



INSTRUCTIONS FOR THE MEDICAL CONDITIONS UPDATE FORM (05/10/2019) (MCU, VERSION 2, 07/30/2014)

I. General Instructions

The purpose of the MCU form is to provide a single place to record updates on select medical conditions. The ARIC study continues its interest in collecting data on the FIRST time a participant reports that a physician told them they had each of the 10 medical conditions on the form. Only the questions for conditions that do not already have a Yes answer (with heart failure and weak heart questions being one combined condition) should be asked at each call. This form is not completed for deceased participants.

MCU version 2.0 has been uploaded into CDART and all data previously collected from condition questions in the AFU, SAF and GEN forms, as well as MCU version 1.0, has been propagated to version 2.0, OCCURRENCE 5. The MCU is a single occurrence form. Open the same occurrence of the form at each AFU or SAF interview. There will not be an MCU form available to update in the instance when a participant has NEVER historically reported any of the medical conditions listed on the form. In the instance where there is not an MCU form available to update, open the MCU form and add data as usual. The OCCURRENCE number of new MCU records will be 1.

The condition questions that need to be answered on the MCU form at each AFU or SAF interview are the ones that are either blank or filled with No answers. If the condition question is blank, it should be updated to either Yes or No, depending on the answer given by the participant. If the condition question is already filled with Yes, tab through to the next condition. If the answer to the heart failure/weak heart condition is already prefilled with Yes when the form is opened to update, then tab through the associated questions, items 8a through 11b. An instruction has been loaded into item 8a ('Tab to Q12, 8a-11b BLANK') reminding the interviewer to leave items 8a through 11b alone if the participant has previously reported heart failure/ weak heart.

While completing the MCU, interviewers may need to request authorization to contact the participant's physician for information on a heart failure/weak heart diagnosis. When the participant reports that he/she has been diagnosed for the first time as having heart failure/weak heart by a physician during the time frame specified in the AFU or SAF, the interviewer initiates the process that enables ARIC to send that physician a request to complete the Physician Heart Failure Survey Form (PHF).

Consent to Release Protected Health Information

The PHF form is sent to each physician to whom the participant provides consent to release medical information to ARIC. An example of the Consent to Release Protected Health Information document is provided at the end of these QxQ instructions (Appendix 1). In addition, consent for access to the participant's medical records is also needed to investigate admissions to emergency rooms or admissions to hospitals that are located outside of the ARIC Study Areas. If consent to access medical records was given by the participant or their proxy at Visit 5, that is sufficient permission for this purpose. Cohort participants who did not participate in Exam 5 will need to provide a signed medical release if their response to the AFU determines the need to contact their care provider.

II. Detailed Instructions for Each Item

Administrative information

- 0a. Enter the date of contact or the date the form is last updated in DMS. This field will be overwritten each time the form is completed.
- 0b. Enter the staff ID of the telephone follow-up interviewer who last updates this form. This field will be overwritten each time the form is completed.

- 0c. Enter whether the participant or the proxy/informant is being interviewed. This field will be overwritten each time the form is completed.

Section I

This section is asked of the participant only. If the proxy/informant/other person is contacted and the participant is reported to be alive, go to section 2, item 6.

1. Ask the participant whether a doctor told them they had high blood pressure since their last contact.
- 1a-b. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have this condition. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview.
2. Ask the participant whether a doctor told them they had diabetes since their last contact.
- 2a-b. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have this condition. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview.
3. Ask the participant whether a doctor told them they had chronic lung disease since their last contact. Chronic lung disease includes COPD (chronic obstructive pulmonary disease), chronic bronchitis, emphysema, bronchiectasis, and pulmonary fibrosis.
- 3a-b. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have this condition. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview.
4. Ask the participant whether a doctor told them they had asthma since their last contact.
- 4a-b. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have this condition. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview.
5. Ask the participant whether a doctor told them they had peripheral vascular disease since their last contact.
- 5a-b. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have this condition. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview.

Section II

This section is asked of the participant or the proxy/informant. Q6 through Q11b of this section should be skipped if Q6 or Q7 is prefilled with 'Yes', the participant has previously reported heart failure/weak heart.

- 6-7b. These items are only completed for participants who have never reported heart failure or a weak heart. Question 7 refers to heart failure with other terms physicians or patients may use to refer to heart failure. Thus, it is only asked of participants who answer No to question 6 (as specified by the skip).
- 8a-8e. The name of the physician who first indicated that the cohort member has heart failure/weak heart is recorded in question 8a. Note: If the participant previously reported a heart failure/weak heart diagnosis then Q8a will be prefilled with the instruction *Tab to Q12, 8a-11b BLANK*. If the physician's name is unknown or the information is unavailable, enter the name of the clinic, emergency service or hospital service where the encounter took place. In addition to the name of the establishment, indicate whether this is an emergency service, an outpatient clinic, or other facility. A release of medical records is not requested if the physician's name is unknown, nor for

encounters that occurred in an emergency service, an outpatient clinic or a hospital, nor is a PHF form sent.

Record the name and address of the physician's address in items 8a-8d. Then enter the date heart failure or weak heart was diagnosed in month/year format (specific day is not needed) in item 8e. If the participant reports being told by a physician they have heart failure/weak heart during a hospital stay, then the data in items 8b-8d may be repeated in items 11a or 11a1.

Script:

If speaking to the participant: **“The ARIC study would like to ask your doctor to tell us more about your health. If you agree to do this, I will send you a form that tells your doctor that you authorize the ARIC study to get this information. Once you sign that form and mail it back to me, I will contact your doctor’s office.”**

If speaking to the proxy/informant/other: **“The ARIC study would like to ask [name’s] doctor to tell us more about his/her health. If you agree to do this, I will send [name] a form that tells the doctor that [name] authorizes the ARIC study to get this information. Once [name] signs that form and mails it back to me, I will contact the doctor’s office.”**

9. If yes, remember to update the PHF (Physician Heart Failure Survey Form) item 0c once the release form is sent to the participant. When the release form is returned, change answer on PHF item 0c. This will help reconcile the requested and returned releases from the participants. A PHF form is not sent if the physician's name is unknown, nor for encounters that occurred in an emergency service or outpatient clinic (thus, a release of medical information is not requested). In such a case, a special missing value for Item 9 is set to 'Not applicable.'

ARIC now requests a PHF form of all newly reported diagnoses of heart failure/weak heart, whether or not the participant reports being hospitalized at that time. Thus, if the physician's name and location information are known, a release of medical information and a PHF are requested even if the participant responds "yes" to question 10 ("At that time, were you (Was [name]) hospitalized or did you [name] stay in a hospital observation unit? ")

10. Indicate whether the participant was hospitalized for incident heart failure or a weak heart. This includes observation stays in a hospital. "Observation stay" is an administrative term of how an overnight visit is billed. Observation stays are usually less than 24 hours, but they may be up to several days long. Consider only visits that are at least overnight in the hospital or observation area. Admissions to rule out a suspected heart failure/weak heart, as well as discharge diagnoses of heart failure/weak heart, are both coded YES.

- 11a-11b. The term "hospitalized" includes staying overnight or hospital observation in any acute or chronic care facility which excludes nursing homes. Emergency room only or outpatient only visits not involving an overnight stay are coded as NO. If the participant or informant is unsure, doesn't know or can't provide information about the overnight hospitalization(s), enter NO. Select hospital from drop down list. If the hospital is not on the drop down list, enter the hospital name and location. Enter the admission date in month/year format (specific day is not needed).

Items 11a through 11b pertain to the first time a heart failure/weak heart-related hospitalization occurred. Any subsequent heart failure/weak heart-related hospitalizations should be reported on the hospitalizations section of the AFU or SAF.

12. This question specifically asks about a physician-diagnosed atrial fibrillation.

12a-12b. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have this condition. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview.

Script:

If speaking to the participant: **"Since we last contacted you, have you been told by a doctor or health professional that you have:"**

If speaking to the proxy/informant/other: **"Since we last contacted [name], has [name] been told by a doctor or health professional that he/she has:**

13a-13d2. These questions refer to conditions and diagnoses mentioned by the participant's physician or other health professional. Do not define or describe these conditions. If the participant has not heard the term or does not know the meaning of the condition, enter as No. Enter the date and contact year that the participant tells you 'yes' a doctor told them they have the conditions. This date is not the date the participant was told they had the condition, but is the date of either the AFU or SAF interview. Other health professional can include nursing home health care staff familiar with the participant's medical history.

CLOSURE SCRIPT:

"Thank you very much for answering these questions. You have previously provided us with information on how to contact you. To help us contact you in the future, please tell me if the information I have is still correct."

[Update the CIU form as necessary.]

"Thank you very much for answering these questions. We will call _____ in about six months."

Appendix 1



Consent to Release Protected Health Information

I hereby give my consent for:

_____ *doctor(s) and/or health care provider(s)*

to provide information from my medical records, including treatments and/or hospitalization between: _____ and _____

to the *Atherosclerosis Risk in Communities (ARIC) Study* at the University of _____

Purpose, Restrictions, and Re-disclosure:

The health information that is released will be used only for research purposes by the ARIC study at its Field Center at the University of _____ and the ARIC Coordinating Center at the University of North Carolina at Chapel Hill, and will be held in strict confidence. **All information released WILL NOT be re-disclosed.** I place no limitations on information pertaining to diagnosis and history of illness to be used for research by ARIC.

Revocation Statement and Expiration:

I understand that my participation in ARIC is not conditioned upon signing this authorization and that I may revoke the authorization at any time by requesting such in writing to the ARIC Study Field Center at ____ < **address, phone number** > ____, except to the extent that action has already been taken in accord with this consent. This consent is effective upon signing and shall remain valid for the duration of the ARIC study (2011-2016). A photocopy of this document is as valid as the original.

Name: _____ Date: _____

(PLEASE PRINT)

Signature _____

If legal representative or proxy, sign below and state relationship and authority to do so:

Signature of legal representative/proxy: _____

Relationship/Authority _____ Date _____