



INSTRUCTIONS FOR THE PARTICIPANT SAFETY SCREENING FORM (PSA)

I. General Instructions

The Participant Safety Screening Form is completed prior to the visit, either during scheduling or during the reminder phone call. That way, the information is current in the CDART database as the site is preparing for the clinic visit. The information should be reviewed and verified with the participant just before or just after administering the informed consent. Because this form collects information that might exclude a participant from a certain component or measurement that is offered at the visit, it is important to review eligibility based upon the questions in the PSA prior to starting the visit.

The instructions in this QxQ also apply for the ARIC Generation 2 Study. However, the PSA information will not be used in the Participant Visit Snapshot Report for that study since that report is not used for ARIC Generation 2.

Following an explanation of the ARIC exam, the interviewer requests an opportunity to verify the individual's eligibility for all procedures. The presence of conditions or special needs recorded on this form initiates a series of steps to ensure the participant is excluded from contraindicated procedures, and that any special needs are met to the extent possible to accommodate the participant at the visit. These steps include:

- Recording the information in the PSA directly into CDART
- Informing the participant of which procedures to avoid
- Running the Participant Snapshot report [or the XX report – which could be either 'exclusions' or 'inclusions' / 'ineligible' or 'eligible' for certain visit components – really depends on what the field center staff find most helpful for how they operate] in CDART in advance of the visit, **after** the reminder phone call and the PSA information has been collected and entered in CDART
- Verifying the information in the PSA with the participant before the exam begins
- Placing a sticker on his/her name tag to ensure study technicians are aware of the contraindication or need
- Noting any exclusions/contraindications on the Exam Itinerary Checklist for routing purposes during the exam.

The Participant Safety Screening form should be entered directly into CDART as it is collected. If paper must be used, then the form must be keyed into CDART within 24 hours of data collection. Note that failure to exclude participants who are contraindicated for portions of the examination constitutes a protocol violation or deviation.

When the PSA is verified before the exam begins, if any changes are needed, make those updates in the existing occurrence of the form in CDART. Do not create a new occurrence of the form.

Once the PSA is keyed into CDART, the responses are reflected in the Participant Visit Snapshot report in CDART. The pertinent information should also be recorded on the Exam Itinerary Checklist.

Printing the [ppt snapshot / xx report] **after** the PSA form is entered in CDART (not before) is critical to ensuring that ineligible participants are excluded from certain visit components.

II. Detailed Instructions for Each Item

1. *Are you on any medication for diabetes or any other medication prescribed by a physician that needs to be taken on a schedule?*

Record whether the participant is taking medication for diabetes or any other prescribed medicine that needs to be taken on a schedule. If the answer is 'Yes', then record the details (that will be helpful for clinic staff to know) in item 1a in CDART.

Any medication taken routinely by the participant – on any scheduled – is recorded as 'Yes'. Only medications that are taken occasionally are recorded as No. The purpose of this question is to prompt ARIC staff to review the medications taken on a schedule at the time the visit is scheduled. As described in Manual 2, the participant is then asked to take specific medications on their prescribed schedule, or to defer others until after the blood draw. At the time the participant's visit is scheduled and/or at reception after signing the informed consent, arrangements are made for the participant to have access to medication that needs to be taken in the course of the exam at set time, and with food if required.

2. *Do you need any other medical support that we should be aware of?*

Answer 'yes' if the participant has special needs, and record in 2a (such as a wheelchair or walker).

3. *Do you have either a heart pacemaker or defibrillator (AICD)?*

An answer of 'Yes' is an exclusion to the BIA machine. BIA devices pass a low-level electrical current through the body. Although the current is typically harmless for most individuals, it could interfere with certain electronic or electrical implanted medical devices, especially those that rely on bioelectrical signals or battery-dependent regulation. The Tanita scale should also be set to "weight only" mode for participants with these devices or other internal electronic devices.

Category	Device Example	Contraindication Rationale
Cardiac Devices	Pacemaker	Potential interference with cardiac rhythm control
	Implantable cardioverter defibrillator (ICD)	Risk of inappropriate shock or failure to deliver therapy
	Cardiac resynchronization therapy device (CRT-P/CRT-D)	Interference with synchronized pacing
Neurological Implants	Deep brain stimulator	Interference with neuromodulation signals
	Vagal nerve stimulator	Altered vagal tone regulation
	Spinal cord stimulator	Pain or movement control interference

Insulin Delivery Devices	Implanted insulin pump (e.g., Medtronic MiniMed)	May misfire or fail due to electrical signal interference
Cochlear Implants	Cochlear implant	Unknown effects on implant electronics
Other Electronic Implants	Retinal implant	May be affected by low-current electrical fields
	Sacral nerve stimulator	Neuromodulation disruption
	GI electrical stimulation device	Electrical interference with digestive stimulation

4. *Do you have a history of skin allergic reaction to adhesive tape?*

An answer of 'Yes' is an exclusion to the CGM study.