CITY Visit Information Worksheet

Subject ID: _____ **Namecode:** _____

1a. Investigator taking responsibility for the visit: _____

1b. Coordinator taking responsibility for the visit: _____

2. Visit date:

_____ _____ / _____ _____ / _____ _____ _____ _____ ☐ Missed
(mm/dd/yyyy)

If *Missed*, reason (select only one):

- ☐ Bad weather
- ☐ Travel difficulty
- ☐ Financial issue
- ☐ Poor health
- ☐ Personal issue
- ☐ Work issue
- ☐ Subject on vacation
- ☐ Visits too lengthy
- ☐ Investigator away
- ☐ Clinic appointment not available
- ☐ Site forgot to schedule
- ☐ Difficulty contacting subject
- ☐ Poor outcome
- ☐ Good outcome
- ☐ Adverse event
- ☐ Unknown
- ☐ Other

2a. If *Other*, describe:

_____

_____

_____

OUT OF WINDOW

☐ **Visit was completed out of window**

1. Reason visit was completed out of window (select only one):

- ☐ Bad weather
- ☐ Travel difficulty
- ☐ Financial issue
- ☐ Poor health
- ☐ Personal issue
- ☐ Work issue
- ☐ Subject on vacation
- ☐ Visits too lengthy
- ☐ Investigator away
- ☐ Clinic appointment not available
- ☐ Site forgot to schedule
- ☐ Difficulty contacting subject
- ☐ Poor outcome
- ☐ Good outcome
- ☐ Adverse event
- ☐ Unknown
- ☐ Other

1a. If *Other*, describe:

_____

_____

_____

CITY Diabetes Screening (A) Worksheet

Subject ID: _____ **Namecode:** _____

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.**

Individuals must meet all of the following inclusion criteria in order to be eligible to participate in the study.

1) Clinical diagnosis of T1D, with either age of T1D diagnosis < 10 years of age OR a history of positive T1D related antibodies in the medical record
2) Age 14-<25 years
3) Diabetes duration ≥ 1 year
4) Total daily insulin requirement ≥ 0.4 units/kg/day
5) HbA1c 7.5% to <11.0% (Point of care device or local lab measured as part of study at screening visit)
6) Insulin regimen involves a consistent modality of insulin administration with either use of an insulin pump or at least 3 multiple daily injections of basal and bolus (meal time) analogue insulin. Insulin pump must not have been started within 3 months of consent with no plans to change regimens in the next 6 months
7) Perform at least 2 blood glucose meter checks per day from self-report at screening and an average of at least 2 checks per day from meter download during blinded CGM run in
8) Blinded CGM must be used a minimum of 200 hours (equivalent to 8.3 days) with an average of 1.8 calibrations per day during the blinded CGM screening period.
9) Participant comprehends written and spoken English
10) Participant understands the study protocol and agrees to it (if applicable)

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

Individuals who meet any of the following criteria are not eligible for the study:

1) Use of unblinded personal CGM and/or flash CGM, outside of a research study, as part of real-time diabetes management in the last 3 months
2) Unable to use CGM device for minimum number of hours during blinded pre-randomization period or skin reaction from adhesive that would preclude participation in the randomized trial
3) Started on non-insulin medication for blood glucose control within the past 3 months or plans to begin within the next 6 months
4) The presence of a significant medical disorder that in the judgment of the investigator will affect the wearing of the sensors (such as a skin condition), or the completion of any aspect of the protocol.
5) More than 1 episode of DKA in the past 6 months as defined in the adverse events chapter.
6) The presence of any of the following diseases:
   - Asthma or any condition present in the last 6 months where treatment is a systemic or daily inhaled corticosteroid
     - Intermittent treatment with inhaled corticosteroids does not exclude subjects from enrollment
   - Cystic fibrosis
   - Addison's disease
     - Adequately treated thyroid disease and celiac disease do not exclude subjects from enrollment
7) Inpatient psychiatric treatment in the past 6 months or daily intensive outpatient psychiatric day treatment in the past 3 months.
8) Pregnant (positive test confirmed at screening) or planning to become pregnant in the next 12 months.
9) Need for use of acetaminophen or acetaminophen-containing products on a regular basis during the 6 months of the trial
10) Participation in a diabetes related intervention study in the past 6 weeks.
11) Any medical, psychological or social situation where per investigator discretion it may be difficult for participant to participate fully in the intervention
12) Any condition, per investigator assessment, that could impact reliability of the A1C measurement, such as (but not limited to) hemoglobinopathy, hemolytic anemia, chronic liver disease; chronic GI blood loss, red blood cell transfusion or erythropoietin administration within 3 months prior to screening

DEMOGRAPHIC INFORMATION

1. Sex:

☐ Male ☐ Female

Ethnicity and race must be self-reported by the study participant. Read the following questions aloud to the study participant exactly as written and record the responses below:

2. Do you consider yourself to be 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?

☐ White

☐ Black/African American

☐ Asian

☐ Native Hawaiian/Other Pacific Islander

☐ American Indian/Alaskan Native

☐ More than one race

☐ Unknown/not reported

If *More than one race* selected, please specify:

_____

DIABETES HISTORY

1. Date of diagnosis of diabetes:

_____ _____ / _____ _____ / _____ _____ _____ _____

(mm/dd/yyyy)

☐ Approximate ☐ Unknown

2. Age at diagnosis:

_____ Years ☐ Approximate ☐ Unknown

3. Severe Hypoglycemia

3a. Estimate of when most recent severe hypoglycemic event (as defined below) occurred:

☐ Never

☐ < 3 months ago

☐ 3-<6 months ago

☐ 6-<12 months ago

☐ 1-<5 years ago

☐ 5-<10 years ago

☐ ≥10 years ago

3b. Estimated number of severe hypoglycemic events in the last 12 months (as defined below):

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5-10 ☐ ≥10

Severe hypoglycemia *is 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.*

3c. Estimated number of severe hypoglycemic events involving seizure/coma ever:

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5-10 ☐ ≥10

i. If >0 severe hypoglycemic events involving seizure/coma, how many events occurred in the last 12 months:

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5-10 ☐ ≥10

4. DKA

4a. 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

☐ 1-<5 years ago

☐ 5-<10 years ago

☐ ≥10 years ago

4b. Estimated number of definite or probable DKA events in the last 12 months (as defined below):

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5-10 ☐ ≥10

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

1. Insulin Modality (*check all that apply*):

☐ Pump

☐ Injections

☐ Inhaled (e.g., Afrezza)

☐ None of the above (participant does not take insulin)

1a. If *pump*, how long has the participant been using an insulin pump?

☐ <3 months

☐ 3-<6 months

☐ 6 months-<1 year

☐ 1-<2 years

☐ 2-<5 years

☐ ≥5 years

Diabetes Screening (A) Worksheet – Page 3

1b. Manufacturer/model of pump:

☐ Animas 2020	☐ Medtronic 507C	☐ Medtronic Paradigm 712
☐ Animas IR 1000	☐ Medtronic 508	☐ Medtronic Paradigm 715
☐ Animas IR 1200	☐ Medtronic 511	☐ Medtronic Paradigm 722
☐ Animas IR 1250	☐ Medtronic 551 (530G)	☐ Medtronic Paradigm 723 (Revel)
☐ Animas Vibe	☐ Medtronic 554	☐ Medtronic Paradigm 754 (Veo)
☐ DANA Diabecare II	☐ Medtronic 751 (530G)	☐ Nipro Amigo
☐ Deltec Cozmo	☐ Medtronic 754	☐ One Touch Ping
☐ Disetronic D-Tron Plus	☐ Medtronic Paradigm 512	☐ Roche Accu-Chek Spirit Combo
☐ Disetronic H-Tron Plus	☐ Medtronic Paradigm 515	☐ Roche Insight
☐ Disetronic Spirit	☐ Medtronic Paradigm 522	☐ Tandem t:slim
☐ Insulet OmniPod Insulin Mgmt. Sys.	☐ Medtronic Paradigm 523 (Revel)	☐ Other
☐ Medtronic 507	☐ Medtronic Paradigm 554 (Veo)	☐ Unknown

If *Other*, please specify: _____

2. Average units of insulin per day *(record each type of insulin on the Insulin Form)*:

2a. Total daily insulin in units:

_____ ☐ Unknown

2b. Total daily basal insulin for pump users or long/intermediate acting insulin (including NPH) for injection users, in units:

_____ ☐ Unknown

2c. Number of boluses per day for pump users, number of injections of short acting insulin per day for injection users, or number of inhaled doses per day for short acting inhaled insulin:

_____ ☐ Unknown

3. Average number of blood glucose tests per day:

3a. From meter download:

_____ ☐ Glucose meter data not available

3b. From participant self-report:

_____ ☐ Self-reported data not available

CONTINUOUS GLUCOSE MONITOR USE

1. Indicate status of CGM (real-time unblinded) use:

☐ Never

☐ In past, but not current

☐ Current

Current CGM use *is defined as INSERT PROTOCOL SPECIFIC DEFINITION*

Diabetes Screening (A) Worksheet – Page 4

If current CGM user, complete the following:

1a. How long has the participant been using a CGM?

- ☐ <3 months
- ☐ 3-<6 months
- ☐ 6 months-<1 year
- ☐ 1-<2 years
- ☐ 2-<5 years
- ☐ >=5 years

1b. Which CGM device type is being used?

- ☐ Abbott
- ☐ Dexcom
- ☐ Medtronic

1c. In the past month, about how many days has the participant used continuous glucose monitoring (CGM)?

_____ days ☐ Unknown

MEDICAL HISTORY

1. Does the participant have any pre-existing medical conditions other than T1D?

☐ Yes ☐ No *(If yes, please complete the Medical Conditions form)*

MEDICATIONS

1. Is participant currently taking any medications?

☐ Yes ☐ No

1a. Was the participant taking any <u>non-insulin</u> medications <u>daily</u> for blood sugar control coming into the visit?

- ☐ None
- ☐ Prescription drug
- ☐ Non-prescription nutraceutical/vitamin
- ☐ Both prescription and non-prescription nutraceutical/vitamin
- ☐ Unknown

Please ensure all insulins have been entered on the Insulin form and all OTHER medications have been entered on the medications form

CITY Diabetes Physical Exam Worksheet

Subject ID: _____ **Namecode: _____**

PHYSICAL EXAMINATION

☐ **No physical exam performed**

1. Weight

_____ Units: ☐ lbs ☐ kg ☐ **Not measured**

2. Height

_____ Units: ☐ in ☐ cm ☐ **Not measured**

3. Blood pressure (Systolic/Diastolic):

_____ / _____ mm/Hg ☐ **Not measured**

4. Heart Rate:

_____ bpm ☐ **Not measured**

5. Temperature:

_____ Units: ☐ Celsius ☐ Fahrenheit ☐ **Not measured**

6. Fingerstick blood glucose result: _____ Units ☐ **mg/dL** ☐ **mmol/L** ☐ **Not measured**

7. Were any clinically significant abnormalities found on the physical exam?

☐ Yes ☐ No

7a. If *Yes*, describe:

_____

8. Identity of clinician who performed test procedures:

_____

8a. If *Other*, please record name:

_____

CITY Diabetes Local HbA1c (A) Worksheet

Subject ID: _____ **Namecode: _____**

LOCAL HBA1C

1. Date of Test:

_____ _____ / _____ _____ / _____ _____ _____ _____

(mm/dd/yyyy)

2. Method of testing:

☐ DCA point of care

☐ Afinion point of care

☐ Other point of care

☐ Lab

☐ Unknown

3. HbA1c Results:

_____ %

4. Identity of clinician who performed test procedures:

_____

CITY Diabetes Socioeconomic Information (A) Worksheet

Subject ID: _____ **Namecode:** _____

SOCIOECONOMIC INFORMATION

1. Please select the highest level of education completed by the participant (or primary caregiver for participants <18 years of age):

- ☐ Less than 1st Grade
- ☐ 1st, 2nd, 3rd, or 4th Grade
- ☐ 5th or 6th 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

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

3. What kind of health insurance or health care coverage does the participant have?

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

Government-sponsored health coverage plan including the following:

- ☐ 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

- ☐ Single service plan (e.g., dental, vision, prescriptions)
- ☐ No coverage of any type
- ☐ Unknown
- ☐ Does not wish to provide

CITY Diabetes Pregnancy Test (A) Worksheet

Subject ID: _____ **Namecode: _____**

1. Date of urine pregnancy test:

_____ _____ / _____ _____ / _____ _____ _____ _____ ☐ **Pregnancy test not done**

(mm/dd/yyyy)

1a. Result: ☐ **Negative** ☐ **Positive**

1b. Brand of test used: _____

1c. Lot number of test used: _____

1d. If *not done*, why:

- ☐ Participant is male
- ☐ Surgically sterile
- ☐ Post-menopausal
- ☐ Pre-pubertal
- ☐ Other

i. If *Other*, please describe:

_____

_____

_____

2. Identity of clinician who performed test procedure: _____

CITY Screening Complete the Visit

Subject ID: _____ Namecode: _____

1. Were any of the data for this visit transcribed from another source (e.g., medical record, study visit worksheet) rather than directly entered on the website?

○ Yes ○ No

If yes, complete the following:

1a. Source used (check all that apply):

- **CRF worksheet**
- **Electronic medical record (EMR)**
- **Written participant chart**
- **Discharge summary**
- **Test/lab result**
- **Other**

If *Other*, describe:_____

1b. Were any of the following key data transcribed:

CRF Question

Local HbA1c

Source

CRF worksheet
Electronic medical record (EMR)
Written patient chart
Discharge summary
Test/Lab result

***Please upload local HbA1c report to Coordinating Center for review**

CITY Medical Conditions Form

Patient ID:

Namecode:

MEDICAL CONDITION

Estimate dates if necessary. If only the year is known, enter "January" as the month. When the day of the month is required but unknown, enter "1." Enter all medication treatment at the time of enrollment and started after enrollment on the Medications Form after entering the medical condition on this form.

Record medications in use during the study on the Medication Form.

1. Medical Condition: _____

2. Present prior to study enrollment?

☐ Yes ☐ No

2a. If *Yes* (present prior to enrollment), complete the following:

i. Approximate duration 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
☐ Unknown

ii. Treated with medication:

☐ Current ☐ Past ☐ Never

2b. If *No* (started or occurred after enrollment/randomization), complete the following:

i. Date of diagnosis: _____ _____ / _____ _____ / _____ _____ _____ _____ (mm/dd/yyyy)

☐ Approximate ☐ Unknown

ii. Treatment of the medical condition (select only one):

☐ None
☐ Medication
☐ Surgery
☐ Medication and Surgery
☐ Dietary Management
☐ Other

iii. If *Other*, describe:

_____
_____
_____

Patient ID:

Namecode:

Enter the recovery date for all conditions active at the time of enrollment or develop later that resolve during study.

STATUS OF CONDITION

1. Medical condition status:

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

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

Recovery date: _____ _____ / _____ _____ / _____ _____ _____ _____ ☐ Approximate
(mm/dd/yyyy)

CITY Medications Form

Patient ID:

Namecode:

MEDICATION

If treatment is for a medical condition or adverse event, a 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

Patient ID:

Namecode:

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 (either pre-existing or occurred during the study), indicate condition(s):

_____ **or**

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

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

_____

CITY Insulin Form

Patient ID:

Namecode:

INSULIN

Types of insulin will be recorded on this form. Doses will be recorded on visit forms.

If the pump is used routinely and injections are only used when there is a pump failure, only record the insulin used in the pump.

If both the pump and injections are used together (or sometimes one and sometimes the other), record the insulins separately (e.g., if the same insulin is sometimes used in a pump and sometimes in injections, enter separate records for each).

1. Insulin Name:

- ☐ Afrezza (insulin human)
- ☐ Apidra (Glulisine)
- ☐ Degludec
- ☐ Humalog (Lispro)
- ☐ Humalog 50/50
- ☐ Humalog 75/75
- ☐ Humulin 50/50
- ☐ Humulin 70/30
- ☐ Humulin N (NPH)
- ☐ Lantus (Glargine) 1 time per day
- ☐ Lantus (Glargine) 2 times per day
- ☐ Levemir (Detemir) 1 time per day
- ☐ Levemir (Detemir) 2 times per day
- ☐ Novolin 70/30
- ☐ Novolin N (NPH)
- ☐ Novolog (Aspart)
- ☐ Novolog 70/30
- ☐ Regular (R) (Humulin R or Novolin R)
- ☐ Toujeo (Glargine, U300)
- ☐ U500 Human R Regular
- ☐ Velosulin

2. Route:

☐ Pump ☐ Injection ☐ Inhaled

2a. If injection or inhaled, what is the usual frequency of injections per day?

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ Unknown

3. Start Date of Insulin Type:

- ☐ In use at time of enrollment
- ☐ Started after enrollment
- ☐ Unknown

3a. If started after enrollment, start date:

_____ _____ / _____ _____ / _____ _____ _____ _____ ☐ Estimated ☐ Unknown
(mm/dd/yyyy)

4. Stop Date of Insulin Type (if permanently discontinued during the study):

_____ _____ / _____ _____ / _____ _____ _____ _____ ☐ Estimated ☐ Unknown
(mm/dd/yyyy)

CITY Diabetes Hypoglycemic Event Worksheet

Subject ID: _____ **Namecode:** _____

Please complete AE Form in addition to this form.

Reportable hypoglycemia *is defined as an event that required assistance of another person due to altered consciousness to actively administer carbohydrate, glucagon, or other resuscitative actions. 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. By definition, events that meet these criteria are reported as Serious Adverse Events. Hypoglycemic events are also considered reportable If the above criteria are not met but emergency evaluation or treatment was obtained from a health care provider; these events are considered Adverse Events and not Serious Adverse Events unless one of the criteria for SAE is met.*

1. Date of event:

_____ _____ / _____ _____ / _____ _____ _____ _____

(mm/dd/yyyy)

☐ Approximate ☐ Unknown

1a. Indicate the approximate time of day of the event:

☐ 00:01 – 03:00
☐ 03:01 – 06:00
☐ 06:01 – 09:00
☐ 09:01 – 12:00
☐ 12:01 – 15:00
☐ 15:01 – 18:00
☐ 18:01 – 21:00
☐ 21:01 – 00:00
☐ Unknown

2. Was the glucose level checked on a home blood glucose meter?

☐ Yes ☐ No ☐ Unknown

2a. If *Yes*, what was the result? _____ ☐ mg/dL ☐ mmol/L ☐ Unknown

3. Was the participant wearing a CGM sensor at the time of the event (either alone or as part of an automated insulin delivery system)?

☐ Yes ☐ No ☐ Unknown

3a. If *Yes*, what was the glucose reading at the time the event was identified?

_____ ☐ mg/dL ☐ mmol/L ☐ Unknown

4. Was the participant wearing an automated insulin delivery system at the time of the event?

☐ Yes ☐ No ☐ Unknown

4a. If *Yes*, was the system in auto mode or manual mode?

☐ Auto Mode ☐ Manual Mode ☐ Unknown

5. Please select all of the following that apply for this event:

☐ Seizure
☐ Loss of consciousness
☐ Required assistance
☐ Ambulance called

☐ EMT assistance

☐ Evaluated or treated by health care provider (not EMT)

6. Was glucagon given?

☐ Yes ☐ No ☐ Unknown

7. Was the participant hospitalized or treated in the Emergency Room?

☐ Yes ☐ No ☐ Unknown

If *Yes*,

7a. Where was the participant treated?

☐ ICU only

☐ Floor only

☐ ICU and Floor

☐ Emergency Room only

☐ Unknown

7b. Duration *(leave blank if participant was treated in the emergency room only)*:

_____ days (use a midnight census and estimate if necessary ☐ Unknown

8. Cause of Event

8a. Is there any evidence that a study device (e.g., blood glucose meter, CGM, and/or pump) contributed to the event (either device malfunction or improper use by user)?

☐ Yes ☐ No

If *Yes*, please complete a Device Issue Form.

8b. Is there any indication of non-study device-related factors that contributed to the occurrence of the event?

☐ Yes ☐ No

If *Yes*, explanation of contribution of non-study device-related factors to the event:

_____

_____

_____

9. Outcome

☐ Fully recovered ☐ Other ☐ Unknown

If *Other*, describe:

_____

_____

_____

CITY Diabetes Severe Hyperglycemia or DKA Event Worksheet

Subject ID: _____ **Namecode:** _____

Please complete AE Form in addition to this form.

Severe Hyperglycemia or Diabetic Ketoacidosis *is defined as INSERT PROTOCOL SPECIFIC DEFINITION*

1. Date of event:

_____ _____ / _____ _____ / _____ _____ _____ _____

(mm/dd/yyyy)

☐ Approximate ☐ Unknown

2. Glucose level: _____ ☐ mg/dL ☐ mmol/L ☐ Unknown

3. Ketones: _____ ☐ Unknown

3a. Serum: _____ ☐ mg/dL ☐ mmol/L

3b. Urine: ☐ Negative ☐ Small ☐ Medium ☐ Large ☐ Extra Large

4. HCO3: _____ ☐ Unknown

5. pH: _____ ☐ Arterial blood ☐ Venous ☐ Unknown

6. BUN: _____ ☐ Unknown

7. Symptomatic cerebral edema: ☐ Yes ☐ No ☐ Unknown

8. Was the participant wearing a CGM sensor at the time of the event (either alone or as part of an automated insulin delivery system?

☐ Yes ☐ No ☐ Unknown

8a. If *Yes*, what was the glucose reading at the time the event was identified?

_____ ☐ mg/dL ☐ mmol/L ☐ Unknown

9. Was the participant wearing an automated insulin delivery system at the time of the event?

☐ Yes ☐ No ☐ Unknown

9a. If *Yes*, was the system in auto mode or manual mode?

☐ Auto Mode ☐ Manual Mode ☐ Unknown

10. Cause of Event

10a. Is there any evidence that a study device (e.g., blood glucose meter, CGM, and/or pump) contributed to the event (either device malfunction or improper use by user)?

☐ Yes ☐ No

If *Yes*, please complete a Device Issues Form.

10b. Is there any indication of non-study-device-related factors that contributed to the occurrence of the event?

☐ Yes ☐ No

If *Yes*, explanation of contribution of non-study device-related factors to the event:

_____

_____

_____

11. Outcome

☐ Fully recovered ☐ Other ☐ Unknown

If *Other*, describe:

_____

_____

_____

12. In the judgment of the investigator, did the event meet study criteria listed above for DKA?

☐ Definitely

☐ Probably, based on available information

☐ No (i.e., Hyperglycemia event but not DKA)

☐ Cannot determine from available information

CITY Pre-Randomization Final Status Form

Subject ID: _____ **Namecode: _____**

Complete this worksheet for a study participant with an ID obtained who will not be randomized into this study.

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*
- ☐ Lost to follow up prior to randomization – *detail efforts to contact participant in COMMENTS*
- ☐ Participant/Parent requests to withdraw – did not withdraw consent in writing
- ☐ Participant/Parent requests to withdraw – formally withdrew consent in writing
- ☐ 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.**

WITHDRAWAL REASON COMMENTS
_____ _____ _____ _____
If reason for withdrawal is *Death*, complete the following: **Date of Death:** _____ _____ / _____ _____ / _____ _____ _____ _____ (mm/dd/yyyy) **Cause of Death:** _____ _____ / _____ _____ / _____ _____ _____ _____ (mm/dd/yyyy)