alive in the 1940s via focus groups and key informant interviews and will be used to derive means and ranges of exposure-related parameters, such as consumption of contaminated foodstuffs, collection and use of water, time spend outdoors, and building materials. These parameter values will be used with historical fallout deposition data in fallout dose assessment models to estimate external and internal radiation doses to typical persons in all counties in New Mexico by ethnicity and age. The estimated doses will be used with literature-derived risk and parameter values on risk/unit dose to project the excess cancers expected (per 1,000 persons within each stratum) including uncertainty on each estimate. Endpoints are leukemia, thyroid cancer, stomach cancer, colon cancer, and all solid cancers combined.

This data collection is needed to accomplish the overall Trinity Study goals, which are to: (1) Estimate external and internal radiation dose to the four primary organs/tissues of interest (thyroid, stomach, colon, and red bone marrow) from primary radionuclides in nuclear testing fallout in each county of New Mexico as a result of the Trinity test, stratified by age, gender, ethnicity, and conditions of exposure (low, medium, high); (2) in each county, estimate the number of excess cancer cases to organs of interest per 1,000 (hypothetical) persons stratified by age, gender, ethnicity, and conditions of exposure (low, medium, high).

The study data will be collected via focus group and individual interview. Between 10 and 15 focus groups with up to 8 participants are planned. These participants will be 70 years old and older, living in New Mexico, who were alive at the time of the Trinity nuclear test and living in any of 19 Native American pueblos/tribes or Hispanic/Latino and non-Hispanic white communities in or near the fallout region in New Mexico. Additionally, up to 30 individual interviews are planned with key informants chosen to represent a variety of experiences and expertise. Individuals who prefer not to take part in a focus group will be interviewed individually as key informants. The investigators will collaborate with community representatives who will recommend potential participants for either the focus groups or interviews.

The objective of the focus groups and interviews is to collect information directly from community members who were alive at the time of the Trinity test, or with direct knowledge of specific life circumstances, cultural patterns, and dietary practices of Native Americans, Hispanics/Latinos, or non-Hispanic whites living in New Mexico at this time. In this study, two interviewers, including one with extensive experience working with tribal communities, will moderate the focus groups and conduct in-depth interviews. Translators and interpreters with experience in the study populations will be presented when needed. Each focus group and interview will be scheduled for no more than two hours and will take place in office settings, community facilities, or municipal facilities.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 395.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Instrument	Number of respondents	Frequency of response	Average time per response (in hours)	Annual burden hours
Individuals	Screener	300	1	10/60	50
	Consent Form	150	1	10/60	25
	Focus Groups	120	1	120/60	240
	Pre-Focus Group Guide	120	1	10/60	20
	Key Informants and Academics Interview	30	1	120/60	60
Totals		300	720		395

Dated: March 1, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–05426 Filed 3–10–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 60-Day Comment Request; Population Assessment of Tobacco and Health (PATH) Study

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443–8755 or Email your request, including your address, to: *PATHprojectofficer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 60 days of the date of this publication.

Proposed Collection: Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925–0675, expiration date 5/31/2016—EXTENSION—NIDA, NIH, in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a request to continue the Population Assessment of Tobacco and Health (PATH) Study's conduct of methodological studies in support of improvements in the Study's approaches for data and biospecimen collection. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual or biannual interviews and collects biospecimens from adults and youth to inform FDA's regulatory actions under the Family Smoking Prevention and Control Act. The methodological studies under this extension will continue to enhance the approaches used by the PATH Study for data and biospecimen collections to obtain high quality and useful data; minimize respondent burden; and achieve and maintain high response, retention, and follow-up rates.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 29,750.

ESTIMATED ANNUALIZED BURDEN HOURS

Data collection activity	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
In-person surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Web surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Focus groups and individual in-depth qualitative interviews.	Adults	1,000	1	2	2,000
	Youth	1,000	1	2	2,000
Biospecimen collection	Adults	1,000	1	15/60	250
Total		20,000	20,000		29,750

Dated: March 7, 2016.

Genevieve deAlmeida-Morris,

Project Clearance Liaison. NIDA, NIH.

[FR Doc. 2016–05431 Filed 3–10–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Clinical Trials Reporting Program (CTRP) Database (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Jose Galvez, MD, Office of the Director, National Cancer Institute, 9609 Medical Center Drive, 1W468, Rockville, MD 20852 or call non-toll-free number 240–276–5206 or Email your request, including your address to: *jose.galvez@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Clinical Trials Reporting Program (CTRP) Database, 0925–0600, Expiration Date 05/31/2016—EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) Database is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP Web site to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.