# Manual 44
# Screening and Recruitment Procedures

**Last updated:** **February 14, 2024**

## Overview of ARIC Gen2

ARIC Gen2 is funded by an NIH grant from the NHLBI, R01 HL158022 (Co-PIs: Selvin and Chen). The overarching goal of the grant is to evaluate the link glucose patterns (hypo- and hyper-glycemia) with cardiac arrhythmias in adults with type 2 diabetes in the community. To accomplish this goal, we will use simultaneous 2-week continuous monitoring of heart rhythm (BioTel ePatch) and continuous glucose monitoring (Abbott CGM) in adults with type 2 diabetes. Older adults (aged 80 or older) will be recruited from within the ARIC Study, starting at Visit 10. ARIC does not currently include any participants younger than 80 years of age. Thus, ARIC Gen2 will involve additional recruitment of new participants with type 2 diabetes who are aged 50 to 80 years.

The ARIC Gen2 study will be nested within the existing ARIC study and clinic visits for ARIC Gen2 participants will occur in parallel with ARIC participants. Highly trained staff at the four established ARIC field centers will be responsible for the ARIC Gen2 study as well.

### Study Sites

ARIC Generation 2 (ARIC Gen2) will be conducted at the four established ARIC Field Centers: the George Comstock Center in Washington County, Maryland; the University of Mississippi Medical Center in Jackson, Mississippi; the University of Minnesota, Minneapolis, Minnesota, and Wake Forest University, Forsyth County, North Carolina. The Coordinating Center for this study is at the University of North Carolina, Chapel Hill.

## Overview of the Field centers

Highly trained staff at the four established ARIC field centers will be responsible for the recruitment of the ARIC Gen2 participants.

### George Comstock Field Center in Washington County, MD

The George Comstock Field Center is a dedicated research facility where County residents were recruited and followed in the ARIC Study. The ARIC Study, as well as a number of other NIH-funded studies are conducted in the Comstock research facility, which houses 30 employees in approximately 10,000 square feet of space dedicated to community-based research with multiple examination rooms, conference rooms, and research space. Dr. Josef Coresh is the Director of this Center. The Comstock Center is located in Hagerstown, Washington County, Maryland, 75 miles from the Johns Hopkins University campus. The research center has handicap accessible entrances from the street, waiting rooms, examination rooms, interview rooms, phlebotomy and blood processing rooms with space for refrigerators and a freezer, lounge, conference rooms, file rooms, storage space, kitchens for preparation of snacks, and handicap accessible restrooms. The center has adjacent free parking. The Department of Epidemiology faculty and administrative staff oversee and advise on clinical and study conduct issues. The current project coordinator at the Center oversees space and staff sharing issues.

### The University of Mississippi Medical Center in Jackson, MS

The University of Mississippi Medical Center (UMMC) has a long history of excellence in cardiovascular and neuro-epidemiologic research including recruitment and retention of African American participants for several large NIH-funded population-based studies (such as ARIC). The site has recruited and followed City residents for the ARIC Study. Dr. Thomas Mosley is the

principal investigator for the ARIC Jackson Field Center at UMMC. The ARIC Field Center is conveniently located on UMMC's campus in a state-of-the-art research building which includes office, interview, and examination rooms. Facilities consist of a reception area and waiting room, multiple interview/procedure rooms, nurses' workstation and office space, kitchen, storage areas with locking file cabinets, and phlebotomy and sample processing area with multiple -70°C freezers. Parking is conveniently located.

**The University of Minnesota, Minneapolis, MN**
The ARIC Field Site in Minneapolis, located at the Epidemiology Clinical Research Center at the University of Minnesota has recruited and followed residents of selected Minneapolis suburbs (Golden Valley, Robbinsdale, Crystal, New Hope, Plymouth, Brooklyn Center, and Brooklyn Park) for the ARIC Study. The Epidemiology Clinical Research Center (ECRC) is located one block away from the offices of the Division of Epidemiology and Community Health, about 0.5 miles from the University of Minnesota Hospital on the Minneapolis campus, and is readily accessible from all parts of the Twin Cities metropolitan area (within three blocks from two major interstate highways). The ECRC occupies one floor (17,758 square feet) of a two-story building and includes reception area, offices for staff, examination rooms, interview rooms, ultrasound, phlebotomy and blood processing rooms, freezer room, lounge, conference rooms, and storage space. The building meets current regulations for handicapped accessibility and has free adjacent parking spaces.

**Wake Forest University, Forsyth County, NC**
The Forsyth County ARIC Field Site is located at Wake Forest University. The Public Health Research Center (PHRC) is the site for clinic examinations for County residents for the ARIC Study and is located in the Piedmont Plaza I building on the Wake Forest University Baptist Medical Center campus. The PHRC provides investigators within the Division of Public Health Sciences with facilities and staff to perform multi-center clinical trials and observational research. The PHRC is easily accessible to all study participants as it is located on the ground floor of the Piedmont Plaza I Building, within a half mile of the main hospital, and is handicap accessible. With over 5,600 square feet of space, the PHRC has 18 rooms, a laboratory, a large waiting area, adequate parking that is free of charge, and many additional amenities to enhance the research experience of participants.

**Study Population**

This study will enroll at least 400 total participants across the four Field Centers. Each Field Center will enroll approximately 100 participants. Participants will be community-dwelling adults aged 50 to 80 years of age (inclusive) with a diagnosis of type 2 diabetes.

**Key Procedures**

Each participant enrolled in ARIC Gen2 will complete a clinic visit with assessment of demographics, medical history, cognitive and physical function. CGM and ePatch monitors will be placed on all participants at the clinic visit. These devices will be worn simultaneously for up to 14 days following the visit. Participants will receive phone calls on Days 3 and 14 to answer questions and remind them to wear the devices (Day 3) and instruct them to remove and return the device (Day 14). The devices will be returned to the clinics in a pre-paid mailer following instructions provided at the clinic visits. Participants will be followed over time using procedures established in the ARIC Study including semi-annual calls and hospital chart review.

**Consent**

A signed consent form is obtained from each participant. The consent form describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

Purpose: To inform the prospective participant as much and as accurately as possible about:

- The procedures involved in the study
- What is expected of participants who consent to enroll in the study
- What the study can and cannot provide to the participant
- What are the reasonable risks and benefits
- What are the alternatives to participation
- To document the participant's consent to participate in screening, and all of the respective procedures involved.
- To provide a prospective participant with a legal document summarizing the study and his or her rights as a study participant.
- To provide the participant with ongoing explanations and continuing information that help the participant decide whether to begin or continue in the research study.

Consent administration

- Before printing a blank consent form, check to ensure that you have the current IRB-approved consent document.
- In a quiet, private location, review the entire consent form with the participant, ensuring that the participant comprehends all the information.
- Participants should be given sufficient opportunity to ask questions, and questions should be answered as consistently and as completely as possible, both before and after consent is requested.
- Participants should be given sufficient time to consider their options.
- Participants lacking capacity to provide informed consent are not eligible for the ARIC Gen2 study
- Participants who are not willing to wear the ePatch and CGM sensors for up to 14 days are not eligible for the ARIC Gen2 study.
- If a participant does not wish to participate in tests or procedures other than the CGM or ePatch monitoring mentioned in the consent form they may refuse specific

components by crossing it out and printing their initials next to it on the consent form, or by having the study staff mark the consent form according to their instructions.
• Ensure that all optional components of the consent form have been signed and that the participant signs the overall consent document and dates it.
• Record the date and time that the consent document was signed, and sign your name as the person obtaining consent.
• Give the participant a copy of the signed consent document, and keep a copy of the signed consent document in the participant's research file.

Screening Call (before consent)

Phone screening procedures will assess eligibility, including:

- Age 50-80 years
- Diagnosis of type 2 diabetes
- Willingness to wear the CGM and ePatch devices
- Willingness to provide biospecimen samples (blood and urine)
- Willingness to participate in follow-up calls and medical record abstraction

Timing of Consent Process

• The ARIC Gen2 Main Study Consent (including HIPAA authorization) must be obtained at the start of the baseline visit before any research data are collected
• The participant may be given the consent documents to review prior to the in-person visit
• The study staff obtaining consent should allow sufficient time at the visit to review the consent document and address any of the participant's questions or concerns.

Consent Document handling

• Signed consent documents are legal documents, and should be kept in the participant's clinical center file together with his/her other study forms and documents
• Signed forms are not part of individual's institutional medical record, but part of his/her study record in the ARIC Gen2 study
• Consent documents may be examined during site visits.

Changes to the consent document

• Changes deemed necessary will be made to the consent statement and submitted to the IRB for review and approval by the field site PI and site study coordinator.
• The revised consent, once IRB-approved, will be distributed to site staff, along with a consent version guide summarizing the changes and/or a tracked-changes version of the consent. The revised consent will also be accessible through the IRB.

Participant's change or revocation of consent

• Participants may revoke their consent to use and disclose information at any time by notifying the PI/site study coordinator in writing
• Revocation would not affect information already collected in the study, or information that was disclosed previously
• Participants can change their mind about any of the consent options.
• Any of these changes to consent options should be signed and dated on the consent form and documented on a new form

**Eligibility and Enrollment**

Purpose
To determine whether potential participants meet the eligibility criteria outlined in the protocol and are good candidates for participation in the ARIC Gen2 study

Inclusion criteria
To be eligible for the study, participants must meet all of the following criteria:
• Age 50-80 years (inclusive)
• Fluent English-speaker
• Community-dwelling
• Resident of the local area and not planning to move within the next four years
• History of self-reported physician-diagnosed type 2 diabetes (persons with prediabetes or other forms of diabetes are NOT eligible)
• Willingness to participate and adhere to the protocol, including wearing the CGM and ePatch devices for up to 14 days following the clinic visit and follow-up (semi-annual phone calls and hospital chart review) for at least 4 years
• Willingness to provide biospecimen samples (blood and urine) at the visit
• Willing and able to return the CGM and ePatch devices in a pre-paid mailer following the 14-day wear period
• Willingness to provide consent and information needed for participation in follow-up phone calls and medical chart abstraction

Exclusion criteria
• Current participation in the ARIC Study (ARIC participants with diabetes will be recruited for this ancillary through their normal clinic visits)
• Dementia or otherwise deemed unable to consent for themselves
• Living in a nursing home or a long-term care facility
• Implantable medical device such as a pacemaker or neurostimulators
• History of allergic skin reaction to adhesive tape
• Planning to move out of the local area within the next four years

Note: No participants are excluded on the basis of race/ethnicity or sex.

**Recruitment and Retention**

Integration within the existing ARIC Study
The ARIC Study is a large prospective cohort study that initially enrolled 15,792 participants aged 45-64 years at the four Field Centers. The Jackson cohort enrolled entirely African American adults. Approximately 15% of participants enrolled in ARIC at the Forsyth County site were African American adults. The participants enrolled at the two other Field Centers were primarily white adults. ARIC participants have received multiple assessments of cardiovascular and diabetes risk factors and cognitive measures over the past 30+ years. The ARIC Study is well-described with over 2000 published manuscripts in peer-reviewed journals. Details of the ARIC Study design have been published and can be found at:
https://sites.cscc.unc.edu/aric/description

Visit 10 of the ARIC Study is scheduled to start in December 2022. We aim to start recruitment for the ARIC Gen2 cohort at Visit 10. The ARIC Gen2 study will be nested within the existing ARIC Study and clinic visits for ARIC Gen2 participants will occur in parallel with ARIC participants. We will recruit proxies, family members, and friends of currently enrolled ARIC

participants. We will expand outside of ARIC (community-based recruitment) if needed to meet enrollment goals.

Recruitment for ARIC Gen2

Recruitment will be based at the four established ARIC field sites (Washington County, MD; Jackson, MS; Forsyth County, NC; Minneapolis Suburbs, MN). We will leverage the current contact with ARIC participants during to recruit family members and proxies (with a potential expansion to friends and neighbors) with **a history of diagnosed type 2 diabetes**, age 50-80 years old, community-dwelling, and fluent English-speakers. Each of the four field centers will target to recruit approximately 100 ARIC Gen2 participants (total N=400).

Recruitment strategies

Recruitment will be coordinated with current ARIC activities (phone calls, mailings) to reduce burden on the Field Center staff and participants.

1) We will make inquiries during the currently scheduled semi-annual follow-up phone calls with current ARIC participants to ask them if they may have a family member, friend, or neighbor who might be eligible and interested in participating
2) We will recruit proxies who accompany original ARIC participants to the clinic during ARIC Visit 10 – distribution of informational fliers
3) Staged postcard mailings to current ARIC participants and proxies to invite proxies, family members, friends, or neighbors to participate; these can be sent out in small batches (n=~50 to avoid influx and spread out work). We can follow-up with these individuals by phone.
4) Expand outside of proxies if needed to improve response rate

We will allow for flexibility regarding approaches depending on Field Center preferences

All recruitment materials are reviewed and approved by the IRB prior to use.

**Participant Screening**

Screening Data Capture (Ripple Software or similar)

- Eligibility
- Date of birth
- Name
- Mailing address
- Home phone
- Mobile phone
- Other phone (if applicable)
- Email
- Proxy name, address, phone
- Proxy relationship
- Family member already in ARIC Study
- Relationship to family member in ARIC Study
- Scheduling

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

Questions people might ask about why you are calling, and some 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.

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 [give name of academic institution] about a medical study of diabetes we are conducting."*

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

*"Do you have 10 minutes or so to hear about the study."*
If **yes**, continue to Screening Script.
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."*

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 [Name of Institution], 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.*

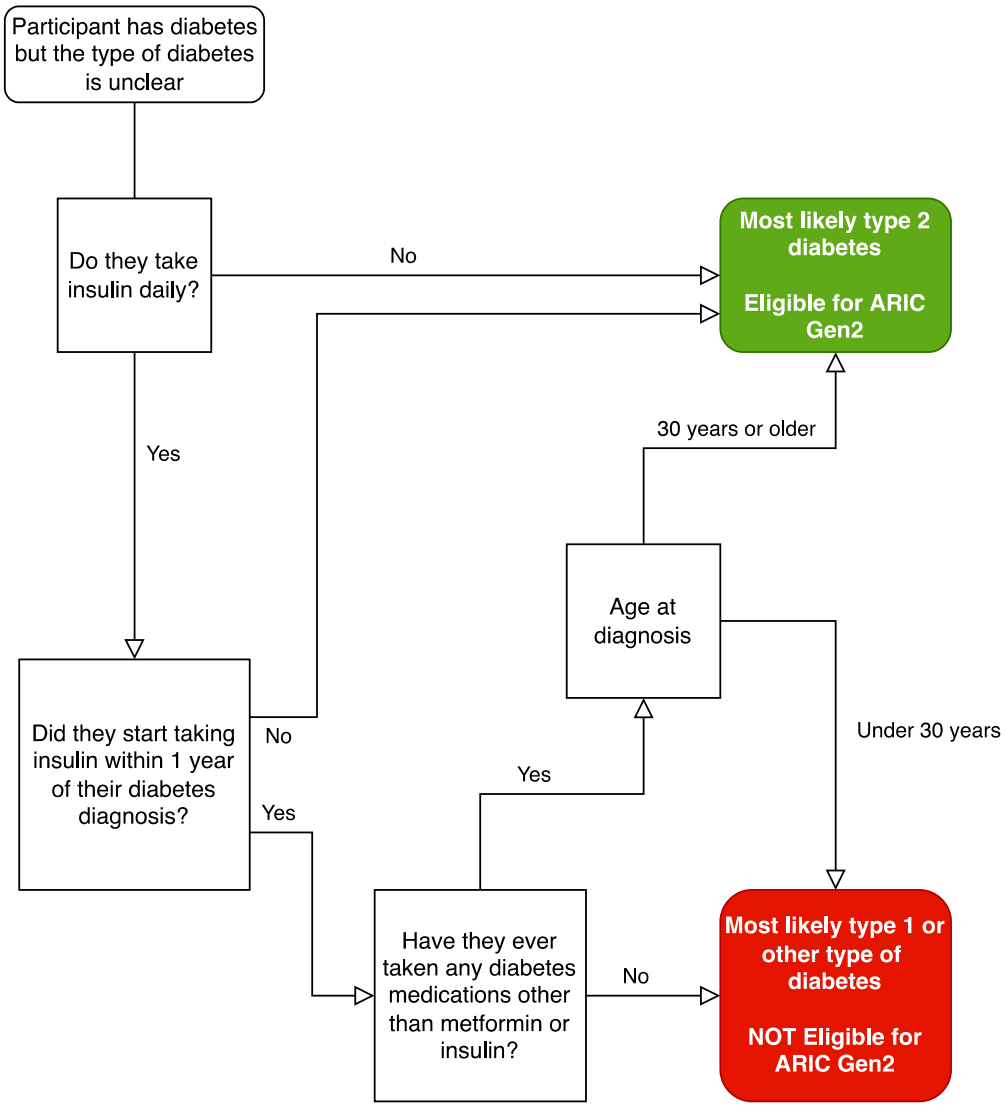
*"Your personal information will not be kept if you choose not to enroll in the study or if you do not qualify to be in the study."*

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 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. 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.




For participants who report a history of type 2 diabetes, *"This 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."*

<u>If eligible:</u>
*"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.

See **Appendix** for information on the CGM and ePatch devices.

*"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 of 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 the clinic examination, and some 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."**

Pre-exam mailing and phone call to eligible participants

To enhance response following the scheduling telephone call by study staff, mail the participant a packet prior to the scheduled appointment. This pre-appointment packet confirms the examination date and time and reviews preparation procedures. Prior to the examination, contact the participant with reminder calls.

**Retention**

To maximize adherence to study procedures and minimize loss to follow-up, only those participants determined by study personnel to fully understand the commitments of the study and are likely to follow the study protocol including wearing of the CGM and ePatch devices for up to 14 days will be enrolled. Individuals who are likely to move out of the area within the next four years will not be enrolled in the study. The following procedures are implemented to enhance retention:

When scheduling the clinic visit, ask participants about:
• Preferred time and date of examination
• How participants prefer to get the clinic visit
• Need for assistance getting to or moving around the clinic
• Existence of any medical conditions (e.g., dietary restrictions, amputation, impaired hearing or vision) which might affect the examination and/or type of snack provided
• Timing of any upcoming travel, procedures, or tests (i.e., CT scan, MRI) that might interfere with the participant's ability to wear the CGM and ECG sensors for the 14 day period

Free parking is provided to all participants. Participant study incentives will include study-related items (pens, bags, mailed holiday cards) and a modest payment when the CGM and ePatch devices are returned to the clinic ($25 per device for a total of $50 for the return of the two devices). We will also compensate for completion of other aspects of the protocol. The total compensation will vary by field center.

Contact participants by telephone to reschedule the appointment if eligible participants fail to arrive for a scheduled appointment or cancel their appointments. Try to address any concerns the participant may have, and address barriers to participation during this call.

Each no-show case will be individually reviewed by the interviewer and, when necessary, by the supervisor. Efforts to engage the participant will include a combination of telephone contacts, letters, and the possibility of offering an abbreviated exam. Field site staff, in consultation with the study coordinator and/or field site PI and/or quality control committee, will determine how

long to continue contact efforts. A participant will only be considered 'withdrawn' if they explicitly request to withdraw from the study.

**Follow-up**
We will conduct semi-annual calls and hospital chart review following current ARIC procedures. Information need for participant tracing, including social security number, will be collected at the clinic visit following consent.

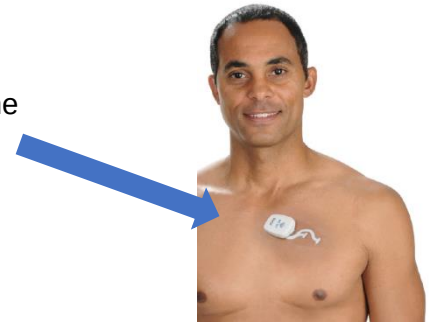
**Summary of ARIC Gen2 Visit**

| Procedure/Form | Visit 10 Time (min) | ARIC Gen2 Time (min) |
|---|---|---|
| Consent, HIPAA, Update (CIU), Safety (PSA), IC tracking (ICT) | 10 | 20 |
| Imaging Recruitment | 12 | -- |
| Medications Survey Part 1 and 2 (MSR) | 5 | 5 |
| Sitting Blood Pressure (SBP) | 10 | 10 |
| Anthropometry (ANT) | 4 | 4 |
| Biospecimen (BIO): Blood Draw (non-fasting), Urine Collection | 15 | 15 |
| Demographics (DEM), Medical History (MHX) | | 10 |
| Neuro Block A + Trails A & B (ESU, MME, NCS, CDP) | | 25 |
| Audiology (AUD) + Hearing Handicap Inventory (HHI) | 23 | -- |
| Hearing and Noise Exposure - Short Form (HNES) | 5 | -- |
| Grip strength, chair stands, balance, 4m walk (PFX) | 15 | 15 |
| Two Minute Walk (TMW) | 5 | -- |
| Zeno Gait Mat (ZGM) | 10 | 10 |
| Smoking and Alcohol Use (ALC) | 0 | 5 |
| Physical Activity Questionnaire (PAC) | 7 | 7 |
| Pregnancy and Reproductive Health (women only) RHX | | 5 |
| Continuous glucose monitoring + ePatch (REQUIRED) | | 15 |
| BP Ancillary Studies: OH, HBPM, ABPM (low priority) | 35 | 35 |
| Ancillary Study: Peripheral Neuropathy | 30 | 30 |
| End of Visit Review—Summary of Results (RAR) | 10 | 10 |

Note: Times for visit components in ARIC Gen2 are likely conservative (based on ARIC participants who are older and more likely to have cognitive and physical impairments).

**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.

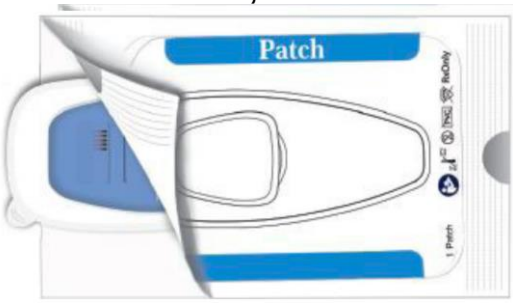
**Figure 1. Examples of people wearing the CGM sensor**

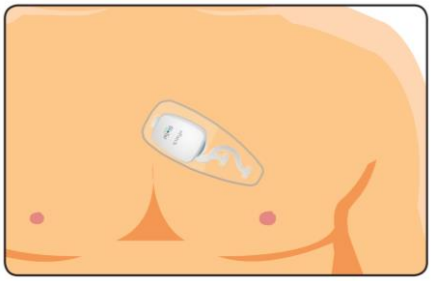
There is minimal risk or discomfort associated with the use of CGM sensor. The main risk is skin irritation.

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/