CITY Visit Information (Contact) Worksheet

Subject ID: _____ **Namecode:** _____

1. Name of person conducting contact: _____

2. Contact 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

☐ **Contact was completed out of window**

1. Reason contact 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 Contact Form

Participant ID: _____ **Namecode:** _____

NON IN-PERSON CONTACT INFORMATION

1. **Select who participated in the contact:**
   - ○ Participant only
   - ○ Participant and parent/ guardian
   - ○ Parent/guardian only – participant was not available/refused
   - ○ Other

1a. If *Other*, describe: _____

CGM TRAINING non-in person contacts at 1 week, 4 weeks, 19 weeks

1. **Was CGM training provided to the participant and/or caregiver during the contact?**
   ○ Yes ○ No

1a. If Yes, what was the need for the training? (select all that apply).

Participant and/or caregiver required additional training on:

- ☐ Sensor insertion
- ☐ Sensor placement/skin reaction and adhesion
- ☐ CGM device/alerts
- ☐ CGM Calibration
- ☐ Remote monitoring/SHARE
- ☐ Downloading CGM data to Clarity
- ☐ Reviewing glucose trends/graphs
- ☐ CGM troubleshooting
- ☐ Other

If *Other*, describe: _____

CGM SENSOR USE

1. Based on participant's self-report, on average how many days per week does the participant use the study CGM sensor?

O 0 O 1 O 2 O 3 O 4 O 5 O 6 O 7

1a. If *less than 6*, indicate reason (select any of the following that apply):

☐Skin irritation

☐Uncomfortable or painful for to wear

☐Alarms too frequently

☐Does not provide accurate readings

☐Too difficult to operate

☐Too busy to use it

☐Forget to use it

☐Does not provide information that is helpful for diabetes management

☐Too big or interfered with certain clothing or activity/exercise

☐Other

If *Other*, describe: _____

2. If 0 days, has the particiapnt discontinued CGM use?

O Yes O No

3. Based on participant's self-report, on average how many weeks per month does the participant use the study CGM?

O 0 O 1 O 2 O 3 O 4 ☐**Not applicable (1 week visit and has not been using for a month)**

CGM BENEFIT HANDOUT

1. Was the participant reminded about the benefits of using CGM?

O Yes 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 Follow-up Complete the Contact 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 _____