



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

DIVISION OF EPIDEMIOLOGY, SERVICES, AND PREVENTION RESEARCH

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TO: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, HHS
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From: Kevin P. Conway, Ph.D., COR, PATH Study, DESPR
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SUBJ: Non-substantive Change Request for the Population Assessment of Tobacco and Health (PATH) Study (OMB NO. 0925-0664, Expiration Date 11/30/2015)

This is a non-substantive change request for the Population Assessment of Tobacco and Health (PATH) Study to launch its baseline wave on September 10, 2013.

Updates in this package are based on the teleconferences between OMB and PATH Study staff on April 5, 2013, April 25, 2013, and June 10, 2013; on the email from OMB for the PATH Study team on May 15th and the memo in reply sent by the PATH Study on May 29th; and on the follow-up from the June 6th meeting held by OMB on the coordination of tobacco-related information collections.

The attached package includes revised/updated Supporting Statements A and B, and all attachments (including English and Spanish versions of the instruments and materials). We seek OMB's approval by or before July 10, 2013 for the PATH Study to launch the baseline wave on September 10, 2013.

The field test was conducted under OMB No. 0925-0664 (expiration 11/30/2015) from December 6, 2012 to March 6, 2013. The field test was important for assessing PATH Study procedures, instruments and survey materials, and systems under field conditions. Over the period of the field test, in 15 purposively selected primary sampling units (primarily counties), field interviewers completed 1,170 Phase 1 (household) screeners, 698 Phase 2 (individual) screeners, 480 adult extended interviews, 122 youth extended interviews, and 128 parent interviews; in addition, interviewers and/or health professionals collected 350 buccal cell

samples, 249 urine samples, and 187 blood samples. Results of the field test are summarized in Section A.2c in Supporting Statement A and in Section B.4 of Supporting Statement B.

The estimated burden for the baseline wave is 136,889 hours. This is lower than the estimated burden of 138,514 hours reported for the baseline in the original package approved for the field test. The lower number results from a combination of fewer youth and parent interviews estimated for the baseline and refinements made to several instruments based on the field test to reduce burden on participants.

As discussed at the June 10th teleconference, the attached package now includes the PATH Study Field Test Report, which contains a tabular summary of the field test findings and comments on their implications for the baseline (Attachment 2 of Supporting Statement A). Based on the field test findings, and as discussed at the June 10th teleconference, an attachment has been added (Attachment 22 of Supporting Statement B) on the precision calculations under the best- and worst-case scenarios in the baseline wave. A new paragraph has also been added in the duplication section (A.4) regarding efforts by the PATH Study to coordinate and harmonize its data collection activities with those of other tobacco-related survey studies within HHS.

We look forward to receiving your response to this non-substantive change request. In the meantime, please feel free to contact me, if you have any questions about the request.