# **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.

1. **Attachment 13A, The Duplicate Salt Sample Collection Form (Non Sub Study Participants)** will be discontinued.
	1. 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**).
	2. 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.
	3. 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.
	4. The proposed changes will improve data quality and respondent satisfaction.
2. 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.
	1. 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**).
	2. 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.
	3. 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.
3. 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.
4. 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**).
5. 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.

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| **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.

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| 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 |