

## ATTACHMENT B: November 2010 Conference Call Notes

Pre-Submission Teleconference Meeting with  
Health Information National Trends Survey (HINTS) Project Team and OMB  
11/29/2010 (Updated 12/9/2010 based on Feedback from NIH/OMB)

### Attendees:

|   |  |
|---|--|
| Margo Schwab (Epidemiologist, OMB)                  | <i>HINTS Project Team Members including:</i> |
| Brian Harris-Kojetin (Statistician, OMB)            | Brad Hesse                                   |
| Mikia Currie (NIH Project Clearance Branch)         | Rick Moser                                   |
| Vivian Horovitch-Kelley (NCI PRA Clearance Liaison) | Teri Davis                                   |
|   | David Cantor                                 |
|   | Kelly Blake                                  |
|   | Lila Finney Rutten                           |

### Margo asked about why lapse in HINTS renewal of OMB clearance?

Brad answered that in past it was a bi-annual survey, occurring every 2 years with OMB clearance. This occurred for three cycles - started in 2001 and ended in 2009. The hiatus occurred because of lack of funding and because they wanted to implement the recommendations from a program evaluation. The new version of HINTS is funded for a 4 year cycle with the first year conducting advance materials testing and a small field test. Then 14,000 participants will be recruited over the next 3 years in 4 separate data collections each connected through some similar, and some new, modules. Additionally, the new version of HINTS was developed to be more inclusive of new technology and moving away from the lengthy process of a bi-annual survey.

### Margo asked whether the goals are the same or different from the previous HINTS?

Brad responded that the goals are the same and that they want to be more responsive to new technology. Additionally, now there is interest by other Federal agencies. These agencies include: Office of National Coordinator (DHHS) and the FDA. ONC has contributed content and the FDA has contributed both funding and content.

### Margo asked the HINTS team to explain the new design.

David responded that they wanted to take into account the long perspective because technology changes so quickly. So there are 4 independent cycles, each with 3500 completed interviews/responses, which makes a total of 14,000 responses. Each respondent is asked to complete the survey once. There is a core content module that will be repeated in all 4 modules and then there will be repeating and new content modules, administered at each of the 4 cycles.

Teri added that the plan is to submit multiple sub-studies under Gordon Willis' generic (#0925-0589) and then submit the full package. Along with the full package they will submit an exhaustive list of questions/items. Then prior to each cycle administration they will test the items using Gordon's sub-study clearance.

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Brian asked what the mode of survey was.

David responded that primarily it is a mailed survey. In the past they did random digit dialing (RDD) vs. Address-based Sampling (ABS, i.e., mail). The ABS outperformed the RDD in terms of better response rates and better data. The HINTS team will continue to do experimentation with the items, varying the way to present items, etc.

Margo asked whether there are single or multiple field tests? Would the goal of the field test would be to refine the wording or to choose content?

Gordon clarified that it is actually a pilot test that is being planned. He explained that there would be just one pilot test to occur prior to the administration of Cycle 1. And Gordon's generic clearance covers pilot testing.

Teri responded that the goal of the pilot test would be to refine the wording. The HINTS community is submitting ideas for new content/questions. Brad added that it was important though to figure out how to add new information/content to the cycles, especially when they are looking out at 2014 and it is difficult to predict now, what will be new content in the future.

Margo asked if they would know about new content 90 days or more in advance of testing?

Brad answered yes, they would know.

Brian said that the HINTS team should plan to:

- 1) Submit a "reinstatement" with as much information about methodology, plans and items/content up front as possible. If possible spell out what modules will be in what cycles, leave blanks for uncertainties. [Viv's note: Submit separate files/attachments for Cycle 1 Questionnaire vs. Cycle 2, etc.].
- 2) Conduct the sub-studies under Gordon's clearance as outlined in the Proposal schedule (10/26/2010). [Viv's note: See modified schedule below based on this conversation]
- 3) Then, if there is a minor change in a single item, or something looks similar to what it was in the past, then it is OK to make the change.
- 4) However, if it is a more substantive change then contact OMB for a teleconference and OMB will decide whether to submit a:
  - a. Non-substantive change request (more than just #3, above)
    - i. Viv's note: This is a memo and yellow highlights to show survey changes.
  - b. Substantive changes in content *with time* then submit a "revision" AT THE SAME TIME that a 60-day is published. Then submit a 30-day Federal Register Notice. OMB will approve the submission once it arrives (i.e., 90 days minimum).
    - i. Viv's note - This is a full submission with highlighting changes in yellow to SSA/SSB and survey changes.

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- c. Substantive changes in content *with no time* (e.g., a new development and/or timely) then submit a “revision” and OMB will agree to waive the publication of the 60-day FRN, and submit the 30-day FRN for publication at the same time the revision is sent to OMB. OMB will approve the submission (i.e., 30-45 days minimum).
  - i. Viv’s note – This is a full submission with changes in yellow to SSA/SSB and survey changes.

### Margo also noted that:

- The reinstatement should cross-reference Gordon’s generic clearance (OMB No. 0925-0589)
- Gordon’s full generic should cross-reference HINTS (OMB No. 0925-0538)
- That Mikia/Vivian should structure the questionnaires so that it would be easy for the public and OMB to see the proposed substantive changes.
  - o [Vivian’s note: Submit separate files/attachments for Cycle 1 Survey vs. Cycle 2, etc. and outlining the different (or same) modules within each cycle.]
- The “Reinstatement” submission could be submitted to OMB before the Cycle 1’s questionnaire is final. Then during the 30-day FRN period a \*final\* version of Cycle 1 Survey can be uploaded to ICRAS and they will review it. We would request that ICRAS and ROCIS be opened for amendment so that the files can be replaced with the revised ones, based on results of testing.

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**ATTACHMENT:** Overall OMB schedule, including both main OMB submissions and generic submissions.

Text in blue is related to substudy submissions

| Date                                | Activity  | Description  |
|-------------------------------------|---|--|
| November 2010                       | Substudy #1 OMB package   | Submit a generic sub-study to conduct focus groups to test the advance materials   |
| December 2010                       | Substudy #2 OMB package   | Submit a generic sub-study to conduct cognitive testing on the Cycle 1 instrument  |
| January 2011                        | Substudy #3 OMB package   | Submit a generic sub-study to conduct a field test   |
| February 2011                       | Substudy #1 initiation  | Conduct the focus groups   |
| March 2011                          | Substudy #2 initiation  | Conduct cognitive tests on Cycle 1 instrument  |
| March 2011                          | Reinstated OMB Package with DRAFT Cycle 1 Survey  | Submit a reinstatement package to NCI and NIH for initial approval for all 4 cycles of HINTS 4; to include list of potential questions for all cycles. |
| April-May 2011                      | <b>60-Day FRN (public comment period)</b>   |  |
| May 2011                            | Substudy #3 initiation  | Conduct field test   |
| June-July 2011<br>(or early August) | <b>30-day FRN (public comment period) and OMB Review</b><br>Add FINAL protocol changes and FINAL Cycle 1 Survey to OMB package already under review   |  |
| October 2011                        | Cycle 1 data collection starts  |  |
| January 2012                        | Substudy #4 OMB package   | Submit a generic sub-study to conduct cognitive testing on Cycle 2 instrument  |
| April 2012                          | Substudy #4 initiation  | Conduct cognitive tests on Cycle 2 instrument  |
| May 2012                            | Cycle 2 Submission Type determined by OMB – Either:<br>• Non-substantive Change Request OR<br>• Revision and either publish 60-day (submit ICR concurrently to OMB) or waiving 60-day FRN, and publish 30-day FRN | Submit Cycle 2 data collection for approval  |
| July 2012                           | Cycle 2 data collection starts  |  |
| October 2012                        | Substudy #5 OMB package   | Submit a generic sub-study to conduct cognitive testing on Cycle 3 instrument  |
| January 2013                        | Substudy #5 initiation  | Conduct cognitive tests on Cycle 3 instrument  |
| February 2013                       | Cycle 3 Submission Type determined by OMB (see Cycle 2)   | Submit Cycle 3 instrument for OMB clearance  |
| April 2013                          | Cycle 3 data collection starts  |  |
| July 2013                           | Substudy #6 OMB package   | Submit a generic sub-study to conduct cognitive testing on Cycle 4 instrument  |
| October 2013                        | Substudy #6 initiation  | Conduct cognitive tests on Cycle 4 instrument  |
| November 2013                       | Cycle 4 Submission Type determined by OMB (see Cycle 2)   | Submit Cycle 4 instrument for OMB clearance  |
| January 2014                        | Cycle 4 data collection starts  |  |

Text highlighted in green indicates agreements made with OMB.