



# PROCEDURE COMPLETION FORM

ID NUMBER:

FORM CODE:

DATE: 06/01/2011  
Version 1.0

*The purpose of this form is to indicate when procedures were completed; specifically ECHO, ECG, Spirometry, PWV/ABI and MRI. Local alerts are noted in this form for ECHO, ECG and MRI.*

## PROCEDURE: Echocardiography

1. Was the echocardiography exam performed? Yes   
No  → **GO TO QUESTION 5**

2. Date of Procedure: / /   
Month Day Year

3. Staff ID:

4. Were any alert conditions noted?  
 Yes →→→ Specify Alert: \_\_\_\_\_  
 No Action Taken: \_\_\_\_\_

## PROCEDURE: Electrocardiogram

5. Was the 12-lead electrocardiogram performed? Yes  → **GO TO QUESTION 6**  
No

If not, why not?  hardware malfunction or lack of supplies → **GO TO QUESTION 10**  
 insufficient time available or room not available → **GO TO QUESTION 10**  
 other → **GO TO QUESTION 10**

6. Date of procedure: / /   
Month Day Year

7. Staff ID:

## 8. Heart square measurements:

O-E .

O-V6 .

9. Were any alert conditions noted?  
 Yes →→→ Specify Alert: \_\_\_\_\_  
 No Action Taken: \_\_\_\_\_

**PROCEDURE: Pulmonary Function**

10. Was the pulmonary function exam performed? Yes   
No  → **GO TO QUESTION 13**

11. Date of Procedure: //  
Month Day Year

12. Staff ID:

**PROCEDURE: Pulse Wave Velocity / ABI**

13. Was the pulse wave velocity exam performed? Yes   
No  → **GO TO QUESTION 16**

14. Date of Procedure: //  
Month Day Year

15. Staff ID:

**PROCEDURE: MRI**

16. Was the MRI performed?

- .....Yes, Completed → **GO TO QUESTION 17**
- .....Attempted, but incomplete → **GO TO QUESTION 16b**
- .....Not attempted

a) Not attempted (reason):

- 1.....No show → **SAVE AND CLOSE FORM**
- 2.....Rescheduled → **SAVE AND CLOSE FORM**
- 3.....Refused to sign informed consent form → **SAVE AND CLOSE FORM**
- 4.....Other, specify: \_\_\_\_\_ → **SAVE AND CLOSE FORM**

b) Attempted but incomplete MRI (reason):

- 1.....Claustrophobia → **SAVE AND CLOSE FORM**
- 2.....Other, specify: \_\_\_\_\_ → **SAVE AND CLOSE FORM**

17. Date of Procedure: //  
Month Day Year

18. Staff ID:

19. Were any alert conditions noted?

Yes    →→→ Specify Alert:  
 No        Action Taken:


**SUMMARY REPORT SENT TO PARTICIPANT**

20. Was a copy of the Summary of Results report sent to the participant?

Yes   
No

21. Was the report a full or partial report?

Full   
Partial

22. Date the report was sent:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			



## INSTRUCTIONS FOR THE PROCEDURES COMPLETION (PRO) FORM

### I. General Instructions

The Procedures Completion Form (PRO) is designed to: (a) track which component exam procedures were performed for the participant; (b) provide local alert/referral information for the echocardiography, 12-lead electrocardiogram, and MRI; and (c) track the status of the Summary of Results report.

Field center staff are responsible for obtaining and entering the procedure completion status as well as any possible alert/referral information from the technicians and local lead medical personnel (e.g., local MRI radiologist). Staff members are also responsible for tracking and entering the status of the Summary of Results report.

This form may be accessed more than once, since exam component procedures may not be completed on the same day and the data from the central labs and reading centers will not be available for up to 5 weeks after all related component procedures are performed and data/specimens send to the central agencies. Consequently, field center staff should determine whether a copy of this form previously has been entered in the DMS before attempting to enter a new form.

The study participant does not need to be present when this form is completed, although it is likely that much of the form will be completed while the participant is undergoing his/her exam procedures. The information required is gathered at the time of the study visit as well as after results have been obtained from local specialists (e.g., echocardiography, ECG, or MRI).

### II. Detailed Instructions for Each Item

- 1 – 4b. (Echocardiography): Record whether the echocardiography component was performed (Item 1), the date when it was performed (Item 2), and the technician staff ID number of the technician who performed the echocardiography component (Item 3). Obtain from the technician or lead medical staff member the information on whether any alert conditions were seen in the scan (Item 4), the details of the alert (Item 4a), and what step(s) were taken to address the alert conditions (Item 4b). If any problems occurred during the echocardiography procedure, document the problems in a note log for Q1.
- 5 – 9b. (12-lead electrocardiogram (ECG)): Record whether the ECG component was performed (Item 5), the date when it was performed (Item 6), and the technician staff ID number of the technician who performed the ECG (Item 7). Record the heart square data (Items 8a and 8b). Obtain from the technician or lead medical staff member the information on whether any alert conditions were seen during the procedure (Item 9), the details of the alert (Item 9a) and what step(s) were taken to address the alert conditions (Item 9b).
- 10–12. (Pulmonary Function): Record whether the pulmonary function component was performed (Item 10), the date when it was performed (Item 11) and the technician staff ID number of the technician who performed the pulmonary function component (Item 12). If any problems occurred during the pulmonary function test, document them in a note log for Q10.
- 13–15 (Pulse Wave Velocity/ABI): Record whether the pulmonary function component was performed (Item 13), the date when it was performed (Item 14) and the technician staff

ID number of the technician who performed the pulmonary function component (Item 15). If any problems occurred during the PWV/ABI procedure, e.g., the transducer failed and incomplete measurements were obtained, document the problem(s) in a notelog for Q13.

- 16–19b. For a participant excluded from MRI [based upon at least one response of 'Yes' on the MRI Exclusion Form (MEF)], PRO questions 16-19 can be left blank. Only participants who are selected for Stage 3 AND who are eligible for MRI based upon the MEF should have PRO items 16-19 completed.

For those who are not excluded, record whether the MRI (MRI) was performed (Item 16), the date when it was performed (Item 17), and the technician staff ID number of the technician who performed the MRI (Item 18).

If any images were obtained, record as completed in item 16. This will allow you to enter the date of procedure to be matched with the reading center data.

Obtain from the technician or local MRI radiologist the information on whether any alert conditions were seen during the procedure (Item 19), the details of the alert (Item 19a) and what step(s) were taken to address the alert conditions (Item 19b). If any technical problems occurred during the MRI, record them in a note log for Q16b.

The Scheduling Report for Stage 3 (MRI) in CDART DMS requires that the RTS form, Section D, reflects the current participant status for those eligible for MRI. Thus, for the following question, update the RTS with the appropriate response as follows:

- 16. a) No show ..... update the RTS with “G”
- Rescheduled ..... update the RTS with “B”
- Refused to sign informed consent form ..... update the RTS with “C”
- Other, specify ..... update the RTS with the status that is most appropriate

- 20–22. (Summary Report): These items should only be completed under two sets of circumstances: the first is when a participant requests a copy of his/her summary of results report (even if the report is incomplete), and the second is when the data needed for the report is complete. Consequently, there is a chance that this section may be completed twice – once when the partial report is sent to the participant, the second time when the results are complete. Do not enter a new form to document the second time; instead, update Items 20 through 22 to reflect the final date that the full summary of results report was sent to the participant.