Supporting Statement A For:

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

Date: TBD

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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. 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. 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 combined. The Radiation Epidemiology Branch (REB) successfully conducted a pilot field study in 2014 showing the practicality of the proposed methods and confirming qualitative dietary information obtained in a comprehensive literature review on diet.

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/nuclearexplosion.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 each 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 $\geq$ 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 15 focus groups with up to 8 participants in each group. For comparison purposes, five of the focus groups on the lifestyle and dietary patterns of non-Hispanic whites will be included. In addition, we will conduct up to 30 key informant interviews.

The study team plans to recruit up to 150 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 a table about their family members in 1945, to facilitate completion of the wall charts during the focus groups (**Attachment 8**).

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 15 focus 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.

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 compensation for time and travel expenses, 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). 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.

Privacy Impact Assessment

The focus groups and interviews will not include personally sensitive questions. The NIH Privacy Act Officer has reviewed this submission and determined that the Privacy Act does not apply to this data collection effort.

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 personally 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 395. The total annual respondents are 150 interviewees, with up to 300 respondents screened. The focus group study is planned based on findings from the pilot study which was completed prior to the start of the larger study. It is anticipated that the 15 focus group interviews (up to 8 participants per group) will take up to 2 hours each, and 30 individual interviews will also take up to two hours each. These 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)	300	1	10/60	50
	Consent Form (Attachment 15)	150	1	10/60	25
	Focus Groups (Attachment 9)	120	1	120/60	240
	Pre Focus Group Guide (Attachment 8)	120	1	10/60	20
	Key Informants and Academics Interview (Attachment 7)	30	1	120/60	60
Totals		300	720		395

The annualized cost to respondents is $8,022.45. This was calculated by using the $20.31 hourly mean wage rate for "All occupations" occupation code 00-0000 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	395	$20.31	$8,022.45
Total	395		$8,022.45

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.

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					
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					
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 tribal resolutions					$40,390
Other Costs					$0
Travel					$33,400
Other Costs – Non-travel data collection expenses (software, 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-contributiong 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.

Supporting Statement B For:

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

Date: TBD

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LIST OF ATTACHMENTS

B. STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

Sampling Frame

The respondent universe consists of ethnic groups in New Mexico for which little data relevant to 1945 is available, in particular, for the Native American and the Hispanic groups, as well as non-Hispanic whites.

Potential participant subjects may include any of the following: community elders, tribal members, and people with firsthand knowledge of food practices in New Mexico in the 1940s or 1950s. Other key informants, such as tribal health representatives, promotores de salud, historians, representatives from academia, and advocates who can provide firsthand knowledge and/or academic expertise about the communities that can provide additional sources of information will be collaborated with. The population (2010 U.S. Census) of New Mexico of persons ≥ 70 is over 184,000. In New Mexico, 46% of the population is Hispanic/Latino, 41% of the population is non-Hispanic white, and 9% Native American.

Inclusion criteria

To be eligible to participate in focus groups or interviews, individuals must self-identify as a New Mexico tribal community member, Hispanic/Latino or non-Hispanic white, and have firsthand knowledge about lifestyle and dietary patterns in New Mexico during the 1940s or 1950s. According to the 1940 census, New Mexico had a population size of 531,818 with 275,427 whites (52%), 34,510 (6%) self-identifying as Native American and 221,881 (42%) Hispanic/Latino (of any race). The focus group participants will include non-Hispanic whites, Hispanics and Native Americans who are currently ≥ 70 years old and in the 1940s resided in communities in or near the fallout region in NM (**Attachment 2**) including Native American pueblos and tribes. Participants will be identified from Native American experts and community liaisons. The focus groups will be conducted in different ecoregions or urban/rural settings among the various ethnic groups.

Sample Size

The study team plans to recruit up to 150 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 study team intends to conduct 15 focus groups with up to 8 participants in each group. For comparison purposes, five focus groups on the lifestyle and dietary patterns of non-Hispanic whites will be included. In addition, we will conduct up to 30 key informant interviews. The chart below describes the number of data values that will be collected from the focus group participants.

Race/ethnicity	**Native American**		**Hispanic/Latino**			**Non-Hispanic White**		
No. focus groups	5		5			5		
Residence	Mountain	Desert plains	Urban north	Urban south	Small town /Rural	Urban north	Urban south	Small town /Rural
No. focus groups	2	3	1	1	3	1	1	3
Participants[1]	16	24	8	8	24	8	8	24
Response cells about women[2]	96	144	48	48	144	48	48	144
Response cells about men[3]	80	120	40	40	120	40	40	120
Response cells (total)	176	264	88	88	264	88	88	264

1 *Assumes 8 members of each focus groups*

2 *Assumes 5 age groups (infant, 1-4, 5-10, 11-15, 16+) and preganant or breastfeeding women*

3 *Assumes 5 age groups (infant, 1-4, 5-10, 11-15, 16+)*

B.2 Procedures for the Collection of Information

Participant Identification and Recruitment

Potential focus group members and key informants may include any of the following: community elders, tribal members, and people with firsthand knowledge of food practices in New Mexico in the 1940s or 1950s. To be eligible, individuals must self-identify as a New Mexico tribal community member, Hispanic/Latino or non-Hispanic white in order to participate in an interview, and have firsthand knowledge about lifestyle and dietary patterns in New Mexico during the 1940s or 1950s. According to the 1940 census, New Mexico had a population size of 531,818 with 275,427 whites (52%), 34,510 (6%) self-identifying as Native American and 221,881 (42%) Hispanic/Latino (of any race)(U.S. Census Bureau, 1940).

We plan to recruit up to 150 elders to participate in the focus groups and interviews. A university contractor in New Mexico will collaborate with community groups, e.g., *Las Mujeres Hablan* (a network of women-led organizations in NM interested in health and nuclear issues), community health representatives, *promotoras de salud* and other community leaders engaged with the NCI team to identify and recruit potential participants for the focus groups. Subjects will be screened for eligibility (**Attachment 5**) and provided with a letter about the study prior to the conduct of any interviews (**Attachment 6**). The scheduling and coordination of the focus groups will be under the direction of the university contractor. Once all IRB and OMB approvals to conduct interviews are in place and appropriate preliminary meetings have taken place with community leaders and potential participants, the focus groups will be scheduled. If the intended participants do not attend the focus group at the designated time, any eligible persons arriving will be consented and interviewed. If only one person attends, he or she will be interviewed as a key informant rather than as focus group member. If a participant would rather not be interviewed in a group, he or she will be interviewed as a key informant.

We will target recruitment efforts for people who resided in geographic areas that lie within or on the outskirts of the primary fallout pattern from the Trinity test (**Attachment 2)**.

Approval to conduct focus groups and interviews in the noted communities will be obtained from appropriate community leaders prior to recruiting study participants. IRB approval has been obtained from the Albuquerque Area Indian Health Board for the focus groups and key informant

interviews, and tribal resolutions from two Tribal Nations have been obtained. Tribal resolutions will be obtained for any Tribal Nation where we will conduct focus groups. NCI REB support services contractor, Social & Scientific Systems (SSS), will established a subcontract with a university researcher in New Mexico in order to allow us to collaborate and conducted the interviews and focus groups. The university contractor will be responsible for the following tasks:

- Requesting and securing required Tribal Resolutions
- Conduct study outreach in local communities
- Recruiting participants
- Issuing compensation
- Securing interview meeting locations
- Transportation
- Providing food and refreshments
- Co-moderating during focus groups/interviews
- Hiring translators and interpreters as needed

Data Collection Procedures

The main purpose of the data collection is to quantify the range of dietary intakes for different categories of age, sex, ethnic group, and ecoregion. In addition we seek information about other radiation-related exposure pathways such as building materials of houses and schools, and time spent outside by sex and age (all relevant to assessing external dose). Quantitative and qualitative data recalled about the individuals' family will be collected through the focus group sessions while more general information about the community will be collected through the Key Informant interviews.

This approach, to ascertain prior exposure to nuclear radiation is a qualitative research technique that relies heavily on probing questions by the interviewer to elicit thoughts, memories, and interpretations by subjects, and can be related to key events in their past. The 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). As such, the technique is well-suited for the collection of oral histories of the type to be collected within the current study. In brief, cognitive interviewing involves the use of probe questions that lead the subject to elaborate on the topic under discussion. Given that human memory, especially of long-distant events, 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.

Focus group moderator guide

The Trinity focus group moderator guide was designed using the REB study of fallout exposure in Kazakhstan (Land et al., 2015; Land et al., 2008; Schwerin et al., 2010) as guide. It includes detailed probes in the form of open-ended questions, and data collection sheets carefully designed to elicit the data sought. Prior to the focus group discussions, participants will be greeted, consented (**Attachments 8 and 14**), and complete a table about their family members.

They will then do a card sorting exercise related to the frequency food items that were consumed in their families. The pre-focus group guide is available in **Attachment 8**. The moderator focus group guide (**Attachment 9**) is divided into the following sections: Greetings, Logistics, Introductions, Daily Life at the Time of the Test, and Food and Drink (frequency and quantities consumed). A specific amount of time is allowed for each section to ensure that all sections are covered during the two-hour time given to each focus group.

Focus group exercise

After the consenting process and introductions, the moderator will begin with discussion of the time period, living situations, number of family members, etc. The moderator will direct the discussions and allow for members to deliberate as needed on various topics.

Card sorting

The focus group interview will begin with a 10-minute card sorting exercise. Card sorting is a useful mixed-method tool which allows for quantitative and qualitative mapping of concepts from the participants' point of view. From the list of foods identified in the pilot study, those foods that are important sources of exposure to radionuclides were selected for a card sorting exercise. Cards will be printed with the image and name of each food of interest. Each participant will be asked individually to sort the cards into two piles: those foods consumed by his/her community in 1945 (or 1940s and 1950s), and those foods that were not. This exercise aims to determine the foods consumed by specific communities. Sorting through the images helps to familiarize the participant with the food items that we are most interested in quantifying during the focus group interview. From the many types of foods that were consumed, participants will then be asked to sort the foods according to food groups and then rank the foods in order from most to least frequently consumed. The sorted and ranked cards will be stapled together in their piles and will be later recorded and collated with the rest of the information gathered in the wall chart exercise (described next) of the focus group.

Wall Chart

Questions will be asked about consumption patterns of the individual's family members; quantification will be made for each food item, for each age group, and for each gender. The information will be recorded on a wall chart by the co-moderator as well as by the note takers. The types of food will be listed across the top of the table and the age groups will be listed in the rows of the table (**Attachment 9**). Each participant will be asked to estimate the amount of each food consumed by each age group using samples of typical serving ware, which were identified during the pilot study. This method was previously used by members of the Trinity Team and was proven effective in the reconstruction of diet from the distant past among an elderly Kazakhstan population (Schwerin et al., 2010).

If permission is given by all participants, there will be an audio recording made of the session. Translators/interpreters with experience in the study populations and who are certified to translate and interpret will be present when needed. Participants will not be identified by full name in any recorded materials. Audio recordings will be destroyed at the conclusion of the study. At the end of the session, participants will be transported home as needed and compensation will be mailed to them. Participants can leave the session at any time and will still receive their compensation and transportation.

Following each focus group session, there will be a debriefing with the focus group moderators, NCI team members, and any consultants on site. Any items that may need further clarification, elaboration or verification will be incorporated into the subsequent focus group written record. Any modification of procedures or further clarification of a topic will be incorporated into subsequent focus groups. Upon completion of focus group sessions in each geographic region, the research team will gather to review the notes taken by the co-moderator and a second member of the research team. During that time, lists of recurring themes will be generated, typical quotes from participants will be noted, and terms, phrases and findings that have language or cultural significance and may not be conveyed well when translated, will be discussed.

Upon completion of the data collection phase, we will use transcripts, notes and charts to prepare a report of the focus groups. These notes and supplementary material will be used to help assess the nature and extent of uncertainty of what was reported during the focus group. Preparation of the focus group reports will be assisted through consultation with SSS (Social & Scientific Systems). Quantitative estimates of food intake and other lifestyle descriptions (e.g., typical time outdoors) will be synthesized into tables for development of the models of lifestyle and diet to be used in the exposure assessment.

In-depth interviews with Key Informants

For each diet or lifestyle topic, there is a series of questions. The study team has designed an in-depth key informant interview guide (**Attachment 7**), including detailed open-ended questions to help stimulate participant memory. One team member will conduct each individual interview, while another will be responsible for recording the information. The interviewers will encourage the subject to provide an estimate or answer to all of the questions posed.

The topics of the questions cover the roles of women and men within their social structure, specifically with regard to the production and consumption of food during the time of the Trinity test as well as lifestyle habits of community members. The interview guide is divided into sections addressing dairy, meat, and vegetable consumption, source, and storage of milk/milk products. It also focuses on building materials of houses and schools, availability of milk/milk products, home remedies, time outdoors, and grazing practices. There is a specific amount of time allotted to each section to ensure that all sections are covered during each in-depth interview. The guide does not elicit information about quantities of dietary constituents consumed. This in-depth interview guide was pilot tested and proved to be an effective tool during the Phase 1 study.

Prepare focus group data for analysis

During the focus groups and interviews, the study team (composed of two NCI moderators, one with extensive experience working with tribal communities and one with Hispanic communities, and up to two observers) will take notes and record numeric data (e.g., age-specific estimates of the quantity of cow milk consumed) onto the moderator guide (**Attachment 9**).

Detailed transcripts of the interview and provision of spreadsheets from the wall charts will be prepared by the REB support services contractor, SSS, following the completion of the fieldwork. Trinity study investigators will abstract the results of the focus/groups interviews with regard to key radiation exposure pathways and create a database to be used in dose reconstruction efforts. The transcripts and data collection sheets will summarize the interview data and prepare them for

calculating summary statistics as a basic model of the Native American, Hispanic, and non-Hispanic White diets with regard to key radiation exposure pathways. From the transcripts and data collection sheets, variables will be created and used for summarizing the results of the interviews.

Data quality measures will be a major component of the interviewer approach. The study team will use focus group and interviewing guides to elicit information in which all aspects of the study protocol are standardized and described in detail. Each section of the guide will have a specific time allotted so that all sections are covered during each focus group session or in-depth interview. As stated above, the note-takers will collect responses on data collection sheets thus improving the consistency of questions across interviewees. For focus groups, the information collected on data sheets will be supplemented by data collected on a large wall chart. The audio recordings of the interview session will be used to generate and check transcripts; this will improve the reliability of the data.

In an effort to assess the quality of the focus group data obtained in the proposed study, we have included 5 focus groups comprised of Non-Hispanic whites. For efficiency, they will be in the same locations as planned focus groups for Hispanics within the fallout zones. These focus groups will be conducted in the following ecoregions; a small town in a mountainous region in the south, an urban area in a mountainous region in the north, an urban area in a plains region in the north, and a rural area in a plains region in the central area.

The data obtained in the focus groups will be compared with published data on "Estimation of 1945 to 1957 Food Consumption" prepared for the Hanford Technical Steering Panel and the Centers for Disease Control and Prevention (Anderson et al., 1993). In that compendium, data were taken from a 1977-78 USDA National Food Consumption survey and estimated intakes back to particular years based on food disappearance data as well as home production for rural areas. While their focus was on Oregon and Washington State, they evaluated differences by region for intakes of key foods, including milk, and found no difference with the region that included New Mexico but significant differences with other regions. Sensitivity of their backcasting method was tested against local and national surveys that were conducted between 1965 and 1969. They found better agreement of their backcasting method for particular years of the local surveys than with a USDA survey conducted in 1965-66. Given their careful methods and agreement with smaller surveys, the assumption will be made that their method will also be appropriate for the 1945 time period. The data are available by urban or rural status, season, age and sex groups that match the groupings in our focus group guide.

We will compare intakes of milk, spinach, eggs and lettuce, each grouped into 4 categories, stratified by age and sex, estimated from the focus groups with those in the published data using chi-square tests. We will consider $p<0.01$ a statistically significant difference to account for multiple testing. If there is systematic under or over-reporting for all four foods we will consider using that information to correct the results from the focus groups (understanding that it is based on very small sample sizes).

Overall, if the ranges for a given item are consistent between communities/interviewees, age-specific summary tables will be created for reported milk and dairy consumption, other food consumption (e.g. green leafy vegetables, grain, fruit, and meat), water consumption and source, building construction materials, and time spent outdoors. In addition to summary statistics (e.g. mean), these tables will contain measures of variability (e.g. standard deviation, minimum, maximum).

Estimation Procedures

Radiation dose

When estimating radiation doses, it is necessary to distinguish between *external* and *internal* sources of radiation. *External* exposure occurs when radiation from a source outside of the body penetrates the body and is absorbed within it, while *internal* irradiation results from exposures to radionuclides that are within the body, i.e., radioactive materials that have been taken into the body through ingestion or inhalation.

For estimating both external and internal radiation exposure from fallout, the most essential input data are historical measurements of exposure-rate from radioactive fallout deposited across New Mexico at a specified time (relative to the detonation time). Our dose assessment is to be based on the analysis of fallout exposure-rates (Quinn, 1987) which extended from the detonation site towards the northeast supplemented with an extension by Cederwall and Peterson (Cederwall & Peterson, 1990) to the northern border of NM based on meteorological analysis.

The deposition density (radioactivity of each nuclide deposited per unit area of ground) of individual fallout radionuclides will be estimated from published factors (Hicks, 1981; Hicks, 1982; Hicks, 1985; Hicks, 1990) and the exposure-rates decay corrected to time of deposition. Deposition density on plant materials, more correctly called *interception*, will be estimated for leaves of vegetables, plants, and fruits that contribute to dietary intake. Interception calculations will use historical data on precipitation in New Mexico in the 48 hours following the Trinity test. Plants known to have been consumed by grazing animals and New Mexico populations are listed in Table 3 of **Attachment 3**. Based on considerations of standing biomass and leaf area, plants will be grouped by similarities such that a simplified interception modeling strategy can be developed.

Using a series of radiation exposure models that have been developed for other assessments of fallout exposures but adapted for the Trinity test, information from estimated deposition density on the ground and of interception onto plants will be combined with data on lifestyle and dietary patterns to estimate internal and external organ doses received by the population of New Mexico. This strategy was used in the study of exposures in Kazakhstan (Land et al., 2015; Land et al., 2008) and in the Marshall Islands risk projection (Land et al., 2010).

External irradiation after Trinity was dominated by gamma radiation from radioactive decay of fallout deposited on the ground. The model for external dose calculation is presented in detail by Simon and colleagues (Simon et al., 2006). They estimated the external dose received in villages near the site of the first Soviet nuclear test in Kazakhstan, which was a nuclear device nearly identical to Trinity. Individuals receive higher doses when they are outside than when they are indoors because the gamma radiation is reduced by the shielding provided by building materials. The magnitude of the shielding effect depends on the materials (e.g., wood, adobe, or stone) and design of the building. Typically, thick adobe (mud) walls

provide greater shielding from outdoor radiation than do older-style wood frame houses. In the NCI's 2008 report to Senator Bingaman, it was assumed that construction materials used for houses and buildings were those typical to NM (National Cancer Institute, 2008a, 2008b). Moreover, estimates of the typical numbers of hours spent outdoors by different age groups were used in dose calculations. None of those values have yet been corroborated by field data collection.

Internal irradiation results from exposures to radionuclides deposited in the body, mainly via ingestion of contaminated foods or water, but also by inhalation of contaminated air. In addition to fresh milk, animal tissues and organs as well as all plants can be contaminated with radioactive iodines, especially Iodine-131 (I-131 or ^{131}I) and Iodine-133 (I-133 or ^{133}I). Generally, fresh milk, leafy vegetables and possibly animal organs (e.g., thyroid glands-if consumed) are the most important contributors to the dose to the thyroid gland. The thyroid is the most highly exposed of all organs. Mother's breast milk can also be contaminated with radioiodines if the woman consumed locally produced dairy products. Factors to quantitatively estimate the concentration of radioiodine in mother's breast milk are available (Simon et al., 2002). A list of foods consumed is presented in **Attachment 3**.

For organs and tissues other than the thyroid gland for which the radiation dose will be assessed, including stomach, colon, and red bone marrow, fallout radionuclides other than radioiodines typically dominate the dose. For example, for the case of Marshall Islanders exposed to radioactive fallout, Simon et al. (Simon et al., 2010) calculated that the internal dose to the colon was dominated by ^{239}Np, ^{132}Te, ^{140}Ba, ^{99}Mo, ^{140}La, while exposure of the red bone marrow was dominated by ^{132}Te, ^{89}Sr, ^{140}Ba, ^{99}Mo, and ^{239}Np, and exposure of the stomach was dominated by ^{239}Np, ^{132}Te, ^{132}I, ^{133}I, ^{99}Mo, and ^{140}La.

Internal dose may result from consumption of foods other than dairy foods though milk products typically contain the highest concentration of radioiodines. Drinking water can contain radioactive contamination though the magnitude depends on the source of the water, physical factors that would affect dilution (e.g., stream flow) and the degree to which the water was exposed to the open atmosphere. Open water catchments would be more susceptible to contamination than well water. Consumption of leafy vegetables, herbs, and medicinal plants, whose leaves can collect and retain fallout particles, can also result in significant intakes by man. In addition, meat and bread or other flour-based foods can contain radioactive contamination though they are more susceptible to contamination with longer lived radionuclides, e.g., ^{137}Cs.

In addition to the estimation of radionuclide intakes via dairy foods, the dose assessment will incorporate the estimate of radionuclide intakes via drinking water, leafy vegetables, and animal flesh, in particular, organs such as the thyroid of small mammals that may have been consumed as part of the diets of tribal communities (Harper et al., 2002). The dose assessment will also account for special sources of radionuclide intake, such as breastfeeding (Simon et al., 2002) and inadvertent and intentional ingestion of soil (Maxwell & Anspaugh, 2011; National Council on Radiation Protection and Measurements, 1999; Simon, 1998), a pathway of concern in dry, dusty conditions, e.g., found in the desert environment of New Mexico.

Pathway dose modeling and established dosimetry models for fallout (Beck et al., 2006; Kleinhans, 2010; National Cancer Institute, 1997) will use air, food, and water intake rates as derived from published data for white populations (Kleinhans, 2010; National Cancer Institute, 1997) combined with focus group findings and the data obtained from interviews with tribal

community members, Hispanics/Latinos, and non-Hispanic whites combined with the data obtained from literature, Phase 1 field notes to estimate typical age-specific radiation organ doses per unit of radioactivity deposited on the ground for each of the three ethnic groups. Using those values, typical ranges of radiation doses to residents can be estimated within each county by combining the estimates of dose per unit deposition with the radioactivity deposition densities that will be estimated for each county precinct of New Mexico. Finally, the average dose with each county for groups defined by age group, gender, and ethnicity will be derived based on weighting by the population size in each area of the county with differing fallout deposition

Several factors and calculations will be updated, compared to the 2008 calculations, in order to improve the previous exposure assessment. These factors include:

- Based on list of plants from Phase 1 interviews, a review of fallout interception on plants based on plant characteristics and their availability within each ecozone,
- Geographic distribution of the radionuclide contamination on pasture grass following the detonation estimated from the aforementioned exposure-rate monitoring data,
- Occurrence of precipitation, and the local rainfall rate (derived from historical meteorological records),
- Radionuclide concentration in cow and goat's milk (with emphasis on radioactive iodines) estimated by typical amounts of pasture grass consumed by the animal per day and the location-specific contamination of the grass,
- Typical values and ranges of daily consumption rates for food items of interest for representative sex and age groups (adults (16+), 11-15-years old, 5-10-years old, 1-4-years old, infant to 1- year old, breastfeeding mothers, pregnant women),
- Age-specific organ dose coefficients corresponding to intake of each radionuclide as derived and recommended by the International Commission on Radiological Protection (*98*).

Diet and Lifestyle Models

The model diets, as noted earlier in this Protocol, are intended to be age-, ethnic group-, ecoregion- (and possibly gender-) specific, and to include descriptions of the foods regularly consumed in summer months in the mid-1940s as well as quantitative estimates of the frequency and quantity (measured in mass) of each. While such an undertaking would be difficult to impossible to achieve for individuals, a risk projection only requires that diets and doses be assessed for representative (typical) persons in each strata (age, gender, ethnicity, ecoregion). The data from the focus groups to be conducted, supplemented with data obtained from key informant interviews, will be used to assess mean values (i.e., representative) and ranges of the amounts of foods consumed. The strategy of using focus group and interview information to develop model diets was used in the REB study of thyroid disease in Kazakhstan (Land et al., 2015) - a study of exposure to radioactive fallout from Soviet nuclear tests which included the Soviet test of a device that replicated Trinity. Details on the data collected and the model diets constructed were published by Schwerin et al, 2010 (Schwerin et al., 2010).

Lifestyle models emphasize exposure-related attributes that differ from dietary intake. The primary variables of interest are the materials used for home construction and amount of time

spent in- and outdoors during summer months. Other variables that may be identified in focus groups and interviews will be incorporated as dictated by the availability of data.

Models will be derived based on literature, Phase 1, and Phase 2 data.

In addition to point estimates of each parameter, a range of values will be generated from the data in order to quantify the uncertainty.

Dose and Uncertainty Assessment

Methods of assessing exposures are described above. In this section, uncertainty of dose is addressed.

Uncertainty of diets and related radiation doses will be assessed, though in less detail than for the Kazakhstan analytic epidemiologic study. In this study, the data collected will be used to estimate plausible ranges of diet and lifestyle and to propose probability density functions to describe variation within each county and stratum (where strata are defined by ethnicity, age, and gender). Well-developed uncertainty analysis techniques based on Monte Carlo sampling (numerical simulation) will be used to assess uncertainty in dose and in risk.

In short, the organ dose to any person is a function of physical factors (*PF* in eq. 1 below) related to fallout deposition and concentration in foodstuffs, human factors (*HF* in eq. 1, e.g., diet, dwelling type, time spent in and outdoors), and dose conversion factors (*DF* in eq. 1) which convert the radioactivity intake (for internal exposure) and the air exposure rate (for external exposure) to radiation dose:

$$D = f(PF, HF, DF) \quad (1)$$

Physical factors are numerous and include the parameters of fallout deposition that are partially summarized in the fallout map provided in Appendix A but also include fallout transit time, factors to describe interception by plants, weathering effects, and that quantitatively describe uptake and retention in foodstuffs. A detailed accounting of all physical factors was conducted in the NCI study of thyroid disease in Kazakhstan (Land et al., 2015) but is also employed in the NCI fallout dose calculator that is now being updated (http://dceg.cancer.gov/tools/public-data/risk-calculator-offline), studies of Chernobyl fallout (Drozdovitch et al., 2015), and studies of Nevada Test Site fallout (Beck et al., 2006; National Cancer Institute, 1997; Till et al., 1995).

Human factors in this context are diet (daily intakes of each food type by strata) and lifestyle parameters, in particular, type of residential construction, and time spent in and outdoors in summer months.

In the dose assessment strategy for this study, three doses within each county and strata will be estimated: a high value, a mean value, and a low value. These doses will effectively encompass the plausible range of true dose for anyone who self-identifies in a particular stratum. For this purpose, the minimum, mean, or maximum dose will use the minimum, mean, or maximum value of fallout (from the map in **Attachment 2**), respectively, in county. The numerical values of the other physical factors needed to compute dose will be median values derived from literature-based probability density function that are summarized in numerous publications. Similarly, low, mean, or maximum of the human factors (as derived from the focus groups) for each strata will be used to estimate the low, mean, and maximum dose per county.

The combination of PF, HF, and DF factors needed to estimate the point estimate and the uncertainty of the low, mean, and high doses (by strata within each county) will be computed from a Monte Carlo sampling of the relevant parameter distributions.

Risk Projection

Overview

The analytic approach for risk projection in the Trinity study will be similar to that used in the cancer risk projection conducted for the population of the Marshall Islands who were also exposed to radioactive fallout from nuclear testing (Land et al., 2010) with some specific differences. We will estimate external and internal radiation dose to the four tissues of interest. The first difference is that we will follow the recommendations of the National Academy of Sciences in their Biological Effects of Ionizing Radiation (BEIR VII) report which was released shortly prior to the Marshall Islands work (Land et al., 2010). Second, these doses will be applied to baseline cancer rates, lifetables, and published sex- and organ-specific risk coefficients to derive the corresponding excess cancer cases per 1,000 persons in each group specified by certain strata such as age at exposure, sex, and ethnicity. Cancer risk estimates per 1,000 will be presented in terms of the number of cancers by organ site that already likely occurred and that are projected to occur among non-Hispanic whites, Hispanics/Latinos, and Native American populations in New Mexico as a consequence of exposure to fallout from the Trinity test.

Study population

We have obtained several sources of underlying population counts for these analyses: the 1930, 1940, and 1950 U.S. census reports which contain population counts by county, in addition to the Handbook of North American Indians (Ortiz, 1979; Sturtevant & Ortiz, 1983), which contains more detailed information of population distributions of various tribal communities in New Mexico. In brief, the total population of New Mexico in 1940 was reported to amount to 531,818 people, including over 270,431 non-Hispanic whites, 221,881 Hispanics (of any race), and 34,510 Native Americans (U.S. Census Bureau, 1940; Ortiz, 1979).

While the number of non-Hispanic whites and Hispanic whites combined is available by county through the 1940 census, the number of people in each of the two ethnic groups is only available for the state of NM as a whole through a 5% sample. Several sources of U.S. census data will be used to estimate the number of Hispanic whites separately from non-Hispanic whites by county. The 1930 census contained a "race" category for "Mexican" which represented birth place in Mexico or parents' birth place in Mexico. This definition would suggest that Hispanic whites represent approximately 15% of the total NM population. The 1940 census, which was based on a 5% sample, indicates that Hispanic whites (using the definition of Spanish mother tongue) represent 41.7% of the entire population of NM. We will use the distributions of "Mexican race" across counties based on the 1930 census scaled to the more inclusive 41.7%. We will set the number of Hispanic whites to equal the total population when the estimated number of Hispanic whites exceeds the known total population for that county. To obtain the total population alive in 1945 during the time of the test, we will interpolate the 1940 and 1950 census population estimates.

Baseline cancer rates

Incidence rates for specific cancer sites vary from population to population, as well as over calendar time, across ages/birth cohorts, sex, and race/ethnicity groups within a population. New

Mexico state cancer incidence rates prior to the establishment of the NM SEER registry in 1973 are limited (Jemal et al., 2010), but we are currently working with the head of the NM tumor registry to obtain cancer incidence data by age as early as 1969 for the state of NM (Wiggins, 2015). Cancer incidence rates for Hispanic whites became available in 1981 through SEER. Native American cancer incidence rates are available through the "Other" category in the NM registry and through the Arizona Indian Registry, which was also established in 1973. Cancer rates have been historically lower in Hispanic whites in NM than in non-Hispanic whites. In the absence of state data, national data from the first three major cancer incidence surveys conducted in the United States have been obtained. These are the Ten Cities Surveys of 1937 and 1947 (also referred to as the First and Second National Cancer Surveys), and the Iowa study of 1950 (Dorn, 1944; National Institutes of Health, 1954; National Institutes of Health, 1955). The areas surveyed included about 10 percent of the U.S. population and was representative of the geographic distribution of Northern, Southern, and Western cities with populations greater than 100,000, but was not entirely demographically representative of the U.S. population. Denver, Colorado was the city closest to New Mexico. From 1950 to 1957, the End Results in Cancer program provides cancer incidence by age from 4 central registries and 9 hospital registries across the United States (Crittenden et al., 1961). We have obtained these documents providing cancer incidence to either use directly or triangulate with the preferred method of estimating cancer incidence.

Mortality rates are available for the whole of the United States from 1930 through the National Center for Health Statistics. Cancer mortality in New Mexico for non-Hispanic whites, Hispanic whites, and Native Americans have been estimated for the period of 1958-1982 (Becker, 1993). In the absence of cancer incidence data for NM by race/ethnicity, for more lethal cancer sites we may use mortality rates to estimate incidence by calculating the ratio of incidence to mortality during a period when both measures were available and extrapolating back in time to the calendar period of interest. To improve these estimates, we may incorporate a lag-time, i.e., time from cancer diagnosis to death available from hospital based registries in New Mexico.

To the degree possible, the limitations of the limited baseline cancer rate data will be addressed by uncertainty analysis techniques as follows. We will linearly extrapolate rates from 1969 to 1950 by fitting Poisson regression models adjusted for sex and racial/ethnic group. Sources of uncertainty in our risk projection model will include those inherent in the calculation of baseline cancer rates and due to the extrapolation method as well as the estimates of average organ dose within each stratum. To obtain confidence intervals for excess cancer case estimates, we will perform a parametric bootstrap procedure for each cancer site. In that method, we will generate bootstrap case counts in each demographic stratum by drawing from a Poisson distribution whose mean is the count predicted by the risk projection model. We will then re-fit the Poisson model to the resulting case counts and use the re-fitted models to predict cancer rates. We will repeat this procedure 1000 times, and then compute the variance of the prediction based on the 1000 predicted values. This approach will provide variance estimates that account for all sources of variation (under some mild assumptions). We will provide a detailed table of the baseline cancer rates that were used for our calculations in a final manuscript. Each factor used in the calculation of the excess number of cancers per 1,000 people has an associated uncertainty, including radiation doses, parameter values of dose-response models, and other factors used for the risk projections. The uncertainty of each component will be characterized by probability distribution functions and the error propagated by Monte Carlo methods as in previous REB studies on exposures and risks in the Marshall Islands and in Kazakhstan and as described in

previous paragraphs.

Radiation risk models

Weighted BEIR VII dose-response models will be used for estimating the excess relative risk and excess absolute risk per unit dose of radiation (National Research Council, 2006). Most of the radiation dose-response coefficients used for risk projection are based on the analyses of the Japanese atomic bomb survivors (Preston et al., 2007), which are considered the gold standard in radiation risk assessment. However, unlike the acute, direct external radiation exposures experienced by persons exposed to the Hiroshima and Nagasaki atomic bombings, the exposures associated with the Trinity fallout event will be considered to be continuous. Latency periods of different lengths will be considered, depending on the cancer site using an approach developed by the National Institutes of Health (National Cancer Institute, NCI-CDC Working Group to Revise the NIH Radioepidemiological Tables, 2003; National Institutes of Health, 1985).

Population distribution, race/ethnicity-, ecoregion-, organ-, sex-, age-specific doses, and organ- and sex-specific risk coefficients will be used to project the corresponding cancer risk estimates for the different population subgroups considered.

Uncertainty

Sources of uncertainty in our risk projection model will include those inherent in the calculation of baseline cancer rates and due to the extrapolation method as well as the estimates of average organ dose within each subgroup (e.g., age at exposure, gender, and ethnicity). To obtain confidence intervals for excess cancer case estimates, we will perform a parametric bootstrap procedure for each cancer site (Robbins et al., 2015). We will generate bootstrap case counts in each demographic stratum by drawing from a Poisson distribution whose mean is the count predicted by the risk projection model. We will then re-fit the Poisson model to the resulting case counts and use the re-fitted models to predict cancer rates. This approach will provide variance estimates that account for all sources of variation (under some mild assumptions). We will provide a detailed table of the baseline cancer rates that were used for our calculations in the final manuscript. Each factor used in the calculation of the excess number of cancers per 1,000 people has an associated uncertainty, including radiation doses, parameter values of dose-response models, and other factors used for the risk projections. The uncertainty of each component will be described using probability distribution functions and the error propagated by Monte Carlo methods as in previous studies we have conducted (Drozdovitch et al., 2015; Land et al., 2010; Land et al., 2015).

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Ability to gain and retain participation in study is crucial to gathering accurate data on lifestyle and diet for this group during the 1940's. Advanced community outreach to raise awareness about the project and to encourage participation will be utilized. Invitation letters along with supporting materials from recognized leaders and organizers within the local community will be distributed to potential participants in advance of making contact to request their participation in the study.

To maximize response rate study investigators will also create flyers (**Attachment 4**) that will be distributed to each community, recruiting potential participants. In addition, they will be using community health research networks within each tribal nation and with the Latino community.

They will be working with *promotoras de sa*lud (community health workers) in these networks who will identify potential participants. This proposed recruitment approach has worked successfully on previous studies with these communities. NCI will establish a contract with a university researcher who has extensive experience working with the communities and organizations of interest.

Interviews and focus groups will be conducted at community locations in Albuquerque and New Mexico tribal communities that are frequented by (and convenient to) members of the intended study population. These may include tribal elderly centers, tribal cultural centers, Hispanic/Latino community centers, and/or urban senior centers. Efforts will be made to ensure participation is easy and non-burdensome as possible.

Participation rates and retention will be maximized through several other means such as: providing incentives, extensive moderator training, and consent forms **(Attachment 15).** Discussion and interview materials will be available in Spanish, English, and other native languages as required. The study investigators anticipated a 50% response rate. It is anticipated that 50% of those screened will participate in either the focus groups or an individual interview.

B.4 Test of Procedures or Methods to be Undertaken

In 2014, a successful pilot study was conducted, via individual interviews, collecting information on lifestyle and diet for 9 key informants of Native Americans and Hispanics\Latinos living in New Mexico who were alive at the time of the bomb (currently $\geq$ 70 years old). More information on the pilot study is found in **Attachment 3**. The pilot study established collaborations and partnerships in the target communities, identified the logistics needed to conduct focus groups, and proved the feasibility of recruiting Hispanic and Native American participants aged 70+, who were alive at the time of the Trinity bomb. Moreover, the data from the pilot phase was used to inform the design of this larger study, which will collect lifestyle and diet information via a series of targeted focus groups. The information acquired from these 9 individual interviews was used to refine the focus group guide (**Attachment 9**).

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals who were consulted on the statistical aspects of the study and individuals who will be involved in collecting and/or analyzing data are shown in **Attachment 17.**

ATTACHMENT 1 – Background on the Trinity Project

ATTACHMENT 1 – Background on the Trinity Project

Background

The Trinity nuclear test was the culmination of the Manhattan Project that began in 1942 to develop an atomic bomb. The nuclear device that became known as Trinity was designed and fabricated at the Los Alamos Laboratory in northern New Mexico and tested in south-central New Mexico at the Alamogordo Bombing and Gunnery Range on July 16, 1945. Trinity was the first test of a nuclear fission device in the history of the world and resulted in the first nuclear explosion. The device served as a prototype for the Fat Man plutonium implosion device used one month later in the bombing of Nagasaki, Japan.

Investigators in the Radiation Epidemiology Branch (REB) of the Division of Cancer Epidemiology and Genetics (DCEG) have been involved for many years in the development of methods to estimate radiation doses and cancer risks from exposure to radioactive fallout from nuclear testing in the U.S. and at sites worldwide. In particular, Drs. Andre Bouville (retired) and Steve Simon (presently head of the REB Dosimetry Unit) have conducted considerable research in this area and have experience with dose assessment at multiple nuclear test sites worldwide (Beck et al., 2006; Bouville et al., 2002; Gilbert et al., 2002; Land et al., 2010; Land et al., 2015; Land et al., 2008; Simon & Bouville, 2002; Simon et al., 2004; Simon et al., 2006; Simon et al., 2010).

The NCI published a now well-known two-volume report on exposure of the American people to the Nevada Test Site (NTS) fallout (National Cancer Institute, 1997). That report was reviewed by the National Academy of Sciences, Institute of Medicine (Institute of Medicine, 1999) and shortly afterwards, the NCI developed the first on-line web-based calculator so that members of the public alive during the years 1951-1962 could estimate their thyroid dose and thyroid cancer risk from exposure to the NTS fallout. Information on Iodine-131 from nuclear weapons testing fallout can be found on the NCI's website (http://www.cancer.gov/ cancertopics/causes/i131) as well as the web-based calculator (https://ntsi131.nci.nih.gov/). Both have been the subject of substantial interest over the years since their creation.

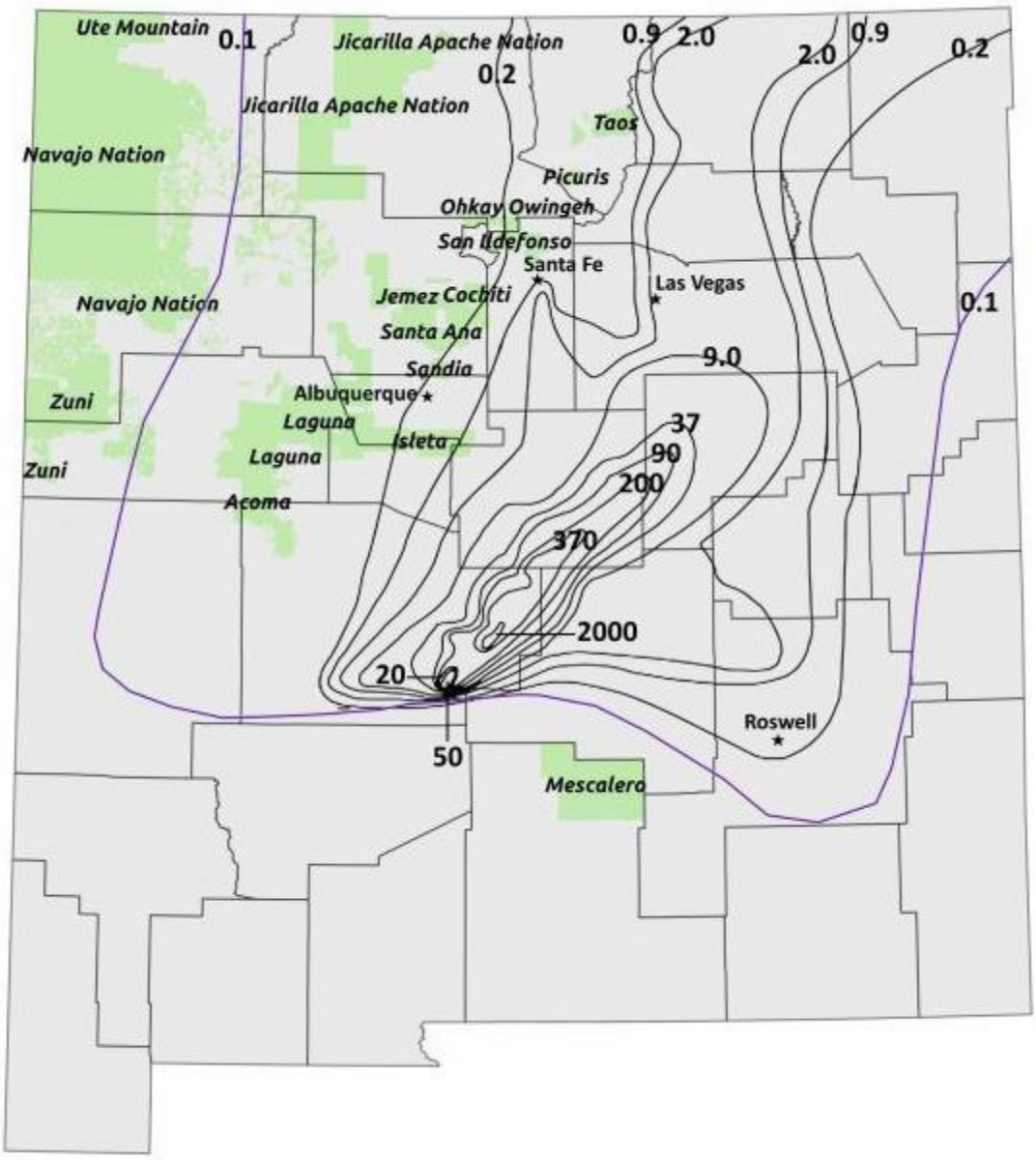
Senator Jeff Bingaman (D, NM) of the Senate Committee on Energy and Natural Resources, requested the NCI in late-2007 to estimate the health risks to the New Mexico population from the Trinity nuclear test conducted in 1945. In response to this request, Drs. Bouville and Simon prepared a preliminary assessment of radiation doses to New Mexico residents and delivered a brief report to Congress in early 2008 (National Cancer Institute, 2008a, 2008b). The NCI dose assessment for Trinity, however, was never prepared for submission for publication in peer-reviewed literature because of the tenuous nature of many assumptions made in the assessment, particularly with respect to dietary patterns in 1945. While some modeling of Native American lifestyles and radiation doses from nuclear testing has been undertaken (Frohmberg et al., 2000), little information is available, in particular, about dietary patterns among tribal community members or Hispanics\Latinos in the southwestern U.S. in the 1940s. In the preliminary study, crude estimates of age-specific, county average doses were derived for the populations residing in the 19 New Mexico counties that were deemed to be most affected by radioactive fallout from the Trinity test site and in certain other locations in New Mexico (**Attachment 2**). The dose estimates were provided for the thyroid gland and bone marrow, which are the target tissues for two sentinel malignancies associated with fallout radiation exposure: thyroid cancer and

leukemia, respectively. The estimated thyroid doses mainly accounted for the consumption of dairy products (primarily fresh milk) contaminated with Iodine-131 from the fallout (resulting in *internal dose*) and dose to the bone-marrow that arose from the decay of radioactive fallout on the ground (resulting in *external dose*). The crude assumptions that were made regarding the dietary and lifestyle habits of the populations of New Mexico were more relevant to the white population than to the Hispanic or to the Native American populations.

Since the preparation of the NCI's report to Congress, REB investigators have substantially improved their dose assessment methodology. These methods have been used for a risk projection study of persons exposed to radioactive fallout in the Marshall Islands (Kleinhans, 2010) and an epidemiologic study for persons exposed to radioactive fallout in Kazakhstan near the Semipalatinsk nuclear test site used by the Soviet Union (Drozdovitch et al., 2011; Land et al., 2008; Schwerin et al., 2010). In order to comprehensively apply these improved dose assessment methods to the Trinity test, the acquisition of appropriate lifestyle and dietary input data for the populations in New Mexico is required. In particular, information is needed about the lifestyles and diets of tribal community members and Hispanic populations for which no special assumptions were made in the preliminary 2008 assessment.

ATTACHMENT 2 – Fallout Map of New Mexico

ATTACHMENT 2 – Fallout Map of New Mexico



Map of New Mexico showing county outlines and overlaid with composite of exposure- rate iso-contours based on Quinn (*85*) and Cederwall and Peterson (*86*). Green colored areas are Native American pueblos. Trinity ground zero (detonation site) is located at the lower central location were contours converge (northwest of Mescalero Apache pueblo). Note: iso-contours are not indicative of radiation dose but are lines of equal exposure rate (mR/h) from fallout deposited on the ground normalized to 12 hours post-detonation. Data derived from iso-contours are used as input data to radiation dose calculations.

ATTACHMENT 3 - Trinity Study: Phase 1 Summary of Findings

ATTACHMENT 3 - Trinity Study: Phase 1 Summary of Findings

September 15-30, 2014

Introduction

Between September 15-30, 2014 the Trinity Field team traveled to New Mexico to conduct Phase I of the **Study to Collect Data on Diet and Lifestyle Patterns to Improve Estimation of Radiation Doses and Health Risks from Exposure to Radioactive Fallout from the Trinity Nuclear Test.** The aims of Phase 1 of the Trinity study were to:

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 Phase 1 trip. This Report will summarize the methods and results for Aims 4-6.

Aim 4

To determine the feasibility of recruiting Hispanic and Native American participants > age 69, we set out to recruit and interview 9 key informants from a variety of geographic areas across New Mexico. Participants were recruited by using social networks of local collaborators, attending community events, and screening individuals who contacted the NCI after reading about the study in local newspapers.

The field team successfully recruited and interviewed 9 elders, between ages 69 and 101 years old from 6 diverse geographic locations (mountains, urban, rural). These participants included: 4 males and 5 females; 3 Native American, 6 Hispanic; 2 tribal Nations, and 5 New Mexican counties. The breakdown by each participant can be found in Table 1.

While we were limited by OMB regulations to recruit only 9 individuals, we identified more eligible participants and these contacts have been saved for potential participants in Phase II. Leaders of Tribal Nations also informed us of how many other members of their community would be eligible for Focus Group Interviews during Phase 2, which demonstrated the feasibility of conducting future Focus Groups.

Aim 5

To collect information about diet and lifestyle practices, we developed and administered the Key Informant Interview Guide with 9 participants. These interviews either took place in participants' homes or private spaces provided by local community centers. For each interview there were up to two interviewers and up to two note takers. Each interview was also audio-recorded and later transcribed. Using a structured key informant guide, participants were asked to recall the summer

of 1945 and then to report on their and their families' consumption of water, meat, dairy, vegetables, and traditional foods. Participants also reported how food was prepared and from where it was sourced. All participants reported on the types of homes their community lived in, the types of festivities that took place in the summer of 1945, and the amount of time people of different ages spent outdoors. If participants indicated that they could not remember specific aspects of their diet or lifestyle in 1945, this was noted and the interview proceeded. Overall, the participants (with the exception of the woman aged 101 years) were able to recall what life was like in their part of New Mexico in 1945. Overwhelmingly, as participants thought about their lives as children, they would comment how different life was back then from now. Specifically, they remarked how most of the food came from their surroundings.

Table 2 summarizes number, geographic location and ethnicity of participants who reported important pathways of exposure during key informant interviews. The next section summarizes each section of the table and provides specific excerpts from the interview transcriptions to provide further ethnographic details.

Water

Access to water varied from participant to participant. Drinking water came from a variety of sources depending on the geographic location, including: acequias, ditches or streams (56%), cisterns (11%), wells (33%), piped water (33%), or a combination of these. All of the participants with piped water lived in urban areas. About one-third of participants remembered their families also collecting rain water in barrels, but specified that this water was normally used for cooking, especially beans.

Meat

Participants reported eating the meat from cows, sheep, pigs, elk, deer, chickens, small wild birds, rabbits, and squirrels. Meat from these animals was either eaten soon after butchering during special occasions, such as summer Feast Days or fiestas, or hung to dry and later cooked into stews. Participants (44%) confirmed eating the organ meat from lamb, chickens, rabbits, elk, deer, and pigs; however it was more likely consumed by people of lower socioeconomic position. When talking about the meat that would be served during the summer Feast Days, Participant 2 explains:

"No, we would not use the internal to feed the people [..], but we would save those internal organs. So anyways, you know, […] for the family use only. For example, like the sheep, that's what my grandma used to clean out you know, the inside the thing and the heart [or] liver. And I don't think the people that actually came to eat, they want you know, pure meat, you know, and not anything internal. Like who wants to be eating that you know, during the Feast Day as well, too? So, we saved those anyway, you know. And they were cleaned out anyhow then. [The] way I'd seen my grandma do this, she would go down to the creek or to the ditch and clean all the inside out and washed them out and then they would be sort of like tie them up and dry them out."

A majority of participants (67%) reported eating dried meat, also known as jerky or *carne seca*. Many people made their own dried meat by hanging it on clotheslines, under the porch roofs or, as one Native American reported, from teepee poles. Participants reported either drying the meat that they butchered themselves or drying meat that they purchased or traded with surrounding communities.

The majority of jerky was made from beef, deer or elk; pigs and lamb were more likely butchered and stored in other ways. Rancher families, who were typically Hispano, were more likely to eat sheep than families that did not have ranches. About a third of participants also reported hunting and fishing.

Dairy

All 9 participants reported drinking cows' milk, although there was variety in the type, amount and frequency of milk consumed. If families owned cows or goats, which was particularly common in rural areas, then they milked and consumed about a gallon of milk on a daily basis. Any milk that was left over was used in cooking; many people remembered their mothers using the milk to make a white gravy or Atole, a blue corn and milk drink.

If families did not own their own cows, they (about 33%) purchased milk either from neighbors or nearby stores. This was more common in urban areas, where milk consumption was also common but probably drank less frequently. Hispanics made cheese and often traded with neighbors, including Native Americans which accounts for about 67% of participants who reported eating cheese. Canned milk was also consumed but this was usually reserved by adults to drink with their coffee.

Although it is widely believed that there are high rates of lactose intolerance among Native American populations, we found no evidence that this was the case among the people interviewed in New Mexico. Participant 4 summarized this best when he told us, "I'm told there are people who are lactose intolerant but if they had, I didn't-- I frankly didn't know anybody who complained of anything like that at that time."

Vegetables

Participants confirmed the consumptions of many of the same vegetables that were documented in the literature review and provided the names of many other wild leafy greens that were gathered from the wild, including wild asparagus, verdolagas (purslane), quelites (lambsquarters or wild spinach), and watercress. Cactus fruits, prickly pear, and mescal were consumed by at least 20% of the participants. There were numerous other plants, unique to the desert, that were reported to be used in teas and as natural remedies.

The vast majority of participants (89%) reported both growing and collecting vegetables and fruits. Many vegetables were grown in home gardens and eaten soon after picking, and only sometimes rinsed. Vegetables were either cooked into stews or hung to dry. Many people mentioned drying zucchini, calabacitas, and melons. Participant 1 specified that these were left to hang outside, "Where the sun could get them".

Traditional Foods

The majority of participants reported similar staple foods when describing their diet. These included chili, beans, corn, squash, potatoes, wild spinach, dried meat and tortillas. There were certain regional dishes made from these dishes that participants mentioned eating, including posole (corn and pork stew), atole (corn, ash and milk porridge drink), menudo (organ meat dish), and chili. Participants (66%) also confirmed the consumption of clay, ash and soil in some of these dishes. Earth was also consumed directly by licking adobe from walls.

Aim 6

The results from the literature review and key informant interviews were combined and collectively analyzed in order to develop tools for Phase II of the study. These tools consist of a comprehensive a list of foods (Table 3), card sorting exercise and the Focus Group Guide (Appendix E.3. Table 3 includes the list of foods generated from those documented in the existing literature and those that were reported to be consumed during Phase I key informant interviews. This list will be further categorized and internal doses will be attributed to these foods. Because of the diversity in diets and lifestyles across the various communities of New Mexico, it will be necessary to determine which foods were commonly consumed by which communities. Therefore, we designed the card sorting exercise, which is a widely used mixed-method, to determine the consumption and frequency of foods consumed by each community included in the Focus Groups. The Focus Group guide has been developed to quantify the amounts of each foods consumed according to gender and age. Wall charts were designed to facilitate discussion among participants and to incorporate novel foods identified during Phase I of the Study. For example, atole and white gravy have been added to the Dairy wall chart (#1) since these were commonly consumed dairy products unique to New Mexico. Wall Chart 6 asks about the **source** of drinking water and specifically includes the numerous water sources that were identified by Phase I. We have also included a Wall chart (#7) to gather information regarding the amount of earth ingested.

Conclusions

Phase 1 of the Study was successful in recruiting Hispanic and Native American elders to provide information about diet and lifestyle practices in New Mexico in the 1940s and 1950s. The elders seemed able to recollect events and practices from the past and report on them to the satisfaction of the team. From these initial field efforts, the study team has established the feasibility of conducting Phase 2 of the study and has designed community-informed tools to conduct this research.

Table 1. Descriptions of Phase 1 participants

Participant #	Geographic area	Sex	Hispanic/NA*	Age (y)
1	Rural	F	Hispanic	80
2	Mountains	M	NA	75
3	Rural	F	Hispanic	101
4	Urban	M	Hispanic	80
5	Urban	F	Hispanic	84
6	Urban	F	Hispanic	77
7	Mountains	M	NA	70
8	Rural	M	Hispanic	80
9	Mountains	F	NA	76

*Native American

Table 2. Number and percentage of participants reporting important dietary and lifestyle pathways of exposure

Pathway	n	%	Geographic Location	Ethnic Composition
Water				
Piped water	3	33	Urban	Hispanic
Acequia, ditch, stream	5	56	Rural	Hispanic and Native American
Well	2	22	Rural	Hispanic and Native American
Rain barrels	3	33	Rural	Hispanic and Native American
Cistern	1	11	Rural	Hispanic
Meat				
Organ	4	44	Rural/Urban (low SES)	Hispanic and Native American
Hunted	3	33	Rural	Hispanic and Native American
Fish	3	33	Rural	Hispanic and Native American
Dried Meat	6	67	Urban/ Rural	Hispanic and Native American
Dairy				
Cows' Milk	9	100	Urban/ Rural	Hispanic and Native American
Goats' Milk	2	22	Mountains	
Cheese (cow or goat)	6	67	Rural/ Mountains	Hispanic and Native American
Canned	4	44	Urban/ Rural/ Mountainous	
Butter	3	33	Rural	Hispanic
Vegetables				
Garden	8	89	Urban/ Rural/ Mountains	Hispanic and Native American
Wild	8	89	Urban/ Rural/ Mountains	Hispanic and Native American
Earth Consumed				
Adobe/ dirt	3	33	Urban/ Rural	Hispanic
Clay	3	33	Rural/ Mountains	Native American
Ash	3	33	Rural/ Mountains	Hispanic and Native American
Housing				
Adobe	4	44	Urban/ Rural/ Mountains	Hispanic and Native American
Adobe and wood	4	44	Urban/ Rural/ Mountains	Hispanic and Native American
Wood only	1	11	Mountains	Native American

Table 3: List of Foods by Food group consumed in New Mexico during the 1940-1950s.

Animals			Plants					Natural Elements	
Dairy	**Herbivore**	**Omnivore**	**Low Plant or Shrub**	**Nuts and grains**	**Root Vegetable**	**Leafy Greens**	**Fruit**	**Water**	**Clay or Soil**
arroz con leche	antelope	bear	Alfalfa	acorns	beets	yerba buena	elderberries	well water	adobe
boiled eggs	bighorn	birds	amaranth (seeds and greens)	agave and mescal leaves	carrots	asparagus	gooseberries	cistern	ash
butter	bison	bobcat	aulospermum purpureum	alcoholic beverages made from plants	garlic	brew of herbs (leaves, twigs, etc.)	grapes	ditch	ash, in atole
Cheese	bone, stew	bush or wood rat	bark of pinus ponderosa	avas	gum, from tree	cabbage	raspberries	water, rain for cooking	clay
cheese; cow	buffalo	chipmunk-like	bell peppers	baked/boiled white corn tamales	Mariposa Lily root	calitas	squaw berries	water, spring	dirt
cheese; goat	cattle	chorizo (pork, beef, chicken)	buffalo grasses		mescal tubers	celery	strawberries	piped water	juniper ashes
cheese; longhorn	chicken	lard	Calabacitas		onions	chemo podium (greens)	agarita berries		juniper branches, used to clean ovens
cottage cheese	chicken; gizzard	morongo	cattail, rootstocks	blue corn meal mush	potatoes	chimaja	apples		native salt
cream gravy	cow	pig	Chamomile	breads: wheat and corn	radishes	cilantro	apricots		volcanic
eggs	deer	pig , loin	Chenopodium	cactus	resembling sweet potato	dried spinach	bananas		
ice cream	donkey	pig, blood	chile peppers	cactus fruits	rhubarb	hai chideh	bitter red berries		
manteca (butter)	dove	pig, feet	cogswellia orientalis		root chew	herbs (oregano)	boysenberry		
milk	dried fish	pig, head	colorado bee	cereal	rutabaga	horsemint	cherries		

			plant						
milk; cow	dried jerky	pig, skin	Cota	chicos	sedeg tubers	lettuce	choke cherries		
milk; goat	ducks	rodents (rats)	Cucumbers	choke cherry cakes	small wild potato,	locust blossoms	citrus fruits		
milk; in bread	elk	soap, pig fat		cholla cacti fruit	sweet potato	mint	datil		
natilla	fish		descurainia Sophia	coffee	turnips	osha	figs		
pastel de queso	goat		dried muskmelon	corn (Blue)	White potatoes	parsley	grapefruit		
queso fresco	guinae, hens		dried pumpkin	corn (common varieties)	Wild carrot roots	purslane	hackberries		
rennet	horse		dried watermelon	crackers	wild onion	spearmint	hawthorn fruits		
milk; canned	locusts			flour	wild potato	spinach	juniper berries		
	mountain sheep		dried, squash	fried bread	yucca	squash blossoms	mulberries		
	mule		Gourds	fruit of screw bean	dried yucca	string beans	opuntia fruit		
	mutton/lamb		Grass seeds			wild celery	oranges		
	neck, stew meat		green chili	green corn		Wild Greens (purslane, asparagus, and quelites)	peaches		
	ox		Guaco			Wild mountain tea	pears		
	prairie dogs		Horsebeans	hops		Wild spinach	plums		
	quail		Indian perfume	hotcoats (corn meal)		wild tobacco	sumac berries		

	rabbit		inner bark and sap of box elder and inner bark of pine and aspen-sweeteners	Indian banana, skin peeled		peppermint	wild plum		
	sardines		inner bark of pine used for sweetener, bee honey	Indian millet		Wild mountain tobacco	currants		
	sheep		Itchee	Lechuguilla		verdolagas			
	sheep, intestines (liver)		Juniper	Maguey		tobacco			
	squirrel		juniper bark, smoked	mescal		watercress			
	tuna		Melon	mesquite					
	turkey		Milkweed	mesquite beans					
			Mushroom	mesquite pods					
			Muskmelons	mezcal					
			narrow leaf grass	molasses					
			Peas	nopales					
			Pennyroyal	oatmeal					
				oats					
			prunus melanocarpa	orobanchaceae					
			Pumpkin	peanut butter					
			rhus Canadensis	peyote					
			rocky mountain bee plant	pinole bread					
			rosemary seeds	pinon nuts					
			Sagebrush	pinus edulis					
			Saltweed	popcorn					
			screw bean						

			seeds; pigweed, tumbleweed, and grasses like dropseed	rice					
			shepherd purse	saguaro fruit					
			silver nightshade berries	smoking cornhusk or "green corn"					
			skunk brush	sotol- prepared in the same manner as agave					
			Snakeweed	sunflower seeds					
			Snakeweed	timothy					
			Solanum Jamesii						
			sporobolus cryptandrus	walnuts					
			spruce leaves	wheat					
			stalks of bear grass and amore (roasted and peeled)	wheat					
			Tomatoes						
			Tomatoes						
			tule, rootstocks						
			Vetch						
			Watermelon						
			white evening primrose fruits						
			Wide leaf Yucca dried fruit						
			wild pea pods						
			Wine						

			wolf berries/ tomatillo						
			wood sorrel						
			yucca fruit						
			yucca glauca						
			tuna (cactus fruit)						
			bean, pinto						
			Beans						
			prickly pear						
			Cantaloupe						
			green beans						
			green onion						

<u>Appendix 4A</u> – Recruitment Flyer (English)

OMB #: 0925-XXXX
Expiration Date: XX/XX/XXXX

NCI Study of the Cancer Risks from the Trinity Nuclear Test

Purpose of NCI Trinity Study

The National Cancer Institute is conducting a study to estimate the Radiation dose and the cancer risks to the New Mexico population from the Trinity nuclear test in 1945.

To make this assessment, scientists need a good understanding of the diet, activities and way of life of Native Americans, Latinos, and other ethnic groups living in New Mexico at the time.

Scientists will conduct interviews of groups and individual people in tribal and other communities living at the time of the test to gather information about lifestyles and diet in 1945.

NCI will share results from this study with the people of New Mexico via the media and tribal and community newsletters.

Why estimate exposure?

- People living in New Mexico at the time of the Trinity test were exposed to different levels of radiation depending on where they lived and the kinds of food they ate.
- People who were exposed to radiation from the Trinity test in 1945 could face higher cancer risk.
- Scientists estimate radiation exposure as a preliminary step to estimating the number of cancers that might have occurred from exposures.
- Accurate estimates of radiation exposure cannot yet be made because of lack of information on diets and ways of life in the 1940s.

Study Activities

- Reach out to communities to help identify those who were alive in 1945 and living in New Mexico.
- Conduct group and individual interviews with community members now 70 years of age and older to gather detailed information on typical ways of life.
- Analyze individual and group interview data to develop a good description of typical diet and lifestyle in 1945.
- Estimate radiation exposures for typical persons in all ethnic and age groups in New Mexico from the Trinity nuclear test.
- Estimate the number of cancers likely to have occurred in the New Mexico population as a consequence of exposure to fallout from Trinity.

Contact Person:

Mary Alice Scott

New Mexico State University

Las Cruces, NM

(575) 646- 5935

mscott2@nmsu.edu

BENEFITS OF PARTICIPATION

- ✓ **Better understanding** of diet and way of life in New Mexico tribal and other communities in the 1940s.
- ✓ **Improved estimates** of radiation exposure and cancer risk for those alive at the time of the nuclear test in all ethnic groups.
- ✓ **Gift card** to honor community members who participate in the interviews.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

<u>Appendix 4B</u> – Recruitment Flyer (Spanish)

Estudio del NCI sobre los Riesgos de Cáncer resultantes de la Prueba Nuclear Trinity

Propósito del estudio Trinity del NCI

El Instituto Nacional del Cáncer (NCI) está llevando a cabo un estudio para estimar la dosis de radiación y los riesgos del cáncer resultantes de la prueba nuclear Trinity en 1945 para población de Nuevo México.

Para hacer esta evaluación, los científicos necesitan tener una buena comprensión de la alimentación, actividades y estilo de vida de los indígenas americanos y de otros grupos étnicos que vivían en Nuevo México en aquel entonces.

Los científicos entrevistarán a grupos y a individuos en comunidades tribales y en otras comunidades que vivían al momento de la prueba a fin de reunir información sobre estilos de vida y alimentación en 1945.

El NCI compartirá los resultados de este estudio con el pueblo de Nuevo México a través de los medios de comunicación y de boletines informativos tribales y comunitarios.

¿Por qué calcular la exposición?

- Las personas que vivían en Nuevo México al momento de la prueba Trinity estuvieron expuestas a diferentes niveles de radiación dependiendo de dónde vivían y de los tipos de alimentos que comían.
- Las personas que estuvieron expuestas a la radiación de la prueba Trinity en 1945 podrían enfrentar un riesgo mayor de cáncer.
- Los científicos calculan la exposición a la radiación como un paso preliminar para calcular el número de cánceres que podría haber ocurrido debido a la exposición.
- Todavía no se puede hacer un cálculo exacto de la exposición a la radiación debido a la falta de información sobre su alimentación y modos de vida en los años de la década de 1940.

Actividades de Estudio

- Contactar a las comunidades para ayudar a identificar a las personas que estaban vivas en 1945 y que vivían en Nuevo México.
- Llevar a cabo entrevistas de grupo e individuales con miembros de la comunidad actualmente de 70 años de edad en adelante para reunir información detallada sobre los modos de vida típicos.
- Analizar los datos de la entrevista individual y de grupo para elaborar una buena descripción de la dieta típica y del modo de vida en 1945.
- Calcular las exposiciones a la radiación para personas normales en todos los grupos étnicos y etarios en Nuevo México resultantes de la prueba nuclear Trinity.
- Calcular el número de cánceres que probablemente hayan ocurrido en la población de Nuevo México como consecuencia de la exposición al polvo de la explosión de la prueba Trinity.

Persona de Contacto:

Mary Alice Scott

New Mexico State University

Las Cruces, NM

(575) 646-5935

Beneficios de la Participación

- ✓ **Una mejor comprensión** de la dieta y del modo de vida en las comunidades tribales y otras comunidades de Nuevo México en los años 1940.
- ✓ **Mejores cálculos** de la exposición a la radiación y del riesgo de cáncer para las personas que estaban vivas en la época de la prueba nuclear en todos los grupos étnicos.
- ✓ **Tarjeta de regalo** para premiar a los miembros de la comunidad que participan en las entrevistas.

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
National Institutes of Health

ATTACHMENT 5 – Screener (English/Spanish)

ATTACHMENT 5 – Screener (English/Spanish)

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by [face-to-face interview to complete this instrument so that we can better understand the diets and way of life of Native Americans, Hispanos, and non-Hispanic whites in New Mexico around the time of the Trinity nuclear test.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

Screener to Recruit Hispanic/Latino non-Hispanic White and Native American Focus Group and Individual Interview Participants

Recruit up to 150 participants who are

- Hispanic/Latino, non-Hispanic White or Native American
- 70 years or older (Alive in 1945)
- Resided in New Mexico or on one of New Mexico's tribal reservations (if Native American) during the 1940s and 1950s
- Ideally, helped to care for children in his or her community during the 1940s

Overall aim is to

- Recruit up to 120 participants for 10-15 focus groups of 6-8 participants each.
- Recruit up to 30 participants for individual interviews
- Aim for an even balance between Hispanic/Latino, non-Hispanic White and Native American interviews and focus groups

Note: The screening interview may be conducted in English or Spanish. Screening interviews with Native American persons who are more comfortable in their native language may be conducted with the help of an interpreter fluent in either English or Spanish and the interviewee's native language.

SCREENER

Hola, soy _____ de [nombre de compañía]. Estoy llamando de parte del Instituto Nacional del Cáncer (National Cancer Institute en inglés). El Instituto Nacional del Cáncer está realizando un estudio sobre estilo de vida y hábitos alimenticios de la gente en su comunidad durante los años 1940 —y quiere incluir su punto de vista. Necesito hacerle unas preguntas para saber si puedo invitarle a participar en una entrevista. Sus respuestas serán completamente confidenciales y privadas y no se compartirán con otros.

Usted recibirá una pequeña compensación por su participación. Mis preguntas hoy solo requieren unos minutos.

¿Puedo continuar con mis preguntas?

Hello, I'm _____ from [name of firm]. I'm calling today on behalf of the National Cancer Institute, or NCI. NCI is conducting a research study about the lifestyle and dietary habits of people in your community during the 1940s—and would like to include your views. I need to ask you just a few questions to determine whether I can invite you to participate in an interview or group discussion Your responses will be completely confidential and private and not shared with others. You will receive a small honorarium for your time. My questions today will only take a couple of minutes.

May I continue with my questions?

BACKGROUND QUESTIONS

1. Es importante que hablemos con personas que eran niños en 1945. ¿Me puede decir su edad? / *It's important for us to speak to people that were alive in 1945. Can you tell me your age?*

   RECORD EXACT AGE_____

   (IF OVER THE AGE OF 70, CONTINUE. OTHERWISE, TERMINATE.)

2. ¿Usted vivía en Nuevo Mexico durante los años 1940 y 1950? / *During the 1940s and 1950s, were you living in New Mexico?*

   Sí / *Yes*_____

   Terminate>> No _____

   Terminate>> **Refuse _____**

3. ¿Se considera usted … / *Do you consider yourself …*

Hispano(a) o Latino(a) / *Hispanic or Latino*	Si/ *Yes* _____ No _____
India Americano(a) or Nativa de Alaska / *American Indian or Alaska Native*	Si/ *Yes* _____ >> Go to 6
Blanco(a) / *White*	Si/ *Yes* _____ >> Go to 6
Negro(a) o Africano(a) Americano(a) / *Black or African American*	Si/ *Yes* _____ >> If Yes and Hispanic is No, then Terminate
Asiático(a) / *Asian*	Si/ *Yes* _____ >> If Yes and Hispanic is No, then Terminate
Nativa de Hawaii o Otra de las islas Pacífico / *Native Hawaiian or Other Pacific Islander*	Si/ *Yes* _____ >> If Yes and Hispanic is No, then Terminate

4. ¿Cuál considera usted que es su país de origen? / *Which do you consider you country of origin?*

[Record country]_____

IF THE ANSWER IS USA, PLEASE PROBE FURTHER BY ASKING:
¿Cuál es su origen o ascendencia Hispana? / *Where does the Hispanic origin come from?*

[Record country]_____

5. ¿Prefiere, participar en una entrevista en español, en inglés, o en otro idioma? / D*o you prefer to participate in the interview in Spanish, English, or another language?*

Español / *Spanish* ____
Lo mismo - No hay preferencia de idioma / *Either - No preference* ____
Inglés / *English* ____
Otro idioma / *Other language* ____
[Record language]_____

6. **[SOLO PREGUNTE SI #3=NO / ASK ONLY IF #3=NO]** ¿Durante los años 1940 y 1950, vivía usted en un terreno indígena? / *During the 1940s and 1950s, were you living on tribal land?*

Sí / *Yes*_____
Terminate>> No _____
[Record living location] _____

7. ¿Durante los años 1940 y 1950, tuvo contacto diario con los niños? / *During the 1940s or 1950s, did you have daily contact with children?*

Sí / *Yes*_____
Terminate>> No _____

8. ¿Durante los años 1940 y 1950, ayudó a cuidar a los niños? / *During the 1940s or 1950s, did you help to care for other children?*

Sí / *Yes*_____
No _____

ATTEMPT TO RECRUIT AT LEAST SOME RESPONDENTS WITH EXPERIENCE CARING FOR CHILDREN. (THIS IS PREFERABLE, BUT NOT ESSENTIAL.)

DEMOGRAPHICS

9. ¿Cuál es su sexo? / *What is your gender?*

Female _____
Male _____

10. ¿Cuál es el nivel o grado de educación más alto que usted ha completado? / *What is the highest level of education you have completed?* **[Attempt to recruit a balanced mix but it is not required]**

Octavo grado o menos ***Less than high school*** **_____**

Algo de escuela secundaria (High School) ***Some high school*****_____**

Graduado de escuela secundaria o escuela vocacional, GED *High school or vocational school graduate GED* _____

Algo de universidad ***Some college*** **_____**

Graduado de universidad ***College degree*** **_____**

Estudios o título posgraduado como una Maestría o un Doctorado ***Post Graduate degree*** **_____**

TERMINATE LANGUAGE: **Muchas gracias por su tiempo. No podremos incluirle en nuestro estudio. Gracias por su tiempo e interés. Que tenga un buen día / noche. /** ***Thank you very much for your time. We're not going to be able to include you in this study. Thank you for your time and interest. Have a good day/evening.***

INVITE TO INTERVIEW

Gracias por responder a mis preguntas. Como le había mencionado, estas entrevistas se están llevando a cabo en nombre del Instituto Nacional del Cáncer para saber más sobre el estilo de vida y hábitos alimenticios de la gente en su comunidad durante los años 1940. Nos gustaría incluir sus puntos de vista.

Para que podamos conocer su experiencia y punto de vista, me gustaría invitarle a participar en una entrevista en persona. Cinco personas que trabajan para el Instituto Nacional del Cáncer estarán presentes durante la entrevista.

Thank you for answering my questions. As I mentioned this study is being conducted on behalf of the National Cancer Institute about lifestyle and dietary habits in your community in the 1940s and we'd like to be able to include your views.

In order for us to learn from your experience firsthand, I would like to invite you to participate in a group discussion or a one-on-one interview. Up to four people that work for the National Cancer Institute will be present during the interview.

TRANSPORATION AND LOGISTICS

11. Would you like to have the interview close to where you live? If so where?

[Record]_____

12. Le animamos a traer a alguien a la entrevista que puede apoyarle. / *We encourage you to bring someone to the interview who can support you.*

¿Cuales personas lo acompañarán? *Which people will accompany you?*

[Record]_____

13. ¿Usted necesitará cuidado de niños durante la entrevista ? / *Will you need childcare during the interview?*

Si/*Yes* _____

No _____

14. ¿Usted necesitará transportación para poder participar en la entrevista? / *Will you need transportation so that you can participate in the interview?*

Si/*Yes* _____

No _____

La entrevista durará una hora y media y se llevara acabo en _____. Tengo varios horarios disponibles en [FECHAS] para que podamos realizar la entrevista cuando sea conveniente para usted.

El propósito de la entrevista no es tratar de venderle algo. Tampoco le llamarán por teléfono una vez termine la entrevista para tratar de venderle algo. Para compensarle por su tiempo y los gastos de viaje, usted recibirá un certificado de $50 por llegar a la entrevista. ¿Podemos contar con su participación y coordinar el día y la hora de su entrevista?

The interview will last up to two hours and will take place at _____. I have several time slots on [DATES], so we can conduct the interview when it's convenient for you.

This is not a sales effort of any kind and no one will call on you as a result of your participation. To compensate you for your time and travel expenses, you will receive a gift certificate for $50 for coming to the interview. Can we schedule your participation?

Le enviaremos una carta de confirmación como recordatorio el día y la hora de la entrevista. También le llamaremos una semana antes y un día antes de la entrevista para recordarle. Como solamente estamos invitando a un pequeño número de personas, estaremos contando con su presencia. Es sumamente importante que la entrevista comience a tiempo. Si usted usa lentes o espejuelos, recuerde traerlos a la entrevista. Si por algún contratiempo le resulta imposible asistir a la entrevista, no mande a alguien en su lugar. Por favor llame a _____al número _____ e infórmenos. Anote el número por si lo necesita. Gracias.

We will send you a letter and we will also call you to remind you of the time and date. We will call you the week before and the day before to remind you. Since we are only inviting a select number of people, we will be counting on you to attend. If you wear reading glasses, please bring them with you. If for some reason you cannot come, do not send someone else in your place. Please call _____ at _____. Please write the number down, in case you need it later. Thank you.

Check day and time; see details below

NAME: _____

ADDRESS: _____

CITY: _____

ZIP CODE: _____

PHONE: (DAY) _____

(EVE) _____

(CELL) _____

(EMAIL) _____

Interview Dates -**TO BE DETERMINED**

Interview Time Slots - *Time slots for interviews with persons needing an interpreter in the same language should be arranged consecutively if possible.*

DATE TBD	DATE TBD	DATE TBD
9:30 am	9:00 am	9:00 am
11:00 am	10:30 am	10:30 am
12:30 am	12:00 am	12:00 am
2:30 pm	2:00 pm	2:00 pm
4:00 pm	3:30 pm	3:30 pm
5:30 pm	5:00 pm	5:00 pm
6:45 pm [over-recruit]**	6:15 pm [over-recruit]**	6:15 pm [over-recruit]**

Table1. Current ages for recruitment and their age for recalling the 1940s and 1950s

Current age	Born	Age in 1945	Age in 1940	Age in 1950	Age in 1959
70	1945	0		5	14
71	1944	1		6	15
72	1943	2		7	16
73	1942	3		8	17
74	1941	4		9	18
75	1940	5	0	10	19
76	1939	6	1	11	20
77	1938	7	2	12	21
78	1937	8	3	13	22
79	1936	9	4	14	23
80	1935	10	5	15	24

81	1934	11	6	16	25
82	1933	12	7	17	26
83	1932	13	8	18	27
84	1931	14	9	19	28
85	1930	15	10	20	29
86	1929	16	11	21	30
87	1928	17	12	22	31
88	1927	18	13	23	32
89	1926	19	14	24	33
90	1925	20	15	25	34
91	1924	21	16	26	35
92	1923	22	17	27	36
93	1922	23	18	28	37
94	1921	24	19	29	38
95	1920	25	20	30	39
96	1919	26	21	31	40

ATTACHMENT 6 - A. Participant Letter (English and Spanish)

ATTACHMENT 6 - A. Participant Letter (English)

Dear Participant,

Scientists at the National Cancer Institute have invited you to be a part of a project to better understand the diets and way of life of Native Americans, Hispanics and non-Hispanic Whites in New Mexico in the 1940s and 1950s, around the time of the Trinity nuclear test. You are being asked to participate in a group discussion, known as a focus group, or an individual interview. We will ask you to tell us about activities and eating habits in your family and community in the summer months of the 1940s and 1950s. The discussion will take up to two hours. We invite you to share your experiences and memories. There are no right or wrong answers to any of our questions.

The information you share with us will be put together with the answers from other group discussions and interviews. We will not use your name or the name of your town or community. If you agree, we will audiotape the discussion. All recordings and written notes from our discussion will be kept private and secure.

Answering the questions of the interviewer may raise some troubling memories or leave you feeling upset by memories of the time of the Trinity test. You can skip any question that is uncomfortable for you. You may also leave the discussion/interview at any time without penalty. You will be compensated $50 for your time. You are welcome to bring a family member or friend to stay with you during the discussion. Childcare will also be provided.

The National Cancer Institute has a list of local healers and other support resources. Your interviewer is happy to leave you with a copy of that information.

Thank you for contributing your time to help us with our research.

Sincerely,

Steve L. Simon, PhD

Mary Alice Scott, PhD

Silvia Salazar, MPA

Nancy Potischman, PhD

ATTACHMENT 6.B. Participant Letter - Spanish

Estimado Participante:

Los científicos del Instituto Nacional del Cáncer le han invitado a formar parte de un proyecto para comprender mejor las dietas y el modo de vida de los indígenas americanos, hispanos y blancos no hispanos en Nuevo México en la década de 1940 y 1950, en la época de la prueba nuclear Trinity. Se solicita que participe en un debate de grupo, conocido como grupo de enfoque, o en una entrevista individual. Le pediremos que nos cuente sobre actividades y hábitos alimentarios en su familia y en la comunidad en los meses de verano de la década de 1940 y 1950. El debate llevará de una a dos horas. Le invitamos a que comparta sus experiencias y recuerdos. No existen respuestas correctas o incorrectas a ninguna de nuestras preguntas.

La información que comparte con nosotros se incluirá junto con las respuestas de otros debates de grupo y entrevistas. No usaremos su nombre ni el nombre de su ciudad o comunidad. Si usted está de acuerdo, grabaremos la conversación. Todas las grabaciones y notas escritas procedentes de nuestra conversación se mantendrán en forma privado y seguro.

Responder las preguntas de la entrevista puede hacer que surjan algunos recuerdos inquietantes o hacer que se sienta alterado por los recuerdos de la época de la prueba Trinity. Puede dejar de responder cualquier pregunta que le resulte incómoda. También puede dejar la conversación/entrevista en cualquier momento sin que haya sanción alguna. Se le pagará $50 por su tiempo. Siéntase con la libertad de traer a un familiar o amigo para que esté con usted durante la conversación. También se proporcionarán servicios de cuidado infantil.

El Instituto Nacional del Cáncer tiene una lista de curadores (curanderos) locales y otros recursos de apoyo. Su entrevistador(a) con gusto puede dejarle una copia de dicha información.

Gracias por colaborar con su tiempo para ayudarnos con nuestra investigación.

Atentamente,

Dr. Steven L. Simon

Dra. Mary Alice Scott

Silvia Salazar, Maestría en Administración Pública (MPA)

Dra. Nancy Potischman

ATTACHMENT 7 – Key Informant Interview Guide

ATTACHMENT 7 – Key Informant Interview Guide

(All guides will be translated into Spanish in real time)

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by face-to-face interview to complete this instrument so that we can better understand the diets and way of life of Native Americans, Hispanos, and non-Hispanic whites in New Mexico around the time of the Trinity nuclear test.

Public reporting burden for this collection of information is estimated to average 120 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

Key Informant Interview Guide

Hello, my name is _____. Thank you for agreeing to speak with me today. I am working on a study of radiation exposure and long-term health effects conducted jointly by the (local contact organization) _____ and the National Cancer Institute in Bethesda, Maryland. The National Cancer Institute is part of the National Institutes of Health, which supports research on medical issues.

The goal of today's interview is to learn about diets, activities, and living conditions around the time of the TRINITY nuclear test in July of 1945 in southern New Mexico, including information about foods and drinks.. This will help our team from the National Cancer Institute in their studies of radiation exposure and long-term health effects.

You are knowledgeable in the daily life during the 1940s and 1950s, particularly in the summer around the time of mid-July and I appreciate your willingness to share your knowledge with me.

[INTRODUCE COLLEAGUES/ NOTE TAKERS]

We are going to be talking about the time around 1945. What do you remember from this time?

1. In 1945:
    a. How old were you?
    b. Where were you?
    c. Can you tell me about the house you grew up in?
    d. Did you keep animals?
    e. Did you have a garden?
    f. Was there an acequia or a stream nearby?

2. Were you aware of the bomb test north of Alamogordo in July?
    a. Can you tell me what you know or remember about it?
    b. When did you hear about this event?
    c. From who or what source did you hear about it?

3. Can you tell me about the events that occur in the summer, particularly in July?

[Additional Probes]:

a. As you know, there are feasts days, in the summer. Can you tell me what happens in preparation for summer feast day?
b. What happens at the summer feast days?
c. Do people come from neighboring areas? Whole families?
d. What about afterwards (continue to eat feast day foods?)?
e. Are there other community events around that time?

I. Fresh Water sources

1. First, I want to ask you about household water supplies in your community. Can you please tell me about the water you drank in 1945?

2. What kinds of homes were common at that time (ex. Mud-based Adobe homes, box cars)?

3. To the best of your knowledge, did anyone in your community have indoor plumbing (meaning, water piped into their home) in 1945?

[If no, skip to #4]

If yes:

a. To the best of your memory, how many households (% of homes) had indoor plumbing?
b. Do you know where that water came from?
    i. If yes, where?
c. Did the majority of water for those households come from that source?
    i. If no, list other sources:
d. Were there times that the piped water would run out?
    i. If yes: where would people get water?

4. Where did households without indoor plumbing get their water for drinking? (Primary Source)

___Well/ground water
___Rain water
___Acequia or ditch
___Cisterns
___River
___Lake, pond, or other standing water source
___Arroyo
___Creek/streams

___Other: _____

5. Describe how people in the community without indoor plumbing accessed water sources. (i.e. with buckets, what size, who hauled the water…?)

6. To the best of your memory, how often would the water be brought to the home (in the summer)?

7. How long would it last during the summer?

8. Did households store water? **[If no, skip to #9]**

If yes:

a. Where did people store water? (ex. In the house, outside or both)
b. Was drinking water stored separately from water used for other things (i.e. cooking, irrigation)?
c. Were any storage containers for drinking and cooking open to the air or covered?

9. Where did water in animal troughs come from?

II. Consumption of small mammals

I want to ask about small animals that might be eaten, particularly in the summer, close in time to the Feast Day of Santa Ana or other summer activities.

10. Was it common to trap or hunt small animals? **[If no, skip to #15]**

11. What kinds of small animals were caught, hunted, killed for food?

12. How was [each] prepared and cooked?

13. Were all the parts of small animals eaten by people, including the organs?

a. If no, what were some parts not eaten?

14. Were there special rules concerning who ate particular parts of the animal?

a. If yes, who ate what parts of the animals?

15. Were there other types of animals that were eaten? (rabbits, sheep, goat, pig, chicken, pack rats, beaver, turtle)
[If no, skips to #17 (Native American) or #18 (Hispanic/Latino/Chicano)]

a. Were organs of those animals typically eaten?
b. During the summer, would meat be dried outside and eaten later? (Jerky)
c. Were there special rules concerning who ate particular parts of the animal?

i. If yes, who ate what parts of the animals?

16. What types of meat were cooked in stews? What parts of the animal were cooked in the stews?

Native American only:

17. Would there have been a communal hunt during July? (Related to Feast Days?)
    a. What parts of the animal would be eaten right away? What parts would be saved for later?
        i. (if Saved) –For how long would animal meat be kept?

Hispanic/Latino only:

18. Would there have been a matanza/special butchering party during July? (related to Feast Days?)
19. What parts of the animal would be eaten right away? What parts would be saved for later?
    a. (if Saved) -For how long would animal meat be kept?
    b. Did you make broths from bone?
    c. Did you use bone meal for fertilizer?

III. Vegetables with Leaves that are Eaten

Now let's talk about vegetables. We understand that chile is a central part of food in New Mexico.

20. Did your family eat or grow chile?
    a. Where did your family get their chile from? (Particular area?)
    b. Did you hang ristras for storing chile?
        i. Were they inside or outside your home?

21. I am interested to know about eating green, leafy vegetables, like wild spinach, purslane, lettuce and cabbage. It is the leafy part that is of interest. Please tell me about your habits around eating green vegetables.

22. Was it common to eat green leafy vegetables in summer? **[If No, skip to section IV]**

23. What kinds of green leafy vegetables were eaten?

24. Were most of them grown where you lived, in a household garden or perhaps in a community garden like a victory garden?
    a. If yes, which vegetables were grown in family garden?
    b. Did your family eat all the vegetables that were grown in the garden? Did you share with family, friends, neighbors?
    c. For how long would vegetables be kept?

25. Did you eat vegetables from somewhere else?
    a. If yes, how far away would the vegetables have been grown?

26. Did you eat vegetables gathered from the wilderness?
    a. Where would you gather these wild greens?

27. Did you buy most of them from a store?

    a. Were they eaten raw or cooked?
    Please tell me about how they were prepared for eating? (stew in <u>outdoor</u> pot? Details about how much in a family stew?)

28. How often were they eaten during the summer, particularly around the time of the summer feast days? [Every day? Once a week, 2 times per week, etc.?]

29. Was it common to eat cactus during the summer?

IV. Lactose Intolerance (Milk Consumption)

Next, I want to learn if people drank milk. Please tell me about your milk consumption in 1945.

30. Was it common to drink fresh or canned milk? **[If no, skip to section VII]**
    a. If yes: ___Fresh (Continue) ___Canned **[If canned, skip to section VII]**
    b. If fresh, was it consumed as a drink, in coffee, or as an ingredient in stews, breads, etc.?

31. Did some people in the community, not drink fresh milk (not canned) because they were allergic or it made them sick? (for example, they were lactose intolerant)
    a. How common was that in this community?

[TRY to get %; START WITH INDIVIDUAL, THEN FAMILY, NEIGHBORHOOD, COMMUNITY, for example, "How many people were in your family; how many of them did not drink milk?"]

32. Did some people in the community, not consume foods from milk products such as cheese because they were allergic or it made them sick?
    a. Are these the same people who stayed away from milk itself?

V. Milks **[Skip this if informant says that most did not drink milk]**

Now let's talk about all the different types of milk available around 1945, and where they came from.

33. What types of milk were available from July through September? (*Interviewer's Note: Be sure to probe on each of the types of milk below)*

    ___Cow

    ___Goat

    ___Sheep

___Other:_____

34. Can you tell me about where people got their milk from – for example, their own animals, neighbors, Trading Posts or did they get their milk some other way?

___Their own animals

___Neighbors

___Stores

___Other:_____

a. Did this vary by type of milk – cow, goat, other?

___Cow

___Goat

___Sheep

___Other:_____

35. Did you get milk from other communities?

a. If yes, do you know how long it was from the time the animals were milked to when the milk was consumed?

b. Did this vary by type of milk – cow, goat, other?

___Cow

___Goat

___Sheep

___Other:_____

36. Did you consume each day's milk on the same day it was collected?

a. If no, what with done with the left over milk?

b. Did this vary by type of milk – cow, goat, other?

___Cow

___Goat

___Sheep

___Other:_____

37. Where was the milk stored? How long could different types of fresh milk be kept?

a. Did this vary by type of milk – cow, goat, other?

___Cow

___Goat

___Sheep

___Other:_____

38. In the summertime, how often was milk consumed? (Everyday? Every other day? Once a week? etc.)

Now we have some questions about children (school aged or 5-12) and their milk drinking habits.

39. Who was responsible for feeding children?

40. What types of milk did children drink for breakfast, lunch, and dinner?
    ___Cow
    ___Goat
    ___Sheep
    ___Other: _____

41. Did they drink milk at other times of day? Yes

a. If yes, When?_____

42. How much milk was typically consumed on a single day? **[show plastic glasses of different sizes to show as examples]**

43. If milk came from your own animals, how much time was there between when the animals were milked and when the children drank the milk?

44. Was milk ever available in only limited amounts (less than they might want)?

    a. If so, who would receive the milk first – for example, pregnant women, babies, children, men?

45. What types of milk were available in limited amounts? **[Be sure to ask all of these questions]**
    ___Cow
    ___Goat
    ___Sheep
    ___Other: _____

46. Was the milk ever diluted with water when consumed? (taste, or to make it last longer or for more people to be able to drink it)

47. Who drank more milk? Girls or Boys? Pregnant or nursing women? Babies? Men?

    a. Did this vary by type of milk?
    ___Cow
    ___Goat
    ___Sheep
    ___Other: _____

48. Were kids in school or some kind of summer activity in July (1945) where milk would have been provided?

a. If so, was it produced (on the pueblo/in the community) or brought in from a commercial source?

VI. Other Dairy Products

[SKIP this if informant says that no one consumed milk products]

49. Were there other foods made from the milks, such as soft cheeses ?
(List all and ask about process, as in questions below, ask if they made cottage cheese if not mentioned)

(Ask #52 and #53 only if reported as being made)

50. Can you describe to me the process of making *(cottage, soft)* cheese? **[Skip to section VII if not consumed]**

    a. What type of milk was it (cow, goat, other)?
    ___Cow milk
    ___Goat milk
    ___Other:_____

    b. How much milk was needed?
    c. How long did it take before it was ready to eat?
    d. How long could it be stored?
    e. Did the recipe or way of making cottage cheese vary by family or by community?

51. Were there any other dairy products that you can think of?

VII. Breastfeeding

52. Was it common for mothers to breastfeed their babies? **[If no, skip to section VIII]**
    a. Typically, how many months were babies breastfed at that time (total months including after solid foods started)?

53. Was the diet of breast feeding mothers different?
    a. If yes, in what ways was it different?

54. Did breastfeeding mothers consume fresh milk?
    a. How many times per week or per day?
    b. How much each time?
    c. Did they eat the small animals, including organs?
    d. Did they eat leafy vegetables?

VIII. Access of Food & Storage

I want to ask you where you got your food during 1945.

55. Were foods purchased at a store or market regularly? If yes, which foods?

56. Do you know where the store or market purchased its milk, vegetables, and fruit?

57. Were home grown goods exchanged at the store or market and did they sell/exchange them within the community?

58. What foods were collected from the wild? If so, where (in relation to the tribe/community) would food be collected from and what types of food? **[Show map]**

59. We understand that breads, either wheat or corn, were a main part of the diet. Where was the wheat and corn grown? Where was it milled? How long did it take to mill (if elsewhere)?

60. Summer is a time when many fruits are available to eat. What fruits were eaten and where did you get them from?

I want to ask you about how food was stored.

61. *During the summer*, where was food kept before it was eaten? Inside, outside, covered?

For communities near mountains only:

I want to ask you about domestic animals that families might have owned.

62. During the summer months, would animals move to other places for grazing?
    a. If yes, could you show us where on the map would this grazing area might be? **[Show map]**

VIII. Traditional Diets

We are interested to know of traditional diets that may be special to (Tribal Nations, Hispanic/Latino or non-Hispanic White).

63. At that time, were there any specific types of food that were special to this community in general?

64. We have come across some recipes that include both clay and ash as ingredients. Did people cook with or eat clay or ash or lick adobe?

    a. If so, was this during the summer?
    b. How was it used in food preparation or cleaning?
    c. Would women consume food that contained clay during pregnancy?
    d. About how much were consumed each day, week, month?
    e. Did children eat food that contained clay?

65. Did you eat or make tortillas?
    a. If yes, please describe the ingredients and process of making tortillas.
    b. If the tortilla's used lime, where did the lime come from?
    c. Did you use texquite as a leavening? Can you describe how you used it? Do you know where you got the texquite?

66. Were home remedies used in the summer months or during summer festivals?
    a. If yes, which home remedies were commonly used?
    b. Were any of the remedies chewed or drunk as a tea? Yes ___ No ___
    c. If yes, which ones?
    d. Where did you get the ingredients used in the home remedies?
    e. How were they prepared? If dried, where were they left to dry?

67. Were there any other activities that would require eating special foods around the time of the summer feast days?

68. In addition to tobacco, were any other plants (green corn or other herbs) smoked? We are not asking about plants used for ceremony or intoxication.
    a. Where did the plants come from?

VIX. Other

73. We are doing this research because we want to understand the possible pathways that radiation entered people bodies at the time of Trinity. Based on what we discussed today, are there any other issues related to life during 1945 that you think may be relevant to our research?

71. Please tell us about the daily activities of people in your community. For men, women and children please estimate hours spent at home, playing, at school, then total amount of time indoors, outdoors. What would atypical day schedule be from waking to bed time? Are weekends different? Is it different for boys and girls?

[END – thank the participant for their time and knowledge]

ATTACHMENT 8 – Pre-Focus Group Guide

ATTACHMENT 8 – Pre-Focus Group Guide

(All guides will be translated into Spanish)

Pre-Focus Group Guide

I. Greetings

Welcome. My name is _____ and this is my colleague, _____. I work for the University (*to be specified later*) and my colleague works for the National Cancer Institute. The National Cancer Institute is part of the National Institutes of Health, which does research on many diseases such as diabetes and cancer.

The goal of today's meeting is to learn about people's diets, activities, and living conditions around the time of the Trinity nuclear test in July of 1945. This will help our team from the National Cancer Institute in their studies of radiation exposure and long-term health effects.

II. Consent and privacy (10 minutes)

We hope that you will speak freely about your memories, feelings, observations, and opinions because it will help us to understand what daily life was like for you and your relatives at the time of the nuclear test. We want everyone to feel comfortable participating in this group. Let's agree to make sure that everyone has a chance to speak. Please know that there is no requirement for you to answer questions or participate in any discussions that make you feel uncomfortable. We will be making notes about your recollections and general reactions to the discussion.

You will be personally identified only with first name and month of birth. We will also ask you for your relatives' first names and years of birth.

With your permission, we would like to audiotape today's interview. The recording will only be used to help us with writing the report and conducting an analysis. Please let me know if I have your permission to record this interview. If so, I will turn on the recorder now. You can stop the interview at any time or choose not to answer any question without penalty. There may be questions that I will ask that you may not be able to answer. That is expected and OK. Please just

let me know if you do not know the answer to a question and we will move on to the next question. Because we have a limited amount of time there will also be points in the interview where I may move the discussion to another question. If there is time in the end, we can always revisit a topic.

Before we start, we need you to read and sign a consent form. Please read through the form as I read it out loud. Please take your time to make sure the consent form is clear to you. Please let me know if you have any questions.

[If participant agrees – and has signed a consent form – proceed with taping the interview. If participant is uncomfortable or unsure, proceed without taping.]

Do you have any questions for me before we get started?

Moderator Note: File signed forms in an envelope with the date, time, and code for the community name clearly written on the front.

III. Family Demographics

Now we would like to know about your immediate family. These would be your brothers and sisters living in the same house. *(Does not have to be a blood relative, can be step-sibling as long as living in the house)*

Please tell us the names of each of the family members living in your household in 1945. For each relative, please tell me the relative's first name, and gender, what year your relative was born and where they were born (geographic location).

Table 1. Focus Group Participant Family

First Name	Gender	Year of Birth	Place of Birth

ATTACHMENT 9 – Focus Group Guide and Wall Charts

ATTACHMENT 9 – Focus Group Guide and Wall Charts

(All guides will be translated into Spanish)

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by face-to-face interview to complete this instrument so that we can better understand the diets and way of life of Native Americans, Hispanos, and non-Hispanic whites in New Mexico around the time of the Trinity nuclear test.

Public reporting burden for this collection of information is estimated to average 120 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

Focus Group Moderator Guide

NCI interviewer name_____

University Interviewer name _____

Date of interview_____

Interview start time _____ Interview end time _____

I. Greeting

Welcome. My name is _____ and this is my colleague, _____. I work for the University (*to be specified later*) and my colleague works for the National Cancer Institute. The National Cancer Institute is part of the National Institutes of Health, which does research on many diseases such as diabetes and cancer**.**

II. Card Sorting (10 minutes)

While we are waiting for everyone to arrive, I would like you to complete this individual activity. These cards include the names and pictures of foods that you may have eaten in 1945.

1. Please sort them into two piles: 1) foods your community ate in 1945 and 2) foods your community did not eat in 1945.

2. From the pile of cards of foods you ate, please sort them into piles based on food groups, for example you may want to group all the milk products together.

3. For each pile of cards sorted into food groups please put the cards in increasing order from the foods you ate the most frequently to the foods you ate the least frequently.

Please keep these cards in order. One of the interviewers will now collect the cards from you and staple them in the piles that you have created.

III. Greeting (10 minutes)

Welcome. My name is _____ and this is my colleague, _____. I work for the University (*to be specified* later) and my colleague works for the National Cancer Institute. The National Cancer Institute is part of the National Institutes of Health, which does research on many diseases such as diabetes and cancer.

It is a pleasure to be with you here today. Both my colleague and I have been working in the Native American and Hispano community for the past _____ years. Two people from the National Cancer Institute are also in the room with us today and they are also part of the team that is conducting this project. Their names are _____ and _____.

(Colleague name) _____will be helping me today so that we can capture your comments and feedback. _____ (Colleague name) will let me know if I have covered everything I need to ask or if there are any questions I need to ask you. To protect your privacy , I will not use your full name.

The goal of today's meeting is to learn about people's diets, activities, and living conditions around the time of the Trinity nuclear test in July of 1945. This will help our team from the National Cancer Institute in their studies of radiation exposure and long-term health effects. Most of you and your siblings were less than 18 years old in the 1940s. Some of you may also remember what your parents, grandparents, and aunts and uncles ate and how they spent their time. You are all knowledgeable about the daily life practices of people living in your communities at that time, in the summers in the 1940s and 1950s, and we appreciate your willingness to share your knowledge with us.

IV. Logistics (5 minutes)

I have a set of items to discuss with you today. This discussion should last no more than 90 minutes. I'll be asking questions, and (colleague name)_____, who works with me, will help with note-taking during our discussion.
Your feedback will be kept private. The results will be reported to the National Cancer Institute in a summary. The names of tribal communities, specific towns or cities will not be included but kept private.

V. Introductions (10 minutes)

Again, I want to thank everyone for coming today. The National Cancer Institute and the University are working together to study radiation exposure and long-term health effects.

Many of you already know each other, but it would be helpful to me if we could introduce ourselves. Please say your first name and the month of birth.

VI. Developing context and stimulating recall (30 minutes)

Let's spend a few minutes thinking about the summer of the 1945.

1. In 1945:
    a. How old were you?
    b. Where were you?
    c. Can you tell the group about the house you grew up in?
    d. Can you tell the group who lived in the house?
    e. Did you keep animals?
    f. Did you have a garden?
    g. Were acequias or a stream nearby?

2. Can you share a little bit about the events that occur in the summer, especially in July?
    a. Were there any special feast days or Fiestas that happened in July?
    b. Is there any other memory about the summer of 1945 that sticks out in your mind? We will refer to this memory throughout or discussion to help you remember what life was like then.

3. What would you typically eat for breakfast, lunch and dinner?

We just talked about events that took place in the summer of 1945. Now let's talk about the food and activities of children and adults in the late summer and fall months, July through October, following the nuclear test in July of 1945.

VII. Wall Charts

For this next part, let's talk about milk and milk products that were eaten at the time of the test or in the summer of 1945.

1. Was it common to drink fresh or canned milk?

2. Now, I'd like to ask you about the fresh animal milk that you and your family drank. I'm going to ask you what kind and how much of each type of milk you and your family typically drank when you were young. Let's give answers for girls and boys separately for each age group. If people drank milk in their coffee, or cooked with it in foods like atole or white gravy, think about those milks too.
    a. When your siblings were less than a year old, how much of each of these types of milk did your child drink?
    b. When your siblings were 1 to 4 years old, how much of each of these types of milk did they drink?
    c. When your siblings were 5 to 10 years old, how much of each of these types of milk did they drink?

d. When your siblings were 11 to 15 years old, how much of each of these types of milk did they drink?
e. When your siblings were 16 years old or more , how much of each of these types of milk did they drink?
f. Were there any differences between the **types** of milk that **boys** and **girls or children and adults** drank?
g. Were there any differences between the **amounts** of milk that boys drank compared to girls? If so, who drank more? How much more? Did this depend on age?
h. Was drinking milk different on days when children were not in school- Sundays- than days when they were in school?

Notetaker's Note: For each cell in table below, please record the number of cups of milk consumed of the various types by age group. If a participant cannot answer a question, please note this and any reasons given (e.g., can't remember, don't know). For each age and type of milk, please write down the quantity of amount consumed, with an indication of units (cups per week, glasses per day, etc.), using container models to standardize the units. Please note amounts for a boy and a girl and if milk was not consumed at all by a child. Please write down one response per participant unless the participant offers different estimates for each gender.

Wall Chart 1. Amounts of milk and milk products

	Cows' Milk		Goats' Milk		Cheese (cow)		Cheese (sheep or goat)		Atole (blue corn, milk, ash*)		White Gravy		Other	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Infant to age one year old														
1-4 year old														
5-10 year old														
11-15 year old														
16 year old – adult														
Pregnant and breastfeeding women														

Now, I'd like to ask you about breast feeding of infants. The women in our group can answer these questions.

3. Did your mother breastfeed her children?
    a. If so, how many months total did she breastfeed each child?
    b. At about what age were some other foods and milk eaten besides breast milk? What were these foods?
    c. Did breastfeeding mothers drink fresh milk? How many times per day or week? About how much each time?
    d. Was the diet of breastfeeding mothers different? If yes, in what ways was it different? Did they more or less eat organ meat, leafy greens, fruit than other adults?

Wall Chart 2. Breastfeeding and age when babies ate solid food

	Breastfeeding (Months)		Cows' Milk		Goats' Milk		Organ meat		Leafy Greens		Fruit		Other	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Breastfeeding babies														
Breastfeeding mothers														

Notetaker's note: For each cell in the breastfeeding column, please record (1) whether the participant recalls the mothers' breastfeeding, (2) duration of breastfeeding- from birth to what age, (3) at what age other foods besides breast milk were introduced, and (4) what were these foods

4. For this next part, let's talk about the types of meat your relatives typically ate in 1945. Tell me about the eating of large animals (cows and venison), medium animals (sheep, goat, pig) and small animals (rabbits, squirrels)? How much of this did your siblings and relatives eat? [*record on table*]
    1. How often and how much did you and your family eat large animals? [*record on table*]
    2. How often and how much did you or your family eat small animals (rabbits, squirrels, etc)? [*record on table*]
    3. How often and how much did you or your family eat medium animals (sheep, goats, pigs)? [*record on table*]
    4. How much dried meat such as jerky or carne seca did you and your relatives eat?
    5. Probe: Did you or your relatives eat organ meat, either prepared in a stew, moronga, or as sausage? How much would each person eat?

Wall Chart 3.Amount of Meat Eaten

	Large Animals		Small Animals		Medium Animals		Dried Meat		Organ meat (morongo, sausage, stew, etc)		Other	
	M	F	M	F	M	F	M	F	M	F	M	F
Infant to age one year old												
1-4 year old												
5-10 year old												
11-15 year old												
16 year old –adult												
Pregnant and breastfeeding women												

5. For this next part, let's talk about the vegetables your relatives typically ate in 1945. Tell me about the eating of leafy greens, root vegetables, cacti, grains, chiles, etc.? How much of this did your siblings and relatives eat? [*record on table*]
    a. Probe: Were there any differences between the **types** of vegetables that **boys** and **girls** ate?
    b. Probe: Were there any differences between the **amounts** of vegetables that **children ate compared to adults** ? If so, who ate more? How much more?

Notetaker's Note: For each cell in table below, please write down the different answers offered by participants in the 1940s. If a participant cannot answer a question, please note this and any reasons given (e.g., can't remember, don't know). For each age and vegetable, please write down amount consumed with an indication of units (cups per week, , spoons per day, grams per day, etc.). If a participant reports a vegetable product that is not listed, record the name of the product and the responses provided by the participants to that item. Please write down one response per participant with the number of children consuming that amount unless the participant offers different estimates for some/each of her children.

Wall Chart 4. Amounts of Vegetables and Grains Eaten

	Leafy greens (wild and garden)		Cacti		Root vegetables (potatoes, beets, turnips)		Grains (wheat or corn)		Grasses		Squash		Chile		Other	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Infant to age one year old																
1-4 year old																
5-10 year old																
11-15 year old																
16 year old – adult																
Pregnant and breastfeeding women																

6. Let's talk about the fruits you ate during the summer. How much fruit did you and your relatives eat?
    a. Probe: How much dried fruit did you and your relatives eat in the summer and early fall?
    b. What fruits were canned? When did you eat canned fruit and how much did you eat?

Wall Chart 5. Fruit

	Berries		Apples/peaches/ apricots/ plums/ choke cherries		Dried (muskmelon, etc)		Canned		Other	
	M	F	M	F	M	F	M	F	M	F
Infant to age one year old										
1-4 year old										
5-10 year old										
11-15 year old										
16 year old –adult										
Pregnant and breastfeeding women										

7. Now I am going to ask you about drinking water and the sources of drinking water in 1945.
    a. From where did your household obtain their drinking and cooking water?
    b. Did your younger or older siblings drink more water?
    c. Did pregnant or breastfeeding women drink more water? About how much water would they drink in a day?

Notetaker's Note: For each question, please write down the different answers offered by participant.

Wall Chart 6. Water used for drinking and cooking

	Drinking Water	Cooking water
Well		
Cistern		
Barrel		
Plumbing		
Acequias		
Other		

8. When we were visiting New Mexico last year, some people told us that they remember their siblings or parents licking the adobe on their homes or collecting coffee cans of soil to snack from. Perhaps they craved the flavor and nutrients in the earth.
    a. Did people in your community eat adobe or soil?
    b. About how much and how often would they eat adobe or soil?
    c. Are there other ways people would have eaten soil, such as on their hands or dust on plates?

Wall Chart 7. Adobe

	Adobe				
Infant to age one year old	No	Yes	How much?	How often?	How was it eaten (licked, scraped, collected in a can, other?
1-4 year old					
5-10 year old					
11-15 year old					
16 year old–adult					
Pregnant and breastfeeding women					

VIII. Daily life in the 1940s and 1950s (30 minutes)

9. Think about where you and your siblings spent your time (home, with neighbors, working in the fields, other) in the summer of 1945, specifically July. What types of activities did children do inside (eating meals, household chores) and how many hours a day did your children spend indoors when they were in these age groups?

a. Probe: Did boys and girls have different daily schedules?
b. Probe: Did the amount of time spent indoors differ for boys and girls? If so, who spent more time indoors and how much more?
c. Probe: How many hours a day did men spend outdoors?
d. Probe: How many hours a day did women spend outdoors?
e. Probe: Was time spent indoors different on weekends (Sundays)? Did children spend more or less time indoors on Sundays?

Moderator Note: Go through probe for all age groups. Example: For children aged 1-4 years old, how much time per day did they typically spend indoors in the 1940s and 50s? What types of activities were they doing when inside? If they say "all day", ask how many hours that would be.

Notetaker's Note: For each cell in the table hanging on the wall, record average hours spent indoors for boys, girls, men, then women. If a participant cannot answer a question, please note this and any reasons given (e.g., can't remember, don't know…).

Wall Chart 8. Time spent indoors July to October

Age of Child	Between breakfast and lunch				Between lunch and supper			
	Time spent indoors (Hours)		Activities		Time spent indoors (Hours)		Activities	
	M	F	M	F	M	F	M	F
Infant to age one year old								
1-4 years								
5-10 years								
11-15 years								
16+ years to adult								

VIII. Conclusion

We've reached the end of our talk today. Thank you all very much for your time and what we have shared. Does anyone have any questions? Is there something about the topics we covered today that we did not address?

Moderator Note: Thank participants and distribute incentives and remind them of reports back to community.

ATTACHMENT 10 – Background on Dietary Recall of the Past and Use of Focus Groups

ATTACHMENT 10 – Background on Dietary Recall of the Past and Use of Focus Groups

Dietary recall of the past

When asking participants to self-report data on daily life activities, researchers are relying on autobiographical memory (Brewer, 1986, 1994) and responses to questions are provided as a result of multistage recall processes (Tourangeau, 1984). Self-report of daily life activities or dietary intake is a complex task of cognitive processes that can be prone to distortion. Epidemiologic studies typically use food frequency questionnaires, structured interviews of foods consumed, and food diaries to ascertain dietary data (Willett & Lenart, 1998). Although some researchers note concern for errors in autobiographical dietary recall (Dwyer & Coleman, 1997; Marshall, 2005; Wu et al., 1988) and others note the influence that current intake could have on the accuracy of recall (Bakkum et al., 1988; Byers et al., 1983; Dwyer & Coleman, 1997; Dwyer et al., 1989; Friedenreich et al., 1992; Jensen et al., 1984; Rohan & Potter, 1984; Thompson et al., 1990; van Staveren et al., 1986; Wu et al., 1988), most highlight the utility of retrospective dietary recall as a reliable indicator when the recall period is from 1 to 10 years (Ambrosini et al., 2003; Byers et al., 1987; Jain et al., 1989; Lindsted & Kuzma, 1990; Tourangeau, 1984; Willett, 1998), 15–20 years (Jensen et al., 1984), and with time periods exceeding 20 years (Dwyer et al., 1989; Maruti et al., 2005; Pietinen et al., 1988; Wolk et al., 1997). It is well accepted that it is better to inquire about the past diet than to use current diet as an estimate of the past.

There are few alternatives for assessing dietary data in the distant past. Studies to date have used different dietary methodologies at two time points and evaluated differences in nutrients and foods that could be compared. One study had the original food record data to evaluate the validity of childhood dietary intake recalled by adults (median age 50 years) more than 3 decades later (Dwyer et al., 1989). Although general validity based on food records was poor, recall for dairy foods were better recalled than many other foods (r=0.25 for age 5-7, r=0.22 for age 18 and r=0.55 for age 30). Recall of adolescent diet by women aged 40-65 at entry showed reasonable reproducibility for two administrations of a food frequency questionnaire (FFQ) about high school diet (overall r=0.57, r=0.66 for alcohol) (Frazier et al., 1995). Validity of adolescent dietary intakes recorded with food records and recalled after 48 years with a food frequency questionnaire showed some foods (e.g., diet soda r=0.99, hot breakfast cereal r=0.93, hot beverages r=0.70, eggs r=0.51, potatoes r=0.54) were recalled reasonably well after 3-6 decades but nutrients and other foods were not well recalled (Chavarro, et al., 2009b).

Although adults can report their own diet to about 25 years in the past (Friedenreich et al., 1992), little work has been done on recall of their children's intake in the distant past. Chavarro et al. (Chavarro et al., 2009a) studied the validity of maternal recall of preschool diet for children aged 3–5 years using an FFQ after 43 years. Results indicate that while some foods (e.g., eggs r=0.47, high carbohydrate foods r=0.40) were recalled reasonably well, there was a general lack of validity for nutrients and foods from maternal responses based on a FFQ four decades later when compared with food records. The food frequency questionnaire provides a different type of information than food records and requires different cognitive tasks than those used in the planned focus groups.

The study designs used in the studies to date are not germane to current work of assessing general dietary habits or to the inherent utility of group dynamics to recall activities in the distant

past. Although difficulty in recall may remain an issue, focus group discussions among participants about lifestyles and events of that time period should improve recall of the type and amounts of foods consumed. The distributions of intakes for age/gender groups derived from these data will improve the dose estimation. Smith et al. (Smith et al., 1991) examined the reliability of dietary recall and concluded participants tend to rely on generic memory as the recall period increases and may be basing their reports on generic memory but added that "If dietary reports are based substantially on generic memory, perhaps generic memory is what epidemiologists should ask about". Focus groups take advantage of recurring events in the past that characterize generic memory.

Use of Focus Groups

Recent data suggests that elders benefit from group discussions of topics from the past. In fact, it was found that "collective recollection of past memories enhances memory performance" (Haslam et al., 2010) and a story reminiscence group was associated with enhanced cognitive outcomes (Haslam et al., 2014). In general, groups were found to be superior to individual recollection of past events.

Although focus group data may not be generalized to larger populations (Edmunds & American Marketing Association, 1999; Merton et al., 1990; Morgan & Krueger, 1997), there may be occasions when it is the only reasonable alternative to conducting numerous in-depth individual interviews. Previous research used focus group interview methodology both in the United States and abroad to collect data about nutrition knowledge, attitudes, and intake patterns among the general population and in a village setting (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). These focus groups were primarily designed to collect qualitative dietary data such as types of foods consumed, beliefs about the health and nutritional value of foods, and reasons for eating certain foods. In at least two studies, participants were also asked to quantify frequency or amount of food/drink consumed or fed to children (Edmonds, 2005; Kruger & Gericke, 2003). Focus group interviews seems to be the best research approach available because they have been shown to increase participant comfort when individuals are gathered into homogeneous groups (Kitzinger, 1995; Krueger & Casey, 2000; Lakshman et al., 2000), generate a broader range of thoughts than individual interviews (Kitzinger, 1995), and allow for a general discussion of memorable events among participants along with the judicious use of recall cues that have been shown to aid autobiographical memory recall (Brown et al., 1998; Klein & Kihlstrom, 1986; Klein & Loftus, 1988; Klein et al., 1989; McDonough & Gallo, 2008; Rogers et al., 1977; Smith & Hunt, 2005).

Kazakhstan Focus Groups

In a similar radiation exposure study (Land et al., 2015) of dairy food consumption in the distant past among rural communities in Kazakhstan, there was a novel use of focus groups to attain distributions of intakes among children and young adults (Schwerin et al., 2010). In contrast to previous studies on recall of dietary intakes in the past, the focus group methodology may have improved recall through the discussions about the events, lifestyles and practices. The teams' observations suggested that much back and forth comments about village life during this period may have aided recall. Consistent general answers elicited through focus group interviews should improve the estimation of dose. Although the specific amounts may not be accurate for a

given individual, the probability of consuming a particular amount for a child of a specific age, gender, and ethnicity will be more reliable than previous assumptions.

Some of the lessons learned from the Kazakhstan experience with relevance to the New Mexico focus groups were as follows: (1) when asking about the quantity and volume of dairy consumption, use of glasses and dishes graduated in size and volume and that were commonly used by residents in that time period were important as reference points; (2) for a more clear understanding of information being collected a large poster-sized paper wall chart was used where assistant moderators would record consumption data for the entire group to view and guide the moderator, which could improve data quality; (3) questions in the focus group guide were few and simple; and (4) a predictable pattern of responding was created to ease cognitive burden; participants were methodically stepped through questions for each child age group (i.e., for children from birth to 12 months old, 1 to 3 years old, 4 to 6 years old, 7 to 14 years old, and age 15 and older) by dairy consumption (i.e., first for milk type: breast milk, cow, goat, sheep, and mare; second for dairy products).

Several assumptions were modified as a result of information obtained from the focus groups. In particular, assumptions previously held by the study team were disproven and new information was gained. Through the focus groups, it was learned that there was no difference between boys and girls for the types of milk and dairy products consumed, children did not drink camel milk, young children did not consume large quantities of fresh horse and sheep milk, consumption by Russian and Kazakh children differed by the amount and type of milk; in contrast to the Kazakh's intakes the Russian children did not consume any goat, sheep, or horse milk. It was learned that horse milk was only available 1 to 2 months a year, which impacted its relevance to radiation exposure. Finally, previously no information was available about milk intake during pregnancy and lactation, which is important for *in utero* and infants' exposure. This information helped develop dose estimates for the most vulnerable groups.

As a result of the mortality of other village elders over time, it may be that participants available for the study had different daily life practices than others who had died. There is no way to discount this potential bias but questions were designed to ask about their own life practices and follow-up probes asked if their experience was different from others in the village they knew. There was no indication in the data that the participants' responses were different from typical village life at that time and there were many similarities across communities. The general differences of reported intakes by age and ethnicity and consistencies across focus groups suggest some underlying validity to the reports.

<u>ATTACHMENT 11</u> - Summary of Findings from the Literature Review of Native American and Hispanic Diets in New Mexico in the 1940s

ATTACHMENT 11 - Summary of Findings from the Literature Review of Native American and Hispanic Diets in New Mexico in the 1940s

Lauren Houghton, Anna Romanyukha, Cheryl De Aguiar, Abigail Ukwuani, Silvia Inéz Salazar, Laura Eichelberger and Nancy Potischman

Introduction

Trinity was the first test of a nuclear device to develop a deployable atomic bomb and was detonated on July 16, 1945 35 miles (56 km) southeast of Socorro, New Mexico (NM), at the new White Sands Proving Ground, which incorporated the Alamogordo Bombing and Gunnery Range. The communities living in and around the test site received no advanced notice about the test (personal communication from representatives of Las Mujeres Hablan, September 2013). Community leaders in New Mexico assert that the area surrounding the test site was populated (ibid). In 2008, experts at the National Cancer Institute (NCI) prepared a preliminary set of radiation dose estimates from exposure to radioactive fallout from the Trinity test for the population of NM as described in the 1940 census. The NCI dose estimates were primarily based on data on exposure rates that were measured immediately after the test and that are now publically available in published reports. The NCI's initial dose estimates were never published in the peer-reviewed scientific literature because of incomplete information regarding internal radiation doses from foods and some lifestyle factors. Mainly, researchers lacked information on dietary and lifestyle habits of Native Americans[1] and Hispanic[2] groups living in New Mexico at the time of the test. These variables are important, as contaminated food products, particularly dairy foods, may have been a source of internal radiation exposure from fallout from Trinity.

Over the past year, a literature search was conducted focusing on dietary patterns of Native American and Hispanic groups living in New Mexico in the 1940s to assess possible dietary exposure to internal radiation after the detonation of the Trinity device. The main focus was on foods consumed that would potentially contain radioactive iodine though the findings are also relevant to the other 60 radionuclides that will be estimated in the Trinity Study. The findings from this literature review were used to inform the development of a guide for key informant interviews. The guide was used as the basis to interview four Native Americans and five Hispanic elders who were alive at the time of the test. These in-depth interviews ascertained typical diets and provided data that could be compared with the information obtained in the literature review. Later, assuming that the NCI can locate additional elders in New Mexico from the Native American and Hispanic communities, the NCI plans to conduct focus group interviews for the purpose of quantifying the consumption rates of the important foods that both the literature review and key informant guides have identified. The amount of each food consumed will be used in the estimation of radiation doses to all age groups and ethnic groups in New Mexico. Based on this work, NCI investigators plan to refine their original dose estimates, using information collected on diet and lifestyle that was not available earlier and from those calculated doses, estimate the number of cancers to have been caused in New Mexico from exposure to Trinity fallout.

[1] For the purpose of this review, we are using the term Native American to refer to the group of 12 indigenous southwest tribes for which literature were available.

[2] The terms Hispanic, Spanish, Spanish-American, Mexican, Mexican-American, Latino and Chicano were used interchangeably throughout the literature. For the purposes of this review, we have chosen to refer to the group collectively as Hispanic.

Methods for Literature Review:

NIH Librarians assisted in the literature search after consultation with our Trinity team. After speaking to experts in the field, search terms became more focused so that specific sources of exposure could be better understood. The best results were obtained by searching full text sources, tracing cited references, and then reading and analyzing retrieved items for relevance. The literature search resulted in an in-depth review of 28 sources, which covered dietary practices for 12 different Native American tribes and pueblos, including the Navajo, Apache, Santa Ana Pueblo (traditional name: Tamaya), Zuni Pueblo (traditional name: Shewena), San Juan Pueblo, Santa Clara Pueblo (traditional name: Kha'p'oo Owinge), Taos Pueblo (traditional name: Tuah-Tah), Zia Pueblo, Jemez Pueblo (traditional name: Walatowa), Laguna Pueblo (traditional name: Ka'waika), and Cochiti Pueblo (traditional name: Kotyit), and several Hispanic communities in northern New Mexico and southern Colorado. Although the NIH librarians conducted a comprehensive search of available literature, limited dietary information was available for Native American and Hispanic groups living in New Mexico in the 1940s. While it is understood that diet among Native American and Hispanic communities would vary, the literature review could not distinguish the unique dietary habits among the different groups. The information from this review will be used to provide a foundational understanding of common regional practices and will be used to develop the talking points for the key informant guide. The interviews will augment, confirm and clarify the information obtained through the literature review.

While studying the literature for each tribe, pueblo or Hispanic community, the focus was on six main food groups with relevance to exposure to iodine and other fallout radionuclides: large animals, small animals, plants, fruits, dairy foods, and drinking water. Some identified behaviors specific to New Mexico pueblos did not fit in these pre-determined categories so four other categories were added: Animal Diet, Medicine, Ritual Foods and Other Sources. The team reviewers listed the types of food, the preparation, the frequency of consumption and where possible, the specific amounts (e.g., grams and tablespoons). Once all sources and the list of foods were reviewed, the foods were classified by three levels of potential exposure: high, medium and low. The results of this report are based on existing literature, and that may not reflect actual dietary practices from that time, thus supporting the need for further interviews with people from the area.

Summary of Findings and Questions

Typical Diet

According to literature reviewed, it appears that the typical meals consumed by Native American and Hispanic groups in the 1940s consisted of meat (typically cooked into a stew), bread (made from wheat and/or corn), lard, beans, small amounts of vegetables, coffee and sugar. By 1940, most of these foods were apparently purchased rather than grown or foraged. Typically, three meals were eaten per day and each family ate together. The Hispanic diet appears similar to the Native American diets except that Hispanics consumed more dairy products and chile. It was anticipated that one important route of exposure to Native Americans would have been through consumption of the thyroid glands of animals and for Hispanics, through consumption of dairy products. It was not possible to verify these *a priori* hypotheses through the literature review.

The in-depth interviews and focus groups will address these and other issues raised in the literature review.

- Consumption of wild small animals, fish and poultry appears to have been "low" among the groups studied, with the possible exception of rabbits among some Native Americans, including the Taos, Santa Ana, Santa Clara, Zia, Apache and Navajo.
    - Further inquiry is needed to determine if a communal rabbit hunt (among Native American tribes and pueblos) or a matanza – roast pig feast (among Hispanics) would have taken place in mid-July in the mid-1940s.
- Sheep, goat and pig consumption were found to be "medium to high frequency", especially among the Zia and Zuni.
- Even though the consumption of leafy greens appears to have been low on average, leafy greens can be a source of radiation exposure if their collection and consumption were high at the time of the Trinity test. The field team needs to establish in future interviews:
    - The frequency and amount of leafy greens, especially wild spinach and other wild plants, at the time of Trinity.
    - Which leafy greens were consumed by the Hispanics, where and when chile peppers were harvested and processed, as chiles were prominent in the sauces accompanying many meals.
- The leafy plants used for tea could be potential sources of radionuclide intake (as they grow, and hang to dry) so their preparation and quantity consumed should be assessed through the key informant interviews.
- Fruit consumption was classified as "low to medium frequency" among all groups.
    - The fruit hung to dry may have collected fallout
    - Seasonal fruit, such as berries, wild plum (among San Juan pueblo), and prickly pear (among the Apache), may have been consumed in high frequencies at the time of Trinity. The guide should help determine if prickly pear and other similar fruit were peeled prior to consumption.
    - The key informant guide should also seek to determine which fruits were consumed by Hispanics, and if locally grown plums were consumed during Trinity.
- The source and storage of water are important since it would have been consumed in coffee and used in cooking.
    - It is unclear if the acequias (water system) are a potential exposure pathway; the key informant interviews should seek this information.
- Large animal meat was classified as "high frequency" among Native American tribes and pueblos, and "low to medium frequency" among Hispanics.
    - Since organ meat was often consumed soon after the animal killing, meat from these animals may be a potential source of radionuclide intake. Mutton could be a source of radionuclide intake as various radionuclides can be collected in the animals' thyroid gland, muscle, and bones. Although bone was probably not

directly ingested, it was an ingredient in all of the stews. The same applies for the bones from the other large animals consumed, such as deer, bison and antelope.

  - Further inquiry is needed to determine if sheep would have been slaughtered and consumed in mid-July when the Santa Ana Feast Day and other mid-summer Feast Days are reported to have taken place.
  - Another potential source of radionuclide intake could come from meat hung up to air dry and contaminated by fallout, further inquiry would also be needed.

- Among the various Native American tribes and pueblos milk consumption is classified as "low to medium frequency," and is age dependent.
  - Native American adults were probably exposed to a low degree from this source since there is little documentation that of Native American tribes or pueblos consumed large volumes of milk. In one description of Zuni living, the milk added to the frequent coffees was canned, condensed milk and purchased from the trading post.
  - Children under 2 years of age may have been exposed to radionuclides through breast feeding and consumption of animal milk, which may include cow, goat, and sheep.
  - Consumption of milk from various sources, age dependency and prevalence of lactose intolerance need to be confirmed by interviews.
- Some Hispanic communities consumed milk and dairy products; however milk consumption and age dependency among specific Hispanic groups need to be confirmed by interviews because there are conflicting accounts in the literature.
- For many of the Native American tribes and pueblos, plant and crop consumption is classified as "low frequency" with the exception of wheat and corn, which was consumed with "high frequency" among the Navajo, Santa Ana, Zuni, San Juan, Santa Clara, Zia, Jemez, Pecos, and Apache.
  - Assess how much of the wheat consumed was grown and processed locally to determine if this would be a potential source of exposure.
- For the Hispanic groups, plant and crop consumption was classified as "medium to high frequency" depending on the plant or crop. In addition, the non-vegetable plant consumption (e.g., teas) was classified as "low."
- Medicinal teas were consumed but the amount of plants used in teas deems consumption as "low frequency" among Native Americans and Hispanics. Key informants could be asked if there were specific home remedies or medicinal teas consumed during the summer months.
- Key informants should be asked about the growing and gathering of tobacco, and the digging and uses of clay.
  - The consumption of clay is important but most likely a low source of exposure. The key informant interview should gather information on clay consumption as

there may be consumption by particular groups and the extent of usage in cooking is unclear.

- Smoking and cooking of plants (tobacco, green husks of corn) was classified as a potentially "low" exposure.

Cultural Factors:

- Various festivals, such as The Feast Day of Santa Ana celebrated on July 26th, may have activities of importance for radiation exposure. The descriptions suggest that preparations for the festivals began several weeks before the day, possibly including the time of the Trinity detonation.
    - The festivals were important to each Pueblo as well as the surrounding Pueblos who traveled to join in the festivities.
    - Asking participants to remember such festival times, may help them recall the specific time of year
    - Other Feast Days celebrated with festivals took place between late June and early July. St. Bonaventure or San Buenaventura Day, like other Feasts Days, featured special consumption patterns such as eating small mammals.
    - There are specific accounts of Native American men going to mountainous areas to gather spruce and other wild plants for the festivities. It is important to obtain details of these Feast Days, particularly including the food preparation directly before and after the activities. We recognize that discussion of information related to ceremonial activities is private and sharing of this information is at the discretion of the participants.
    - The key informant guide should also ask whether the Hispanics also participated in the same or similar summer festivals or Feast Days.
- Between the 1920s and 1960s, the US Forest Service introduced grazing regulations
    - Reductions in livestock numbers may have impacted consumption of medium and large animals in the 1940s.
    - The grazing patterns of animals should be established by key informants and focus groups to determine whether animals grazed in areas of the fall out.
    - It would be helpful to discuss with key informants the butchering and sharing of animal meat from communal herds during this time
- Trading Posts
    - In reading an ethnographic account of a Zuni mother preparing the family meal, many of the ingredients were purchased from nearby trading posts.
    - The source of foods sold in trading post needs to be established to determine if the food was locally sourced or sourced from an area within the fallout.
    - It is unclear if Hispanics were also associated with either selling or buying food from the trading posts.
- Food preparation

- The preparation of meat dishes among Native American often involved many parts of the animal being cooked into a stew. More details about how meat was butchered and prepared will be queried through key informants and focus groups.
- Ovens were located outdoors and also sealed and cleaned with natural substances such as clay and spruce. Food and water storage areas were also outdoors and so the locale of these storage areas should be determined.

Conclusion

The review of literature resulted in a long list of foods likely to have been consumed in the 1940s. Ethnographic details helped contextualize the food preparation and consumption patterns. The foods were rated into what appeared to be high, medium and low categories of consumption, and importance in the overall diet, but the reviewed literature could not adequately assess the amounts of each food consumed. The focus was on general dietary patterns but also noted discrepancies in trends that may be particularly relevant to certain Native American and Hispanic groups during the time of year that Trinity took place. It was not possible to ascertain specific information about many aspects of food consumption based on the literature review. For example, it was not clear if particular organs (i.e., thyroid gland) were given to certain family members or if the organ meat was handled differently than other parts of the animals. In addition, information was available on only some of the Native American populations and further detail is needed about unique and common aspects of population groups.

Questions raised from the literature review have been added to the Key Informant Guide. The next steps are to compare the findings from this literature review with academic experts and responses from four Native American and five Hispanic key informants. Later, focus groups can verify these dietary practices and quantify the consumption of the important foods that both the literature review and key informant guides have identified. These data will be used to estimate radiation doses to selected organs for typical persons alive at the time of the test in all ethnic groups in New Mexico and subsequently used to estimate the number of cancers that might have been caused by exposure to radioactive fallout from the Trinity test.

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ATTACHMENT 12 - TRINITY STUDY CONSULTANTS

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<u>ATTACHMENT 13A</u>. Participant Receipt - English

ATTACHMENT 13A. Participant Receipt - English

The Trinity Study

Participant Receipt

This form serves as documentation of receipt of compensation for time and travel expenses by individuals participating in this research study.

I, _____, have received the amount of $50 for my participation in the Trinity Study.

(Print name)

_____ _____

(Participant's signature) (Date)

ATTACHMENT 13B. Participant Receipt - Spanish

Attachment 13B – Participant Receipt - Spanish

El Estudio de Trinity

El recibo para participantes

Este _____ sirve come documentación de recibo del la _____ por gastos de tiempo y de viaje para individuals que participant en este studio de investigación.

This form serves as documentation of receipt of compensation for time and travel expenses by individuals participating in this research study.

Yo, _____, han recibido la cantidad de $50 para mi participación en el Estudio de Trinity.
(Nombre)

_____ _____
(Firma de particpante) (Fecha de hoy)

<u>APPENDIX 14</u> – IRB Approvals: (i) DHHS and (ii) Albuquerque Area Indian Health Board

Department of Health & Human Services

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

iRIS Reference Number ***354455***

Type of Action: Submission Response for Initial Review Submission Form
Project Number: P152616

02/22/2016

TO: Steven Simon
NCI - Radiation Epidemiology Branch

FROM: Chairperson, Special Studies Institutional Review Board, NCI

SUBJECT: Action on Clinical Research Protocol

The response to stipulations for your Initial Review of your protocol and consent document, "Study to Estimate Radiation Doses and Cancer Risks from Radioactive Fallout from the Trinity Nuclear Test ," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by expedited review.

The SSIRB has taken the following action:

X	Approved as written. Forwarded to the CC OPS for administrative processing.
	Approved with stipulations pending re-review by SSIRB Chair. See review.
	Approved with stipulations pending re-review by a subcommittee of the Board. See review.
	Deferred pending response to stipulations and re-review by the full SSIRB. See review.

Albuquerque Area Indian Health Board Inc.

Tóhajiilee Band of Navajos * Jicarilla Apache Nation * Mescalero Apache Tribe
Ramah Band of Navajos * Southern Ute Indian Tribe * Ute Mountain Ute Tribe

July 2, 2015

Dr. Steven L. Simon
Radiation Epidemiology Branch
National Cancer Institute
National Institute of Health
9609 Medical Center Drive
Room 7E442, MSC 9778
Bethesda, MD 20892

RE: SWT-2014-003: Study of Lifestyle and Dietary Patterns among Native Americans and Hispanic/Latinos in New Mexico at the Time of the Trinity Nuclear Test.

Dear Dr. Simon:

On July 2, 2015 the Southwest Tribal Institutional Review Board (IRB) reviewed your status report and renewal application, "Study of Lifestyle and Dietary Patterns among Native Americans and Hispanic/Latinos in New Mexico at the Time of the Trinity Nuclear Test." The Southwest Tribal IRB accepts your status report and **approves** the renewal application. Work on the project MAY continue. This approval is for a period of one year from the date of the original approval date and will require continuation approval if the research project extends beyond **June 5, 2016.** This IRB letter should be shared with any applicable IRBs.

This IRB letter should be shared with any applicable IRBs. If you make any changes to the protocol during the period of this approval, you must submit a revised protocol to the Southwest Tribal IRB for approval before implementing the changes. Accordingly, you are required to notify the Southwest Tribal IRB of any occurrence(s) of adverse events. Furthermore, if the results of the research are used to prepare papers for publication or oral presentations at professional conferences; manuscripts or abstracts must be submitted to the Southwest Tribal IRB for pre-publication approval. Results of research should be reported to participating tribes.

If you have questions about the IRB's decision, please contact Rachell Tenorio, Southwest Tribal IRB Coordinator at rtenorio@aaihb.org or (505) 764-0036 and she will forward communication to Southwest Tribal IRB members. We appreciate your interest in providing the benefits of health research to southwest tribal communities.

Sincerely,

Marvin Sarracino
Chair, Southwest Tribal IRB

ATTACHMENT 15A - Informed Consent

ATTACHMENT 15A- Informed Consent

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by face-to-face interview to complete this instrument so that we can better understand the diets and way of life of Native Americans, Hispanos, and non-Hispanic whites in New Mexico around the time of the Trinity nuclear test.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

Identification of the Project	Project to study the diets and way of life of Native Americans, Hispanics and non-Hispanic Whites in New Mexico during the time of the Trinity nuclear test.
Statement of Age of Subject	I am at least 18 years of age and I am in good physical health. I want to participate in the project being done by the National Cancer Institute, Bethesda, MD 20850.
Purpose	The purpose of this project is to learn about people's diets, activities, and living conditions around the time of the Trinity nuclear test in July of 1945. This will help our team from the National Cancer Institute in their studies of radiation exposure and long-term health effects.
Procedures	I am being asked to participate in a group discussion (focus group) or individual interview about activities and eating habits around the time of the Trinity nuclear test in July 1945. The discussion/interview will take up to two hours. There will not be any right or wrong answers to the questions. I will just be sharing my experiences and memories. There is an option to participate in either the focus group or individual interview.
Confidentiality	I understand that the information I will share will be put together with the answers that each group or person will provide. I understand that my name will not be used, nor will the name of my town or community be used. The group discussion will be audiotaped if all participants give their permission. The interview will be audiotaped if I give my permission. A recording of my voice will not be played to others besides the people in charge of this project. This document and any audio recordings will be kept in a locked cabinet. Both will be destroyed by December 31, 2020. The National Cancer Institute will follow all applicable privacy and confidentiality laws and

	regulations, and will do all that they can to keep private the information I share private.
Risks	I understand that participating in this project may cause some small risks. I may get upset when I talk about the time of the Trinity test. I can skip any questions, leave the discussion or stop the interview at any time.
Benefits, Freedom to Withdraw, & Ability to Ask Questions	I understand that the purpose of this project is not to help me personally. The National Cancer Institute hopes to learn about - activities and eating habits around the time of the Trinity nuclear test in July 1945. I am free to ask questions or stop participating at any time and without penalty. I understand that there will be no impact or adverse effect on existing healthcare benefits should I refuse to participate or withdraw from the study. I understand that the results of the project do not include the ability to determine my individual future health risks. I understand that the National Cancer Institute will provide me with the name of local healer or other resource if I want it. I understand that the National Cancer Institute will not pay for this healer or other resource.
Contact Information of Investigators	Steven L. Simon National Cancer Institute Telephone: (240) 276-7371 Email: ssimon@mail.nih.gov

Printed Name of Research Participant Signature of Research Participant Date

_____ _____ _____

Printed Name of Witness Signature of Witness Date

_____ _____ _____

Tape recording	Do you give permission to make an audio tape recording? Yes No

<u>Attachment 15B</u> – Informed Consent Form – Spanish

Attachment 15B – Informed Consent Form – Spanish

No. de la OMB (Oficina de Gerencia y Presupuesto): 0925-XXXX
Fecha de caducidad: xx/xx/20xx

La recopilación de esta información está autorizada por la Ley de Servicio de Salud Pública, Sección 411 (42 USC (Código de los EE. UU.) 258a). Los derechos de los participantes del estudio están protegidos por la Ley de Privacidad de 1974. La participación es voluntaria y no hay sanciones por no participar o por abandonar el estudio en cualquier momento. La denegación a participar no afectará sus beneficios en forma alguna. La información recopilada en este estudio se mantendrá de manera confidencial en la medida en que lo permita la ley. Los nombres y otra información de identificación no aparecerán en ningún informe del estudio. La información proporcionada se combinará con la de todos los participantes del estudio y se reportará en forma de resúmenes. Se le está contactando mediante una entrevista personal para que complete esta entrevista a fin de que podamos comprender mejor las dietas y el modo de vida de los indígenas americanos, hispanos y blancos no hispanos en Nuevo México en la época de la prueba nuclear Trinity.

Según la información del público, se estima que el tiempo necesario para recopilar esta información es en promedio de 10 minutos por respuesta, incluyendo el tiempo para revisar las instrucciones, investigar las fuentes de datos existentes, reunir y mantener los datos necesarios y completar y revisar la información recopilada. **Una agencia no puede llevar a cabo ni patrocinar una recopilación de información, y una persona no está obligada a responder a la misma a menos que (la agencia) exhiba un número de control de OMB válido en vigencia.** Envíe los comentarios concernientes a esta estimación de tiempo o a cualquier otro aspecto de esta recopilación de información, incluyendo sugerencias para reducir este tiempo a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). No devuelva el formulario completo a esta dirección.

Identificación del Proyecto	Proyecto para estudiar las dietas y el modo de vida de los indígenas americanos, hispanos y blancos no hispanos en Nuevo México durante la época de la prueba nuclear Trinity.
Declaración de edad del individuo	Soy mayor de 18 años de edad y gozo de buena salud física. Quiero participar en el proyecto que está llevando a cabo el Instituto Nacional del Cáncer, Bethesda, MD 20850.
Propósito	El propósito de este proyecto es aprender sobre las dietas, actividades y condiciones de vida de las personas durante la época de la prueba nuclear Trinity en julio de 1945. Esto ayudará a nuestro equipo del Instituto Nacional del Cáncer en sus estudios de la exposición a la radiación y sus efectos sobre la salud a largo plazo.
Procedimiento	Se solicita que participe en un debate de grupo (grupo de enfoque) o en una entrevista individual sobre las actividades y hábitos alimentarios durante la época de la prueba nuclear Trinity en julio de 1945. El debate/entrevista llevará hasta dos horas. No habrá ninguna respuesta correcta o incorrecta a las preguntas. Simplemente estaré compartiendo mis experiencias y recuerdos. Existe la opción de participar en el grupo de enfoque o en la entrevista individual.
Confidencialidad	Entiendo que la información que compartiré se colocará junto con las respuestas que proporcionarán cada grupo o persona. Entiendo que no se hará uso de mi nombre, tampoco se usará el nombre de mi ciudad o comunidad. Si todos los participantes dan su autorización, el debate de

	grupo será grabado. Si yo doy mi autorización, la entrevista será grabada. La grabación de mi voz no será reproducida ante otras personas salvo ante las personas a cargo de este proyecto. Este documento y cualquier grabación de audio se guardarán en un gabinete cerrado con llave. Ambos serán destruidos antes del 31 de diciembre de 2020. El Instituto Nacional del Cáncer observará todas las leyes y reglamentos de privacidad y confidencialidad pertinentes y hará todo lo posible por mantener en confidencialidad la información que comparto en privado.
Riesgos	Entiendo que participar en este proyecto puede causar algunos riesgos pequeños. Puede que me altere cuando hablo sobre la época de la prueba Trinity. Puedo saltear cualquier pregunta, dejar la conversación o detener la entrevista en cualquier momento.
Beneficios, libertad para retirarse y capacidad para responder preguntas	Entiendo que el propósito de este proyecto no es ayudarme de manera personal. El Instituto Nacional del Cáncer espera aprender sobre las actividades y los hábitos alimentarios durante la época de la prueba nuclear Trinity en julio de 1945. Tengo libertad para responder preguntas y para dejar de participar en cualquier momento sin sanción alguna. Entiendo que no habrá ningún impacto ni efecto adverso en los beneficios de atención médica en caso que me niegue a participar o abandone el estudio. Entiendo que los resultados del proyecto no incluyen la capacidad de determinar mis riesgos futuros de salud individual. Entiendo que el Instituto Nacional del Cáncer me proporcionará el nombre del curador (curandero) local u otro recurso si yo así lo quiero. Entiendo que el Instituto Nacional del Cáncer no pagará a este curador ni a otro recurso.
Información de contacto de los investigadores	Steven L. Simon Instituto Nacional del Cáncer Teléfono: (240) 276-7371 Correo electrónico: ssimon@mail.nih.gov

Nombre del Participante de la Investigación en letra de imprenta	Firma del Participante de la Investigación	Fecha
_____	_____	_____

Nombre del Testigo en letra de imprenta	Firma del Testigo	Fecha
_____	_____	_____

Grabación	¿Da su autorización para hacer una grabación en cinta de audio? Sí No

ATTACHMENT 16 - Communications Plan for the NCI Trinity Cancer Risk Study

ATTACHMENT 16 - Communications Plan for the NCI Trinity Cancer Risk Study

Background

NCI's Congressional mandate requires that we communicate with the American public about our research program. Many stakeholders will be interested in the outcome of the Trinity Cancer Risk Study. To effectively disseminate results from this effort NCI has developed the following communications plan.

Communications Goals / Objectives

NCI investigators intend to communicate not only the scientific goals and objectives of the Trinity study, but also its progress, findings, and future plans. The study team has designated Ms. Jennifer Loukissas and Ms. Silvia Salazar, as co-leads for community outreach and communications management. Together with Dr. Steve Simon, Ms. Loukissas and Ms. Salazar have already engaged in numerous interviews with television, print, radio, and online news outlets following the study's progress, including the pilot phase of the project.

Target Audiences

External to NCI/HHS:

- Advocacy groups in New Mexico, including the Tularosa Basin Downwinders Consortium and Las Mujeres Hablan
- Local leaders and key community members from New Mexico and Native nations within the state borders
- Academic experts in biomedical sciences, anthropology, sociology, cultural studies, etc., at universities in New Mexico.
- Radiation-related advocacy groups in New Mexico
    - For example: Concerned Citizens for Nuclear Safety, Embudo Valley Environmental Monitoring Group, New Mexico Alliance of Nuclear Worker and Advocacy and Cold War Patriots
- Reporters: Upon request, no proactive distribution (In conjunction with the NCI Press Office)
- Congressional delegation of New Mexico, via their staff (In conjunction with the NCI Legislative Office)

Internal to NCI/HHS:

- Federal agencies including the HHS sister agencies (Centers for Disease Control and Prevention, Indian Health Services), and others as appropriate
- NCI leadership and staff who interact directly with external audiences (Office of Government and Congressional Relations, Cancer Information Service/Office of Public Inquiries, Office of Advocacy Relations)

Strategies and Tactics

The study team will create materials in English and Spanish, and other languages if needed. In accordance with the regulations of the Southwest Tribal IRB, and to protect tribal confidentiality and privacy, NCI will not publish the names of the communities involved in the study (in particular Tribal communities), unless permission is granted on behalf of the tribe.

Materials will include the following:

- PowerPoint slides describing the study to be delivered by study investigators, or their proxy, at community meetings
- Study summary posted to DCEG website (http://dceg.cancer.gov/research/how-we-study/exposure-assessment/trinity and http://dceg.cancer.gov/research/how-we-study/exposure-assessment/trinity-espanol)
- Talking points describing the study for use in media interviews, internal communications, and discussions with external stakeholders
- Plain language summary of pilot results to be posted to the web and shared with stakeholders
- Statement of intent for future research

The materials above will be shared by email and on the DCEG website.

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ATTACHMENT 17 – Data Collection and Analysis Individuals and Consultants

ATTACHMENT 17 – Data Collection and Analysis Individuals and Consultants

Individuals Consulted on Statistical Aspects and Individuals Collection and/or Analyzing Data

- Steven L. Simon, PhD – PI – Staff Scientist (Radiation Epidemiology Branch, DCEG, NCI) (240) 276-7371, ssimon@mail.nih.gov
- Nancy Potischman, PhD – CO-PI – Nutritional Epidemiologist (Radiation Epidemiology Branch, DCEG, NCI) (240) 276-6893, potischn@mail.nih.gov
- André Bouville, PhD – Dosimetry Expert, contract (Radiation Epidemiology Branch, DCEG, NCI (retired)) (240) 276-7416, bouvilla@exchange.nih.gov
- Elizabeth Cahoon, PhD – Research Fellow (Radiation Epidemiology Branch, DCEG, NCI) (240) 276-7401, Elizabeth.cahoon@nih.gov
- Ruth Pfeiffer, PhD – Senior Investigator (Biostatistics Branch, DCEG, NCI) (240) 276-7317, Pfeiffer@mail.nih.gov
- Lauren Houghton, PhD – Associate Research Scientist (formerly of Epidemiology and Biostatistics Program, DCEG, NCI; now at Columbia University) (212) 342-0246, lh2746@columbia.edu
- Silvia Salazar, MPA – Informatics Research Laboratory Manager (Office of Communications and Public Liaison, NCI) (240) 276-6631, salazarsi@mail.nih.gov
- Whitney Arroyave, PhD - contractor (Social & Scientific Systems) (301) 628-0463, warroyave@s-3.com
- Mary Alice Scott, PhD – New Mexico State University (575) 646-5935, mscott2@nmsu.edu

ATTACHMENT 18 - References

ATTACHMENT 18 - References

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