

B. Collections of Information Employing Statistical Methods

1. Respondent Universe

Descriptions and Source of Study Population. Subjects will be residents of four villages near the SNTS or along the fallout track of the nuclear tests, which were selected from among the eight villages participating in the 1998 screening study (described in Section A). Two primarily Russian villages were selected from among the study villages to the northeast of the test site and two among the three study villages to the south and southeast of the test site which are primarily, if not completely, Kazakh. The presence of substantial numbers of ethnic Kazakhs in the predominantly Russian villages provides some latitude for distinguishing between location and ethnicity as determinants of housing construction and diet. We selected focus group villages with moderate to high fallout exposure levels because the subject of the study, modification of the pathways by which deposited radioactivity results in radiation dose to the thyroid gland, is of course important mainly to the extent that there is significant radioactivity to begin with. We intend to extrapolate our inferences to the remaining villages. Individual doses based on the modeled doses will be fitted to existing nodule prevalence data, and the dose response analysis will specifically take into account the estimated uncertainty structure of the resulting individual dose estimates. We will not assume that individuals with the same predictor values (age, sex, ethnicity, etc.) are identical, but will postulate an informed subjective within-group uncertainty distribution. It is important to note that these four villages are the most important in terms of estimated deposit of radioactive fallout (which was entirely a function of location) and size of the exposed population. These villages also correspond to two distinct lifestyles in terms of ethnicity, housing construction, and agricultural practices and, because the two predominantly Russian villages have significant numbers of ethnic Kazakhs, should allow us to investigate the

extent to which ethnicity per se and geographic location (availability of timber for housing construction and suitability for intensive agriculture compared to herding) can be separated as modifiers of radiation dose. Selection of study subjects is presented below under participant recruitment.

Three of the four focus groups recruited for each village will be female. Women of Kazakh, Russian and other ethnicities are eligible for participation. There will be no children involved in this study because the purpose is to learn about dietary patterns and daily living during events that occurred over fifty years ago. Men will be recruited for the fourth focus group in each village, which will be concerned with questions of dairy animals raised and seasonal pasturing and supplemental feeding of the milk animals contributing to children's diets.

Participant Inclusion Criteria. To be eligible, individuals must speak Russian or Kazakh, be able to participate in a two hour focus group session, and have a verified history of residing in the village during the 1950s. Verification of residence history will be based on regional records. Two sets of participants will be recruited for the study.

1. Women: In each village, 24 women will be recruited for three different focus groups.

Two alternates will also be selected for each group. Women will be selected who are age 70 years and older and who had children or provided care to children (i.e., younger siblings, nieces and nephews) during the 1950s. The first priority is to recruit women whose own children were <21 years during the 1950s. If necessary, women who provided care to children other than their own (e.g., younger siblings, nieces and nephews) during this period) will be recruited. Subjects will be chosen who have experience caring for children of different ages at the time of the nuclear tests. In order to recruit women who

had children of different ages (<21 years) during the 1950s, Kazakh study staff from the SSMA will screen potential participants for their children's years of birth.

2. Men: In each village, eight Russian or Kazakh men will be recruited who are now 70 years of age and older and who were engaged in farming and care of dairy animals at the time of the nuclear tests. Two alternates will also be selected for each group.

Participant Exclusion Criteria. The focus group interviews will be conducted in Russian and Kazakh and therefore individuals who do not speak at least one of these languages will not be eligible for participation. It should be noted, however, that it would be extremely rare to find a village resident who is not fluent in at least one of these languages in the villages selected for the study.

Estimated Number of Participants. NCI investigators propose to conduct four focus group interviews in each of four villages with eight participants in each group. Study staff will recruit three focus groups of women and one focus group of men in each village. NCI investigators estimate that the total number of men to be interviewed will be 32 and the total number of women to be interviewed will be 96, for a grand total of 128 study participants.

Estimated Response Rate. We anticipate that 90% of recruited individuals will participate in the focus group interviews.

2. Procedures for the Collection of Information

Data Collection Procedures. The primary exposure assessment tool is the focus group interview. The proposed study will use a structured focus group moderator guide to collect those data which are necessary and currently unavailable for the dose reconstruction effort and to confirm data previously ascertained. Previous studies in the United States and abroad (including

similar village settings) have successfully utilized focus groups to collect data about nutrition patterns (Satia et al., 2000 [10], Vuckovic et al., 2000 [12], Kruger and Gericke, 2003 [6], Edmonds, 2005 [1], Elmubarak et al., 2005 [2]).

The group structure and probing is expected to benefit recall and participation. The extensive literature research indicates that focus groups may stimulate in-depth individual participant responses more than individual interviews (Edmonds, 2005 [1]) and participants may be more comfortable speaking in a group situation (Kitzinger, 1995 [5], Lakshman et al., 2000 [7]). Participant interaction is a unique and compelling feature of focus groups (Kitzinger, 1995 [5], Twinn, 1998 [11], Lakshman et al., 2000 [7], Mclafferty, 2004 [8], Rabiee, 2004 [9], Edmonds, 2005 [1]) where participants share their experiences to describe the range of experiences in a group as well as the reasons for differences among participants. The group-level data to be collected from the focus groups is consisted with the group-level data provided from much of the existing data sources.

As discussed in the previous section, NCI investigators have selected two primarily Kazakh villages (Kaynar and Karaul) and two primarily non-Kazakh villages (Dolon and Kanonerka) for focus group data collection. Focus group interviews will be conducted during 2007. At least one RTI focus group expert and two members of the NCI study team will be on-site to oversee the focus group interviews. In each village, three focus groups of approximately eight women each (mothers or caregivers of children living in the villages at the time of the nuclear tests) and one focus group of approximately eight men are planned. The focus group literature indicates that the optimal number of participants is between 4 to 10 participants per group (Kitzinger, 1995 [5], Rabiee, 2004 [9]). The women's groups will provide critical information about children's milk and dairy consumption patterns during the 1950s, the general period of the nuclear tests. In order to capture the potential variability of consumption patterns,

there will be multiple groups per village. There is only one men's group per village because there are fewer living elderly men in the villages than there are women and less variability to capture because the questions are primarily focused on village-level practices. The difference in the number of women's and men's groups in part reflects the priority of information sought from each group. Information about children's consumption of milk and time spent outdoors are the most important factors (beyond residential history) affecting internal and external dose estimates.

In Dolon and Kanonerka, there will be one group of Russian women and one group of Kazakh women. In one of the villages, a second group of Russian women will be conducted. In the other village, the third group will be Kazakh women. Thus, in total, NCI investigators will conduct three groups of Russian women and three groups of Kazakh women from these ethnically-mixed villages. In Karaul and Kaynar, all three women's groups will be Kazakh only as these populations are nearly 100% Kazakh. The men's group will include Russians and Kazakhs. Again, this reflects the availability of fewer older men available to participate in the groups and reduced likelihood of variation by ethnicity of farming practices within a given village. Each focus group session will be documented using audio tape recorders and notes taken by an assistant and another member of the research team. All notes will be recorded on a laptop computer using a note-taking template designed by the NCI. Participants will be identified by first name only in all recorded materials. No personal identifiers will be recorded in the notes. Audio recording of the sessions will begin only after participants have introduced themselves to the group. Audiotapes will be destroyed at the conclusion of the study.

The focus groups will solicit information about season-specific practices of dairy consumption patterns, time spent outdoors, and agriculture practices during the months of August- October for the general period of the 1950s. Although a specific test year in each village

will be used as a focal point to stimulate recall, participants will not be limited to reporting diet for a specific year. Season is more important than is the exact year.

Subject identification and recruitment. The subjects will be selected from among living residents of the villages who were in the village at the time of the test and will not be restricted to the 1998 screening study participants. The most important reason for this is that many individuals from the cohort were too young at the time of exposure to recall their intakes so mothers and caretakers are required to collect these data. Given that many cohort members' mothers are no longer alive, the best approach for obtaining information about children's dietary practices is to include in the focus groups women who resided in these villages who had children or took care of other children who were less than 21 years of age during the 1950s. An alternative methodology is to conduct in-depth individual interviews. Individual interviews, however, would require conducting one-hour individual interviews for 24 women per village, instead of interviewing four groups in each village for two hours. The time and costs for interviewing individuals are prohibitive. Further, it would be very difficult for the women to recall the information sought without the aid of group discussion as is offered by the focus group.

Approval to conduct the study in the selected villages will be obtained from the regional administration prior to participant recruitment. During the pilot study to be conducted in Kazakhstan in March, NCI staff will work with the collaborator, Dr. Zhumadilov, to identify eligible participants from village and regional records and consult with the local administration and head doctors. These local personnel (administrators and doctors) are an integral part of the community and have detailed knowledge about the residents which is critical for participant recruitment.

To be eligible, individuals must speak Russian or Kazakh, be able to participate in a two hour focus group session, and have a verified history of residing in the village during the 1950s. Verification of residence history will be based on regional records. Two sets of participants will be recruited for the study, as described in section **B.1**.

Staffing and Training. The focus groups will be led by a trained moderator and two assistants, all fluent in Kazakh and Russian. One assistant will be responsible for recording (typing or writing) the focus group sessions and the other will focus specifically on recording the numeric data on the charts. Since the moderator and assistants are critical members of the study team, they will be interviewed and hired during the pilot study in March by NCI staff and the focus group expert. The moderator and assistants will be selected by their ability to demonstrate familiarity and comfort with the study population and a willingness to learn about the focus group methodology and collaborate with the NCI on this project. During the focus groups, the moderator and assistants will be supported by the focus group expert and members of the study team from NCI who will be on-site in Kazakhstan. This will enable us to make necessary on-site accommodations or changes to subsequent focus groups.

Before data collection commences, NCI, with help from RTI and a translator, will provide a rigorous week to 10-day training program and practice in focus group methodology in the U.S. for the Kazakh moderator and assistants. The training will emphasize that their responsibility is 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. The training sessions will provide an opportunity for the moderator and assistants to practice conducting the focus groups. They will be videotaped and the tapes reviewed with the moderator and assistants to discuss what they have done well and where there

are areas for improvement. The tapes will also be useful for the moderator and assistants to look through when preparing for the actual focus groups.

During the fieldwork, following each focus group session, there will be a debriefing with the focus group moderator, assistants, SSMA collaborators and NCI staff on site. Any items that may need further clarification, elaboration or verification will be incorporated into the subsequent focus groups. During this time, lists of recurring themes will be generated, typical quotes from participants will be noted and there will be discussion of terms, phrases and findings that have language or cultural significance and may not be conveyed well when translated.

Data Management and Quality Control. The study team (NCI researchers, collaborators, focus group moderator and assistants) will receive a manual of operations in which all aspects of the study protocol are standardized and described in detail. The manual will include a description of the project, an overview of the focus group methodology, recruitment and group allocation procedures, the informed consent procedures, training and preparation procedures, the focus group moderator guide and post focus group instructions.

Data quality measures will be a part of the focus group approach. The moderator will ask questions from the moderator guide thus improving the consistency of questions across groups within and between villages (Elmubarak et al., 2005 [2]). Further improving the consistency of the data collection process is the use of the same moderator and assistants for all focus groups. Audio recordings of the group session will be made and used to generate transcripts; this will improve the reliability (reproducibility of analysis results from the recording) of the data (Khan et al., 1991 [3]). The audio recording will be supplemented by detailed notes from one of assistants and a second member of the research team. These notes are particularly important for capturing nonverbal observations (Kidd and Parshall, 2000 [4]). The quantitative data will primarily be based on the note taking templates and charts generated by the focus group

members. These notes will be compared to transcripts from the sessions to ensure that the estimates provided by the participants were recorded correctly in the notes.

Transcription, Translation and Coding of Data. The numeric data (e.g., age-, gender- and village- specific estimates of the quantity of cow milk consumed) will be recorded in pre-designed tables during the focus group. Following the focus group sessions, which will be audio-taped, the focus group moderator and assistants will transcribe the audio-taped sessions in Russian according to the standardized method described in the field study manual. NCI staff will oversee translation of the Russian transcripts into English. From the English transcripts, variables will be created to develop an improved dosimetry.

3. Methods to Maximize Response Rates and Deal with Non-Response

Our Kazakh colleagues and we believe that 90% of individuals recruited will participate because this dosimetry study will address directly the fallout exposures that they, their children, friends and/or neighbors experienced. The optimal number of participants for each focus group is 8. We will recruit two alternates to compensate for any shortfall due to illness or no-show. All participants and alternates will be given a small monetary incentive (the equivalent of US \$5.00 in local currency) as a token of our appreciation for their willingness to participate.

4. Tests of Procedures and Methods to be Undertaken

During March 8-17, 2007, NCI and RTI staff traveled to Kazakhstan to test the materials and procedures to be used in the proposed study. Four SSMA staff members were identified as potential moderators and assistant moderators, and each underwent 8 hours of general focus group interview and protocol-specific training. On March 14, the four SSMA staff, along with the visiting NCI and RTI staff, conducted two pilot focus group interviews of 8 women and 8

men. The same eligibility requirements as described for the main study were applied to participants in the pilot study. Participants were given the equivalent of US \$5.00 in local currency as a small token of our appreciation. Results were positive in that all participants could recall information for most of the questions they were asked for the time period immediately following the nuclear testing. Only limited revisions to the focus group methodology and moderator's guides are anticipated. To simplify and enhance data quality, these may include identifying different reference periods to guide recall (e.g., changing from thinking about when they awoke to when they ate their morning meal), reducing the number of questions and probes for the women's focus group guide (e.g., asking about all children, rather than separately for boys and girls), and additional training for the focus group moderators and assistant moderators to elicit information more quickly and record answers uniformly and accurately.

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

A number of individuals have consulted with NCI on the design and analysis plans for the proposed study. NCI Dosimetrists, Drs. Steve Simon and Andre Bouville, will be directly involved in the design of the field study and incorporation of new data into the dosimetry models, and will advise on use of uncertainty densities in future statistical analyses.

The data elements and instrument content development were a collaborative effort between NCI and SSMA, with assistance from RTI. Kiyoo Mabuchi, MD, DrPH will serve as Principal Investigator, and will oversee the preparation and implementation of the field study. Charles Land, PhD, an NCI Statistician, will advise on statistical aspects as needed. Zhaxibay Zhumadilov, MD, PhD, DMSc, the Vice President of Research at the SSMA, is the primary Kazakhstan collaborator. Dr. Michael Schwerin of RTI International has provided consultation

on the design and question format of the focus group moderator guide. **Table 5** names the statistical and dosimetry experts who will be directly involved in the study and **Table 6** lists other principal staff responsible for the conduct of the study.

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