

OMB Protocol Revision

August 23, 2007

STUDY TITLE

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

CDC PROJECT OFFICER

Sharon Roy, MD, MPH
Water and Environment Activity
Division of Parasitic Diseases
Centers for Disease Control and Prevention
4770 Buford Highway, N.E., Mailstop F22
Atlanta, GA 30341-3724
Tel: 770-488-4412
Fax: 770-488-7761
Email: str2@cdc.gov

NATIONAL PARK SERVICE LIAISON

LCDR David Wong, MD
United States Public Health Service
Medical Epidemiologist
National Park Service
Office of Public Health
1201 Eye Street NW
11th Floor, Room 1135
Washington, DC 20005
Tel: 202-513-7160
Fax: 202-371-1349
Email: David_Wong@nps.gov

In order to maximize the response rate for this study, we plan to employ survey methodologies developed by Dillman^{1,2}, including the Total Design Method (TDM), which have been used in other surveys to achieve higher response rates.³⁻⁶ Accordingly, modifications to the study protocol are described below and further identified by *italics*. Key changes based on the phone conference with OMB are **highlighted** and summarized as follows:

- Trip leaders would be identified from the permit database would be contacted after their backcountry exit dates
- An advance letter would be mailed to the trip leaders on their backcountry exit dates to inform them of the study
- A paper questionnaire, return envelop and cover letter would be mailed to the trip leaders 1 week after their backcountry exit dates
- A thank you/reminder letter would be mailed to the trip leaders 2 weeks after their backcountry exit dates
- A replacement questionnaire, return envelope, and cover letter would be mailed to nonresponding trip leaders 4 weeks after their backcountry exit dates
- A second replacement questionnaire, return envelope, and cover letter would be sent by certified mail to nonresponding trip leaders 7 weeks after their backcountry exit dates
- After 8 weeks, non-responding trip leaders who provided phone numbers would be called and asked for their reasons for non-response.

Study Population

The National Park Service regulates backcountry access through the use of permits. All travelers into the backcountry are required to have a permit. Persons caught in the backcountry without a permit are expelled by the backcountry rangers who patrol those areas. The Yellowstone National Park (YELL) backcountry permitting offices use permit numbers to identify groups of people traveling together into the backcountry. One permit is issued per group. Groups may include one person or multiple people traveling together. Data collected for the Yellowstone backcountry permits⁷ 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)

In 2006, YELL issued 4,214 private backcountry permits for 12,673 persons of all ages from May 1, 2006, through Oct. 31, 2006 (considered the backcountry season at this park) and we expect a similar number of permits to be issued for the 2008 backcountry season. Data collected for these permits, including the contact information for the group leaders, are stored in an electronic database at YELL. The group leaders identified on these permits will form the sampling frame for our study.

Protocol Change – As originally proposed, all backcountry visitors during the 2008 backcountry season (est. N=12,673) were going to be asked to participate in a survey following completion of their backcountry trips. Those persons who agreed to further contact were to be sent a survey (either Internet-based or paper-based) 2 weeks following their exit dates from the backcountry. 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. Alternatively, the YELL permit database can be used to identify the approximately 4,214 group leaders during the 2008 backcountry season so that we may contact them after their backcountry trips to complete a survey, first with an advance letter to notify them of the survey and then with the questionnaire itself 2 weeks after their exit dates from the backcountry (see Methods for more details).

Eligibility

Based on revisions to the sampling frame described previously, the following eligibility criteria would apply:

All Yellowstone National Park visitors who (1) *are the group leaders listed on the private backcountry permits in the YELL permit database*; (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 are not designated as the group leaders on the backcountry permits*. Adult backcountry users who fail to complete a questionnaire within 8 weeks from their expected backcountry travel completion dates will also be excluded (see Methods for more details).

Questionnaire

The primary data collection instrument for this study is a self-administered questionnaire (**Appendix A**) that would be provided to respondents in a hard copy (paper-based) or electronic (Internet-based) format. No interviewers would be required. The paper-based and Internet-based questionnaires would 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 would be interviewed about potential exposures during the time they were in the backcountry. Therefore, the potential exposure period would differ for each individual, depending on how long he/she spent in the backcountry. Identification numbers would be printed directly onto paper-based surveys in order to track and remove names from follow-up mailings. Similarly, personal pass codes embedded in the website address for the Internet-based surveys would track the online questionnaires (see Methods for more details).

Methods

All respondents have advance notice of the survey. *Following the Dillman Total Design Method (TDM)¹ for survey implementation, the following steps would be taken:*

1) Identification of backcountry group leaders through the YELL permit database

Protocol Change – This step would replace the consent to further contact forms that would have been given to every backcountry user (in addition to the group leaders) who presented at one of nine YELL backcountry offices as part of the permitting procedure. Those agreeing to further contact after their trips would have been asked to provide contact information. With the proposed protocol revisions, contact information for only the group leaders would be retrieved directly from the YELL permit database on a weekly basis.

2) Advance letter to all backcountry group leaders

This letter (Appendix B) would be mailed to each backcountry group leader on the day he/she leaves the backcountry using the address and date indicated on the YELL permits. The letter would be a personalized correspondence by name using CDC stationary with the signature of the Principle Investigator. This brief letter would introduce the problem of injury and illness in the backcountry and would ask the group leaders to complete a questionnaire to help NPS and CDC develop evidence-based guidelines to address this important problem and protect future backcountry users.

Protocol Change – This step would replace the consent to further contact introduction page.

3) Questionnaire mailing

One week after the indicated exit date from the backcountry, *each group leader would be sent a paper-based questionnaire along with a cover letter (Appendix C) and a postage-paid return envelope. Each mailing would be timed so that the package would be received by the 2-week mark following the backcountry exit date (see the Study Population section above for an explanation of the importance of the 2-week period). The cover letter would be personalized on CDC letterhead with the signature of the Principle Investigator. It would indicate what is being requested, why the request is useful and important, why the respondent was selected, and who to contact with questions. It would also indicate that the answers provided would be kept private to the extent allowed by law and that participation is voluntary. Finally, the cover letter would include a personalized web address (URL) for the Internet-based self-administered*

questionnaire should the person wish to take the survey online instead of completing and returning the paper-based questionnaire. The return of a completed questionnaire would be taken as tacit consent for the survey. This study would involve no procedures for which written consent is normally required outside of the research context. No persons younger than 18 years of age would be enrolled. Data from the paper-based questionnaires would then be manually entered into the electronic database at CDC that would also house the data from the Internet-based questionnaires.

For those persons wishing to complete the questionnaire online, the URL included in the cover letter would contain a personal security pass code embedded in it. The pass code would be unique for each group leader and would restrict questionnaire access to this person. As with the paper-based questionnaire, completion of the Internet-based questionnaire would be taken as tacit consent for the survey. Participants would have the option of completing the Internet-based questionnaire in one sitting or over multiple sessions. For those failing to complete the questionnaire in one sitting, online access to their own semi-completed questionnaire would be granted through the use of the same pass code. Data entry into the study database at CDC would be automatic.

Protocol Change – According to the Dillman TDM, each permit holder would now be sent a printed copy of the survey rather than just those persons indicating they want a printed copy. Because access to the Internet-based questionnaire would be obtained from the URL provided in the cover letter, an email version of the cover letter and an email consent form as outlined in the previously-submitted protocol would not be required with this methodology.

4) Thank you/reminder letter

Two weeks after the indicated exit date from the backcountry, each group leader would be sent a personalized thank you/reminder letter (**Appendix D**) on CDC letterhead with the signature of the Principle Investigator that would thank those who had already responded and request that those who had not yet responded do so. Those who had not yet responded would be informed that their questionnaire had not yet been received. They would be reminded that they are important to the study, that their responses are useful, that their answers would be kept private to the extent allowed by law, and that their participation is voluntary. They would be told that others have already responded and provided with contact information should they have questions. Additionally, they would be provided with the same personalized web address (URL) for the Internet-based self-administered questionnaire should they wish to take the survey online, and would be provided with a phone number to call for a replacement questionnaire should they require it. This letter would contain essentially the same information as the cover letter.

Protocol Change –According to the Dillman TDM, the first reminder would be mailed at 2 weeks. The previously submitted protocol would send a reminder email at 3 weeks for persons who provided email addresses.

5) Replacement questionnaire mailing

Four weeks after the indicated exit date from the backcountry, each group leader who had not yet responded would be sent a replacement paper-based questionnaire along with a postage-paid return envelope, and a personalized cover letter on CDC letterhead with the signature of the Principle Investigator. This cover letter would contain the same information as the previous cover letter (**Appendix C**).

Protocol Change –According to the Dillman TDM, the second reminder (with a replacement questionnaire) would be mailed at 4 weeks. The previously submitted protocol would send a reminder letter and replacement questionnaire at 4 weeks for persons who provided postal addresses and at a reminder email at 4 weeks for persons who provided email addresses.

6) Second replacement questionnaire mailing by certified mail

Seven weeks after the indicated exit date from the backcountry, each group leader who had not yet responded would be sent a package by certified mail. Each package would contain a replacement paper-based questionnaire along with a postage-paid return envelope, and a personalized cover letter on CDC letterhead with the signature of the Principle Investigator. This cover letter would contain the same information as the previous cover letter (**Appendix C**). Additionally, those persons for whom a telephone number is available in the YELL permit database would be phoned 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) would not be accepted after 8 weeks from the backcountry exit dates. Furthermore, access to the Internet-based questionnaire would be denied to those who have not completed their questionnaires within the 8-week period.

Protocol Change –According to the Dillman TDM, the third reminder (with a replacement questionnaire) would be sent by certified mail at 7 weeks. According to the previously submitted protocol, at 5 weeks researchers would call those non-respondents who provided a phone number and give them the options of completing the questionnaire over the phone, by mail, or by Internet. A second replacement questionnaire was not included in the previously-submitted protocol.

7) Final contact

After 8 weeks, non-responding backcountry users who provided phone numbers would be called and asked for their reasons for non-response.

LIST OF ATTACHMENTS

- **Appendix A:** Yellowstone Study Questionnaire
- **Appendix B:** Advance letter
- **Appendix C:** Cover letter
- **Appendix D:** Thank you/reminder letter

REFERENCES

1. Dillman DA. Mail and Telephone Surveys: The Total Design Method. New York: John Wiley. 1978.
2. Dillman DA. Mail and Internet Surveys: The Tailored Design Method. New York: John Wiley. 2000.
3. Filip JC, Ming ME, Levy RM, Hoffstad OJ, Margolis DJ. Mail surveys can achieve high response rates in a dermatology patient population. *J Invest Dermatol*. 2004 Jan; 122(1): 39-43.
4. Sutherland HJ, Beaton M, Mazer R, Kriukov V, Boyd NF. A randomized trial of the total design method for the postal follow-up of women in a cancer prevention trial. *Eur J Cancer Prev*. 1996 Jun; 5(3): 165-8.
5. Wetmore SJ, Agbayani R, Bass MJ. Procedures in ambulatory care. Which family physicians do what in southwestern Ontario? *Can Fam Physician*. 1998 Mar; 44: 521-9.
6. Anema MG, Brown BE. Increasing survey responses using the total design method. *J Contin Educ Nurs*. 1995 May-Jun; 26(3): 109-14.
7. Backcountry Campsite Reservations – Yellowstone National Park. National Park Service. Downloaded 08/23/2007. Available at:
<http://www.nps.gov/yell/planyourvisit/upload/campsitereserv.pdf>