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Public Health Service
National Institutes of Health

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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 on the Proposed Statistical Approach to Be Applied to Biospecimen Data for Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study (OMB No. 0925-0664, Expiration Date 8/31/2018)

The National Institute on Drug Abuse (NIDA), in collaboration with its partner the Food and Drug Administration (FDA), requests OMB approval of the statistical approach, described in this memo, to be applied to the biospecimen data from Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study. This change request is submitted for OMB consideration and approval in accordance with the terms of clearance for Wave 1:

“Results based on the bio-specimen data cannot [be] publicly disseminated until OMB approves a change request under the PRA that explains the statistical approach to be applied to the biospecimen data to address potential non-response bias from lower consent and cooperation rates with this aspect of the study.”

Background

The PATH Study is nearing completion of its second wave of data and biospecimen collection and preparing to launch its third wave. The methods used by the PATH Study for data collection are similar for each wave, and include computer-assisted interviews with probability samples of adults (18 years and older) and youth (12 to 17 years old) on topics pertaining to tobacco use behavior and health (e.g., tobacco-use patterns; risk perceptions and attitudes regarding harmful constituents; and use of new and emerging tobacco products). Biospecimen collection from consenting adults in Wave 1 included the collection of urine, blood, and buccal cell samples. Buccal cells were only collected from the start of Wave 1 until May 18, 2014.¹ All biospecimens

¹ Due to both budgetary and scientific reasons, NIDA submitted a request to OMB for approval to discontinue collection of this biospecimen, effective May 18, 2014.

are safely stored in a biorepository, which also ships selected samples to one or more specialized analytic laboratories for analysis; any unused specimens are shipped by the laboratory back to the biorepository. Results from the analytic laboratories (i.e., biospecimen data) are then transmitted to the Contractor to link with interview/clinical data.

The statistical approach to be applied to the Wave 1 biospecimen data builds on the approach used to address potential nonresponse bias for the Wave 1 interview data. NIDA presented this approach for the interview data in the PATH Study's Wave 2 Interim Report (Attachment 21 of the PATH Study's Wave 3 Revision Request, submitted to OMB in June, 2015).

Overview of the Approach

As described in the PATH Study's Wave 2 Interim Report, the Wave 1 adult weights for the interview data were calibrated through the process of raking to population estimates for demographic characteristics from the American Community Survey.² The adult raked weights adjusted for potential nonresponse bias associated with the household screener and adult interviews for these demographic characteristics. Section 2.3 of the Wave 2 Interim Report indicates that the raked weights reduced differences between estimates from the PATH Study and independent estimates from the American Community Survey.

Starting with the Wave 1 adult raked weights described in the Wave 2 Interim Report, the potential nonresponse bias from the biospecimen collection will be addressed through two steps of weighting adjustments.

1. Adjust the final Wave 1 adult raked weights (ARKWT) of adults who provided biospecimens, so they compensate for similar adults who did not provide biospecimens. This step addresses the potential bias from the consent and cooperation for providing biospecimens, and will be done separately for each biospecimen (urine, blood, and buccal cells).
2. Account for the probability subsampling of biospecimens for laboratory analyses. This step will be performed for each probability sample selected for laboratory analysis.

The two steps for biospecimen weighting will account for potential differences between the full set of Wave 1 adult interview respondents and the set of Wave 1 adults with analyzed biospecimens.

Step 1 addresses the potential for nonresponse bias resulting from the fact that not all of the eligible adults provided biospecimens. Of the 32,320 adults who completed the Wave 1 adult questionnaire, 21,801 (67.5%) provided urine specimens and 14,520 (44.9%) provided blood

² The estimates for demographic characteristics corresponding to the target population of the PATH Study, which excluded active military and persons in group quarters other than college dormitories, were computed from the 2013 1-year Public Use Microdata Sample of the American Community Survey.

specimens. Through May 18, 2014, when collection of buccal cell specimens was discontinued, 12,543 (71.6%) of 17,508 interview respondents in Wave 1 provided buccal cell specimens.³

Step 2 addresses the selection of biospecimens for laboratory analysis. A probability subsample of biospecimens has been selected from specified groups of the population for laboratory analyses. However, laboratory analyses of other Wave 1 biospecimens, or different subsets of biospecimens, could be performed in the future. This weighting plan can be applied to an immediate set of biospecimen data from this round of analysis of selected Wave 1 samples, and to any future probability subsamples of biospecimens.

For the purpose of subsampling biospecimens for laboratory analyses in Wave 1, adult participants were grouped by tobacco product use into 9 groups: (1) current exclusive established users of cigarettes; (2) current established users of other tobacco products; (3) current experimental, but not established, users of any tobacco product; (4) former established users of any product whose last use was within the past 12 months; (5) never users; (6) current established users of cigarettes who are experimental, but not established, users of at least one other tobacco product; (7) former, but not current, experimental users of any tobacco product who were also never established users and whose last use was at any time in the past; (8) former established users of any product whose last use was more than 12 months ago; and (9) adults not in groups 1 to 8. A probability sample of adults has been selected from the first 5 tobacco product use groups to form the “core sample” for laboratory analysis.

Implementation of the Approach

Step 1 for the Wave 1 biospecimen data will yield three separate sets of biospecimen weights: one set for adults who provided urine specimens, one set for adults who provided blood specimens, and one set for adults who provided buccal cells.⁴ Following standard statistical procedures (United Nations, 2005; Brick, 2013), weighting class methods will be used to adjust ARKWT for the adults who provided each type of biospecimen so that the adjusted weights account for the persons who did not provide biospecimens.

Separately for each biospecimen, nonresponse adjustment cells will be formed using variables from Wave 1, including age, race, ethnicity, sex, employment status, health status and related characteristics, education level, household composition, census block characteristics, and the 9 tobacco product use groups. In each adjustment cell, the ARKWTs of the adults who provided the biospecimen will be multiplied by (sum of ARKWT for all adults in the cell who were asked to provide the biospecimen) / (sum of ARKWT for adults who provided the biospecimen in the

³ These represent 38.8 percent of all adults interviewed in Wave 1.

⁴ Although the PATH Study has no current plans to perform laboratory analyses of buccal cells, analyses may be desired in the future, or the Study may resume collecting buccal cell samples in the future. Therefore, weights will be created in Step 1 for the adults who provided buccal cells, but the second step of weighting would only be carried out if the decision is made to perform laboratory analyses.

cell). Additionally, the weights will be raked to the sum of the Wave 1 adult interview weights (ARKWT) for the 9 tobacco product use groups,⁵ age group, and sex.

The result of Step 1 will be a set of weights for each biospecimen that sums to the total of the ARKWT weights for the entire Wave 1 adult sample. This step will adjust the weights to compensate for potential nonresponse bias arising from the cooperation rates for providing biospecimens. The three sets of weights at the end of Step 1 will be used as the base weights for constructing weights for biospecimens that undergo laboratory analysis.

In Step 2, the biospecimen base weight for each biospecimen subsampled for laboratory analysis will be divided by the probability of selection for laboratory analysis. The sum of the Step 2 weights will be approximately equal to the sum of the ARKWT weights for adults who were eligible to be selected for laboratory analysis. For example, because the core sample was selected as a probability sample of the first 5 tobacco product use groups, the sum of the biospecimen weights for the core sample will approximately equal the sum of the ARKWT weights for the adults in these tobacco product use groups.

Weighting Step 1 is carried out independently of Step 2. Therefore, Step 2 can be performed for different subsets of biospecimen data in the future, without a need to repeat the main nonresponse adjustment from Step 1. In addition, using the same set of nonresponse-adjusted weights at Step 1 will help assure consistency across analyses of biospecimen subsamples for Wave 1 and subsequent waves.

In summary, this change request is submitted for OMB approval of the statistical approach to be applied to the PATH Study's Wave 1 biospecimen data. Upon approval by OMB, NIDA and FDA anticipate proceeding with public dissemination of the Wave 1 biospecimen data. This approach is also expected to serve as the basis for meeting similar terms of clearance for both Wave 2 and Wave 3.

References

Brick, J.M. (2013). Unit nonresponse and weighting adjustments: A critical review. *Journal of Official Statistics*, 29, 329-353.

United Nations. (2005). *Designing household survey samples: Practical guidelines*. United Nations Publication ST/ESA/STAT/SER.F/98, New York: United Nations. Available at <http://unstats.un.org/unsd/demographic/sources/surveys/Handbook23June05.pdf>

⁵ Some tobacco product use groups may be combined if the sample sizes are small.