The Atherosclerosis Risk in Communities - Generation 2 Study (ARIC Gen2)
Telephone Screening & Recruitment Script – UMN Field Center

(Adapted from sections in the "ARIC Gen2 Screening and Recruitment Procedures, Manual 44")

Screening Phone Call

The goal of the screening call is to establish eligibility and to schedule the clinic visit. Our overarching goal is to identify eligible and enthusiastic participants who will be likely to complete the full study protocol and who are interested in having a long-term relationship with the ARIC Study. Recruiters will use the screening phone call and answers to the questions below to judge enthusiasm and willingness to participate in all study protocols.

Steps in the screening phase include:

- Phone contact and tracking: 3-5 calls will be attempted for potential participants (depending on messages); leave 2-3 messages as needed
- Eligibility questions
- If eligible and willing to participate, schedule in-person clinic visit

Introductory Sample Scripts

"Hello, may I speak with [state person's full name and title (e.g., Mr., Dr.), if known]. My name is [state your full name]. I am not a telemarketer. I am calling from the University of Minnesota and am returning your call about a medical study of diabetes we are conducting."

Always include the following statement:
"*Taking part in this phone call is completely voluntary*."

"Thank you for your interest in the research study. Do you have 10 minutes or so to hear about the study."
If **yes**, continue.

If **no**, ask, *"When would it be convenient to call you back?"*

If the person agrees to a future contact, record, and state, *"Thank you. I will call again then."*

If the person refuses future contact, end the call. *"Thank you for your time. Goodbye."*

If **yes**, include the following:
"I will be collecting information about you during this phone call. Before I ask you the screening questions, I would like to tell you about what we will be doing with the information you give us.

Whether you join the study or not, the information collected today may be seen by researchers at the University of Minnesota, any sponsor of the study, and those responsible for oversight of the study. We try to make sure that the information we collect from you is kept private and used only for the research study we are discussing.

"Your personal information will not be kept if you choose not to enroll in the study or if you do not qualify to be in the study."

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Screening Eligibility Sample Scripts

"We are calling from the Atherosclerosis Risk in Communities (ARIC) Study to recruit new participants who have type 2 diabetes. This research study is funded by the National Institutes of Health. If you have type 2 diabetes, you are potentially eligible to participate in our study.

Do you have a history of type 2 diabetes?"

If **yes**, continue.

If **no**, then tell the participant they are not eligible and ask if they might be interested in recommending a family member friend or neighbor who might be eligible and interested in the study. Record the information for the new potential participant. If none, *"Thank you for your time."*

Note for recruiters regarding distinguishing between type 1 and type 2 diabetes:

Participants with type 1 diabetes or other forms of diabetes (e.g., gestational diabetes only without type 2 diabetes or MODY (maturity onset diabetes of the young)) are not eligible to participate in this study. Type 2 diabetes is far more common than these other forms of diabetes, but it is important to note that only people with type 2 diabetes are eligible for the study.

People with prediabetes are also NOT eligible for the study.

People with type 1 diabetes will generally know that they have type 1 diabetes.

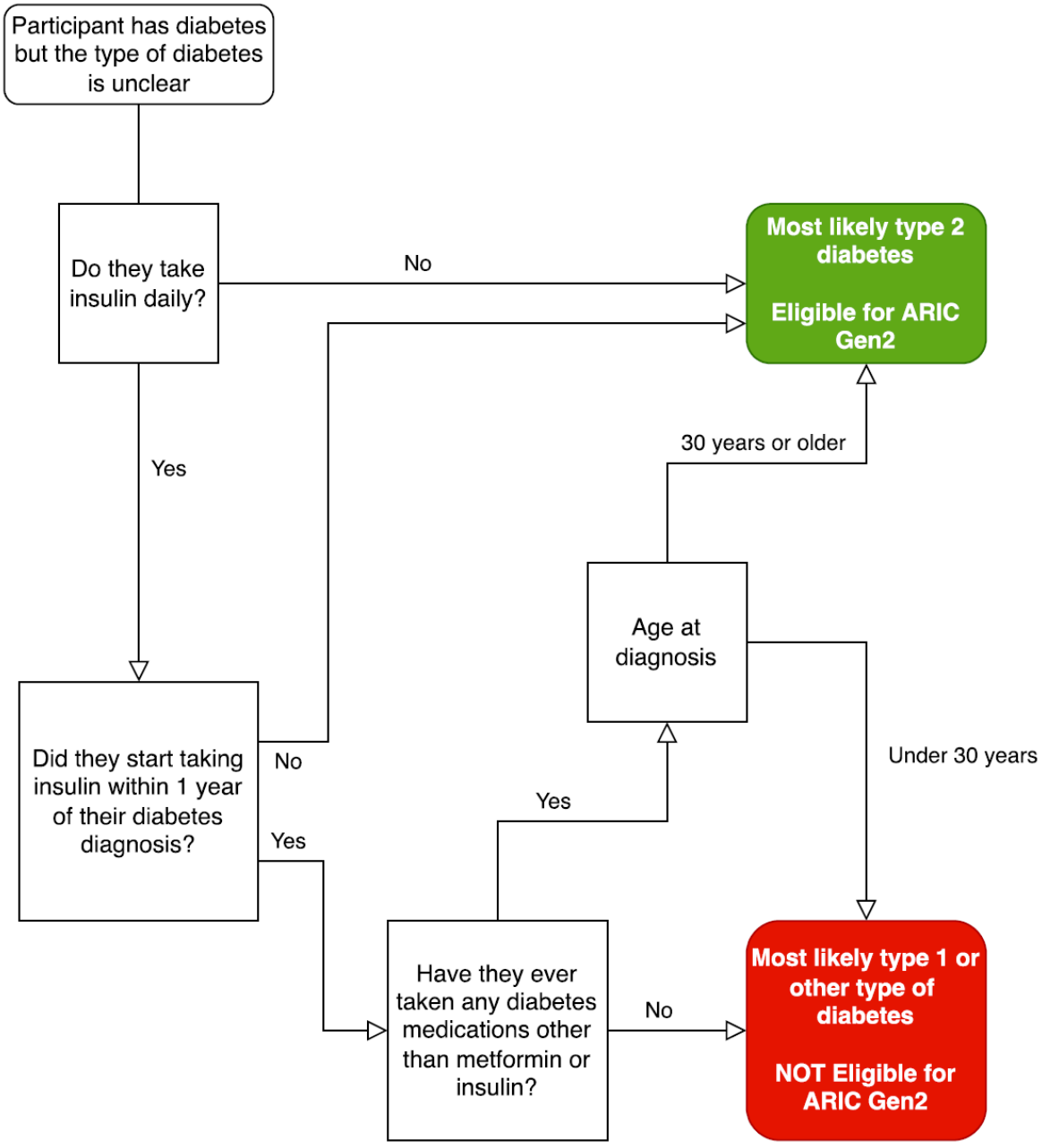
People with type 2 diabetes may be less aware of the "types" of diabetes and may not even be aware that there are different types of diabetes.

To probe for more information about diabetes type, you can ask questions about diabetes treatment. [Refer to the diagram on the next page for additional guidance (copied from *ARIC Gen2 Screening and Recruitment Procedures Manual 44*)]

- People who are only taking insulin (no diabetes pills) and who were diagnosed with diabetes when they were younger than 30 years of age are likely to have type 1 diabetes and should be excluded.

- People taking oral diabetes medications (with or without insulin) are more likely to have type 2 diabetes. However, people with type 2 diabetes can also be treated with insulin. If they are taking insulin for their diabetes, inquiring about whether they were ever treated with oral medications for diabetes, as well as their age when they were first diagnosed, can help distinguish type 1 and type 2 diabetes.

[Diagram from *ARIC Gen2 Screening and Recruitment Procedures, Manual 44*]



For participants who report a history of type 2 diabetes, *"This research study includes people ages 50 to 80 years old.*

Are you in that age range?" If in the age range, ask for **date of birth** and then continue.

If **not**, i.e., the respondent is younger than 50 or older than 80, they are not eligible for the study.

"I'm sorry, but our study only includes people ages 50 to 80 years old.

Is there someone else you would like to recommend for our study who has diabetes and might be in this age range?" Record the information for the new potential participant.

If none, *"Thank you for your time."* End call.

If eligible:
"It appears you might be eligible for this study.

This study will involve coming to the clinic to collect some information, and we will also study your glucose and heart rhythm over 2 weeks. Heart problems can be common in people with type 2 diabetes.

We are interested in measuring your blood sugar (glucose) using a continuous glucose monitor and also measuring your heart rhythm. Your glucose and heart rhythm will be measured using two separate devices that are small and placed on the skin. The glucose monitor is placed on the arm. The heart rhythm monitor is a sticker that is placed on your chest. Both devices are regularly used by medical doctors. The devices are worn at the same time for 14 days, then you will mail them back. We will return to you detailed information on your glucose patterns and heart rhythm if you would like to see the results.

Do you think you would be interested in participating in this study and wearing these devices during a period that is convenient for you?"

If **yes**, continue.

If maybe or **no**, consider probing and answering questions and providing more information to allay concerns about the devices, scheduling, and/or wear time.

"The study will involve a clinic exam and wearing the devices I mentioned. We will also want to get a vial of your blood at the visit and continue to contact you for four years so we can learn about your health. If you are interested in participating, I will ask you a few more questions to make sure you are eligible and then we can discuss scheduling the clinic visit."

Staff should use their discretion to ask additional questions or determine if it is appropriate to terminate the interview, especially if the respondent does not seem enthusiastic.

Additional eligibility questions:
"Do you live in a nursing home or a long-term care facility?" If yes, respondent is INELIGIBLE.

"Do you currently have an implanted pacemaker or defibrillator, a device used to regulate your heart rhythm?" If yes, respondent is INELIGIBLE.

"Do you have an allergy to adhesive tape or bandages?" If yes, respondent is INELIGIBLE.

"Do you plan to move out of [community name] within the next four years?" If yes, respondent is INELIGIBLE.

If the interviewer believes the respondent is eligible and willing to participate in all aspects of the study, then continue with the following sample script:

"Please let me check the spelling of your name." Ask respondent to spell out full name and record.

"What is your street address?"

"Would you please verify your home phone number?" Record home phone number, including area code.

"Are there other phone numbers that I could use to reach you, if necessary, such as a mobile phone or business phone?" Record alternate phone number(s), including area code, in spaces provided.

"What is your email address?" Record information.

"Could you provide us with the name and contact information of a close family member or other individual who could be used to reach you if it was needed?" Record information.

How is this person related to you?" Record information.

"Do you have a family member who is already part of the ARIC Study?" Record information [allow for multiple].

"What is your relationship to the family member who is already part of the ARIC Study?" Record information.

"Thank you for all this information. It will make it easier for us to get in touch with you in the future. Now we need to schedule your clinic visit…."

Schedule visit. Do not, however, schedule a clinic visit for an acutely ill (e.g., COVID, influenza, or bronchitis) participant. Arrange to contact him/her again to schedule an appointment when he/she has recovered. Consider also asking if the respondent has any further questions before ending the call.

Questions people might ask about why you're calling and sample responses:

□ *I don't want to buy anything!*

"**We are not selling anything. We are calling about a new research study on diabetes we want to tell you about."**

□ *How did you get my name?*

"Your name was provided by [insert appropriate information]**. It is important that we choose people from a wide range of the population and your** [friend/family member/neighbor] **thought you might want to learn more about our study. This is a unique opportunity for you to gain some important knowledge about your health."**

□ *I'm too busy.*

"I realize that people are very busy these days. Are there other days and times that are better for you?"

□ *How long will this take?*

"It will only take about 10 to 15 minutes of your time today. I'll move through the questions as quickly as I can." Ask permission to proceed or call back.

Questions people might ask about the clinic exam and sample responses:

□ *I can't help you because I've never had heart problems.*

"We are interested in enrolling all different people with diabetes, even people who have never had heart problems. We are very interested in people who do not have heart disease or other heart problems."

□ *What do I get out of the study?*

"There are several ways in which you might benefit from this study. You will receive, at no cost to you, a medical examination. You will also get two medical devices that are used by medical doctors to provide detailed information about your blood sugar patterns and your heart rhythm. It is possible that we could find a medical condition that you were not aware of. If we did, you would be able to get treatment from your own doctor, if you desired. You will also have the opportunity to participate in an important type 2 diabetes study and help us understand why people with diabetes are at high risk for heart conditions."

□ *What is involved in the clinic examination?*

"We will be doing a number of tests, some of which you may have had before. We will check your height, weight, and blood pressure. We will also ask you a series of questions about your life and health and about your family history. We will also draw some blood to measure the levels of substances such as cholesterol and hemoglobin A1c (glucose control)."

□ *I don't like to have blood drawn!*

"I can understand that. Many people do not like to have their blood drawn. But we have very specially trained personnel and we use small needles to make it easier. The blood tests are very important parts of the study and are needed to compare with other study results."

☐ *I want to know more about the continuous glucose monitor.*

"You will be asked to wear a small sensor on the back of your upper arm that records information on blood sugar (glucose). This sensor has a tiny filament that will go under your skin. The sensor is placed on the skin using a special applicator. Most people do not feel the sensor when it is applied or when they are wearing it. You can go about your daily activities while wearing the sensor. You will wear the sensor for 14 days."

***Note*:** The sensor is the size of two quarters stacked on top of each other. Both the CGM and ePatch sensors can be worn when bathing and showering (see Appendix for more information about the devices).

☐ *What type of continuous glucose monitor is being used in the study?*

"We are using a product called the Libre Pro continuous glucose monitoring system because this system is very easy to use. The monitor records glucose and stores it in the device and then we can download the data later. It is not possible to get 'real-time' measurements of glucose from this system. The device is approved by the U.S. Food and Drug Association, often called the FDA."

☐ *I already wear a continuous glucose monitor. Why do I need to wear another one?*

"You can wear both a personal glucose monitor and also the study glucose monitor at the same time".

Note: It would be somewhat uncommon for someone with type 2 diabetes to be routinely using a continuous glucose monitor (CGM) but it is sometimes used in people with type 2 diabetes who are taking insulin. If a respondent indicates they are already using a CGM system, please verify that the person has type 2 diabetes (not type 1 diabetes).

☐ *I want to know more about the heart rhythm monitor*

"We are using a product called the ePatch device. This is a small, lightweight monitor that is used clinically to monitor for abnormal heart rhythms (arrhythmias). The ePatch is placed on the chest using an adhesive sticker and it is worn for 14 days. You can go about your daily activities while wearing the sensor, including showering. The device is approved by the U.S. Food and Drug Association, often called the FDA."

☐ *Can I wear the devices while swimming?*

"No. You will be asked to refrain from submerging the devices under water during the 2-week wear period. You can, however, wear the devices while taking a shower as long as the devices do not get excessively wet."

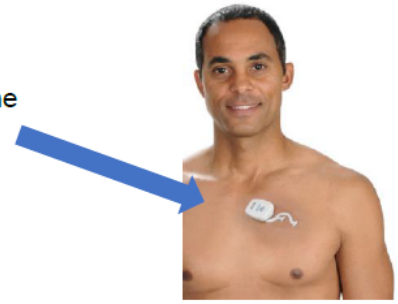
☐ *Do I have to wear both devices* [continuous glucose monitor and heart rhythm monitor] *at the same time?*

"Yes. The main goal of this study is to see how fluctuations in glucose are related to changes in the heart rhythm. Both devices need to be worn at the same time."

Reference pages from *ARIC Gen2 Screening and Recruitment Manual 44*

Appendix. General information about the ePatch and CGM (continuous glucose monitoring) devices

An ePatch heart monitoring sensor will be placed on the chest.



A continuous glucose monitoring (CGM) sensor will be placed on the back of the arm.

The ePatch device (BioTel, Inc) is a small, lightweight monitor that is used clinically to monitor for arrhythmias. The ePatch monitors and stores cardiac rhythm activity for up to 14 days. The device does not provide any real-time information. It stores all the data for later download.

The ePatch will be worn at the same time as the CGM. This will allow us to simultaneously evaluate glucose patterns and patterns in heart activity.

Continuous glucose monitoring (CGM) technology is the recommended approach to the assessment of glycemic variability and hypoglycemia and is being increasingly used in diabetes care. In this study, we will use the FreeStyle Libre Pro device. The Libre Pro device is a masked device, meaning participants will not be able to see to the glucose readings. The device does not provide any real-time information. It stores the glucose readings for later download.

The CGM sensor measures and stores glucose readings when worn on the body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. At the clinic visit, staff will prepare and apply the sensor to the underside of the back of the participant's upper arm. The sensor has a small, flexible tip that is inserted under the skin.

The sensor can be worn for up to 14 days. The back of the arm is where the sensor has been shown to be most accurate.

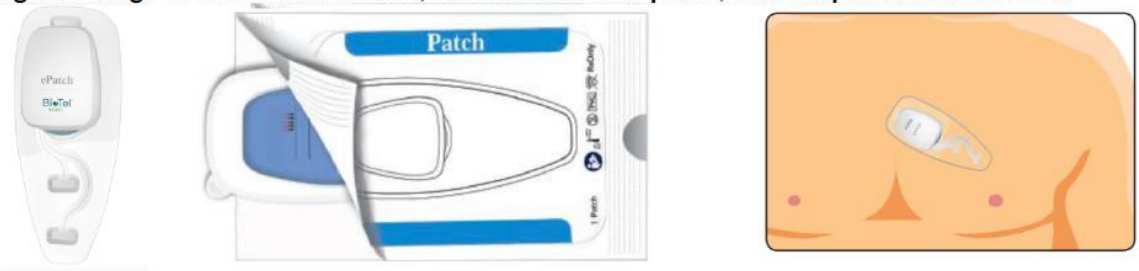
Figure 1. Examples of people wearing the CGM sensor

There is minimal risk or discomfort associated with the use of CGM sensor. The main risk is skin irritation.

Participants will continue routine glucose monitoring as recommended by their doctor.

Both the CGM and the ePatch sensors are water resistant and can be worn while bathing, showing, or swimming. Although, we do not recommend submerging the devices for a prolonged period.

Figure: Image of the ePatch sensor, the self-adhesive patch, and the placement location.



https://www.myheartmonitor.com/device/epatch/