CITY Visit Information Worksheet

Participant 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:

_____

_____

_____

COMMENTS

_____

_____

_____

CITY Randomization Visit Worksheet

Participant ID: _____ Namecode: _____

RAMDOMIZATION CRITERIA

Verify that none of the following have occurred since enrollment (if any have occurred, complete a Final Status form):

- ☐ Use of unblinded personal CGM, outside of a research study, as part of real-time diabetes management
- ☐ Started on non-insulin medication for blood glucose control within the past 3 months or plans to begin within the next 6 months
- ☐ The presence of a significant medical disorder or use of a medication such as oral/inhaled glucocorticoids that in the judgment of the investigator will affect the wearing of the sensors or the completion of any aspect of the protocol.
  - Adequately treated thyroid disease and celiac disease do not exclude participants from enrollment
  - More than 1 episode of DKA in the past 6 months as defined in the adverse events chapter.
- ☐ The presence of any of the following diseases:
  - Asthma if treated with systemic or daily inhaled corticosteroids in the last 6 months
    - *Intermittent treatment with inhaled corticosteroids does not exclude participants from enrollment*
  - Cystic fibrosis
  - Addison's disease
- ☐ Inpatient psychiatric treatment in the past 6 months or daily intensive outpatient psychiatric day treatment in the past 3 months.
- ☐ Pregnant (positive test confirmed at screening) or planning to become pregnant in the next 12 months.
- ☐ Need for use of acetaminophen or acetaminophen-containing products on a regular basis during the 6 months of the trial
- ☐ Participation in a diabetes related intervention study in the past 6 weeks.
- ☐ Any medical, psychological or social situation where per investigator discretion it may be difficult for participant to participate fully in the intervention
- ☐ 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
- ☐ Expectation that participant will be moving out of the area of the clinical center during the next 6 months, unless the move will be to an area served by another study center

ELIGIBILITY VERIFICATION

All of the following criteria must be verified for participant to be randomized.

- ☐ ≥ 200 hours of CGM use during the blinded CGM wear phase
- ☐ An average of at least 1.8 BGM calibrations performed per day
- ☐ Minimum average of 2 BGM measurements per day based on meter download
- ☐ Able and willing to insert CGM sensor and use CGM
- ☐ Skin assessment performed and no adhesive reactions occurred
  participant should not be randomized if a reaction to the adhesive occurred during the run in phase that would preclude participation
- ☐ Investigator has verified that participant is eligible and willing to accept assignment to any of the 2 treatment groups

CGM DATA

Please review the CGM data file and data reports and complete the following:

1 .Number of hours of CGM data: _____ [0-600]

2. Average number of CGM calibrations per day:

□ 1.8	□ 2.3	□ 2.8
□ 1.9	□ 2.4	□ 2.9
□ 2.0	□ 2.5	□ 3.0
□ 2.1	□ 2.6	□ >3
□ 2.2	□ 2.7	

3 .ID of study personnel who reviewed hours of data: _____

BGM DOWNLOAD

1. Was the BGM download reviewed to determine average number of blood glucose checks per day during the run-in period?

○ Yes ○ No

1a. If Yes, Average number of BGM checks per day: _____ [0.0-20.0]

QUESTIONNAIRES

1. Were the participant baseline questionnaires completed?

O Yes - electronically

O Yes – on paper

O No

CITY Diabetes Medical History Updates (A) Worksheet

Subject ID: _____ **Namecode:** _____

ADVERSE EVENTS OR ADVERSE DEVICE EFFECTS (ADE)

1. Did any of the following occur since last visit?

a. Reportable Hypoglycemic event: ☐ Yes ☐ No
If *Yes*, complete AE form and Hypoglycemic Event form.

b. Definite or Probable Reportable Severe Hyperglycemic or DKA Event: ☐ Yes ☐ No
If *Yes*, complete AE form and Severe Hyperglycemia or DKA Event form.

c. Other reportable adverse event or adverse device effect (ADE): ☐ Yes ☐ No
If *Yes*, complete AE or ADE form.

MEDICAL CONDITIONS

1. Did the participant report a new medical condition that does not meet the definition of a reportable adverse event and has not previously been recorded on the Medical Conditions Form?

☐ Yes ☐ No

If *Yes*, please complete the Medical Conditions Form.

DEVICE DEFICIENCIES OR ISSUES

1. Did the participant report having any reportable device deficiencies or issues while using a study device since the last contact?

☐ Yes ☐ No

If *Yes*, complete the Device Deficiencies or Issues Form.

MEDICATIONS

1. Did the participant report any changes or new medications since the last contact?

☐ Yes ☐ No

If *Yes*, please update the Medications Form.

INSULIN

1. Did the participant report any changes in insulin type or insulin delivery method since the last contact?

☐ Yes ☐ No

If *Yes*, please update the Insulin Form.

CITY Central Lab Data Collection Worksheet

Subject ID: _____ Namecode: _____

CENTRAL LAB SAMPLES COLLECTED

1. **Draw Date:_____**

2. **Approximate number of hours participant last ate prior to blood draw: _____ [1-24]**

3. **Identity of clinician who performed blood draw procedure: _____**
   3a. If Other please specify:_____

CITY Complete Randomization Worksheet

Participant ID: _____ **Namecode: _____**

SOURCE DOCUMENTATION

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

1a. If yes, source used (check all that apply):

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

If *Other*, describe: _____

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)

CITY Post-Randomization Final Status Form

Subject 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.

☐ 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 and unwilling to be followed

☐ Finances

☐ Changed insurance

☐ Moved

☐ Other treatment requested and unwilling to be followed

☐ Poor health

☐ Poor outcome

☐ Scheduling/availability issues

☐ Travel difficulty

☐ Visit too lengthy

☐ Unknown

****If reason is not listed, please contact the Coordinating Center. Participants who discontinue use of study treatment should NOT be withdrawn from the study unless unwilling to continue to be followed by study team.**

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