



Participant Safety Screening Form

ID NUMBER:

FORM CODE:

DATE: 04/21/2016
Version 3.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: / /
Month Day Year

0b. Staff ID:

Instructions: This safety screening form should be administered during the appointment reminder call and again prior to the exam. Positive responses to Questions 1 – 4 should be noted on the Exam Itinerary Checklist for routing purposes during the visit.

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

Yes y → **Report on Exam Itinerary Checklist**
No n → **Go to Item 2**

1a. If yes, details: _____

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

Yes y → **Report on Exam Itinerary Checklist**
No n → **Go to Item 3**

2a. If yes, details: _____

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

Yes y → **Report on Exam Itinerary Checklist**
No n

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

Yes y → **Report on Exam Itinerary Checklist**
No n



INSTRUCTIONS FOR THE PARTICIPANT SAFETY SCREENING FORM (PSA)

I. General Instructions

The Participant Safety Screening Form is completed prior to (e.g., during a reminder phone call for the clinic visit) or at the time of the examination. It is recommended that staff with some clinical knowledge administer this form, since probes to positive responses which would exclude someone might need to be implemented and documented.

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 V6 Participant Snapshot report 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.

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 V6 Participant Snapshot report in CDART. The pertinent information should also be recorded on the Exam Itinerary Checklist.

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 Section X.X of 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 wheel chair or walker).

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

An answer of 'Yes' is an exclusion to the BIA machine. The Tanita scale should also be set to "weight only" mode for participants with these devices.

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

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