



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

DIVISION OF EPIDEMIOLOGY, SERVICES, AND PREVENTION RESEARCH

National Institute on Drug Abuse
6001 Executive Boulevard
Room 5160, MSC 9589
Bethesda, Maryland 20892-9589
(301) 443-6504

DATE: April 28, 2014

TO: Office of Management and Budget (OMB)

Through: Report Clearance Officer, HHS
Project Clearance Chief, NIH
Project Clearance Liaison, NIDA

From: Kevin P. Conway, Ph.D., NIDA

SUBJ: Non-Substantive Change Request to Discontinue Buccal Cell Collection in the Population Assessment of Tobacco and Health (PATH) Study (OMB NO. 0925-0664, Expiration Date 11/30/2015)

The National Institute on Drug Abuse (NIDA) requests OMB approval to discontinue buccal cell collection during the 8th month of the PATH Study's baseline wave.

The PATH Study is beginning its 8th month of the baseline wave of data and biospecimen collection. An ongoing review of its three biospecimen collections (urine, blood, and buccal cells) indicates the cost of buccal cell collection outweighs its benefit to the overall research effort. The cost to the Study of the buccal cell collection is projected to be close to original estimates, however, the benefit of PATH Study's collection of buccal cells is lower than originally expected. Although analysis of buccal cells would support the study of specific tobacco-related disease processes over time (e.g., cellular alterations in the mouth associated with direct contact with inhaled smoke), the Study has found that, even under favorable field conditions, buccal swab material can be extremely variable, limited, and subject to degradation.

Urine and blood samples will continue to be collected, and they are expected to yield substantially more useful information than buccal cells regarding markers of exposure to tobacco and use-related disease processes. Consequently, discontinuing buccal cell collection at the 8th month is anticipated to have a negligible, if any, effect on the ability of the PATH Study to meet its objectives.

Discontinuing buccal cell collection for the remainder of the baseline wave would eliminate costs associated with field labor, specialized collection materials and supplies, shipping, secure storage, and processing required to extract RNA and DNA from the samples. In addition, it would reduce the total annual burden hours requested and the estimated

annualized cost to respondents by as much as that shown in the following table. That is, approximately a third of the burden hours and the cost to respondents would be reduced by discontinuing buccal cell collection at the 8th month of the baseline wave. Note that the reduction in absolute burden hours and cost to respondents will be less than that shown because the final adult sample size in the baseline wave is expected to be lower than the sample size projected in the non-substantive change request for the baseline wave.

PATH Study baseline cost to respondents for continuing buccal cell collection beyond 8th month

Type of Respondent and Instrument	Number of Respondents*	Frequency of Response	Average Time Per Respondent	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Adults – Biospecimen Collection: Buccal Cell	42,730 X 0.333 = 14,229	1	18/60	4,269	\$16.27	\$69,457

*Product of number of respondents projected in the non-substantive change request for the baseline wave and the proportion (at least 1/3rd) of baseline wave field period remaining. The actual number of adult respondents is expected to be lower because the final sample size is expected to be lower than that projected in the non-substantive change request for the baseline wave.

Approval of this nonsubstantive request will require the slight modifications shown in the three survey materials (two consent materials and an incentive receipt), attached. None of these materials are information collection forms.

This will result in a decrease to the total burden for this ICR from 136,889 to 132,620. The total number of responses decreased from 560,451 to 546,222.