

OMB#: 0925-0281
Exp. 3/31/2014



Participant Safety Screening Form

ID NUMBER:

FORM CODE:

P	S	A
---	---	---

DATE: 09/01/2011
Version 2.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: / /
Month Day Year

0b. Staff ID:

Instructions: This safety screening form must be completed immediately prior to the exam. Positive responses to Questions 1 – 6 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 → **Report on Exam Itinerary Checklist**
No

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

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

If this is a home visit: Save and close the form. **If this is a clinic visit,** continue to question 3.

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

Yes → **BIA, Bronchodilator Exclusion**
No

4. Has a doctor or health professional ever recommended that you not take albuterol? Albuterol is also called Ventolin, Proventil, Maxair, or Combivent (when combined with another medicine called ipratropium).

Yes → **Bronchodilator Exclusion**
No

5a. Have you had a heart attack, stroke, eye surgery, or surgery to your chest or abdomen in the last 6 months?

Yes → **Pulmonary Test Exclusion**
No

5b. Have you been told by a doctor that you had bleeding inside your eye or the retina, or a tear or detachment to your retina?

Yes → **Pulmonary Test Exclusion**
No

6. Have you ever had a repair of your aorta -- the big artery in your abdomen? A repair may have been done for an aneurysm (ballooning) of the aorta, or for a leak or tear of the aorta, or for blockage in the aorta due to hardening of the arteries.

Yes → **Aortic Scan Exclusion**
No → **End of Form**

6a. Was this done by a surgery to your abdomen or with a graft inserted into an artery in your groin?

Surgical repair → **Aortic Scan Exclusion**
Endograft repair → **Aortic Scan Exclusion**



INSTRUCTIONS FOR THE PARTICIPANT SAFETY SCREENING (PSA) FORM

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 so that questions can be answered appropriately and that probes to positive responses which would exclude someone can be fully 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 recorded on this form initiates a series of steps to ensure the participant is excluded from contraindicated procedures, including informing the participant themselves of which procedures to avoid and placing a sticker will be placed on his/her name tag to make the study technicians aware of this during the field center examination. Positive responses to Questions 1 – 6 should be noted on the Exam Itinerary Checklist for routing purposes during the visit.

The Participant Safety Screening form should be entered into the ARIC study data management system within 48 hours after collection. Note that failure to exclude participant's that are contraindicated for portions of the examination constitutes a protocol violation.

II. Detailed Instructions for Each Item

1. 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, report this on the Exam Itinerary Checklist. Any medication taken routinely by the participant – on any schedule – 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 with the participant at the time the clinic visit (or home visit) is scheduled. As described in Section 5.5 of MOP 2, the participant is then asked to take specific medications on their prescribed schedule, or to defer others until after the blood draw during the exam visit. At the time the participant's visit is scheduled and/or at Reception after signed 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 times, and with food if required.
2. Record whether the participant needs any other medical support. If the answer is yes, report this on the Exam Itinerary Checklist.
3. Record whether the participant has a pacemaker or defibrillator. If the answer is yes, the participant must be excluded from the BRI and Bronchodilator.
4. Record whether a doctor has ever recommended that the participant not take albuterol. If the answer is yes, the participant must be excluded from the Bronchodilator.
- 5a. Record whether the participant has ever had a heart attack, stroke, eye surgery, or surgery to the chest or abdomen in the past 6 months. If the answer is yes, the participant must be excluded from the Pulmonary Test.
- 5b. Record whether the participant has ever been told by a health professional that she/he had bleeding inside the eye or the retina, or a tear/detachment of the retina. If the answer is yes, the participant must be excluded from the Pulmonary Test.

6. Record whether the participant has ever had a repair to the aorta. If the participant answers yes, probe for enough detail to understand the procedure. Record simple angioplasty or stent as 'No'. Record an aneurysm or atherosclerosis without surgery as 'No'. If the true answer is yes, exclude them from the Aortic Scan. If the participant does not know, probe the participant further by describing that a repair of the aorta would have involved either making an incision into the abdomen or flank (surgical repair), or using an endograft placed through a catheter inserted into an artery in the groin (endograft repair).