APPENDIX C – SEKI Pilot Study Methodology

Survey of Illness and Injury Among Backcountry Users in Sequoia and Kings Canyon National Parks
(PRA 0920-0727)

Pilot Study Methodology

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1. Procedures for the Collection of Information

The primary data collection instrument for this study is a self-administered questionnaire that can be provided to respondents in hard copy format (a paper-based questionnaire) or in an electronic (Internet-based) format. No interviewers are required. All respondents have advance notice of the survey. Data collection procedures are based on the following steps, which are described in more detail below:

- Screening (Consent-to-further-contact form)
- Consent to participate in the study
- Completion of the primary data collection instrument, in the format preferred by the respondent

In order to ensure controlled access to the backcountry and safety counseling prior to entry into the backcountry, NPS requires all backcountry users to attend an in-person permitting and registration process at one of five SEKI NPS backcountry offices prior to entering the backcountry. This permitting process occurs within hours to a couple of days before travelers enter the backcountry. Park visitors may reserve dates and routes for their excursions into the backcountry by email, phone, or fax, but each visitor is still required to present in person to a backcountry office in order to receive the permit and safety counseling. This is the only guaranteed point of personal contact between NPS officials and backcountry users because backcountry users are not required to check out after their trips. Therefore, the only time to request consent for further contact is in the backcountry ranger office during the permitting process.

One permit is issued per group. Groups may include one person or a group of people traveling together. The data collected by NPS for the permit is limited to:

1. Name of group leader
2. Address and phone number of group leader
3. Number of persons in the group
4. Dates of entry and exit from the backcountry
5. Route taken in the backcountry
6. Method of travel (i.e., on foot, by animal, by boat)

Of note, the demographic characteristics of the group members, the levels of experience of the backcountry users, and individual contact information are not obtained.

In order to perform a **nonresponse bias analysis**, demographic data and levels of experience will be obtained through the following mechanisms:

1. **Consent-to-Further-Contact Form** - While visiting the backcountry office to obtain their permits and safety counseling, backcountry visitors will receive an introduction page and a two-page paper consent-to-further-contact form that (1) asks for basic demographic information and backcountry experience, and (2) asks if they would consent to be contacted

by investigators after they have completed their backcountry travels. These initial consent-to-further-contact documents will not provide informed consent for the survey – that will be obtained later. The introduction page included with the two-page form informs readers that we are conducting a survey to look at the health of backcountry users – no further details about the content of the questionnaire will be provided at this time to avoid recall bias. To avoid making persons feel pressured or coerced into consenting to participate in the survey, the introduction page of the consent-to-further-contact form informs readers that this survey is not a requirement for obtaining their backcountry permits. Completed consent-to-further-contact forms will then be sent to CDC and, using an Internet-based interview software package called mrInterview™, the information on these forms will be scanned into the study database. This information will be used to compare those people who complete the survey after they return from their backcountry trips (respondents) to those who do not complete the survey (nonrespondents). Results will be included in the final report, as well as a discussion of the implications of any nonresponse bias for park planning and management.

2. **Direct Observation** - Some people will not fill out the two-page consent-to-further-contact form so no information on demographics and experience will be collected on them through the above mechanism. Therefore, to ensure that some information is collected on all persons presenting for a backcountry permit, direct observation will be employed. As the park rangers distribute backcountry permits, they will use a refusal log to provide information about each adult not completing a consent-to-further-contact form. Observations regarding gender, the presence of children in the group, and the reason for refusal (if given) will be recorded on the refusal log. Information such as group size and primary means of transportation in the backcountry can be determined using the NPS permit database as long as the permit number is recorded on the log. The information collected using the refusal log and the NPS permit database will be used to compare persons who refuse to answer complete the consent-to-further contact form (nonparticipants) with those who agree to be contacted and either complete the survey (respondents) or do not complete the survey (nonrespondents). Results will be included in the final report, as well as a discussion of the implications of any nonresponse bias for park planning and management. The refusal log and refusal log protocol have been modified for this study from the survey logs and protocols used by the NPS Social Science Program to conduct nonresponse bias analyses on visitor surveys. Those NPS survey logs and protocols have been reviewed and approved by OMB in the past and are included with current and planned NPS Social Science Program studies as part of their expedited OMB review process.

Backcountry users who consent to further contact and who provide an e-mail address will be sent an introductory e-mail within 2 to 3 weeks after the expected

completion date of their backcountry travel (as obtained from their consent-to-further-contact forms). Two weeks is generally the maximum incubation period for pathogens known to cause illness associated with food, water, and person-to-person transmission. Therefore, those backcountry users who were exposed to these pathogens on their trips would have developed symptoms by the time they are contacted. This e-mail will contain a web address (URL) for the Internet-based self-administered questionnaire. The URL contains a personal security pass code embedded in it. The pass code is unique for each person who consents to further contact and restricts questionnaire access to persons who travel in the backcountry in SEKI during the study period. After logging on to the website, the study participants will see a study consent form that they must read and complete before proceeding further. This consent form explains the purpose of the survey and the types of questions that will be asked. Only those consenting to participate in the study by providing an affirmative answer to the question “Do you agree to take this survey?” will be allowed access to the questionnaire. A signature will not be obtained. This study involves no procedures for which written consent is normally required outside of the research context. No persons younger than 18 years of age will be enrolled. Participants will have the option of completing the questionnaire in one sitting or over multiple sessions. For those who fail to complete the questionnaire in one sitting, online access to their own semi-completed questionnaire is granted through the use of the same pass code. The self-administered standard electronic questionnaire has built-in skip patterns and data entry validation to limit data cleaning. Data entry into the database is automatic.

Those backcountry users who consent to further contact and who provide a postal address will be sent a package within 2 to 3 weeks after the expected completion date of their backcountry travel (as obtained from their consent-to-further-contact forms). This package will contain an introductory letter, a copy of the consent-to-study form stapled to the front of the paper-based questionnaire, and a postage-paid pre-addressed return envelope that participants may use to return the questionnaire to CDC. The return of a completed questionnaire will be taken as tacit consent for the survey. As with the Internet-based version, a signature indicating consent will not be required. Data from the paper-based questionnaires will then be manually entered into the electronic database at CDC.

Backcountry users who consented to be contacted by e-mail but who have not accessed the website within 4 weeks of the expected completion date of their backcountry travel (as obtained from their consent-to-further-contact form) will be sent an automatic reminder e-mail (same as the introductory email) 4 weeks after the expected completion date of their backcountry travel. Those who have still not accessed the website within 5 weeks of the expected completion date of their backcountry travel will be sent a second reminder e-mail. Access to the survey will be denied to participants who have not completed their questionnaires within

6 weeks from their expected backcountry travel completion dates. Participants will not be contacted again after the 6-week period.

Backcountry users who consented to be contacted by regular mail but who have not returned their completed questionnaires within 4 weeks of the expected completion date of their backcountry travel (as obtained from their consent-to-further-contact forms) will be sent reminder letters (same as the introductory letter). Those who have still not returned their completed questionnaires by 5 weeks will be sent second reminder letters, additional consent forms, additional copies of the questionnaire, and postage-paid pre-addressed return envelopes. Participants will not be contacted again after the 6-week period. Participants completing paper-based questionnaires will have 2 extra weeks to send in their documents because of potential delays in regular mail service. Any paper-based questionnaires received at CDC beyond 8 weeks from the expected completion date of backcountry travel will not be included in the analysis because of the increase in recall bias after prolonged periods of time.

The electronic and paper questionnaires ask the same standardized questions about health (before, during and after their backcountry travel), water consumption, water preparation habits, food consumption, food preparation habits, sanitation practices, recreational water use, animal exposure, and demographics. Consenting backcountry users will be interviewed about potential exposures during the time they were in the backcountry. Therefore, the potential exposure period will differ for each individual, depending on how long he/she spent in the backcountry.

The pilot study and the large-scale study will use the same protocol, questionnaire, and other study materials. We hope to conduct the pilot study from September 1-30, 2006 to assess the feasibility, logistics, and response rates for the study. Using this information, we will then modify the protocol as required for the large-scale study to be conducted from May 1 – October 31, 2007.

2. Methods to Maximize Response Rates and Deal with Nonresponse

Backcountry users who consent to be contacted but who do not complete or return their questionnaires within 4 weeks of the expected completion date of their backcountry travel (as obtained from their consent-to-further-contact forms) will be sent reminders. For those persons who consented to be contacted electronically, reminder e-mails will be automatically generated using the mrInterview™ software. This software will also alert investigators if paper-version participants are late in returning their completed questionnaires so that reminder letters can be mailed out. The reminder email and letter are the same as the introductory email and letter. Those persons who have still not completed and

returned their questionnaires by 5 weeks will be sent reminders again (see section B.2 for details about reminders).

To reassure respondents as to the legitimacy of this study and further encourage participation, the National Park Service (NPS) and the Centers for Disease Control and Prevention (CDC) will develop websites housed on NPS and CDC servers describing the study. These websites will be advertised on the consent to complete the questionnaire and at the beginning of the questionnaire. The CDC website has been reviewed and approved by the Division of Parasitic Diseases' Acting Associate Director for Science. The NPS website has been reviewed and approved by the Director of the NPS Office of Public Health.

Out of the estimated 9,050 adult backcountry users at SEKI from May 1 through October 31, 2007, we estimate 3,246 will complete a questionnaire (either Internet-based or paper-based) resulting in a 35.9% response rate after 2 reminders (3,246 / 9,050 * 100 = 35.9%). This response rate is consistent with the response rates obtained by some large continuing health surveys that provide key national health statistics and with National Park Service Social Science Program survey response rates.