

**Supporting Statement B
Request for OMB Review and Approval
Revision**

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STUDY TITLE

Survey of Illness and Injury among Backcountry Users in Yellowstone National Park
(PRA 0920-0727).

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

We plan to conduct a census survey of backcountry users in Yellowstone National Park from May 1, 2008 through October 31, 2008 (the backcountry season). To estimate the approximate number of participants we may be able to survey during the Yellowstone backcountry season, we used data on permit issuance from NPS. From May 1, 2006 through Oct. 31, 2006, NPS issued 97% of its private permits for Yellowstone National Park backcountry travel, with **12,673** persons of all ages traveling into the backcountry during this 6-month period (personal communication). We anticipate a similar number of permits will be issued and a similar number of persons will travel into the backcountry during the same time period in 2008. Discussions with NPS indicate that, anecdotally, children are the minority of backcountry visitors. NPS does not keep statistics on the ages of backcountry users. However, the SEKI pilot study corroborates this statement, since only one backcountry user out of 64 indicated that he was traveling with a child. To be conservative, we estimate that 20% of backcountry users will be children and **80%** will be adults, leaving an estimated 10,138 adult backcountry users ($12,673 \times 0.8 = 10,138$) during the 2008 Yellowstone backcountry season. These **10,138** adult backcountry users will be eligible to participate in the study. We will not be providing our questionnaire to persons younger than 18 years of age.

From the SEKI pilot study, we know that **67%** of adult backcountry users consented to be contacted after their backcountry trips. Therefore, we predict that **6,792** adults ($10,138 \times 0.67 = 6,792$) in Yellowstone will consent to be contacted after their backcountry trips.

The Pew Internet and American Life project estimates that 73% of adults were Internet users in 2006. Approximately 88% of 18-29 year-olds, 84% of 30-49 year-olds, 71% of 50-64 year-olds, and 32% of those age 65 years and older go online. An estimated 84% of adults with some college education and 91% of adults with at least a college degree go online. Furthermore, 80% of adults whose annual household incomes are between \$30,000-\$50,000 go online; this estimate increases to 86% for adults with annual household incomes between \$50,000-\$75,000.³² We know from a survey in Yellowstone National Park in 1999 that 98% of adult backcountry users were 18-65 years old, the average annual household income was \$40,000-\$59,000, and 96% had at least some college education.³¹ The SEKI pilot found a similar demographic picture, with 94% of adult backcountry users being 18-65 years old and 100% having had at least some college education. Therefore, based on the Pew statistics, we estimate that **84%**, or approximately **5,705** adult Yellowstone backcountry users consenting to be contacted after their trips will have access to the Internet ($6,792 \times 0.84 = 5,705$). A literature search failed to provide statistics on the proportion of persons with Internet access preferring Internet-based questionnaires versus paper-based questionnaires. However, from the SEKI pilot study, we know that 100% of the backcountry users who consented to further contact provided us with an email address and 100% preferred to be contacted by email. Therefore, we will assume that **100%** (or **5,705** [$5,705 \times 1.00 = 5,705$]) of consenting adults with Internet access would prefer to use the Internet. This leaves **1,087** persons ($6,792 - 5,705 = 1,087$) who would prefer or are only able to use paper.

For the 5,705 adults willing to be contacted after their backcountry trips and preferring to use the Internet, we estimate a **60%** response rate after two reminders, based on the response rate obtained from the SEKI pilot of those consenting to further contact who actually completed a questionnaire. Therefore, we predict that **3,423 Internet-based questionnaires** ($5,705 \times 0.6 = 3,423$) will be completed after two reminders.

Due to the apparent length of the paper-based questionnaire on first appearance (i.e., not taking into account the number of skip patterns), we estimate only **10%** of those who prefer paper will actually complete the questionnaire, even after two reminders. Thus, we estimate that **109 paper-based questionnaires** ($1,087 \times 0.1 = 109$) will be completed after two reminders.

Therefore, from a census survey of 10,138 adult backcountry users at Yellowstone National Park from May 1, 2008 through October 31, 2008, we estimate that 3,423 persons will complete Internet-based questionnaires after two reminders and 109 persons will complete paper-based questionnaires after two reminders, for a total of 3,532 completed questionnaires.

Table B.1.1 – Estimates of Study Participation

Calculation Step	Estimated Percent	Number of Survey Participants
Estimated number of adult backcountry users in Yellowstone from 05/01/08 – 10/31/08	80%	$12,673 \times 0.8 = 10,138$
% of adults consenting to further contact after their trips	67%	$10,138 \times 0.67 = 6,792$
% of consenting adults with Internet access	84%	$6,792 \times 0.84 = 5,705$
% of consenting adults with Internet access who prefer Internet-based questionnaires over paper-based questionnaires	100%	$5,705 \times 1.00 = 5,705$
% completing Internet-based questionnaires after 2 reminders	60%	$5,705 \times 0.6 = \mathbf{3,423}$
Number of adults consenting to further contact after their trips who prefer paper		$6,792 - 5,705 = 1,087$
% completing paper-based questionnaires after 2 reminders	10%	$1,087 \times 0.1 = \mathbf{109}$
TOTAL		$3,423 + 109 = \mathbf{3,532}$

We have performed power calculations to assess whether a census survey in Yellowstone National Park will have enough power to provide statistically useful information. In addition to analyzing the backcountry users overall, each of the two survey groups (Internet and paper) will need to be analyzed separately and compared to each other to see if there are any systematic biases between the groups before they can be combined for the overall analysis. Therefore, both of these study arms will individually require sufficient statistical power for analysis. For these power calculations, the following goals/assumptions are made:

- The overall study (Internet + paper arms) requires 80% power and 95% confidence (p value < 0.05 ; Type I alpha error = 0.05) to detect a relative risk for illness or injury from uncommon exposures (10 unexposed persons per one exposed person) of **1.25** or larger. Examples of uncommon exposures include but are not limited to the use of UV

light to treat drinking water, the use of newer filter technologies, and physical contact with pack animals.

- Each study arm requires 80% power and 95% confidence (p value <0.05; Type I alpha error = 0.05) to detect a relative risk for illness or injury from uncommon exposures (10 unexposed persons per one exposed person) of **1.30** or larger.
- We assume a 50% rate of illness or injury among backcountry users not exposed to the risk factors under investigation to maximize variance and to make the most conservative power estimates.
- We assume a design effect of two to account for the correlation between persons traveling together under the same backcountry permit. The SEKI pilot study indicates that, on average, two to three persons are included on each backcountry permit. Therefore, since the majority of persons travel in groups, the correlation in experiences and survey responses between group members must be considered and the sample size increased accordingly.

Under these assumptions and goals, we will require **3,168** completed questionnaires to be able to detect a statistically-significant relative risk of **1.25** for uncommon exposures in the overall study.

Table B.1.2 – Power Calculations for Overall Study

Confidence	Power	Expected Frequency of Disease in Unexposed Persons	Ratio of Unexposed to Exposed Persons	Expected Frequency of Disease in Exposed Persons	Relative Risk	Number of Unexposed Persons	Number of Exposed Persons	Total Persons Required (x 2 for design effect)
95%	80%	50%	10:1	61.5%	1.23	1700	170	3,740
95%	80%	50%	10:1	62.0%	1.24	1,560	156	3,432
95%	80%	50%	10:1	62.5%	1.25	1,440	144	3,168
95%	80%	50%	10:1	63.0%	1.26	1,340	134	2,948

We anticipate that we can achieve this goal with the overall study because a conservative estimate of the expected total number of completed questionnaires in a census survey of Yellowstone backcountry users during the backcountry season is 3,532.

We also anticipate that we can achieve our goal of detecting statistically-significant relative risks of 1.30 or greater in the Internet arm of the study. To detect a statistically-significant relative risk at this level requires 2,222 completed questionnaires and we anticipate the Internet arm will obtain 3,423 completed questionnaires.

Table B.1.3 – Power Calculations for Internet Arm

Confidence	Power	Expected Frequency of Disease in Unexposed Persons	Ratio of Unexposed to Exposed Persons	Expected Frequency of Disease in Exposed Persons	Relative Risk	Number of Unexposed Persons	Number of Exposed Persons	Total Persons Required (x 2 for design effect)
95%	80%	50%	10:1	62.5%	1.25	1,440	144	3,168

95%	80%	50%	10:1	65.0%	1.30	1,010	101	2,222
95%	80%	50%	10:1	67.5%	1.35	740	74	1628

In contrast, because we anticipate that the paper arm of the study will have so few completed questionnaires (109), we will not be able to detect a statistically significant relative risk of 1.30 for uncommon exposures in this study arm. However, we will be able to detect a relative risk of 1.80 for common exposures and we believe that this is adequate for assessing whether or not there are any systematic differences between persons completing paper-based questionnaires and those completing Internet-based questionnaires that would preclude merging the two study arms for an overall analysis.

Table B.1.4 – Power Calculations for Paper Arm

Confidence	Power	Expected Frequency of Disease in Unexposed Persons	Ratio of Unexposed to Exposed Persons	Expected Frequency of Disease in Exposed Persons	Relative Risk	Number of Unexposed Persons	Number of Exposed Persons	Total Persons Required (x 2 for design effect)
95%	80%	50%	10:1	65.0%	1.30	1,010	101	2,222
95%	80%	50%	10:1	99.5%	1.99	80	8	176
95%	80%	40%	10:1	96.5%	2.4	70	7	154
95%	80%	35%	10:1	98.0%	2.8	50	5	110
95%	80%	30%	10:1	99.0%	3.3	40	4	88
95%	80%	20%	10:1	90.0%	4.5	44	4	88
95%	80%	50%	1:1	85.0%	1.7	32	32	128
95%	80%	50%	1:1	87.5%	1.75	28	28	112
95%	80%	50%	1:1	90.0%	1.80	24	24	96

Therefore, if we conduct a census survey of all eligible adults traveling into the backcountry Yellowstone National Park from May 1, 2008 through October 31, 2008, we will have enough people to meet the overall goals of our study. However, all eligible adults will need to be asked to participate if we are to achieve the necessary sample size. Therefore, a census survey is required; a survey of a smaller proportion of the population would be inadequate for our needs. Furthermore, the entire cohort of backcountry users traveling during the backcountry season is needed to perform the planned non-response bias analysis using the Yellowstone backcountry permit database (see Sections A.2 and B.3).

2. Procedures for the Collection of Information

For a detailed discussion of required sample size estimation and accuracy (power calculations) and sample selection, see Section B.1. Based on the information and reasoning presented in Section B.1, a census survey of the Yellowstone backcountry users from May 1, 2008 through October 31, 2008 will be performed.

The primary data collection instrument for this study is a self-administered questionnaire that can be provided to respondents in an electronic (Internet-based) format or in a hard copy (paper-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 (Yellowstone study consent-to-further-contact form),
- Consent to participate in the study (Yellowstone study consent form), and
- Completion of the primary data collection instrument (questionnaire), in the format preferred by the respondent.

The Internet-based and paper-based questionnaires ask the same standardized questions about health (before, during, and after 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.

All Yellowstone National Park visitors who (1) require a permit for private backcountry travel (this does not include backcountry users traveling with a commercial operator); (2) who are functionally literate in English; (3) who are 18 years of age or older; and (4) who enter the backcountry within a 6-month period from May 1, 2008 through October 31, 2008 (the main backcountry travel season at Yellowstone National Park) will be eligible to participate in this study.

Persons excluded from the study include: (1) visitors to Yellowstone National Park and persons working in the park who do not have a permit for private backcountry travel (because we will not be able to identify these persons); (2) backcountry users younger than 18 years of age (because children represent the minority of backcountry visitors; because the mechanisms for consenting parents and assenting children through the Internet have not been well established; and because we will obtain indirect information about children through questionnaires completed by other adult travelers accompanying the children); (3) backcountry users who are not functionally literate in English (because the questionnaires, consent forms, and instructions are in English); and (4) backcountry users who do not provide consent for further contact. These persons will be excluded using the consent-to-further-contact form that is completed in person at the Yellowstone National Park backcountry permitting offices before traveling into the backcountry. Adult backcountry users who have provided consent for further contact but who fail to complete the Internet-based questionnaire within 8 weeks from their expected backcountry travel completion dates will also be excluded, as will those who fail to return a completed paper-based questionnaire within 8 weeks from their expected backcountry travel completion dates (see below).

In order to ensure (1) controlled access to the backcountry and (2) 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 nine Yellowstone National Park backcountry permitting 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 permitting 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 for the study is in the backcountry permitting office during the permitting process.

The Yellowstone National Park backcountry permitting offices use permit numbers to identify groups of people traveling together. One permit is issued per group. Groups may include one person or multiple people traveling together. Data collected for the Yellowstone backcountry permits²⁶ (**Appendix F**) include:

- Name and contact information of the group leader (including address, phone number, and email address if available)
- Date of birth of the group leader
- Vehicle license plate number and location where it will be parked
- Group size
- Group affiliation if applicable (e.g., school, church, scouts)
- Dates of entry and exit from the backcountry (i.e., duration of backcountry travel)
- Route taken in the backcountry
- Method of travel (i.e., on foot, by animal, by boat)

Every adult backcountry user who presents to a backcountry permitting office as part of the permitting process will be given a Yellowstone study introduction page (**Appendix H**) and a Yellowstone study consent-to-further-contact form (**Appendix G**) by the rangers operating the backcountry permitting offices. The rangers will be trained on:

- what the purpose of the study is and the details of the study protocol, so that they may explain the introduction page/consent-to-further-contact form and answer questions about the study,
- who to give these documents to (i.e., only to adults 18 years of age or older), and
- how to collect and return the consent-to-further-contact forms to CDC.

The introduction page 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 study, the introduction page states that participation in this study is not a requirement for obtaining a backcountry permit. The consent-to-further-contact form asks if the backcountry user would consent to be contacted by investigators after completing his/her backcountry trip. This form does not acquire informed consent for the questionnaire – that will be obtained later. Backcountry users who consent to further contact are asked to provide the following information:

- their backcountry permit numbers – we will use this number to identify groups of people traveling together and for the non-response bias analysis (see Sections A.2 and B.3);
- the date they expect to leave the backcountry – we need this date in order to know when to send out the questionnaires (see below); and
- their contact information, including their names, email addresses, postal addresses, and phone numbers.

Completed consent-to-further-contact forms will be collected by the park rangers and sent to CDC on a weekly basis by FedEx[®]. Using an Internet-based interview software package called

mrInterview, the information on these forms will be scanned into the study database. Then, depending on what contact information is provided, the following procedures will take place:

Email address provided

Persons who provide an email address will be sent an introductory email (**Appendix K**) within **2 weeks** after their expected backcountry travel completion dates (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 most likely have developed symptoms by the time they are contacted. The introductory email 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 Yellowstone during the study period.

After logging on to the website, the study participants will see a study consent form (**Appendix L**) that they must read and complete before proceeding further. This consent form explains the purpose of the questionnaire (**Appendix M**) 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 Internet-based 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. Data entry into the database is automatic.

Those who have not accessed the website within **3 weeks** of their expected backcountry travel completion dates will be sent an automatic reminder email. This email will be the same as the introductory email and will contain the same URL with their embedded personal security pass codes. Those who have still not accessed the website within **4 weeks** of their expected backcountry travel completion dates will be sent a second reminder email, which will be the same as the first two emails. If they have provided postal addresses, they will also be mailed packages at this time that contain an introductory letter (**Appendix N**), a paper version of the study consent form (**Appendix O**) stapled to the front of the paper-based questionnaire (**Appendix P**) (which asks the same questions as the Internet-based questionnaire), and a postage-paid pre-addressed return envelope that participants may use to return the completed questionnaire to CDC. Finally, those who have not accessed the website or returned a completed paper-based questionnaire within **5 weeks** of their expected backcountry travel completion dates and who have provided phone numbers will be called and given the options of completing the questionnaire over the phone, by mail, or by Internet.

To limit recall bias, completed questionnaires (whether Internet-based or paper-based) will not be accepted after **8 weeks** from the expected backcountry travel completion dates. Furthermore, access to the Internet-based questionnaire will be denied to participants who

have not completed their questionnaires within 8 weeks from their expected backcountry travel completion dates. After 8 weeks, non-responding backcountry users who provide phone numbers will be called and asked for their reasons for non-response.

No email address provided but postal address provided

Those backcountry users who consent to further contact and who provide a postal address will be sent a package within **2 weeks** after their expected backcountry travel completion dates. This package will contain an introductory letter (**Appendix N**), a paper version of the study consent form (**Appendix O**) stapled to the front of the paper-based questionnaire (**Appendix P**), and a postage-paid pre-addressed return envelope that participants may use to return the completed 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 that also houses the data from the Internet-based questionnaires.

Backcountry users who consented to be contacted by regular mail but who have not returned their completed questionnaires within **4 weeks** of after their expected backcountry travel completion dates will be sent reminder letters, which will be the same as the introductory letter. Those backcountry users who have still not returned their completed questionnaires by **5 weeks** and who have provided a phone number will be called and given the options of completing the questionnaire over the phone, by mail, or by Internet.

To limit recall bias, completed questionnaires (whether Internet-based or paper-based) will not be accepted after **8 weeks** from the expected backcountry travel completion dates. For those backcountry users who choose the Internet option after they are telephoned, access to the Internet-based questionnaire will be denied to those who have not completed their questionnaires within 8 weeks from their expected backcountry travel completion dates. After 8 weeks, non-responding backcountry users who provided phone numbers will be called again and asked for their reasons for non-response.

No email address or postal address provided but phone number provided

Those backcountry users who consent to further contact and who provide only a phone number will be called **2 weeks** after their expected backcountry travel completion dates. During this telephone call, they will be given the options of completing the questionnaire over the phone, by mail, or by Internet. Those who provide an email address or a postal address at this time will be included in the corresponding study arm described previously. Those who choose to complete the questionnaire over the phone will remain in this study arm.

Non-responders in this study arm will be telephoned again at **4 weeks** and **5 weeks** of their expected backcountry travel completion dates and offered the same options (phone questionnaire, paper-based questionnaire, or Internet-based questionnaire). Again, those who provide an email address or a postal address at these times will be included in the corresponding study arms described previously.

To limit recall bias, completed questionnaires (whether Internet-based, paper-based, or phone-based) will not be accepted after **8 weeks** from their expected backcountry travel completion dates. For those backcountry users who choose the Internet option after they are telephoned, access to the Internet questionnaire will be denied to those who have not completed their questionnaires within 8 weeks from their expected backcountry travel completion dates. After 8 weeks, non-responding backcountry users will be called again and asked for their reasons for non-response.

Quality Control

Several quality control procedures will be implemented as part of this study:

- The park rangers will be trained to review the consent-to-further-contact forms to make sure the writing is legible and that the necessary components have been completed by backcountry users who consent to further contact (i.e., name, permit number, expected backcountry travel completion date, and one method of contact – email address, postal address, or phone number).
- The data from the consent-to-further-contact forms will be scanned into the study database at CDC for efficiency and to minimize data entry errors. The electronic data will then be cross-referenced with the written data on each form by a CDC investigator to make sure the scanning software has copied the data accurately.
- The Internet-based questionnaire has built-in skip patterns and internal logic controls for efficiently routing the respondent to the relevant questions. The paper-based questionnaire has the same questions and the same skip patterns as the Internet-based version. However, participants completing the paper-based questionnaire must manually follow these skip patterns, which may increase the risk for data entry errors. Additionally, the Internet-based questionnaire will employ a variety of prompts to encourage survey completion, whereas the paper-based questionnaire will have no such prompts.
- The Internet-based questionnaire has data entry validation to limit data entry errors and reduce data cleaning efforts. Furthermore, data entry into the database is automatic thereby eliminating the need for manual data entry, which also limits data entry errors.
- Finally, the CDC principal investigator will manually clean the database at the end of the data collection period.

3. Methods to Maximize Response Rates and Deal with Nonresponse

SEKI Pilot Study Response Rates

The 41% response rate obtained in the SEKI pilot study is higher than the response rates obtained by some large continuing health surveys that provide key national health statistics (such as the FoodNet population studies, with response rates declining to 33% in the last survey cycle¹⁵) and by some NPS Social Science Program surveys (such as the Visitor Survey Card Studies, with response rates of 25%-26%¹⁶⁻²²) (see Section A.2 for details). In spite of these low response rates, such surveys, and others, still provide valuable data to inform recommendations, policies, and programs and we believe the Yellowstone study will have similar value.

Several recent studies have presented strong cases that larger non-response rates, as seen in the examples above, do not necessarily indicate larger biases when the variables of interest (e.g., water and food handling, sanitation and hygiene practices in the backcountry) are unrelated to the factors that produce nonresponse.²³⁻²⁵ We believe that this is the case with the SEKI pilot study and the Yellowstone study. Additionally, the SEKI pilot study data suggest that non-response bias was not significant among the backcountry users, which further supports this assumption (see Section A.2 for details).

Therefore, although we do not anticipate an 80% response rate, we propose to conduct the Yellowstone study, which should, at minimum, have the same response rate as the SEKI pilot study. In fact, we believe that the 41% response rate obtained in the SEKI pilot study is lower than the response rate we will achieve in Yellowstone. We had originally planned a large-scale study in Yellowstone from May 1, 2006 through October 31, 2006 but we only received OMB permission in August 2006 for a pilot study. Due to the lateness in the backcountry season when approval for the pilot study was received, Yellowstone National Park was not willing to undertake the pilot study. Therefore, at the last minute, the pilot study was switched to Sequoia and Kings Canyon National Parks (SEKI) and was conducted in September 2006 at one of the NPS backcountry permitting offices. Consequently, the SEKI rangers had limited preparation time and training before the pilot study began and all the rangers were not fully engaged in the process. By obtaining OMB clearance for the Yellowstone study now, we will have much more preparation time with the Yellowstone rangers to thoroughly train them, to encourage enthusiasm, and to advocate for the study. By better engaging the rangers in the study process in the future, we anticipate we will achieve higher response rates in Yellowstone National Park than we did in SEKI.

Methods to Maximize Response Rates

To maximize response rates, persons who have agreed to participate in the study, but who have not completed the questionnaire, will be sent reminder emails (or reminder letters for those who prefer paper) according to the schedule outlined in the Section B.2. Postage-paid pre-addressed return envelopes will be included in packages sent to backcountry users who prefer paper. The postage-paid pre-addressed return envelopes will hopefully provide an incentive to return the paper-based questionnaires since there will be no mailing costs for participants.

To reassure respondents as to the legitimacy of this study and to further encourage participation, NPS and CDC will develop websites housed on their respective servers describing the study (**Appendix Q** and **Appendix R**). These websites will be advertised on the study consent form 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.

To avoid making persons feel pressured or coerced into consenting to participate in the study, the introduction page and the consent-to-further-contact form advise readers that participation

in the study is voluntary and not a requirement for obtaining a backcountry permit. To dispel any beliefs about negative consequences of the study, the introductory and reminder emails/letters state that this study is not meant to check whether the backcountry user followed the NPS Backcountry Use Regulations. The emails/letters further state that the report sent to NPS will be a summary of all the answers obtained from the thousands of participating backcountry users and will not contain their names. Furthermore, NPS will not be able to link their names to their answers. Their names and contact information will be deleted from our files when the study is finished. After participants have completed the questionnaire, they will not be contacted again. The Yellowstone study consent form also minimizes any perceived negative consequences of this study by stating that there is no penalty for not being part of the study and there is also no risk or cost to the backcountry users if they do agree to be part of the study. The consent form re-iterates that participation is voluntary, respondents may stop at any time, and they can refuse to answer any question at any time. The study consent form further assures backcountry users that CDC and NPS plan to maintain their survey information in a confidential manner, and do not plan to share their information with anyone except authorized members of the study team. We do not plan to publish any identifiable information when we publish the results of this study. All the answers will be kept private to the extent allowed by law and the answers will be stored on a CDC password-protected computer server. All these reassurances are designed to maximize response rates. See Section A.10 for further details of assurances of confidentiality provided to respondents.

Non-Response Bias Analysis

Because we plan to approach the entire cohort of backcountry users in Yellowstone National Park for the entire backcountry season (see Section B.1 for power calculations), we will have information on all backcountry users through all the permits issued during that time.

Yellowstone National Park uses a different permit²⁶ (**Appendix F**) than SEKI and stores its data electronically whereas SEKI uses a paper-based system. In Yellowstone, we will have electronic access to the following information for each person entering the backcountry:

- Name and contact information of the group leader (including address, phone number, and email address if available)
- Date of birth of the group leader
- Vehicle license plate number and location where it will be parked
- Group size
- Group affiliation if applicable (e.g., school, church, scouts)
- Dates of entry and exit from the backcountry (i.e., duration of backcountry travel)
- Route taken in the backcountry
- Method of travel (i.e., on foot, by animal, by boat)

Using the consent-to-further-contact form and the questionnaire, we can determine who are responders (those who complete the questionnaire) and who are non-responders (those who consent to further contact but do not complete the questionnaire). These two groups can then be compared to the permit database to identify the non-participants (those who do not consent to further contact). The information in the permit database can then be used to perform a non-response bias analysis of responders, non-responders, and non-participants based on the

variables listed above. Results of this analysis and a discussion of the implications of any non-response bias will be included in the final report for NPS planning and management purposes.

4. Tests of Procedures or Methods to be Undertaken

The data collection instruments and the patient information materials (i.e., emails, letters, and consent forms) have been reviewed (1) for content by two senior epidemiologists at CDC; (2) for question design, flow, clarity, and timing by one CDC staff member; and (3) for content by the Director of the NPS Public Health Program. The questionnaire, emails, letters, consent forms, and websites have also been pilot-tested by 3 CDC staff members, 1 layperson, and 3 NPS staff members. Furthermore, the NPS website has been reviewed by the Director of the NPS Public Health Program and the CDC website has been reviewed by the Division of Parasitic Diseases Acting Director for Science. All of the above mentioned persons reviewed and tested the instruments and documents but were not otherwise involved in the development this study.

Additionally, the instruments, documents, and methodology were pilot-tested at SEKI in September 2006 (0920-0727 OMB Notice of Action; NOA Date 09/19/2006; Expiration Date 06/30/2007). See Section A.2 for a detailed discussion of the SEKI pilot study findings.

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

Statistical consultants for study design:

- Allen Hightower, CDC – ph. 770-488-7731, email: ahightower@ke.cdc.gov
- Mark Lamias, contractor for CDC* – ph. 404-498-1151, email: bnz6@cdc.gov

Persons who designed the data collection:

- Sharon Roy, CDC – ph. 770-488-4412, email: str2@cdc.gov
- George Larsen, NPS – ph. 307-344-2273, email: George_Larsen@contractor.nps.gov
- Mark Lamias, contractor for CDC * – ph. 404-498-1151, email: bnz6@cdc.gov
- Michael Beach, CDC – ph. 770-488-7763, email: mjb3@cdc.gov
- Charles Higgins, CDC – ph. 202-513-7217, email: Charles_Higgins@nps.gov

Persons who will collect the data:

- Sharon Roy, CDC – ph. 770-488-4412, email: str2@cdc.gov
- George Larsen, NPS – ph. 307-344-2273, email: George_Larsen@contractor.nps.gov
- Mark Lamias, contractor for CDC * – ph. 404-498-1151, email: bnz6@cdc.gov

Persons who will analyze the data:

- Sharon Roy, CDC – ph. 770-488-4412, email: str2@cdc.gov
- George Larsen, NPS – ph. 307-344-2273, email: George_Larsen@contractor.nps.gov
- Mark Lamias, contractor for CDC * – ph. 404-498-1151, email: bnz6@cdc.gov

* Mark Lamias' CDC supervisor is Dale Nordenberg, ph. 404-639-4855, email: dxn2@cdc.gov

OMB APPROVAL REQUEST

We have been seeking OMB approval for this study since 2005, first at Yellowstone National Park and then at Sequoia and Kings Canyon National Parks (pilot study) and now back at Yellowstone National Park (large-scale study). With each previous attempt to obtain OMB approval, advance preparations were made at the park in anticipation of OMB clearance, consuming time and human resources at each park and at CDC. Because of the previous delays in obtaining OMB clearance, NPS is unwilling to expend those resources a third time until OMB clearance has finally been obtained. Once this occurs, preparations at Yellowstone National Park will begin. We are therefore requesting **18 months** of OMB approval rather than 1 year, in order to have enough time to obtain clearance, make the necessary preparations, and complete data collection.

LIST OF ATTACHMENTS

- **Appendix A:** NPS Directors Order 83
- **Appendix B:** US Code Title 42 Public Health and Welfare
- **Appendix C:** SEKI Pilot Study Methodology
- **Appendix D:** SEKI Consent-to-Further-Contact Form
- **Appendix E:** SEKI Refusal Log
- **Appendix F:** Yellowstone Study Backcountry Permit
- **Appendix G:** Yellowstone Study Consent-to-Further-Contact Form
- **Appendix H:** Yellowstone Study Introduction Page
- **Appendix I:** 60-Day Federal Register Notice
- **Appendix J:** IRB Exemption Determination
- **Appendix K:** Yellowstone Study Introductory Email
- **Appendix L:** Yellowstone Study Consent – Internet Version
- **Appendix M:** Yellowstone Study Questionnaire – Internet Version
- **Appendix N:** Yellowstone Study Introductory Letter
- **Appendix O:** Yellowstone Study Consent – Paper Version
- **Appendix P:** Yellowstone Study Questionnaire – Paper Version
- **Appendix Q:** NPS Study Website
- **Appendix R:** CDC Study Website

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