Obtain Participant ID Form

1. Participant Initials: ____ ____ ____ (enter "X" if no middle initial)
2. Date of Birth: ____ ____ **/** ____ ____ **/** ____ ____ ____ ____
3. Study ID of Enrolling Investigator: ____ ____ ____ ____ ____
4. Informed Consent Signed by Participant (or parent/guardian if participant is <18 years old): Signed on: ____ ____ **/** ____ ____ **/** ____ ____ ____ ____
Participants <18 years of age (if applicable) **5. Child Assent Form (participant):** Signed on: ____ ____ **/** ____ ____ **/** ____ ____ ____ ____
6. Separate HIPAA Form Signed by Participant (or parent/guardian if person is <18 years old): (if applicable) Signed on: ____ ____ / ____ ____ / ____ ____ ____ ____
☐ **All signatures and date fields have been properly completed on the informed consent form, assent form, and HIPAA authorization indicated above, as applicable.**

Screening Visit Form

Patient ID:

Namecode:

Visit Date:

SCREENING ELIGIBILITY

Eligibility Verification: **All of the following are eligibility criteria.**

Inclusion Criteria: **Verify that ALL of the following are present by checking each box.**

- ☐ Age ≥6 years
- ☐ Body mass (BMI) <30 in subjects ≥18 years old and between the 5th to 85th percentile for age and sex for subjects <18 years old

Exclusion Criteria: **Verify that NONE of the following are present by checking each box to indicate that each is not present.**

- ☐ History of diabetes
- ☐ Point of care (POC) HbA1c ≥5.7%
- ☐ The presence of a significant medical disorder that in the judgment of the investigator will affect the wearing of the sensors, glucose metabolism, or the completion of any aspect of the protocol
- ☐ The use of any steroid or other medication that in the judgment of the investigator will affect the wearing of the sensors, glucose metabolism, or the completion of any aspect of the protocol
- ☐ Participation in another pharmaceutical drug or device study at the time of enrollment or during the study
- ☐ Females who are pregnant at the time of study enrollment

PHYSICAL EXAMINATION

1. Weight: ____ ____ . ____ kg

2. Height: ____ ____ ____ . ____ cm

POINT OF CARE (POC) HBA1C

1. Date of Test: ___ ___ / ___ ___ /___ ___ mm/dd/yy

2. HbA1C Results:___ ___ . ___ %

DEMOGRAPHIC INFORMATION

1. Gender: ☐ Male ☐ Female

Ethnicity and race must be <u>self-reported</u> by the study participant. Read the following questions (and answer choices as applicable) aloud to the study participant exactly as written and record the responses below;

2. Do you consider yourself Hispanic/Latino or not Hispanic/Latino?

☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown/not reported

3. Which of the following racial designations best describes you? If more than one race, please specify.

☐ White ☐ Black/African-American ☐ Native Hawaiian/Other Pacific Islander

☐ Asian ☐ American Indian/Alaskan Native ☐ More than one race

☐ Unknown/not reported

If more than one race selected please specify: _____

FAMILY HISTORY

1. Does the participant have a first degree biological family member with type 1 diabetes (parent, sibling, or child)?

☐ Yes ☐ No ☐ Unknown

1a. If YES, which family member(s) has/have type 1 diabetes?

☐ Parent

☐ Sibling

☐ Child

☐ Unknown

WORK HISTORY

1. What type of work does the participant do? (if age ≥18 years)

☐ Mainly desk job ☐ Mainly physical activity ☐ Not currently working

MENSTRUAL CYCLE

1. Start date of last menstrual cycle: ___ ___ / ___ ___ /___ ___ mm/dd/yy

☐ **Unknown** ☐ **Not applicable** (male participant or female participant who is prepubertal)

2. End date of last menstrual cycle: ___ ___ / ___ ___ /___ ___ mm/dd/yy

☐ **Unknown** ☐ **Not applicable** (male participant or female participant who is prepubertal

Diabetes Tanner Staging Assessment (A) Worksheet

Subject ID: _____ **Namecode:** _____

☐ No assessment performed because subject is pre-pubertal

1. Date of test:

_____ _____ / _____ _____ / _____ _____ _____ _____

(mm/dd/yyyy)

2. Tanner Staging

2a. Pubic hair: ☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **Unknown**

2b. Breasts (F) or genitalia (M): ☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **Unknown**

Pubic hair (both male and female)
Tanner 1
No pubic hair at all (pre-pubertal) (typically age 10 and younger)
Tanner 2
Small amount of long, downy hair with slight pigmentation at the base of the penis and scrotum (males) or on the labia majora (females) (10–11.5)
Tanner 3
Hair becomes more coarse and curly, and begins to extend laterally (11.5–13)
Tanner 4
Adult–like hair quality, extending across pubis but sparing medial thighs (13–15)
Tanner 5
Hair extends to medial surface of the thighs (15+)

Breasts (female)
Tanner 1
No glandular tissue: areola follows the skin contours of the chest (prepubertal) (typically age 10 and younger)
Tanner 2
Breast bud forms, with small area of surrounding glandular tissue; areola begins to widen (10 11.5)
Tanner 3
Breast begins to become more elevated, and extends beyond the borders of the areola, which continues to widen but remains in contour with surrounding breast (11.5–13)
Tanner 4
Increased breast size and elevation; areola and papilla form a secondary mound projecting from the contour of the surrounding breast (13–15)
Tanner 5
Breast reaches final adult size; areola returns to contour of the surrounding breast, with a projecting central papilla (15+)

Genitals (male)
Tanner 1
Testicular volume less than 1.5 ml; small penis of 3 cm or less (prepubertal) (typically age nine and younger)
Tanner 2
Testicular volume between 1.6 and 6 ml; skin on scrotum thins, reddens and enlarges; penis length unchanged (9–11)
Tanner 3
Testicular volume between 6 and 12 ml; scrotum enlarges further; penis begins to lengthen to about 6 cm (11–12.5)
Tanner 4
Testicular volume between 12 and 20 ml; scrotum enlarges further and darkens; penis increases in length to 10 cm (12.5–14)
Tanner 5
Testicular volume greater than 20 ml; adult scrotum and penis of 15 cm in length (14+)

3. Identity of clinician who performed test procedure: _____

Medications (B) Worksheet

Subject ID: _____ **Namecode:** _____

If treatment is for a pre-existing medical condition or adverse event, a Pre-Existing Medical Condition Form or Adverse Event Form must be completed before the medication is entered.

When you are updating a previously entered medication, if the medication dose or frequency has changed, enter the stop date for the current medication dose and then enter a new record for the new dose.

1. Medication Name: _____

2. Dose per administration (include unit):

Dose: _____ **Unit:** _____ or ☐ Unknown

3. Route (select only one):

☐ S.C. –subcutaneous	☐ Topical – skin	☐ Intra-articular injection
☐ I.V. - intravenous	☐ Vaginal	☐ Retrobulbar
☐ Gtt-drops	☐ Transurethral	☐ Transdermal
☐ I.D.-intradermal	☐ Oral Inhalation	☐ Subconjunctival
☐ I.M.-intramuscular	☐ Nasal	☐ Subtenons
☐ P.O.-by mouth	☐ Sublingual	☐ Intrauterine
☐ P.R.-by rectum	☐ Intravitreal	☐ Topical
☐ Topical – ocular	☐ Peribulbar	☐ Epidural

4. If treatment is for eye or ear, complete:

☐ Right ☐ Left ☐ Both

5. Frequency:

☐ Fixed Regimen
☐ As Needed
☐ One Time Treatment

5a. If *Fixed*, complete the following:

Frequency:

_____ per ☐ Day ☐ Week ☐ Month ☐ Year or ☐ Uncertain

5b. If *As Needed*, approximate frequency (select only one):

☐ >1/d	☐ 2-6/wk	☐ 1/y
☐ 1/d	☐ 1/m	☐ 2-5/yr
☐ 1/wk	☐ 2-3/m	☐ 6-11/yr

6. Indication:

☐ Medical condition prior to enrollment
☐ New medical condition/adverse event
☐ Prevention

6a. If medical condition prior to enrollment (i.e. pre-existing), indicate condition(s):

_____ **or**

☐ **Condition not required to be reported on pre-existing condition form**

Medications (B) Worksheet – Page 2

6b. If "Treatment for Adverse Event," indicate adverse event(s):

_____

☐ **Condition not required to be reported on adverse event form**

7. Start Date of Treatment:

☐ On treatment at time of enrollment
☐ Treatment started after enrollment

7a. If on treatment at time of enrollment:

Start date:

☐ <=30 days
☐ >30 days to < 3 months
☐ 3 months to < 6 months
☐ 6 months to < 1 year
☐ 1 year to < 5 years
☐ 5 years to < 10 years
☐ >=10 years
☐ Unknown

7b. If treatment started after enrollment:

Start date:
Please enter exact date (Month, Day, Year) if known, otherwise estimate the month and year:

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

OR if exact date not known, estimate:

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

☐ Unknown

8. Stop Date *(or mark box if ongoing)*
Please enter exact date (Month, Day, Year) if known, otherwise estimate the month and year:

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

OR if exact date not known, estimate:

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

☐ Unknown ☐ Ongoing

Pre-Existing Conditions (A) Worksheet

Subject ID: _____ **Namecode:** _____

Record any pre-existing medical condition that is either present now, a chronic disease, or a prior condition that could impact the participant's health during the course of the study (e.g., prior MI or stroke).

MEDICAL CONDITION INFORMATION

1. Medical Condition: _____

2. Approximate duration or timing of occurrence (e.g., acute event) prior to enrollment:

- ☐ <=30 days
- ☐ >30 days to < 3 months
- ☐ 3 months to < 6 months
- ☐ 6 months to < 1 year
- ☐ 1 year to < 5 years
- ☐ 5 years to < 10 years
- ☐ 10 years to < 20 years
- ☐ >=20 years

3. Current treatment with medications *(i.e., at time of enrollment):*

☐ Yes ☐ No

If yes, complete medication form if required by protocol.

Complete the Screening Visit Form

Patient ID:
Namecode:

1. If the participant has any pre-existing medical conditions or medications, have they been entered on the study website?
O Yes O No
2. Has the date/time on the study CGM, BGM, and activity trackers been set to the correct local time?
O Yes O No
3. Has the participant been trained on how to calibrate the CGM and reminded not to adjust the date/time on any of the devices?
O Yes O No
4. Was the participant given the home log and a participant information sheet with his/her next visit date?
O Yes O No

Adverse Event (A) Worksheet

Subject ID: _____ **Namecode:** _____

DESCRIPTION OF EVENT

1. Date notified of/identified adverse event:

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

2. Description of Adverse Event

2a. Provide a description of the event:

_____

_____

_____

2b. Enter the code that best describes the adverse event:

SELECT CODE WHEN ENTERING FORM ON WEBSITE _____

2c. If ocular event, select eye *(otherwise, leave blank)*

☐ OD (Right) ☐ OS (Left)

If an event occurred in both eyes, complete an AE Form for each eye

3. Date of onset (or worsening of a pre-existing condition):

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

4. Is the adverse event a worsening of a pre-existing condition present prior to study entry?

☐ Yes ☐ No

5. Was the adverse event an abnormality (or worsening of an existing abnormality) identified on a study visit exam?

☐ Yes ☐ No

6. Maximum intensity (severity):

☐ Mild ☐ Moderate ☐ Severe

Maximum Intensity

Enter the maximum intensity that occurred since the onset of the adverse event. For ongoing events, If the intensity increases at a later time prior to the end of the study, edit the field to indicate the maximum.

Each adverse event is categorized as follows:

Mild – Symptom(s) barely noticeable to subject or does not make subject uncomfortable; does not influence performance or functioning; prescription drug not ordinarily needed for relief of symptom(s).

Moderate – Symptom(s) of sufficient severity to make subject uncomfortable; performance of daily activity is influenced; subject is able to continue in study; treatment for symptom(s) may be needed.

Severe – Symptom(s) cause severe discomfort; severity may cause cessation of treatment with study medication or device; treatment for symptom(s) may be given and/or subject hospitalized.

Adverse Event (A) Worksheet – Page 2

7. Is there a reasonable possibility that the event was caused by a study treatment/study device?

☐ Yes ☐ No

7a. If *Yes*, which study treatment/device?

_____

☐ Uncertain – *(Mark uncertain only when a study involves more than 1 treatment or device and you cannot determine which one caused the event.)*

8. Is there a reasonable possibility that the event was caused by a study procedure?
(i.e., a diagnostic procedure and not a study treatment)

☐ Yes ☐ No

8a. If *Yes*, which study procedure?

_____

Relationship to Study Treatment/Device

Reasonable possibility is not the same as "any possibility." The following should be considered when evaluating the relationship:

- Timing of event
- Patient's history
- Prevalence of finding in population at risk
- Other possible causes - diseases, exposures, therapies, etc.
- Known pharmacology of study drug (and control) or side effect of device

9. Effect on study treatment/device:

☐ No change
☐ Discontinued temporarily
☐ Discontinued permanently
☐ Reduced dose
☐ Reduced use frequency/schedule

10. Does the event meet criteria for a serious adverse event?

☐ Yes ☐ No

If Yes, complete the Additional Information for Serious Adverse Event section below

Adverse Event (A) Worksheet – Page 3

Any adverse event that meets one or more of the following criteria:

1. Results in death
2. Is life threatening
3. Requires inpatient hospitalization or prolongation of existing hospitalization
4. Results in persistent or significant disability/incapacity
5. Is a congenital anomaly/birth defect
6. Constitutes an important medical event that was not life-threatening or did not require hospitalization, but in investigator judgment jeopardized the participant and could have resulted in significant disability or death without medical or surgical intervention

TREATMENT OF ADVERSE EVENT

1. Did patient receive treatment for the adverse event?

☐ Yes ☐ No

If *Yes*, complete the following:

1a. Surgery/procedure

☐ Yes ☐ No

If *Yes*, complete the following:

Type of surgery/procedure:

_____

Date of surgery/procedure:

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

1b. Medication

☐ Yes ☐ No

If *Yes*, list medications here and complete a Concomitant Medication Form for each medication:

_____

_____

_____

1c. Other:

☐ Yes ☐ No

If *Yes*, detail:

_____

_____

_____

Adverse Event (A) Worksheet – Page 4

OUTCOME

1. Outcome

- ☐ Ongoing (further improvement or worsening possible)
- ☐ Ongoing, medically stable (further change not expected)
- ☐ Complete Recovery
- ☐ Recovered with Sequelae
- ☐ Fatal

1a. If *Complete Recovery* or *Recovered with Sequelae*, complete the following:

i. Date of recovery (with or without sequelae):

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

1b. If *Fatal*, complete the following:

i. Cause of death:

_____

ii. Date of death:

_____ _____ / _____ _____ / _____ _____ _____ _____
(mm/dd/yyyy)

ADDITIONAL INFORMATION FOR SERIOUS ADVERSE EVENT

1. Criteria defining event as serious adverse event: *(check all that apply)*

- ☐ Death
- ☐ Congenital Anomaly
- ☐ Life Threatening
- ☐ Hospitalization – initial or prolonged
- ☐ Significant Disability or Incapacity
- ☐ Other _____

2. Weight:

_____ ☐ kgs ☐ lbs ☐ Not available

3. Relevant tests/laboratory data (including dates)?

☐ Yes ☐ No

If *Yes*, list:

_____

_____

_____

Adverse Event (A) Worksheet – Page 5

Provide all appropriate, relevant information, including relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/assessment led to strong consideration of medical-product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated.
Include:

- Any relevant baseline laboratory data prior to the administration or use of the medical product/study procedure
- All laboratory data used in diagnosing the event
- Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

If available, include:

- Any pre- and post-event medication levels and dates (if applicable)
- Synopses of any relevant autopsy, pathology, engineering, or lab reports

4. Other relevant history, including preexisting medical conditions *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*:

☐ Yes ☐ No

If *Yes*, detail:

_____

_____

_____

5. Concomitant medical products and therapy dates (exclude treatment of event)?

(List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at the time of the event. DO NOT include products used to treat the event.)

☐ Yes ☐ No

If *Yes*, please explain:

_____

_____

_____

COMMENTS

_____

_____

_____

Device Deficiency Worksheet B

Reportable Device Issues

All device complaints and device malfunctions will be reported irrespective of whether an adverse event occurred, except in the following circumstances.

The following device issues are anticipated and will not be reported on a Device Issue Form:

- CGM sensors lasting fewer than 10 days
- CGM tape adherence issues
- Battery lifespan deficiency due to inadequate charging or extensive wireless communication
- Intermittent device component disconnections/communication failures not leading to system replacement
- Device issues clearly addressed in the user guide manual that do not require additional troubleshooting.
- Skin reactions from CGM sensor placement that don't meet criteria for AE reporting

Subject ID: _____ **Namecode:** _____

DEVICE DEFICIENCY INFORMATION

1. Investigated device: ***[List of devices updated per protocol]***

☐ iPro
☐ Meter
☐ Other

If *Other*, please describe: _____

1a. Serial number:

_____

☐ Unknown ☐ N/A

2. Type of device deficiency:

☐ Device malfunction
☐ User error
☐ Inadequate instructions/training
☐ Inadequate labeling
☐ Other

If *Other*, please describe:

_____

3. Description of device deficiency:

_____

_____

_____

4. Date problem first occurred/was identified:

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

5. Location of Occurrence:

☐ Home
☐ Inpatient
☐ Clinic (outpatient)
☐ Other

If *Other*, please describe:

_____

6. Frequency:

- ☐ Single Event
- ☐ Intermittent
- ☐ Continuous

Device Deficiency Worksheet B – Page 2

7. Effect on study device:

- ☐ No change
- ☐ Study device modified/adjusted
- ☐ Study device replaced
- ☐ Discontinued temporarily
- ☐ Discontinued permanently

8. Date device replaced or modified and first used by participant (leave empty if not applicable or not yet used by subject):

_____ _____ **/** _____ _____ **/** _____ _____ _____ _____
(mm/dd/yyyy)

RELATED ADVERSE EVENT OR ADVERSE DEVICE EFFECT

1. Did an adverse event or adverse device effect that requires reporting according to the protocol occur in association with this device deficiency?

☐ Yes ☐ No

(If Yes, complete an Adverse Event Form. If No, complete question 1a.)

1a. If not associated with a reportable adverse event or adverse device effect, please describe the likelihood that the device deficiency could have led to an adverse event or adverse device effect:

- ☐ Not assessable
- ☐ Not possible
- ☐ Unlikely
- ☐ Possibly
- ☐ Probably
- ☐ Certainly

☐ Certainly

1ai. If you answered Possibly, Probably, or Certainly related, what adverse event could have occurred? Check all that apply:

- ☐ Hypoglycemia
- ☐ Hyperglycemia
- ☐ Other (indicate below)

_____

Complete the Follow up Visit Form

Patient ID:

Namecode:

1. Does the participant have at least 72 hours of CGM data?

O Yes O No

1a. If <u>no</u>, is the participant willing to wear a sensor for another 10 days?

O Yes O No

Non-Diabetic Sensor
Final Status Worksheet

Patient ID:

Namecode:

Complete this form to report a change in a participant's status prior to the completion of the protocol. Please contact the Jaeb Center before dropping a participant (except for death).

Reason participant's participation in the Study has ended.

Note: If participant is requesting to withdraw, make the appropriate selection based on whether the participant has formally withdrawn consent in writing.

○ ID obtained in error – No study data collected

○ Participant does not meet all screening eligibility criteria- detail in *COMMENTS*

○ Participant/Parent requests to withdraw - did not withdraw consent in writing

○ Participant/Parent requests to withdraw - formally withdrew consent in writing

○ Lost to follow up - *detail efforts to contact participant in COMMENTS*

○ Site withdraws participant – *indicate reason in COMMENTS*

○ Death

If *Death*, Adverse Event Form indicating the fatal event must be completed prior to submitting the Final Status Form.

If *Participant/parent requests to withdraw*, select all reasons that apply and provide additional details in comments:

Reason for participant/parent withdrawal:

□ Adverse event

□ Changed doctor

□ Does not want study treatment

□ Finances

□ Changed insurance

□ Moved

□ Other treatment requested

□ Poor health

□ Poor outcome

□ Scheduling/availability issues

□ Travel difficulty

□ Visit too lengthy

□ Unknown

*** If reason is not listed please contact the coordinating center***

Non-Diabetic Sensor
Final Status Worksheet

Withdrawal Reason Comments:

If reason for withdrawal is *Death*, complete the following:

Date of Death: ___/___/___

Cause of Death: _____