohort (STUDY00015475) has 1/140 patients (0.7%) who had hypoglycemia < 54 mg/dL during the first 24 hours of hospitalization. We think 3% increase (which means 3.7%) is considered clinically significant increase, so among these 85 subjects there cannot be more than 85 x 3.7% = 3.15 subjects that develop hypoglycemia < 54 mg/dL. So, if we find more than 3.15 patients (round to 4) who develop BG < 54 during the recruitment, that is more than 3% increase. Because this is the first feasibility trial to apply the calculator on patients, we plan to enroll 10 subjects first, to demonstrate the calculator dose does not cause hypoglycemia (≤54 mg/dL). After these 10 participants are recruited, we will review and analyze these data. Then we will apply for a modification to increase the sample size.
UW inpatient insulin order set comes with hypoglycemia protocols which will be used to manage hypoglycemia if it occurs.
If hospitalists do not feel comfortable with the calculator doses when they enroll subjects, they will contact PI: Hou-Hsien Chiang in real time, and we will double-check the calculator doses. If these subjects are admitted after midnight and PI: Hou-Hsien Chaing is unavailable for discussion, hospitalists will not enroll the subject. Hospitalists and PI: Hou-Hsien Chiang will then discuss this scenario (subject not enrolled) to understand the reasons hospitalists did not feel comfortable with the calculator dose.

10.2. [DETERMINATION] **Reproductive risks**. Are there any risks of the study procedures to subjects or partner of subjects related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

☒ **No →** Go to question **10.3.**
☐ **Yes →** Answer the following questions:

10.2.a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

Click or tap here to enter text.

10.2.b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required, describe the allowable methods and the time period when contraception must be used.

Click or tap here to enter text.

10.2.c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant.

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinued or modified, or for a discussion of risks, and/or referrals or counseling?

Click or tap here to enter text.

10.3. [DETERMINATION] **MRI risk management**. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

10.3.a. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA)?

☒ **No**

☐ **Yes** → Which agents will be used? *Check all that apply.*

Check all that apply	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

Click or tap here to enter text.

10.3.a.1. The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

Click or tap here to enter text.

10.3.a.2. Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

10.3.b. Who will (1) calculate the dose of GBCA; (2) prepare it for injection; (3) insert and remove the IV catheter; (4) administer the GBCA; and (5) monitor for any adverse effects of the GCBA? Also, what are the qualifications and training of these individual(s)?

Click or tap here to enter text.

10.3.c. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

Click or tap here to enter text.

10.3.d. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

Click or tap here to enter text.

10.4. **[DETERMINATION]** **Unforeseeable risks**. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

☒ **No**
☐ **Yes →** Identify the procedures.

Click or tap here to enter text.

10.5. Subjects who will be under regional or general anesthesia. Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

☒ **No**
☐ **Yes →** Check all the boxes that apply.

- ☐ Administration of any drug for research purposes
- ☐ Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- ☐ Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- ☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery.
- ☐ Administration of a radio-isotope for research purposes**
- ☐ Implantation of an experimental device
- ☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If any of the boxes are checked:

Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and

the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

Click or tap here to enter text.

*** If the box about radio-isotopes is checked, the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6. Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below. For guidance on developing a DSMP, review the ITHS webpage on Data and Safety Monitoring Plans.

DSMP is uploaded to Zipline, in the 'Other attachments' section of the "Local Site Documents" SmartForm.

10.7. Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned, describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

This is not a blind study.

10.8. Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

If anytime the hospitalists decide subjects need to be on IV insulin infusion, they are no longer eligible for this study. In this case, they will be withdrawn from the research without their consent.

If hospitalists do not feel comfortable with the calculator doses and these subjects are admitted after midnight (PI: Hou-Hsien Chaing is unavailable for discussion), hospitalists will withdrawal the subject from the research without their consent.

If the subject has already been given insulin before the study dosage can be administered, they will be withdrawn from the study

10.9. [DETERMINATION] Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Participating in this study has the potential to achieve inpatient glycemic goal of 100-180 mg/dL faster than the standard of care with less manual adjustment.

10.10. [DETERMINATION] Return of individual research results.

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

Review the guidance on Return of Individual Results for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.

10.10.a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

☒ **No**

☐ **Yes →** Answer the following questions (**10.10.a.1** through **10.10.a.3.**)

10.10.a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e., because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

Click or tap here to enter text.

10.10.a.2. Explain which of these results will be offered to subjects.

Click or tap here to enter text.

10.10.a.3. Explain which results will not be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

Click or tap here to enter text.

10.10.b. Is there a plan for offering subjects any results that are not clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

☒ **No**

☐ **Yes →** Explain which results will be offered to subjects and provide the rationale for offering these results.

Click or tap here to enter text.

10.10.c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

The results will not be offered to subjects.

10.10.d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

The results will not be offered to subjects.

10.10.e. Describe any plans to share results with family members (e.g., in the event a subject becomes incapacitated or deceased).

The results will not be offered to family members.

10.10.f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

Review the guidance on Return of Individual Results for information about consent requirements.

☐ **Confirmed**

10.11. Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

☒ **No**

☐ **Yes →** Describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

Click or tap here to enter text.

11. ECONOMIC BURDEN TO PARTICIPANTS

11.1. Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

N/A

11.2. Costs to subjects. Will there be any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed)?

☒ **No**

☐ **Yes →** Provide a description of the costs that may be incurred.

Click or tap here to enter text.

12. RESOURCES

12.1. [DETERMINATION] **Faculty Advisor**. (For researchers who are students or residents.) Provide the following information about the faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

Faculty advisor Dr. Irl Hirsch who is my primary mentor of research fellowship. Dr. Steven Kahn is my co-mentor. All three of us meet weekly to discuss research progress. We also communicate by emails in between meetings.

12.2. UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in ***Zipline***. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, review http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://intranet.medicine.uw.edu/academic-hr/curriculum-vitae-cv

☒ **The CV will be uploaded.**

12.3. UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Examples:
Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.

Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.

Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.

Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Hou-Hsien Tony Chiang: PI of this study.
Research team members who conduct this project are attending hospitalists of the UW internal medicine department.

12.4. Study team training and communication. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ There is no study team

There will be one leading hospitalist at UW Montlake, Harborview and Northwest hospitals each. These lead hospitalists will communicate with me closely regarding details of the study process. Before recruiting subjects, we will hold meetings among the whole research team. During the recruitment, every hospitalist will have cell phone numbers of the lead hospitalists and me, so we can communicate in real-time if any question comes up.

13. OTHER APPROVALS, PERMISSIONS, AND REGULATORY ISSUES

13.1. [DETERMINATION] **Approvals and permissions**. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

N/A

13.2. Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**
☐ **Yes →** Has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

- ☐ **No →** Contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination.
- ☐ **Yes →** Upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.

Click or tap here to enter text.