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 Follow-up Visit Worksheet

Subject ID: _____ **Namecode: _____**

TYPE OF CONTACT- COMPLETE AT 2 WEEK VISIT

1. **Select the type of contact**

   ○ In Clinic Visit ○Video Telehealth ○Phone Call ○Other

   1a. If Other, describe: _____

CONFIRM COMPLETION OF THE FOLLOWING:

BGM REVIEW

1. **What is the average number of fingerstick readings the participant reports having done each day over the last 7 days?**
   _____*[Range: 0-30]* ☐ Unknown

2. **Was the participant's BGM(s) downloaded at the visit?**

   ○ Yes, all BGM downloaded
   ○ Yes, only one BGM downloaded
   ○No

   2a. If Yes, average number of fingerstick readings per day over the last 14 days:
   _____ ***[Range: 0.0-30.0]*** ☐ Unknown

INSULIN USE

1. **Has insulin delivery method changed since last study visit?**
   ○ Yes ○No

   1a. If Yes, Date of Change: _____

   ***If Yes please update insulin changes by entering an insulin form**

2. **Current Method of insulin administration:**
   ○ Pump ○ Injections

   If "Injections" answer question 3 and sub-questions below.
   If "Pump" answer question 4 and sub-questions below.

3. Injection Users:

***Record any changes or new types of insulin on the Insulin Form**

3a. Long-acting or intermediate-acting insulin (such as Lantus, Levemir, U500, or NPH) :

i. Average number of injections per day over the past 7 days:
_____ injections per day [0 - 20] ☐ Unknown ☐ Do not use

ii. Average units of insulin per day on over the past 7 days:
_____ units per day [0.0 – 300.0] ☐ Unknown ☐ Do not use

3b. Short-acting or rapid-acting insulin (such as Humalog, Novolog, Apidra, Fiasp or Regular):

i. Average number of injections per day over the past 7 days:
_____ injections per day [0 - 20] ☐ Unknown ☐ Do not use

ii. Average units of insulin per day on average over the past 7 days:
_____ units per day [0.0 – 300.0] ☐ Unknown ☐ Do not use

4. Pump Users: *Obtain information from pump download over the past 14 days if possible*

4a. Average total daily insulin in units over the past 14 days:
_____ units per day [0.0-300.0] ☐ Unknown

4b. Average total daily basal insulin in units:

_____ units per day [0.0-200.0] ☐ Unknown

4c. Average number of boluses per day:

_____ boluses per day [0-50] ☐ Unknown

☐ Check here if information from pump download

NON-STUDY CGM INITIATION

1. Did the participant initiate using a non-study real-time CGM or flash glucose monitor since randomization?

○ Yes, real time CGM
○ Yes, flash glucose monitor
○ No

1a. If Yes, number of days per week the participant currently uses a non-study real-time CGM or flash glucose monitor: _____ [0-7]

1b. Start date of non-study real-time CGM or flash glucose monitor:
___ ___ / ___ ___ /___ ___ mm/dd/yy

2. Has the participant initiated using automated insulin delivery or a low glucose suspend feature since randomization?

○ Yes ○ No

2a. Start date of automated insulin delivery or low glucose suspend feature?

___ ___ / ___ ___ /___ ___ **mm/dd/yy**

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 Diabetes Local HbA1c (B) Worksheet

Subject ID: _____ **Namecode: _____**

LOCAL HBA1C

☐ **Local HbA1c not done**

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 Follow-up Complete the Visit Worksheet

Patient ID: _____ **Namecode: _____**

SOURCE DOCUMENTATION

1. Were any of the data for this visit/contact 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 patient chart
- ☐ Discharge summary
- ☐ Test/lab result
- ☐ Other _____

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 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)