

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):

- | | | |
|--|---|--|
| <input type="checkbox"/> Bad weather | <input type="checkbox"/> Subject on vacation | <input type="checkbox"/> Poor outcome |
| <input type="checkbox"/> Travel difficulty | <input type="checkbox"/> Visits too lengthy | <input type="checkbox"/> Good outcome |
| <input type="checkbox"/> Financial issue | <input type="checkbox"/> Investigator away | <input type="checkbox"/> Adverse event |
| <input type="checkbox"/> Poor health | <input type="checkbox"/> Clinic appointment not available | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Personal issue | <input type="checkbox"/> Site forgot to schedule | <input type="checkbox"/> Other |
| <input type="checkbox"/> Work issue | <input type="checkbox"/> Difficulty contacting subject | |

2a. If Other, describe:

OUT OF WINDOW

☐ Visit was completed out of window

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

- | | | |
|--|---|--|
| <input type="checkbox"/> Bad weather | <input type="checkbox"/> Subject on vacation | <input type="checkbox"/> Poor outcome |
| <input type="checkbox"/> Travel difficulty | <input type="checkbox"/> Visits too lengthy | <input type="checkbox"/> Good outcome |
| <input type="checkbox"/> Financial issue | <input type="checkbox"/> Investigator away | <input type="checkbox"/> Adverse event |
| <input type="checkbox"/> Poor health | <input type="checkbox"/> Clinic appointment not available | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Personal issue | <input type="checkbox"/> Site forgot to schedule | <input type="checkbox"/> Other |
| <input type="checkbox"/> Work issue | <input type="checkbox"/> Difficulty contacting subject | |

1a. If Other, describe:

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 Unscheduled Contact Worksheet

Participant ID: _____ Namecode: _____

1. Contact type: ☐ Clinic visit ☐ Phone call ☐ Email ☐ Text ☐ Home Visit ☐ Video Chat/Skype2. Contact was made with: ☐ Participant ☐ Parent/Guardian ☐ Spouse or significant other ☐ Other2a. If Other, describe: _____**3. Reason for Visit***Please check one or more of the following:*

- ☐ Participant needed additional device training
- ☐ Participant needed additional protocol/procedural training
- ☐ Participant had a question or problem with diabetes management
- ☐ Participant had a potential adverse event
- ☐ Participant had a potential device deficiency/issue
- ☐ Participant needed study supplies
- ☐ Other

3a. 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:

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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):

- | | | |
|---|--|--|
| <input type="checkbox"/> S.C. –subcutaneous | <input type="checkbox"/> Topical – skin | <input type="checkbox"/> Intra-articular injection |
| <input type="checkbox"/> I.V. - intravenous | <input type="checkbox"/> Vaginal | <input type="checkbox"/> Retrobulbar |
| <input type="checkbox"/> Gtt-drops | <input type="checkbox"/> Transurethral | <input type="checkbox"/> Transdermal |
| <input type="checkbox"/> I.D.-intradermal | <input type="checkbox"/> Oral Inhalation | <input type="checkbox"/> Subconjunctival |
| <input type="checkbox"/> I.M.-intramuscular | <input type="checkbox"/> Nasal | <input type="checkbox"/> Subtenons |
| <input type="checkbox"/> P.O.-by mouth | <input type="checkbox"/> Sublingual | <input type="checkbox"/> Intrauterine |
| <input type="checkbox"/> P.R.-by rectum | <input type="checkbox"/> Intravitreal | <input type="checkbox"/> Topical |
| <input type="checkbox"/> Topical – ocular | <input type="checkbox"/> Peribulbar | <input type="checkbox"/> 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

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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:

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

2. Route:

- ☐ Pump ☐ Injection ☐ Inhaled

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

- | | |
|----------------------------|----------------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 6 |
| <input type="checkbox"/> 2 | <input type="checkbox"/> 7 |
| <input type="checkbox"/> 3 | <input type="checkbox"/> 8 |
| <input type="checkbox"/> 4 | <input type="checkbox"/> 9 |
| <input type="checkbox"/> 5 | <input type="checkbox"/> 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

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<input type="checkbox"/> EMT assistance <input type="checkbox"/> Evaluated or treated by health care provider (not EMT)
6. Was glucagon given? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7. Was the participant hospitalized or treated in the Emergency Room? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
If <u>Yes</u>, 7a. Where was the participant treated? <input type="checkbox"/> ICU only <input type="checkbox"/> Floor only <input type="checkbox"/> ICU and Floor <input type="checkbox"/> Emergency Room only <input type="checkbox"/> Unknown
7b. Duration <i>(leave blank if participant was treated in the emergency room only):</i> _____ days (use a midnight census and estimate if necessary) <input type="checkbox"/> 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)? <input type="checkbox"/> Yes <input type="checkbox"/> No If <u>Yes</u>, 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? <input type="checkbox"/> Yes <input type="checkbox"/> No If <u>Yes</u>, explanation of contribution of non-study device-related factors to the event: _____ _____ _____
9. Outcome <input type="checkbox"/> Fully recovered <input type="checkbox"/> Other <input type="checkbox"/> Unknown If <u>Other</u>, 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:

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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.**

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WITHDRAWAL REASON COMMENTS

If reason for withdrawal is Death, complete the following:

Date of Death: _____ / _____ / _____
(mm/dd/yyyy)

Cause of Death: _____ / _____ / _____
(mm/dd/yyyy)