INSTRUCTIONS FOR THE MICROBIOME RECRUITMENT AND ELIGIBILITY FORM (BRE)

I. General Instructions

The Microbiome Recruitment and Eligibility Form is completed by the staff recruiting for the Microbiome study to track and document the status of each Eligible ARIC participant who is invited for the Microbiome Study.

The form is opened and initiated when the recruitment process begins for a cohort participant. Ultimately, it is to be completed for all ARIC cohort participants who are eligible and for whom an attempt to give recruitment materials is made until recruitment goals are met. Only one record per invited participant is expected for this form. The form is also NOT completed for participants not invited to participate in the Microbiome study (i.e. for those for whom an attempt to give recruitment materials was not made). In cases where the participant could not be reached after numerous attempts or where the participant never explicitly stated whether or not they were interested in the study (item 1), items 0a and 0b should be completed, and item 1 should be marked missing.

The purpose of the BRE is to allow field centers to track the scheduling status of invited participants, not to identify those who need to be recruited. Participants who are eligible to be recruited are identified using the 'V6V7 Ancillary Report' available in CDART.

II. Detailed Instructions for Each Item

0a-0b. Record the completion date and the staff ID in these fields.

1. Record the participant's willingness to participate. If they do not wish to participate, thank the participant for their time.
If attempts to invite a participant to take part in the Microbiome study were made, but contact was never established or the participant did not explicitly state whether or not they were interested (e.g., they asked for time to think about it, requested a phone call back, etc.), mark 1 as missing. A notelog may be added to explain the situation.

2. Record whether or not the participant provided a saliva sample for the oral microbiome measurement. At the start of V7 (Feb 1, 2018), the saliva collection moved from the Microbiome ancillary measure, to part of the V7 protocol. As of February 1, 2018, this question should always be answered with "No."

3. Record whether or not the participant is willing to answer study questions and provide a stool sample. If not, skip to Q9.

4-8. After reading the script corresponding to the participant's responses to 1-3, record the participant's responses to 4-8 to determine if they are eligible to participate in the gut microbiome portion of the study.

9. Determine whether or not the participant is eligible to participate in the study based on the criteria laid out in Q9, and then read the appropriate script.

10. If a participant is given a microbiome kit, record the FedEx tracking number here.

11. Answer this questions relating to reimbursement after determining if the participant is eligible for reimbursement.

12. If a stool sample was returned to the clinic, respond "Yes," and proceed to the clinic only section.

13a-14b. This section is for the clinic only. If a sample is received at the clinic, answer the questions based on when the sample was received.

If participant eligibility is reevaluated at a later date, please update 0b to show the new date. If the participant maintains the same eligibility status, no other changes are needed. If the status changes, please also update other relevant responses (Q9).