

Responses to OMB comments/questions regarding NIH ICR OMB number 0925-0281

Supporting Statement Part A

Question: Thank you for the summary paragraph on page 2 that describes the revisions that are being requested in this ICR-revision. Can you please provide more detail as to what these revisions will entail?

These would include, but are not limited to, changes to the instruments (e.g., wording, addition of questions, deletion of questions, changes in administration format); changes to an aspect of the protocol (e.g., methods of contacting individuals for follow up); changes to the total number or composition of the respondents, etc. (for example, the footnote on Table A12.2 refers to a “Life course socioeconomic status interview” and reference to 'new procedures or methods in section B.4)

At the beginning of section A.12 it would also be helpful have a summary of any changes in protocol or response rates that lead to changes in burden (the burden tables describe only what is being requested, but not the increases or decreases or the reasons for those changes).

Response: In this ICR-revision, the major change is that more detailed information on heart failure is collected from the cohort members and their health care providers. The specific changes are summarized as below:

- Addition of a few questions in the annual follow-up questionnaire to collect information on diagnosis, hospitalization, and treatment of heart failure (Appendices, page 2, Annual Follow-up Form, items 8–10, 46d). These questions and corresponding procedures are being pre-tested at our field centers by qualified staff first, and then by volunteers in the communities.
- Addition of a one-page form (Appendices, page 3, Physician Heart Failure Form) to collect information on heart failure diagnosis and treatment when a participant reports that a physician has diagnosed heart failure during an outpatient visit within the past 12 months. The form will be mailed to each physician for whom the participant submits an authorization for access to information from the physician's records.
- Reduced number of follow-up interviews of the cohort members (13,050 vs. 11,500) because of deaths, refusal, and lost to follow-up of the cohort members.
- Increased number of physician respondents resulting from the physician surveys on reported outpatient heart failure (see second bullet).

The study will continue to contact the cohort members by telephone. Physical examination will not be conducted during the study period.

We concur with your suggestion and will add the summary of changes stated above to the beginning of section A.12.

Loss to Follow up (Table B1.c.3)

Question: Do you have any plans for changes in the follow up protocol designed to sustain current rates of retention?

Response: Completeness of ARIC cohort follow-up has been high. Therefore there is no plan for changes in the follow-up protocol to sustain the retention. We will notify you if any necessary changes occur in future.

ROCIS/Approval question

Question: The Notice of Action for the last activity shows an “original expiration date of 2/28/07” but the ROCIS entry shows an “actual expiration date” of 4/30/07. Was there an extension or 83-C granted for this ICR between 2004 and now?

Response: The expiration date should be 2/28/07. No extension or 83-C was granted for this ICR between 2004 and now. ICRAS reflects the same information we have.

Burden

Question: The ICR burden table shows a decrease in the number of responses of 795. Are these folks who have passed away or those that you expect to lose to follow up based on previous trends?

Response: Yes, the decrease in the number of responses is mainly due to the deaths, refusal, and lost to follow-up of the cohort members.

Question: The ICR burden table shows an increase in the burden per respondent (an additional 635 hours over all). What is this change in burden associated with? The only notation that we find re a potential change in protocol is a footnote to Table A12.2 regarding a Life course socioeconomic status interview. Is this the reason for the change in burden?

It would seem like the burden should actually be down relative to the last approval since no clinical studies are slated for this three year approval period.

Response: The increased burden hour is mainly due to the addition of heart failure questions and clarifications with physicians, which results in 1) increased time per response from 10 minutes to 15 minutes during follow-up interview and 2) addition of physician contact for out-of-hospital heart failure (5 minutes per response). The life course socioeconomic status was previously added to the annual follow-up form for one-time interview only (can be deleted in this and future requests) and is not a new component. As you suggested, we will add a summary of changes to the beginning of section A.12.

Please let us know if you have further questions or would like further clarifications. We appreciate very much your review and comments.