INSTRUCTIONS FOR THE CONTINUOUS GLUCOSE MONITORING—SENSOR INITIALIZATION AND RETURN STATUS (CGMR) FORM

I. General Instructions

The Continuous Glucose Monitoring Sensor Initialization and Return 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 11, and for Gen2 after 1/18/2024, the CGMR Form should be used and <u>not</u> the CGM Form. Two occurrences of the CGM form are allowed. You should use the second occurrence of the form if the participant receives a replacement CGM sensor only.**

Before starting the CGMR 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 Freestyle Libre 3 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 a participant is ineligible to be recruited for CGM participation, mark the CGMR form as permanently missing in the form grid.

Please note that for the Gen2 study, the CGM and ECG Patch should be worn at the same. If these devices are initialized on the same day then the exclusion conditions asked in both the EIO and CGMR forms only need to be asked once of the participant, but need to be recorded in both forms. If the devices are initialized on different days, then the exclusion criteria need to be assessed before each device is placed.

If the participant is pre-eligible and not interested in participating in CGM, then please record the reason why in item 0c.

The CGMR form also asks about the CGM Sensors' Return Status and is completed by ARIC field center staff after the participant returns a CGM sensor to the clinic. It tracks if the participant returned their CGM sensor, number of days the device was worn, the date the device was returned to clinic, and when the clinic shipped the device to Abbott.

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. Save and close form.

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 50 characters long with 48 alphanumeric characters and 2 double-sided arrows. The serial number is the 9-character alphanumeric string found next to the "SN" box on the CGM senor pack. Review the serial number and remove any special characters (ie. Arrows or anything that is not numbers, characters, or letters). Otherwise, **DO NOT** add or remove characters from the scanned serial number. Please note, when the SN is scanned from the QR code that the first two characters after the first double-sided arrow are extraneous. The SN starts with the number "0" which will match the 9-digit number on the CGM package. See example in Figure 2 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 CGMR#4. Do not remove any characters. Ensure that the alphanumeric characters (highlighted) match the serial number on the sensor application pack.

4. CGM sensor serial number   0100357599818005172402291 0T60001191↔210FAHMMW1U↔91

    b. An alternative method to record the sensor serial number is to hand type the serial number into CGMR#4. The sensor serial number is a nine-character alphanumeric string (ex. "0FAHMMW1U") 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 9-character sensor serial number can be found on the top of the CGM sensor pack (highlighted).

Figure 4. The 9-character string can be entered by hand into CGMR#4.

B. CGM Sensor Initialization Information

4. CGM sensor serial number   0F27HUMTT

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

C. CGM Sensor Return Information

6. Indicate whether the participant returned the device. If "No," save and close the form.

7. Specify how many days the participant wore the device.

8. Record the date the device was returned to clinic (MM/DD/YYYY).

   Record the date the device was shipped to Abbott (MM/DD/YYYY)