Supporting Statement A:

STUDY TO ESTIMATE RADIATION DOSES AND CANCER RISK FROM RADIOACTIVE FALLOUT FROM THE TRINITY NUCLEAR TEST (NCI)

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Check off which applies:

- ☒ New
- ☐ Revision
- ☐ Reinstatement with Change
- ☐ Reinstatement without Change
- ☐ Extension
- ☐ Emergency
- ☐ Existing

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LIST OF ATTACHMENTS

A. JUSTIFICATION

This is a request for a new information collection for 3 years. Exposure-related parameter values will be used with historical fallout deposition data in fallout dose assessment models to estimate external and internal radiation doses to representative 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 This Information Collection Request (ICR) is for a radiation-related cancer risk projection study for the residents of the state of New Mexico (NM) potentially exposed to radioactive fallout from the Trinity nuclear test conducted in 1945. Data will be collected on diet and lifestyle from three groups in NM (non-Hispanic white, Hispanic, and Native American) alive in the 1940s via focus groups and key informant interviews. These data will be used to derive means and ranges of exposure-related parameters. Little information is currently available about dietary patterns among Native American community members or Hispanics in New Mexico in the 1940s combined.

A.1 Circumstances Making the Collection of Information Necessary

The Radiation Epidemiology Branch (REB), a branch under the Division of Cancer Epidemiology and Genetics (DCEG), at National Cancer Institute (NCI) of the National Institutes of Health (NIH) is authorized under the Public Health Service Act, Section 411 of the Public Health Service Act (42 USC § 285a), to collect information to generate hypotheses concerning environmental and host determinants of cancer. It is the mandate of the REB to conduct a broad-based research program to identify, understand, and quantify the risk of cancer in populations exposed to medical, occupational, or environmental radiation. The REB mission is to characterize and quantify cancer risks associated with different types of radiation exposure, improve dosimetry, elucidate biological mechanisms of radiation carcinogenesis, and study factors that may modify the carcinogenic effects of radiation exposure. Additional background information and the Trinity fallout map of New Mexico are found in **Attachments 1 and 2**.

A.2 Purpose and Use of the Information

Study Rationale

Indigenous and Hispanic/Latino communities represent a significant proportion of the North and South American populations. However, exposure pathways of underserved and understudied rural populations, particularly, indigenous Native American and Hispanic/Latino, are not well documented in the scientific literature.

Preliminary dose assessment calculations suggest doses to the thyroid glands of young children in two NM counties to be greater than 600 mGy, inferring attributable risk fractions as well as probabilities of causation (for those who developed thyroid cancer) well over 50%. Radiation dose assessments have been conducted for all other nuclear tests in the U.S.; however, no resource presently exists for the public or the scientific community to assess doses to NM residents from Trinity.

Generalizable information about cancer risks from nuclear releases, accidents, and detonations is a high public health and national security priority (see http://www.remm.nlm.gov/nuclear explosion.htm). There is little information available on cancer risks in rural settings at distances

of 40 to 300 km from a nuclear detonation. Moreover, no U.S. studies have considered rural and indigenous Native American or Hispanic/Latino populations. There is no published information that allows the New Mexican populations exposed to Trinity fallout to estimate their doses or cancer risks from the Trinity nuclear test. All other Americans are able to use the NCI I-131 calculator to determine their exposure and thyroid cancer risk from fallout resulting from nuclear tests conducted at the Nevada Test Site. Despite potentially moderate to large doses to some communities in NM, a cancer risk projection for radiation exposure from the Trinity test has not been conducted.

Members of the community in NM who were alive in 1945 would currently be aged 70 years or older, and those able to recall first-hand information from 1945 would currently be aged 80 years and older. Thus, the window of time for conducting interviews of persons alive during the Trinity test is rapidly dwindling. It is anticipated that many participants (those currently aged 70-80) were too young in 1945 to recall that exact year but will report on typical behaviors in the late 1940s and 1950s, which should adequately represent the time-period of interest. The Trinity study team is an interdisciplinary group of scientists and community experts with experience in interviewing, dose assessment, risk projection, and communication, well-suited to carry out all aspects of the study's scientific objectives. From those data, models of diet and lifestyle (predominantly house construction materials, time spent in- and out-doors in summer months) stratified by age, gender, ethnicity, and ecoregion of NM (i.e., high desert plains or mountainous regions) are to be constructed. The collection of dietary and lifestyle information in this study will allow for the best possible estimation of radiation doses and related cancer risks, and to make any important race/ethnicity distinctions**.** The research proposed here will fill a crucial need for data on diet and lifestyle of Native American and Hispanic/Latino cultures in NM that is necessary for the dose and risk assessment for the Trinity test.

Specific Aims and Purpose

The specific aims of this study are to: (i) estimate external and internal radiation dose to the four highest risk organs/tissues of interest (thyroid, stomach, colon, red bone marrow) from radionuclides in nuclear testing fallout in each county of NM as a result of the Trinity test, stratified by age, gender, ethnicity and conditions of exposure (low, medium, high); and (ii) 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 primary purpose of this research is to acquire descriptive as well as quantitative data from which credible models of diets and lifestyle can be assembled for the Native American, Hispanic and non-Hispanic white population groups in the mid-1940s living in New Mexico. From those data, DCEG investigators can complete the dose and cancer risk estimation for residents of New Mexico alive at the time of the Trinity test as requested by Congress and prepare manuscripts for peer-reviewed publications.

As this is a dose reconstruction and risk projection study, data will be sought to improve on unpublished dose estimates of individual internal and external radiation dose and to characterize the underlying dose uncertainties for individuals exposed as children to radioactive fallout from nuclear tests at Trinity. The objective of the data collection itself is to estimate group-specific values (i.e., by age at exposure, gender, and ethnicity) at the time of the nuclear tests and during the months of August through October following the tests during the 1940s in fallout-exposed villages. Such data are required to replace current values and assumptions made in the dose reconstruction models. The final dose estimates will be used to further understand cancer risks following internal and external radiation exposures, with special emphasis on the relative biological effectiveness (RBE) of internal compared to external exposures.

Presently, two types of data collection strategies are planned: (i) focus group interviews with persons who may have personal memories of diet and living conditions around the time of the decade of interest; (ii) key informants and academic researchers who are knowledgeable about diet and lifestyle in New Mexico in the mid-20th century. NCI proposes to use the focus group interview data collection method, which is documented in the literature to be well-suited for this population (Krueger & Casey, 2015; Morgan & Krueger, 1997; Stewart, 2014). The information to be collected in the focus groups was compiled from key informant interview conducted during the pilot phase of the Trinity study, along with information collected from an in-depth literature review.

Pilot Study

During September 15-30, 2014, the Trinity team conducted a pilot study of 9 participants recommended by REB in its 2013 review. Details of the pilot study can be found in **Attachment 3.** A brief review of the pilot study follows here. The aims of Phase 1 of the Trinity study were six-fold:

1. Establish collaborations and partnerships with the advocacy community and academics in New Mexico.
2. Identify collaborators and subject matter experts.
3. Identify logistics and planning for the Phase 2 focus groups.
4. Determine the feasibility of recruiting Hispanic and Native American participants > age 69 years.
5. Collect information about diet and lifestyle practices.
6. Use key informant interview information and literature review for development of Focus Group Guide.

Aims 1-3 were successfully achieved through the pre-trip preparation and during the pilot study field trip.

For Aim 4, the team set out to recruit 9 key informants from a variety of geographic areas across New Mexico. Participants were recruited by using social networks of local collaborators and attending community events. The team successfully recruited 9 participants. Those recruited were between ages 69 and 101 years old and from diverse geographic locations. They included: 4 males and 5 females; 3 Native American, 6 Hispanic; 2 tribal Nations, and 5 New Mexican counties.

For Aim 5, we developed the Key Informant Interview Guide and interviewed 9 participants. Using the structured guide, participants were asked to recall the summers in the 1940s and 1950s and to report on their and their families' consumption of water, meat, dairy, vegetables, and traditional foods. Participants reported how food was prepared and from where it was sourced. All participants reported on the types of homes in their community, the types of festivities that took place in the summers, and the amount of time people of different ages spent outdoors.

For Aim 6, the results from the literature review and key informant interviews were combined and analyzed in order to develop tools for Phase II. These tools consist of the focus group and key informant guides and a card sorting exercise. The focus group guide has been developed to quantify the amounts of foods consumed according to gender and age, and to assess community level factors.

Study Design

Focus groups and individual interviews will be used to collect the data. The focus group participants will include non-Hispanic whites, Hispanics and Native Americans who are currently ≥ 70 years old and resided in the 1940s communities in or near the fallout region in NM (**Attachment 2**) including Native American pueblos and tribes. We intend to conduct 21 focus groups with up to 8 participants in each group. For comparison purposes, eight of the focus groups on the lifestyle and dietary patterns of non-Hispanic whites will be included. In addition, we will conduct up to 42 key informant interviews.

The study team plans to recruit up to 210 elders to participate in the focus groups and interviews. Fliers will be distributed in local communities in both English and Spanish (**Attachment 4)**, and subjects will be screened for eligibility, in either English or Spanish (**Attachment 5**), and provided with a letter, in either English or Spanish, about the study prior to the conduct of any interviews (**Attachment 6)**. It is anticipated that 50% of individuals screened will participate in either a focus group or interview. The focus groups and interviews will collect information directly from community members who were alive at the time of the Trinity test, or from those 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. To this end, this study will use focus groups and individual interviews - research techniques that rely heavily on questions by the interviewer to elicit thoughts, memories, and interpretations by subjects, and can be related to key events in their past. The individual interview, pre-focus group, and focus group guides are found in **Attachments 7, 8, and 9**. Previous studies in the United States and abroad (including similar village settings) have successfully utilized focus groups to collect data about nutrition patterns (Edmonds, 2005; Elmubarak et al., 2005; Hargreaves et al., 2002; Jonsson et al., 2002a; Jonsson et al., 2002b; Kruger & Gericke, 2003; Satia et al., 2000; Vuckovic et al., 2000). The focus group structure and probing-type questions benefit recall and participation, and literature indicates that focus groups may stimulate individual participant responses more than individual interviews and participants may be more comfortable speaking in a group situation. Participants will provide an answer for each cell on the wall charts (**Attachment 9**), which will be used to generate distributions of intakes, time outdoors, etc. The main exposures queried will be consumption of important foods, time outdoors, water sources and storage practices, and building construction in the community. Prior to the start of each focus group, participants will be greeted, consented, and complete the pre-focus group guide (**Attachment 8**) which is a table

about their family members in 1945, to facilitate completion of the wall charts during the focus groups**.**).

The focus groups will be led by a trained lead moderator and moderator's assistant, fluent in either English, the tribal language, or Spanish. Before the actual focus group study takes place, NCI will provide rigorous training and practice in focus group methodology for the field team. The moderator and assistant are critical members of the study team, and their role will be to create a trusting environment, encourage the participation of all group members, and keep the conversation flowing along the parameters set by the focus group moderator guide.

Additionally, individual interviews will be conducted with up to 30 participants, otherwise known as "key informants," chosen to represent a variety of experiences and expertise. The interview will address community level habits (**Attachment 7**), recognizing that Native American tribes in New Mexico live in at least two ecoregions (dry, high-desert or mountain environment). For the purpose of projecting radiation-related cancer risk**,** we intend to construct gender-, and age-dependent lifestyle and diet models for Native American communities for the two ecoregions noted. For the creation of lifestyle and diet models (also with gender- and age-dependence) for Hispanics/Latinos and non-Hispanic whites, we intend to gather information from populations living in rural, small town and urban environments. Additional background on dietary recall of the past and the use of focus groups can be found in **Attachment 10**.

New Mexico Focus Groups

In the proposed study, participants will be asked about general patterns in the community, in their families, and if it was different than others' experiences. Simple questions about lactose intolerance, sources of milk, consumption of small animals, outdoor water sources and time outdoors seem well within the abilities of elder subjects. The moderator of the focus group will judge the abilities and potential veracity of answers.

The main purpose of conducting interviews or focus groups among the ethnic groups of New Mexico is to characterize the ranges of consumption rates of contaminated foodstuffs as well as the ranges of parameters that are important to assess the doses from external irradiation. Plans have been made to conduct 21focus groups: Native Americans in the plains and in the mountains, Hispanic/Latino and non-Hispanic whites living in urban centers, in small towns, and in rural areas. This scheme was developed in an effort to capture a range of behaviors in terms of intakes, building materials, collection and use of water, and time outdoors. In addition, given that activities are not homogenous across the fallout region, we chose to interview groups in varying topographies and community settings. We will test to what extent the ethnic specific focus groups within the same terrain have similar patterns so that we can extrapolate to others of that ethnicity in the same region.

Use of Key Informant Interviews

In addition to focus groups, key informants will be interviewed in order to obtain information on community aspects of diet and lifestyle that might impact dose, e.g., management of dairy animals. The key informant procedure is often used in the testing and development of survey questionnaires (Willis, 2005), but can also be used more flexibly to reconstruct events in one's past (Belli & Callegaro, 2009). Interviewing techniques are commonly viewed as psychologically-oriented approaches that focus on processes such as comprehension and

memory retrieval (Fisher & Geiselman, 1992; Tourangeau et al., 2000) but are also increasingly viewed as closely associated with the qualitative research tradition, emphasizing a strong socio-cultural and anthropological focus. In brief, cognitive interviewing involves the use of questions that lead the subject to elaborate on the topic under discussion. Given that human memory, especially of events long-distant in the past, tends to be reconstructive, probing takes advantage of this by helping the individual to reinstate the context surrounding the memories, and to rely on recalled information as cues to elicit further memories. Questions may be either scripted, or fashioned by the interviewer at the time of the interview using delayed recall questionnaires. For example, a scripted question might be "*Tell me about the place where you were living in (year)*." Based on the subject's response that "*I was living with my family in (city)*", the interviewer might then follow up by asking "*Who was in your family – tell me their names*." In this way, a full set of varied and useful information is developed that can be used to assist in reconstructing the precise information that is of interest.

A.3 Use of Improved Information Technology and Burden Reduction

Due to the nature of this project, incorporating improved information technology for the purpose of data collection is not feasible. We will employ interviews and focus groups to gather information. By approximating a natural discussion format, focus groups provide the opportunity to observe the interaction and potential influence of group participants, which encourage further insights into attitudes, perceptions, and opinions that would otherwise be unlikely to emerge in the absence of group dynamics.

Paper-based notes by the interviewers will be transcribed and then electronically coded, eliminating significant burden to the participants who will respond verbally to most questions and discussion. Upon consent from the participants, we will audio record the focus group discussions to capture all information for accuracy of reporting. The use of electronic reporting is typically not feasible for this form of qualitative work. Forms and questionnaires given to participants such as consent forms and incentive receipts etc. will be developed in user-friendly formats to reduce the time they take to complete.

A.4 Efforts to Identify Duplication and Use of Similar Information

The information to be collected is unique and not found elsewhere. A key part of the study protocol planning activities included review of the scientific literature to determine what information, if any, has been collected on each domain of interest, prior to initial planning of the study. The review examined whether the study goals could be addressed without embarking on an entirely new study (**Attachment 11**).

The review focused on foods consumed that would potentially contain radioactive iodine. The literature search was conducted with key terms of relevance to the region, the populations and time period. The literature search resulted in an in-depth review of 13 books for Native Americans and 15 for Hispanics. The reviewers focused on annotations for six main food groups with relevance to iodine exposure: large animals, small animals, plants, fruits, dairy, and water. There were behaviors that are specific to the New Mexico Puebla that did not fit in these pre-determined categories so four specific categories were added: animal diet, medicine, ritual foods and other sources. The reviewers focused efforts on listing the type of food, the preparation, the frequency of consumption and where possible documenting specific amounts (e.g., grams and tablespoons). These notes were organized into computer spreadsheets: one for Native American sources and one for Hispanic sources. Once all sources were reviewed and the list of foods was

complete, the reviewers ranked the foods by three levels of potential exposure: high, moderate and low. These rankings were based on the frequency of consumption, whether an important pathway of radiation exposure might be involved, or if certain at- risk groups, such as women and infants, differed in their consumption pattern. The foods identified as potentially important sources of radiation were added to the Key Informant Guide. Through the interviews during the pilot study with the Key Informants, the study investigators were able to confirm that these items were consumed, and learned about other important foods not documented in their lists.

There has been other research conducted that estimates radiation dose exposure from environmental sources for other populations. For example, the population in Kazakhstan is one of few populations in which environmental releases of radioactive materials into the atmosphere resulted in substantial internal and external thyroid radiation doses. Other populations include people exposed to fallout from the Nevada Test Site (Lyon et al., 2006), the Marshall Islands (Simon et al. 2010), the Chornobyl reactor accident (Bogdanova et al., 2006) and to atmospheric releases from the Hanford site (Kopecky et al., 2005) and Mayak plutonium facilities (Mushkacheva et al., 2006) in the US and USSR, respectively. Such studies have not been conducted for this population in New Mexico as a result of the Trinity test. There is some data available for Caucasians or African Americans, but the referenced studies and data do not accurately represent the diets of the Native American and Hispanic populations at the time which may result in different quantity of radiation exposure and thus cancer risks. The literature review found no adequate date capable of answering the questions necessary to complete the Trinity risk projection. Therefore, collection of this data is necessary to estimate accurate exposure for these specific populations.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses are involved in this data collection.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time information collection. The consequence of not collecting these data is that NCI dose assessment experts will not be able to properly estimate internal and external radiation doses for individuals exposed to radioactive fallout from the Trinity tests in New Mexico during the 1940's and hence, not be able to properly estimate the cancer risks. This is a quickly aging population so that opportunity to interview these respondents is limited.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with all guidelines of 5 CFR 1320.5. There are no special circumstances required.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on Friday, March 11, 2016, Vol. 81. page 12912-12913. One comment was received requesting an extension of the 60-day Federal Register Notice comment period to May 31, 2016. This extension was published on May 13, 2016, Vol 81, page 29875. One comment was received and the submitter responded.

Members of the Trinity Study have sought advice from local experts as well as interested persons in New Mexico on issues related to planning a field study (**Attachment 12**). To gain the support

and assistance of the local population, an outreach subgroup of the Trinity Study team has held a series of conference calls with stakeholders in New Mexico and has maintained a dialogue on relevant issues by email.

These consultations have included meetings with staff at the DHHS Indian Health Services as well as local academic and state consultants in New Mexico. Additionally, the NIH Library assisted in designing the data collection instruments for this project based on a comprehensive literature search and review to identify existing source of data sources.

A.9 Explanation of Any Payment or Gift to Respondents

As is customary for Native American participants, a meal will be shared by everyone involved in the interviews, including interviewers, participants, language interpreters, caregivers, and children. An incentive of $50.00 in the form of (cash or gift card) will also be given to participants, in appreciation and to offset childcare and travel expenses and their time, following the recommendation of researchers in New Mexico with extensive experience conducting successful community-based participatory research with Native American and Hispanic communities in New Mexico, as well as published recommendations and standard practice of focus groups (Krueger & Casey, 2015; Stewart, 2014; Simmons et al, 2014). A receipt will be signed by each participant (**Attachment 13**).

A.10 Assurance of Confidentiality Provided to Respondents

All information will be kept private to the extent allowable by law. All procedures have been developed in accordance with federal, state, and local guidelines, to ensure that the rights of participants are protected and data are appropriately safeguarded. The NCI and Albuquerque Area Indian Health Board IRB reviewed and approved all instruments, informed consent materials, and data collection, and management procedures. All IRB approval notices are included as Attachments 14A and 14B. NCI will take many precautions to secure participants' identifiable information. The information participants provide during the focus groups will not be linked to the respondents' identities.

The focus groups and interviews will include personally identifiable information (PII). The NIH Privacy Act Officer has reviewed this submission and determined that the Privacy Act does apply to this data collection effort. (**Attachment 19**) PII is being collected in the form of name, race, gender, address, phone number, and email. The applicable SORN is 09-25-0156 "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service HHS/PHS/NIH/OD.

Consent

According to the Code of Federal Regulations §46.117: Documentation of informed consent, an IRB **(Attachments 15A and 15B**) may waive the requirement for the investigator to obtain a signed consent form for some or all key informants if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Participants will be provided a written statement regarding the nature of the research and what will be asked of them.

After the research is conducted, participants will be given contact information for NCI if they have further questions about how their information will be used in the analysis. Study

investigators have been advised that participants may not wish to sign a document of written consent because they may not trust it. For this reason, participants will have the option of choosing between written or verbal consent. Instances of verbal consent will be documented using a witness signature in place of the participant signature. This will take place once information about the study is provided and prior to the initiation of the interview. The interviewers will be working with trained interpreters who are fluent in English or Spanish and the native language of the respondents. During the screening process (which will be interpreted in real time by a trained simultaneous interpreter), respondents will provide information regarding their preferred language for completing the interview. Once a list of eligible respondents and the preferred language for each is prepared, NCI will work with a university subcontractor to have the informed consent form translated into any languages other than English or Spanish that are needed. The resulting translated version of the informed consent form will be provided so that every participant receives a written document describing the study in his/her preferred language. The interview guide will be interpreted in real time by a trained interpreter.

Safeguards

Participants will be asked to use only their first names with researchers and not to provide any other identifying information. The university subcontractor will store consent forms (the only study document that may contain participants' names) in a locked file at their institution. Audio recordings will be stored securely and will be destroyed at the conclusion of the study. More detailed transcripts of the interview or focus groups will be prepared by a contractor following the completion of the fieldwork. The transcriber will be instructed to omit personally identifying information in preparing the transcripts. Transcripts will also be stored by NCI. As outlined in the consent document, these data files (including audio recordings and transcripts) will be password protected and stored at NCI on a secure server accessible only to the NCI investigators listed in this application. Data files will be identified only by a study case number. Additionally, the contractor will be required to sign a privacy agreement.

To maximize privacy and help respondents feel at ease and in control of the data collection, all data collection activities will take place in a private room within a public community building. Before beginning the interview or focus group, the facilitators will confirm that other persons are not in the room and that responses cannot be overheard or ascertained from outside the room. Facilitators will take all necessary precautions to ensure that the space continues to be private throughout the duration of the interview.

Data Storage and Management

A larger database may be created to pool notes collected from different note-takers and shared with the study team. All subjects' information will be anonymized in this database and no identifying information about the participant will be provided. Data will be analyzed and presented at future academic or professional meetings without any PII linked to the data. Quotations may be pulled from the data to illustrate a finding with a general descriptor (e.g., health representative from Taos) but no names or other PII will be associated with the quote.

Information about Voluntary Nature of the Study

Participants will be informed of the voluntary nature of participation in the focus groups. The consent form contains the Privacy Act advisement elements: (1) purpose; (2) the intended uses of the data collected; (3) with whom identifiable data will be shared; (4) the legal authority for data

collection; and (5) that there will be no untoward effect for not responding. The information collected will become part of a system of records in accordance with the Privacy Act of 1974.

A.11 Justification for Sensitive Questions

No sensitive questions are planned to be asked. Participants will be asked questions about (i) likely lifestyle and dietary habits during the 1940s/1950s, (ii) type of building materials of houses and other structures, (iii) sources of dairy products, pasturing and feeding of dairy animals, and (iv) types and amounts of milk and other dairy products consumed near to the time of the Trinity test. None of these questions are considered sensitive.

As is usual for procedures that involve verbal interaction with human subjects, the investigators will assess subject reactions to the protocol, and respond appropriately to any signs of adverse consequences. Although the nature of the questions posed (mainly queries about dietary and other behaviors during a period well in the past) are not expected to be sensitive in any way, it is not possible to make *a priori* assurances that memories do not carry emotional content that could be negative. For example, it is conceivable that subjects who have concerns about the health effects of atmospheric testing of nuclear devices may express anger at the U.S. government, or its agents, for having conducted the tests. The study investigators feel that such reactions are to be expected, and not in themselves a reason that any individual should be removed from the study. However, as in other cognitive or intensive interviewing studies that have been conducted in the past, if subjects become clearly emotionally distressed at any point (e.g., crying), the interviewer will immediately suspend the interview. After several minutes, the interviewer will ask the subject if he/she would like to continue, and state that there is no need to do so if this causes discomfort. If the subject decides to continue, the interview will then be continued until it is finished.

However, if the subject exhibits a clear negative emotional reaction a second time, prior to the end, the interviewer will terminate the interview, and remain with the subject until the point at which the subject is no longer exhibiting such behaviors. In this case, the interviewer will also, before leaving the interview site, make appropriate efforts to locate an individual (friend, family member, or neighbor) who can provide immediate social support to the distressed subject. If a subject terminates an interview prior to completing it, he/she will be asked whether the investigators may make use of the information they were able to obtain. If the subject refuses or is not in a condition to provide such consent, data for that subject will be destroyed, and a substitute subject will be accrued to the study.

A.12 Estimates of Annualized Burden Hours and Costs

The total annualized burden hours are 536. The total number of respondents are 210. 315 respondents will be completing a 10-minute screener (Attachment 5) which yields an annual burden of 53 hours. The 315 respondents will be screened to get 210 participants. The 210 participants will complete a 10-minute consent (Attachment 15) yielding a total of 35 annual burden hours. There will be 21 two-hour focus groups with up to 8 participants per group, totaling 168 respondents and 336 annual burden hours (Attachment 9). The 168 focus group participants will also complete a 10-minute pre focus group guide resulting in 28 annual burden hours (Attachment 8). Additionally, a total of 42 respondents will participate in a two-hour individual key informant interview. The interviews will result in 84 annual burden hours (Attachment 7). Both the focus groups and interviews will each be scheduled for two hours so that participants will not

be rushed through, and will be allowed to relate their memories in a comfortable and welcoming environment. The amount of time needed can be variable, as different participants may wish to tell about their experiences. This story-telling is critical to establishing trust of the research team and to obtain accurate data collection.

A.12 - 1 Estimate of Annual Burden Hours

Type of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Annual Burden Hours
Individuals	Screener (Attachment 5)	315	1	10/60	53
	Consent Form (Attachment 15)	210	1	10/60	35
	Focus Groups (Attachment 9)	168	1	120/60	336
	Pre Focus Group Guide (Attachment 8)	168	1	10/60	28
	Key Informants and Academics Interview (Attachment 7)	42	1	120/60	84
Totals		210	525		536

The annualized cost to respondents is $10,886.16. This was calculated by using the $20.31 hourly mean wage rate for “All occupations” occupation code 00-0000 in New Mexico can be found at the Department of Labor website (http://www.bls.gov/oes/current/oes_nm.htm#00-0000).

A.12 - 2 Annualized Cost to Respondents

Type of Respondents	Annual Burden Hours	Hourly Mean Wage Rate	Respondent Cost
Individual	536	$20.31	$10,886.16
Total	536		$10,886.16

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs other than their time to participate.

A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government is $378,878. Two types of government costs will be incurred including government personnel, and contracted data collection costs. Table A.14-1 shows the salary, expenses and contract costs to complete this information collection. These figures include the costs for study design, development of study materials, focus group member enrollment, data collection, incentive, language translations, data processing, dosimetry model updates, statistical analyses, and report writing. Federal costs are for personnel to oversee contractors and the development of study materials.

Table A.14-1 Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					**$116,288**
Principal Investigator	Title 42	$177,000	35%		$61,950
Principal Investigator	GS 15 Step 4	$142,000	15%		$21,300
Program Analyst	GS13, Step 4	$100,000	10%		$10,000
Program Analyst	GS12, Step 6	$90,400	5%		$4,520
Research Fellow		$91,310	10%		$9,131
Project Director	Title 42	$187,700	5%		$9,387
Contractor Cost					**$215,190**
Support Services (Social & Scientific Systems) (manage day-to-day aspects of the study, prepare IRB and OMB submissions, organize study meetings and monthly stakeholder reports, procure transcription and translations of focus groups and interviews, assist with qualitative coding of interview and focus groups)					$108,800
4 external contractors – dose analysis and reconstruction					
- Dosimetry Expert – assisting in estimating radionuclide depositions from Trinity fallout					$5,000
- Dosimetry Expert – assisting in developing dose models					$31,000
- Dosimetry Experts – review literature on pathway analysis and recommend dosimetry mode parameter values					$30,000
External research contract – University Subcontractor (Recruit participants, organize and procure focus group and interview locations, issue incentives, provide interpreters as needed, conduct outreach in the community, procure					$40,390

tribal resolutions					
Other Costs					**$47,400**
Travel					$33,400
Other Costs – Non-travel data collection expenses (translations of study materials, copies, mailing)					$10,000
Other Costs – Publication page charges					$4,000
TOTAL					**$378,878**

A.15 Explanation for Program Changes or Adjustments

This is a new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The Trinity study ultimately aims to estimate internal and external radiation dose to persons exposed to radiation from the Trinity test and use these estimates to conduct a cancer risk projection. For that purpose, the investigators will estimate external and internal radiation dose to the four primary organs/tissues of interest (thyroid, stomach, colon, red bone marrow) from the most important dose-contributing radionuclides in nuclear testing fallout in each county of NM as a result of the Trinity test, stratified by age, gender, ethnicity and conditions of exposure (low, medium, high); and 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).

After the completion of the data collection, NCI will seek confirmation of the collected data from targeted reviews by knowledgeable persons. NCI intends to thank the communities and participants in a written letter that will also describe plans for how information from the interviews will be used to estimate risk, and the expected timeline for final results, and acknowledge the value of the interviews and focus groups. No information that could identify individual participants or their communities will be included. NCI will provide follow up contact information to participants at the time of the interviews/focus groups should the participant want to connect with NCI at any time to discuss the study. The memo will be submitted to tribal and community newsletters for publication and shared with other outlets as applicable.

Once data from the focus groups/interviews have been collected analyzed and suitable verification can be achieved, the dose assessment and risk projection can be completed. Following that, NCI will begin drafting manuscripts to be published in the scientific peer-reviewed literature. NCI will present the findings to participants and the broader community in meetings in New Mexico (**Attachment 16**), following the approach used by the Centers for Disease Control and Prevention for the Los Alamos Historical Document Retrieval Archive (LAHDRA) project.

NCI will disseminate the findings from the study to the community at public meetings and in a written “plain language” summary of the results. This information will be submitted to tribal and community groups. It will be emphasized that personal exposure estimates cannot be prepared based on either individual or focus group interviews, since the questions will ask about typical dietary habits and lifestyles, rather than individual habits. NCI will provide follow up contact information to participants at the time of the interviews/focus groups should the participant want to connect with NCI at any time to discuss the study.

Table A.16-1 Approximate Project Time Schedule

Data Collection	**After OMB Approval**
Recruit focus group members and individuals for interviews	0-3 month
Conduct focus group and key informant/academic interviews	4-6 months
Translate interviews in other languages into English	6-7 months
Transcribe notes	6-7 months
Analysis & Publications	
Analyze data collected and develop input variables for dose assessment	6-12 months
Incorporate variables into dose assessment models and calculate internal and external doses	12-15 months
Conduct follow-back to study participants for clarifications and verification, as needed	4-24 months
Brief stakeholders on data collected, seek input and prepare report for stakeholders	15-18months
Conduct risk projection	18-21months
Prepare and submit manuscripts on dose assessment and risk projection	21-26months

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date for OMB approval of the information collection will be displayed on data collection instruments and materials. No special exception to this requirement is requested.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.