INSTRUCTIONS FOR THE CONTINUOUS GLUCOSE MONITORING—SENSOR RETURN STATUS (CGR) FORM

I. General Instructions

The Continuous Glucose Monitoring Sensor Return Status Form is completed by ARIC field center staff after the participant returns a CGM sensor to the clinic. This form tracks returned CGM sensors and data and results that were obtained from the sensor.

Only one occurrence of the CGR form is allowed. If the participant is given a replacement sensor for any reason, the return status of both sensors is tracked using the same occurrence of the CGR form. Part A of this form refers to the sensor that was initially applied and Part B refers to the replacement sensor. Part B of the form is only enabled if the response to question 8 is "Yes" – the participant had their initial CGM sensor replaced. Part C of the form is used to determine the results summary that should be sent to the participant.

All raw data files exported from the Abbott software should be attached to the end of the CGR form. All raw data files should follow the standard filename format: **'[ARIC SUBJECTID].csv'**. If the participant had their initial CGM sensor replaced, both data files should be attached in the CGR form when possible. The filename format for the replacement sensor should be: **'[ARIC SUBJECTID]"_R".csv'** to indicate that the file is linked to the replacement sensor.

For help attaching files to a CDART form, please visit https://sites.cscc.unc.edu/aric/cdart-docs (Cohort > Documents > CDART > Opening and Attaching Files in a CDART Form) and look for the document titled "Opening and Attaching Files in a CDART Form"

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.

A. CGM Sensor Return Information

1. Item 1 is the initially applied sensor serial number. This serial number is automatically filled from the first occurrence of the CGM form. Before proceeding, ensure that the serial number listed in this item matches the serial number of the sensor for which you intend to complete section A of this form. If not, review the first occurrence of the CGM form to ensure that the sensor serial number is keyed to the correct participant ID and vice versa.

2. Record whether the CGM sensor was returned to the clinic. If "No," skip to item 8.

3. Record the date that the CGM sensor was received at the clinic.

4. Record whether the data was successfully downloaded from the CGM sensor. If "Yes," skip to item 5.

   4a. If the data was unable to be downloaded from the CGM sensor, indicate the reason why. The options are A—"Sensor damaged," B—"Sensor lost", or C—"Other."

If the response is C—"Other," complete item 4a1. Otherwise, skip to item 8.

        4a1**.** Indicate the other reason why the data was unable to be downloaded from the initial sensor. Skip to item 8 once complete.

5. Indicate whether the .csv raw data file exported from the Abbott LibreView software for the CGM sensor was able to be successfully attached to the form. LibreView is the Abbott cloud-based software used to retrieve participant raw data from the CGM sensor.

6. Indicate whether the 1-page AGP results file (.pdf) was successfully downloaded from LibreView. The AGP results file is the 1-page Average Glucose Profile results report that is sent to participants. LibreView is the Abbott cloud-based software used to generate this report. This report does not need to be attached to this form.

7. Indicate whether the participant wore the CGM sensor for the full 14-day wear period. The number of days worn can be found on the upper left of the pdf results file. If "Yes," skip to item 16.

        7a**.** Indicate the number of days that the participant wore the sensor. This value must be fewer than 14. If the participant wore the sensor for 14 days, return to question 7 and answer "Yes".

8. Indicate whether the participant had the sensor replaced. If "No," skip to item 16. Note that if the participant has a replacement sensor, do not send results until both sensors are returned to the clinic.

B. CGM Replacement Sensor Return Information

Section B will be enabled if it is indicated that the participant had a replacement sensor in question 8.

9. Item 9 is the replacement sensor serial number. This serial number is automatically filled from the second occurrence of the CGM form. Before proceeding, ensure that the serial number listed in this item matches the serial number of the sensor you for which you intend to complete section B of this form. If not, review the second occurrence of the CGM form to ensure that the sensor serial number is keyed to the correct participant ID and vice versa.

10. Indicate whether the CGM replacement sensor was returned to the clinic.

11. Indicate the date that the CGM replacement sensor was returned to the clinic.

12. Indicate whether the participant wore the replacement sensor for the full 14-day wear period. The number of days worn can be found on the upper left of the pdf results file. If "Yes," skip to item 13.

        12a**.** Indicate the number of days that the participant wore the initial sensor. This value should be fewer than 14. If the participant wore the sensor for 14 days, return to question 12 and answer "Yes".

13. Record whether the data was successfully downloaded from the initial sensor. If "Yes," skip to item 14.

13a**.** If the data was unable to be downloaded from the replacement sensor, indicate the reason why not. The options are A—"Sensor damaged," B—"Sensor lost", or C—"Other."
If the response is C—"Other," complete item 13a1. Otherwise, skip to item 16.

13a1**.** Indicate the other reason why the data was unable to be downloaded from the replacement sensor. Skip to item 16 once complete.

14. Indicate whether the .csv raw data file exported from the Abbott LibreView software for the replacement sensor was able to be successfully attached to the form. LibreView is the Abbott cloud-based software used to retrieve participant raw data from the CGM sensor.

15. Indicate whether the 1-page AGP results file (.pdf) was successfully downloaded from LibreView. The AGP results file is the 1-page Average Glucose Profile results report that is sent to participants. LibreView is the Abbott cloud-based software used to generate this report. This report does not need to be attached to this form.

C. CGM Results information

Note: Item 16 has been removed from the CGR form used in the ARIC Generation 2 Study.

16. This item will be computed by CDART and records the serial number for the pdf report that should be mailed to participants.

Save the form and click the arrows [ ] to calculate each field. Be sure to save the form before and after calculating the field, otherwise the response will not be stored. If the participant was given a replacement sensor, wait until the replacement sensor has been returned before sending out any results.

This script field will result in one of four options that should be used by field center staff to help determine the PDF results report that should be sent to the participant.
- The sensor serial number of the first sensor if the participant wore the first sensor for all 14 days and the ACP results file for that sensor was able to be downloaded from LibreView. OR
- The sensor serial number of the longest worn sensor if the participant wore and returned two sensors and successfully downloaded the AGP results for both sensors. OR
- The sensor serial number of the replacement sensor if the AGP results file for the first sensor was unable to be downloaded from LibreView. OR
- The phrase "DO NOT SEND RESULTS" if there is insufficient information to be able to send results. "DO NOT SEND RESULTS" will also appear if it is indicated that the participant had a replacement sensor (in question 8) and information about the replacement sensor has not yet been keyed into Part B of this form.