# 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 Real Time CGM Worksheet

**Subject ID: _____** **Namecode: _____**

## CGM TRAINING PREVIOUS VISIT

1. **Was CGM training provided at the previous visit (randomization visit for CGM group and end of 26 week visit for BGM group?**

   ○ Yes ○No

   **1a. If No, enter reason:_____**

2. **Select the training module that was delivered at the previous visit (select all that apply):**

   ☐ Session 2: CGM Basics
   ☐ Session 3: Advanced CGM
   ☐ Session 4: Using CGM to Minimize Highs and Lows

   ***Note: Session 1: How CGM Works should have been delivered at the screening visit to all participants and reviewed as needed***

3. **Name of study personnel who delivered CGM training at the previous visit: _____**

## CGM TRAINING CURRENT VISIT

1. **Was CGM training provided to the participant at this visit?**

   ○ Yes ○No

   **1a. If No, enter reason: _____**
   **If Yes, answer questions 2-3**

2. **Select the training module that was delivered at this visit (select all that apply):**

   ☐ Session 2: CGM Basics
   ☐ Session 3: Advanced CGM
   ☐ Session 4: Using CGM to Minimize Highs and Lows

   ***Note: Session 1: How CGM Works should have been delivered at the screening visit to all participants and reviewed as needed***

3. **Name of study personnel who delivered CGM training at this visit: _____**

**CGM SENSOR USE**

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

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

**1a. If *less than 6*, indicate reason (select all that apply):**

☐Skin irritation
☐Wanted a break from using it daily
☐ Hesitant/uncomfortable using device
☐Uncomfortable or painful 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 exercise/activity
☐Other

If *Other*, complete the following:
Describe: _____

**2. If 0 days, has the participant 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 – 2 week visit**

**4. Did the particiapnt have the LOW alarm turned on at the visit?**

O Yes O No

**5. Did the participant have the HIGH alarm turned on at the visit?**

O Yes O No

**CGM DATA REVIEW AND USE**

**1. How frequently has the participant been reviewing his/her retrospective CGM data reports (i.e. either on Clarity website or report on Clarity phone application) ?**

- ○ Daily
- ○ 4-6 times per week
- ○ 2-3 times per week
- ○ 1 time per week
- ○ 2-3 times per month
- ○ 1 time per month
- ○ < 1 time per month
- ○ Never

**2. Were the CGM data reviewed with the participant during the visit?**
○ Yes ○ No

**2a. If No, enter reason: _____**

**2b. If Yes, were the participant's insulin doses adjusted at the study visit based on review of CGM data?**
○ Yes ○ No

**2c. If Yes, were there any behavioral recommendations for diabetes management based on review of CGM data?**
○ Yes ○ No

**3. In the past 30 days has the participant used the study CGM for dosing insulin without BGM fingerstick confirmation?**
○ Yes ○ No

**3a. If YES, about how often in the past 7 days has the participant used CGM for dosing insulin without BGM fingerstick confirmation?**

- ○ At least several times per day
- ○ 1 time per day
- ○ Some days but not every day
- ○ Never

**3b. If NO, select all that apply:**

- □ Checked with BGM out of habit
- □ Do not trust CGM values
- □ Not using CGM
- □ Other

**If *Other*, describe**: _____

## CGM VERIFICATION AND INVENTORY

1. **Was the date and time on the CGM receiver or smartphone (if using as display device) reviewed prior to uploading CGM receiver to Clarity?**
   O Yes O No

**1a. If date/time not accurate, enter comment: _____**

**2. Are the alarms/alerts on the CGM receiver working and audible?**
O Yes O No O Not Applicable

**If No, provide the participant with a new receiver and contact Dexcom Support.**

**3.Was a new transmitter provided?**
O Yes O No □Not applicable (52 week visit)

***A new transmitter must be assigned at the 13, 26, and 39 week visits (approximately every 3 months) Please ensure new transmitter linked to smartphone if applicable and data is being shared with clinic***

4. **Was a new receiver provided?**
   O Yes O No □**Not applicable (52 week visit)**

## CGM BENEFIT HANDOUT

1. **Was the participant reminded about the benefits of using CGM?**
   O Yes O No

***Use the CGM Benefit handout as a guide and provide to participants**

# 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 _____