INSTRUCTIONS FOR THE CONTINUOUS GLUCOSE MONITORING—SENSOR INITIALIZATION (CGM10) FORM

I. General Instructions

The Continuous Glucose Monitoring Sensor Initialization Form is administered by ARIC field center staff after the participant has completed any necessary consent forms. This form asks about temporary CGM exclusion criteria as well as the sensor serial number and sensor application date to be able to track the sensor back to the correct participant. **Note, for Visit 10, the CGM10 Form should be used and <u>not</u> the CGM Form.**

Two occurrences are allowed in the CGM form. If the participant meets any of the temporary exclusion criteria, the CGM sensor should not be applied to the participant and the CGM form should be saved and closed before starting Part B. For each future recruitment attempt until the sensor can be applied on the participant, **the same occurrence of the CGM form should be overwritten with updated information**. In the case where the participant is assigned a replacement sensor, **the replacement sensor should be tracked in a new occurrence of the CGM form**.

Before starting the CGM form, ensure that the participant does not have a history of adhesive allergies, a heart pacemaker, or a defibrillator (AICD) and that the participant is able to mail or otherwise return the CGM sensor back to the clinic. These exclusions can be verified by viewing the Participant Snapshot report or items 3 and 4 on the PSA form.

If the participant is not interested in participating in CGM/ePatch, staff should record this information in question 0c of the EIO form. The CGM10 form does not need to be opened or completed, and it also does not need to be marked as Permanently Missing.

II. Detailed Instructions for Each Item

0a. Enter the date the form was completed.

0b. Enter the staff code of the person who completed this form.

0c. Record whether the participant is interested in participating in the CGM ancillary study.

0c1. If the participant indicates that they are not interested in participating in the CGM ancillary study, record the reason why not.

A. CGM Sensor Exclusion Information

1. Record whether the participant has an MRI scan, CT scan, X-ray, or diathermy treatment scheduled in the following 14 days. This item includes any ARIC imaging visits. If "Yes," skip to item 3.

2. Record whether the participant has any air travel scheduled over the next 14 days. If "No," skip to item 4.

> 2a. Since the CGM sensor cannot be worn through regular airport screening machines, record whether the participant is willing to request alternative security screening

procedures for travel. If "Yes," skip to item 4.

3. This question is only asked if the participant meets any of the temporary exclusion criteria in items 1-2. If the participant responds "Yes" that they are willing to participate in the CGM study at a later date, further recruitment attempts may be made starting at least two weeks after the initial recruitment attempt. Record the participant's response, then save and close the form.

B. CGM Sensor Initialization Information

If no sensor exclusion criteria in Part A were met, record the CGM Sensor Initialization Information in items 4 and 5.

4. Record the sensor serial number. There are two acceptable methods to record the sensor serial number outlined below:

a. The preferred method is to use a QR barcode scanner to scan the QR code on the yellow CGM sensor box directly into CGM item #4. When scanned in this way, the serial number will be 48 characters long with 46 alphanumeric characters and 2 backslashes. The serial number is the last 11 alphanumeric characters directly preceding the final backslash. Review the serial number and remove any special characters (anything that is not numbers, characters, or letters). Otherwise, **DO NOT** add or remove characters from the scanned serial number. See example below:

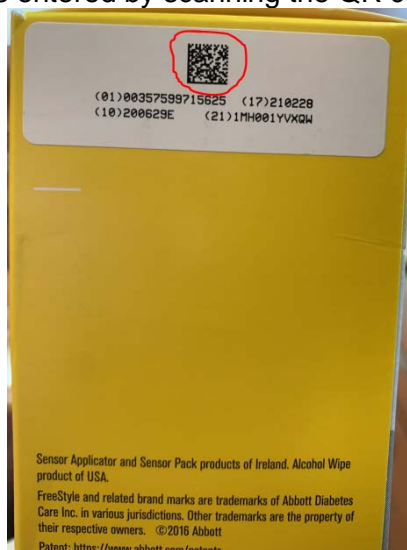Figure 1. The serial number is entered by scanning the QR code on the Yellow Sensor Box.

Figure 2. Scan the serial number directly into CGM#4. Do not remove any characters. Ensure that the last 11 alphanumeric characters (highlighted) match the serial number on the sensor application pack.

b. An alternative method to record the sensor serial number is to hand type the serial number into CGM#4. The sensor serial number is an eleven character alphanumeric string (ex. "1MH001YVXQW") that can be found next to the SN on the sensor pack. If you choose to use this method, be especially careful to ensure that the serial number is entered correctly. It is important to record this identifier correctly so that the sensor can be tracked back to the proper participant. Review the serial number and remove any

special characters (anything that is not numbers, characters, or letters). See example below:

Figure 3. The 11 character sensor serial number can be found on the top of the CGM sensor pack (highlighted).
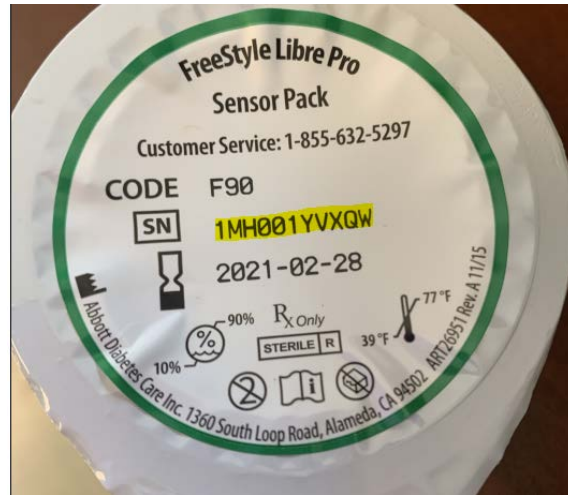

Figure 4. The 11 character string can be entered by hand into CGM#4.

5. Record the date that the sensor was applied to the participant.