QUESTION-BY-QUESTION INSTRUCTIONS FOR MMCC COMMUNITY FINAL DIAGNOSIS FORM (MDX) Community Surveillance Event Version J: 04/07/2016

An MMCC Cohort Final Diagnosis Form (MDX) is completed for each ARIC event that is sent to you as an MMCC reviewer. Please refer, as needed, to the MMCC Case Law Document (Section 5.4 Manual 3) when completing this form.

When you get your case materials, check to see that all available information is included. If the event is a hospital event, a copy of HRAA16 and HRAA22 and/or the discharge summary must accompany the Event Summary Form. If the event involves a death, a copy of DTHA19-21 must be included with the Event Summary Form. For out-of hospital deaths, the availability of narratives from the IFI and COR forms is indicated on the first page of the Event Summary Form.

An autopsy report may be included for cohort surveillance cases only and the availability of this information is also indicated on the Event Summary Form.

If available materials are not included for an event, send the materials back to the MMCC coordinator at the Coordinating Center. Do not attempt to fill out the MDX form with incomplete information.

There are three sections to the MDX form. **Part A** contains administrative information and should be completed for each review. **Part B** is completed by two randomly assigned MMCC reviewers for cohort surveillance hospitalizations. **Part C** is used for death classifications and should be completed for all deaths requiring MMCC review.

For all events, first fill in the Administrative Information section (Part A). In many cases, Batch Number (1.a) and Type of Review (1.b) will be prerecorded to eliminate confusion. Cohort information that may be available to help with diagnosis includes event information, autopsy reports, and ARIC examination and follow-up data.

In some instances, there will be multiple Event Summary Forms and attached materials clipped together. These events are referred to as "linked" events, which are hospitalizations and/or a death that occurred within 28 days of each other. When several events are so linked, EVENT_ID is the ID common to all and is used to identify that set of linked events. The common ID

(EVENT_ID) is listed in the upper left hand side of each Event Summary Form. Use only one MDX Form for linked events occurring within 28 days, as these will be treated as one in analysis. The Coordinating Center (CC) will provide a MDX form for each event already labeled with the EVENT_ID and sequence number.

Instructions for Part A. Administrative Information

1. a. This field will be pre-filled with batch number.

- b. This field will be pre-filled with occurrence number.
- c. Fill in the date of MDX completion.
- 2. This field will be pre-filled with the reviewer code.
- 2b. This field will be pre-filled. Determines the skip pattern for Part B and C.
- 2c. This field will be pre-filled. Indicates whether the event has linked occurrences.

Instructions for Part B. MI Diagnosis

Items 3-5 represent the elements used by the ARIC algorithm for MI diagnosis. For each, circle the letter that correctly characterizes the case under review. For events with a single hospitalization, circle for each

of items 3-5 the letter corresponding to the pain, enzyme, or ECG diagnosis from the Event Summary Form. For linked events, the information on pain, enzymes and ECG contained in the Event Summary Forms may be mixed and matched in answering the respective questions on the MDX. Special cases where HRA question 20 triggers a skip (i.e. no pain, enzyme and ECG information) will result in '*' for pain dx, enz dx, and ecg dx in the Event

Summary Form. (These cases are indicated by a footnote in the Event Summary Form.) For these cases, circle 'A' for pain (MDX3), 'E' for ECG (MDX4), and 'I' for enzyme (MDX5).

3. If the Event Summary Form indicates a possible non-cardiac origin of chest pain (B.1e. =

Y), the pain information will have been reviewed by an MMCC member. The pain criterion may have been downgraded after review as indicated in B1f. Circle "A" if downgraded. If not downgraded, circle the letter corresponding to the pain diagnosis from the Event Summary Form(s) for Hospitalized Events. For linked events, consider pain information from all the Event Summary Forms in determining whether cardiac pain was present.

4. Transcribe the letter corresponding to the ECG diagnosis from the Event Summary

Form(s) for Hospitalized Events items B2a to the Final Diagnosis Form. For linked events, consider ECG diagnoses from all the Event Summary Forms in arriving at the

ECG Diagnosis.

5. If the Event Summary Form indicates possible spurious enzymes to be reviewed (B.3e. =

Y), the enzyme information will have been reviewed by an MMCC member. The enzyme criterion may be been downgraded after review as indicated in B.3f = "ARIC enzyme diagnosis downgraded to Equivocal."

Circle the letter corresponding to the downgraded enzyme criterion if it was downgraded

("E" if changed to Equivocal). If not downgraded, circle the letter corresponding to the

ARIC enzyme diagnosis from the Event Summary Form(s) for Hospitalized Events. For linked events, consider enzyme information from all the Event Summary Forms in determining the appropriate enzyme category.

6. Once questions 3-5 have been answered, save the form and click the arrows in Q6 to run the ARIC algorithm. This is automatically calculated for you.

7a. Review carefully the discharge summary diagnoses, and other attached information to assist you in deciding on the correct MI diagnosis. You may find errors in the algorithm or in abstracted information, or you may find important clinical facts in the discharge summary. If as a result, you do not agree with the ARIC MI diagnosis assigned in Item

6, indicate this fact in Item 7a1. Otherwise circle "Y" in Item 7a, and skip to 7c.

7a1. Record in detail your reasons for disagreement with the ARIC algorithm. Cite the relevant case law, by number, supporting your diagnosis. If no such law exists, propose a new one to cover this and similar cases.

7a2. If disagreeing with the ARIC algorithm, state the relevant case law, as available. 7b. Indicate your preferred diagnosis.

7c. If an Event Summary Form indicates that this event is a death, circle "Y" and proceed to Part C (Death Classification). If the event is not a death, circle "N" and stop.

Instructions for Part C. Death Classification

8. After review of materials pertinent to this event, if, in your opinion, there is evidence that the death was due to a non-atherosclerotic or non-cardiac atherosclerotic process, circle

"Y" for "Yes". Autopsy information may be used to answer this question for cohort surveillance review. If you have responded "Yes" to this item, record the source of evidence by recording the items and forms from the Event Summary Form that provided this evidence. If the item number is not available, record briefly the item content. 9. If a diagnosis of definite MI was assigned in Section B, item 7b (or item 6 if 7b was skipped) and it occurred within 4 weeks of death, circle "Y" for this item. Use autopsy information, if available, to judge whether MI was present within 4 weeks of, or at, death.

Otherwise circle "N" for No. In general, ARIC uses hospital admission date as a surrogate for date of onset of symptoms for the MI, unless the onset of symptoms is after hospital admission.

10. If the death is classified "out-of-hospital" and is not linked to another event, refer to Part B of the "Event Summary for Out-of-Hospital Deaths" and the informant narrative (if any), to determine presence of chest pain within 72 hours of death. Enter that response.

If the death is classified "in-hospital", refer to the Hospital Event Summary Form(s) to determine presence of cardiac pain.

If the death is classified "out-of-hospital" with linked hospitalization(s), combine the information in the "Event Summary Form for Out-of-Hospital Deaths", the informant narrative (if any), and information from the Hospital Event Summary Form(s) to complete this item.

11. After reviewing all available information, including Part D in the Event Summary Form for Hospitalized Events and all special information available for cohort surveillance members, record "Y" for "Yes" if there is evidence of a history of chronic ischemic heart disease, including angina pectoris. If there is clear evidence of neither valvular heart disease nor nonischemic cardiomyopathy mimicking chronic ischemic heart disease, the response to this item is "No". A history of use of medication for angina pectoris may be used as evidence of a history of angina. Autopsy reports and the additional cohort surveillance event information may be used to judge prior history of ischemic heart disease.

12. Review the underlying cause of death code in the header of the Event Summary Form for In-Hospital Events or in Section D of the Event Summary Form for Out-of-Hospital

Deaths. If the code is included among the codes listed in Item 12, circle "Y" for "Yes".

13. Once questions 8-12 have been answered, save the form and click the arrows in Q13 to run the ARIC algorithm. This is automatically calculated for you.

14.a. After reviewing all the evidence, you may feel that a different classification is more appropriate than that specified in Item 13.

If you do not agree with the classification assigned in Item 13, circle "N" for "No",

14a1. Indicate your reason for disagreement in the space provided.

14a2. Cite the relevant case law supporting your diagnosis. If no such law exists, propose a new one to cover this and similar cases.

14b. If you circled "N" in Item 14a, record the letter from the choices in Item 13 that you consider a more appropriate classification.

15.a. If the response to Item 13 is "A" or "B" or "C", circle "Y" and continue to 15.b. If the response to Item 13 is "D" or "E", circle "N" and stop.

b. Using all pertinent information, indicate the interval of time from onset of acute symptoms to death. If time of onset of acute symptoms is unknown, indicate the time interval from point when decedent was last known to be alive and free of symptoms.

Circle the letter corresponding to this interval.