TASK DOCUMENTATION
[Screening Form]

Participant ID: **PtID**

	SCREENING ELIGIBILITY
	Eligibility Verification: **All of the following are eligibility criteria.**
EligCritMet	*Inclusion Criteria:* **Verify that ALL of the following are present by checking each box.** ☐ Clinical diagnosis of type 1 diabetes ☐ Age $\geq$ 18 years ☐ T1D duration $\geq$ 1year ☐ HbA1c $\leq$ 9.0% using point of care device or local lab ☐ Use of an insulin pump for insulin delivery for at least 3 months, with no plans to discontinue pump use during the next 8 months ☐ Participant is able to manage his/her diabetes with respect to insulin administration and glucose monitoring, as assessed by the investigator during the screening visit ☐ Participant understands the study protocol and agrees to comply with it ☐ No expectation that participant will be moving out of the area of the clinical center during the time period of the study, unless the move will be to an area served by another study center.
ExclCritAbsent	*Exclusion Criteria:* **Verify that none of the following are present by checking each box to indicate that each is <u>not</u> present** ☐ Severe hypoglycemia in the last 12 months in which the assistance of another individual was needed or seizure/loss of consciousness in the past 3 years ☐ Significant hypoglycemia unawareness based on the Clarke Hypoglycemia Unawareness Survey defined as at least one of the following being present: survey score >2, survey Q1 is answered as 'I no longer have symptoms when my blood sugar is low', survey Q7 response indicates that symptoms of hypoglycemia are not felt until glucose level is <50 mg/dl, survey Q8 response is never or rarely to the question 'to what extent can you tell by your symptoms that your blood sugar is low' ☐ More than one DKA event in the past year ☐ History of seizures other than due to hypoglycemia ☐ Current use of a threshold suspend pump feature (note: participant is eligible if a pump with this feature was being used but the threshold suspend was not active) ☐ Myocardial infarction or stroke in past 6 months ☐ Estimated Glomerular Filtration Rate (GFR) <30 obtained within the prior 12 months as part of usual care or kidney transplant ☐ Most recent thyroid function test results abnormal, obtained as part of usual care within the prior 2 years ☐ The presence of a significant medical or psychiatric disorder or use of a medication that in the judgment of the investigator will affect the wearing of the sensors, the completion of any aspect of the protocol, or increase risk ☐ Cognitive difficulties in the judgment of the investigator that could impair the individual's ability to follow the protocol or increase risk

	☐ Initiation of a non-insulin drug for glucose control during the past 3 months, planned initiation during the next 8 months, or discontinuation of a non-insulin drug for glucose control during the past 3 months (note: individuals using a non-insulin medication for glucose control for 3 or more months are eligible provided there is no expectation that the medication will be discontinued during the time period of study participation)
	☐ Use of a systemic beta blocker drug
	☐ Regular use of oral corticosteroids
	☐ Anticipated need to use acetaminophen during the time course of the study
	☐ Inpatient psychiatric treatment in the past 6 months
	☐ Currently pregnant or lactating or plans to attempt getting pregnancy during the time period of the study
	) Females with child-bearing potential will be queried about the possibility of pregnancy and a urine pregnancy test will be performed if there is uncertainty as to the possibility of pregnancy. They must agree to use appropriate birth control during the time period of the study. Participants will receive education regarding birth control methods which may be considered as highly effective, which are methods that can achieve a failure rate less than 1% per year when used consistently and correctly and include: o Combined hormonal contraception associated with inhibition of ovulation (oral, intravaginal, transdermal) o Progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable, implantable) o Intrauterine device (IUD) o Intrauterine hormone-releasing system (IUS) o Bilateral tubal occlusion o Vasectomised partner o Sexual abstinence
	☐ Participation in an intervention study (including psychological studies) in past 6 weeks.
	☐ Known adhesive allergy

	DEMOGRAPHIC INFORMATION
Gender	1. **Gender:** O Male O Female
Ethnicity	2. **Ethnicity:** O Hispanic or Latino O Not Hispanic or Latino O Unknown/not reported *See "Personal Census Data" for definitions*

TASK DOCUMENTATION
[Screening Form]

Race	3. Race:
	O White
	O Black/African-American
	O Asian
	O Native Hawaiian/Other Pacific Islander
	O American Indian/Alaskan Native
	O More than one race
	O Unknown/not reported

	DIABETES HISTORY
DiagAge **DiagAgeApprox**	**1. Age at diagnosis of diabetes: _____yrs [Dropdown will use AgeRange selector]** ☐ Approximate
SHMostRec	**2. Severe Hypoglycemia** **2a. Estimate of when most recent severe hypoglycemic event (as defined below) occurred:** O Never O < 3 months ago O 3-<6 months ago O 6-12 months ago O More than 12 months ago
SHNumLast12Mon	**2b. Estimated number of severe hypoglycemic events in the last 12 months (as defined below):** O 0 O 1 O 2 O 3 O 4 O 5 ***Severe hypoglycemia** defined as severe if the event required assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions due to altered consciousness. This means that the participant was impaired cognitively to the point that the participant was unable to treat his or herself, was unable to verbalize his or her needs, was incoherent, disoriented, and/or combative, or experienced seizure or coma.*

TASK DOCUMENTATION
[Screening Form]

DKAMostRec	**3. DKA**
	
	   3a. Estimate of when most recent definite or probable DKA event (as defined below) occurred:
	
	   ○ Never
	
	   ○ < 3 months ago
	
	   ○ 3-<6 months ago
	
	   ○ 6-12 months ago
	
	   ○ More than 12 months ago

DKANumLast12Mon	**3b. Estimated number of definite or probable DKA events in the last 12 months (as defined below):**
	
	   ○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
	
	Definite Diabetic Ketoacidosis *(as defined by the DCCT) is defined as having all of the following:*
	
	   (1) Symptoms such as polyuria, polydipsia, nausea, or vomiting
	
	   (2) Serum ketones >1.5 mmol/L or large/moderate urine ketones
	
	   (3) Either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15
	
	   (4) Treatment provided in a health care facility
	
	Probable Diabetic Ketoacidosis *means in the judgment of the investigator the participant had DKA but not enough information is available to categorize event as meeting the above criteria.*

	CURRENT DIABETES TREATMENT

OthGlucLowerMed	**1. Is participant using glucose-lowering medication other than insulin?**
	   ○ Yes ○ No
	
	   If <u>Yes</u>, add the medication on the Medication Form.

	BGM MONITORING
Fingerstick7DayAve	**1. What is the average number of fingerstick readings the participant reports having done each day over the last 7 days?** _____ *(dropdown)* **[Range: 0-30]**

	SOCIOECONOMIC INFORMATION

EduLevel
 	
EduLevelUnk
 	
EduLevelNoAns
	1. Please select the highest level of education completed by the participant:
	
	   ○ Less than 1st grade
	
	   ○ 1st, 2nd, 3rd, or 4th grade
	
	   ○ 5th or 6th grade

	○ 7th or 8th grade

	○ 7th or 8th grade
	○ 9th grade
	○ 10th grade
	○ 11th grade
	○ 12th grade-no diploma
	○ High school graduate/diploma/GED
	○ Some college but no degree
	○ Associate degree (AA)
	○ Bachelor's degree (BS/BA/AB)
	○ Master's degree (MA, MS, MSW, MBA, MPH)
	○ Professional degree (MD, DDS, DVM, LLB, JD)
	○ Doctorate degree (PhD, EdD)
	☐ Unknown
	☐ Does not wish to provide
AnnualInc **AnnualIncUnk** **AnnualIncNoAns**	**2. In the household where the participant lives most of the time, what is the annual household income from all sources?** ○ Less than $25,000 ○ $25,000 to less than $35,000 ○ $35,000 to less than $50,000 ○ $50,000 to less than $75,000 ○ $75,000 to less than $100,000 ○ $100,000 to less than $200,000 ○ $200,000 or more ☐ Unknown ☐ Does not wish to provide
InsPrivate **InsMedicare** **InsMediGap** **InsMedicaid** **InsSCHIP** **InsMilitary**	**3. What kind of health insurance or health care coverage does the participant have?**

TASK DOCUMENTATION
[Screening Form]

InsIndian **InsState** **InsOtherGov** **InsSingleService** **InsNoCoverage** **InsUnknown** **InsNoAns**	Exclude private plans that only provide extra cash while hospitalized. If participant has more than one kind of health insurance, please select all plans that he/she has. At least one checkbox must be selected. ☐ Private Health Insurance (e.g. commercial, fee-for-service, HMO, PPO, POS) ☐ Medicare ☐ MediGap ☐ Medicaid ☐ SCHIP (CHIP, Children's health insurance program) ☐ Military health care (TRICARE, CHAMPUS, CHAMPVA, VA) ☐ Indian Health Service plan ☐ State sponsored health plan ☐ Other government sponsored health coverage plan ☐ Single service plan (e.g. dental, vision, prescriptions) ☐ No coverage of any type ☐ Unknown ☐ Does not wish to provide

	PHYSICAL EXAMINATION
Weight	**1. Weight:** ____ ____ .____ **kg** *[Range: 20.0-200.0]*
Height	**2. Height:** ____ ____ ____ . ____ **cm** *[Range: 100.0-280.0]*
PEAbnormal	**3. Were any clinically significant abnormalities found on the physical exam?** O Yes O No

CONTINUOUS GLUCOSE MONITOR USE

TASK DOCUMENTATION
[Screening Form]

CGMUseStatus	1. **Indicate status of CGM (real-time) use:**
	
	    O Never
	    O In past, but not current
	    O Current
	
	If current CGM user, complete the following:
	
	1a. How long has the participant been using CGM?
	  O <6 months
	  O 6 months-<1 year
	  O 1-<2 years
	  O 2-<5 years
	  O 5 years
	
	1b. Which CGM is being used?
	  O Dexcom O Medtronic
	
	1c. Does the CGM download show use on at least 21 of the last 28 days?
	O Yes O No
	    If Yes, complete the following:
	      i. **Are CGM glucose values <60 mg/dl less than 10% of the time?**
	        O Yes O No
	      If No, participant is ineligible; complete a Pre-randomization Final Status Form

The left column labels aligned with sections:
CGMUseStatus, **CGMUseDuration**, **CGMUseDevice**, **CGMDLoadMinDays**, **CGMGlucUnder60**