

Change Request

January 2, 2014

“Salt Sources Study”

(OMB no. 0920-0982, exp. date 09/30/2015)

Summary

CDC is currently approved to collect information in an observational study and validation sub study known as the **Salt Sources Study**. After a review of all procedures and questionnaires and an initial pilot with 4 persons, it was noted that minor changes are required to improve the collection and analysis of home tap water samples; the identification of salt samples; respondent understanding of instructions and satisfaction with participating in the study; and data quality.

Justification and Discussion of Changes

CDC requests modification of procedures, data collection instruments and supporting documents as follows:

1. We will collect a larger amount of home tap water. The amount of water required for analysis is 1/2 cup (about 120 ml) which is much greater than previously expected (10 ml).
2. The Home Tap Water Questionnaire will be asked at the end of telephone recruitment rather than at the initial study visit. Participants who are recruited for the home tap water collection will be asked to bring the water sample with them to the initial study visit. The proposed procedural change does not change burden for these participants, but will reduce costs of study implementation. In the original plan, participants who qualified for the home tap water sample collection were not identified until the initial study visit, and they had to follow up by mailing the water sample to study staff. The proposed change will eliminate the cost of mailing the water specimens. It will entail changes to the Telephone Recruitment and Screening Script (**Attachment 4A**) and the Home Tap Water Questionnaire (**Attachment 10A1**).

In addition, Question #2 on the Home Tap Water Questionnaire (**Attachment 10A1**) will be split into two questions, each with one subpart. In pilot testing, this change did not alter the average burden per response, as most participants do not use water softeners or filtration systems.

3. **Attachment 13A, The Duplicate Salt Sample Collection Form (Non Sub Study Participants)** will be discontinued.
 - a. Instead, the information needed to identify the samples will be collected on labels for the baggies used to collect and transport the duplicate salt samples (new **Att 13A1_Bag Label Salt Added at the Table** and **Att 14A1_Bag Label Salt Added in Food Preparation**).
 - b. Key questions about what meals and food(s) the participant added salt to during home cooking will be moved (added) to the **24-Hour Dietary Recall (Attachment 11A)** as part of the food details.
 - c. The questions about what meal and food(s) the participant added salt to at the table will be discontinued. This information is not required to address the study questions.

- d. The proposed changes will improve data quality and respondent satisfaction.
4. Similar changes will be made for duplicate salt sample collection in the sub study. **Attachment 14A, The Duplicate Salt Sample Collection Form (Sub Study Participants)** will be discontinued.
 - a. The information needed to identify the samples will be collected on the baggies used to collect and transport the duplicate salt samples (new **Att 13A1_Bag Label Salt Added at the Table and Att 14A1_Bag Label Salt Added in Food Preparation**).
 - b. Key questions about what meals and food(s) the participant added salt to during home cooking will be moved (added) to the **24-Hour Dietary Recall (Attachment 11A)** as part of the food details.
 - c. The questions about what meal and food(s) the participant added salt to at the table will be discontinued. This information is not required to address the study questions.
 5. The **Study Orientation instructions (Attachment 9)** will be modified as appropriate for all study participants and the Dietary Recall Scheduling component will be separated into its own form (new **Attachment 8A, Dietary Recall Scheduling Form**). Note: Attachment 8A is completed by study staff and does not entail burden to study participants.
 6. The detail that three 24-hour dietary recalls must be weekdays and one must be a weekend day will be added to the Study Orientation instructions (**Attachments 8 and 9**).
 7. Other minor changes to forms and instructions will improve participant understanding. Revised forms are attached along with the *Itemized List of Changes*. Below is a list of revised and new forms.

Attachments
Att 4A_Telephone Recruitment and Screening
Att 4B_Cover letter for those who could not be reached by phone
Att 4C_Cover letter for phone recruits
Att 4D_Fact sheet
Att 8_Study orientation for Non Sub Study
Att 8A_ Dietary Recall Scheduling Form (new - separates scheduling information from Att 8)
Att 9_Study orientation for Sub Study Participants
Att 10A1_Home Tap Water Questionnaire
Att 12A_Food Record Form
Att 12B_Food Record Instructions
Att 13A1_Bag Label Salt Added at the Table (new - Replaces 13A and 14A)
Att 13B_Duplicate salt sample instructions (Non Sub Study)
Att 13C_Duplicate salt sample instructions for participants (Non Sub Study) (new written instruction sheet provided to participants)
Att 14A1_Bag Label Salt Added in Food Preparation (new -Replaces 13A and 14A)
Att 14B_Duplicate salt sample instructions (Sub Study Participants)
Att 15A_24-hour urine collection form

Att 15B_How to collect urine instructions
Att 17A_Study salt questionnaire
Att 17B_Study salt instructions for participants
Att 17C_Study salt record (to be completed by clinic staff)
Att 17D_Study salt procedures for study staff

Effect of Proposed Changes on the Estimated Burden per Response and Data Collection Instruments

There are no changes to the number of respondents or the estimated average burden per response. The total number of questions on the Home Tap Water Questionnaire has increased and two related questionnaires have been eliminated (the Duplicate Salt Sample Collection Forms for Non Sub Study Participants and Sub Study Participants). Estimation of the burden of data collection related to the duplicate salt sample collection was 10 minutes per collection day and on pilot testing, eliminating the Duplicate Salt Sample questionnaires keeps the duplicate salt collection within this estimate. On pilot testing, other changes in instructions and formats of data collection instruments and supporting documents did not change burden estimates.

CDC plans to begin administering the revised instruments in 2014. OMB approval is requested, effective immediately.

Type of Respondents	Number of Respondents	Form Name	No. of responses per participant	Average Burden per Response	Total Burden (in hours)
Adults aged 18-74 years	225	Telephone Recruitment and Screening	1	10/60	38
		Participant Questionnaire	1	10/60	38
		Discretionary Salt Use Questions from NHANES 2009	1	5/60	19
		Height and Weight	1	10/60	38
		Study Orientation (for non-Sub-study and Sub-study participants)	1	20/60	75
		Home Tap Water Questionnaire	1	5/60	19
		24-Hour Dietary Recall	4	30/60	450

		Food Record Form	4	15/60	225
		Duplicate Salt Sample Collection (for non-Sub-study and Sub-Study participants)	4	10/60	150
	15	Water collection form and instructions	1	5/60	1.25
	75	24-hour urine collection	4	50/60	250
		Follow-up Urine Collection Questionnaire	4	10/60	50
		Study Salt Supplement Questionnaire	3	5/60	19
				Total	1,372