

APPENDIX J – IRB Exemption Determination

Roy, Sharon L. (CDC/CCID/NCZVED)

From: Heilig, Charles (Chad) (CDC/OD/OCSSO)
Sent: Saturday, August 12, 2006 10:58 AM
To: Roy, Sharon L. (CDC/CCID/NCZVED)
Cc: Human Subjects Review-OD (CDC); Stokes, Susan (CDC/CCID/OD); Youngblood, Laura (CDC/CCID/NCZVED)
Subject: 4583: request to modify exempt protocol

I have reviewed the request to modify exempt protocol 4583, "Internet-Based Survey of Illness and Injury Among Backcountry Users in Sequoia and Kings Canyon National Park". I find that this modified research activity remains exempt under 45 CFR 46.101(b)(2). Changes to this protocol may not be implemented until they are reviewed and determined to be consistent with the exemption categories. The expiration date is revised to 08/13/2007; you will be asked to confirm that no changes have occurred in the protocol or the related science that would affect the ethical appropriateness of the research or this exemption. Please be advised that the investigators remain responsible for appropriate human research protections even for research that is exempt from regulations for protecting human subjects.

Chad

Chad Heilig, PhD
Manager, Human Research Protection Office
Office of the Chief Science Officer
Centers for Disease Control and Prevention
Mail: 1600 Clifton Rd MS D73, Atlanta GA 30333
Courier: 1600 Clifton Rd MS D73, Bldg 21 Rm 8206, Atlanta GA 30333
Voice: 404-639-4601
Fax: 404-639-4901

Roy, Sharon L. (CDC/CCID/NCZVED)

From: Heilig, Charles (Chad)
Sent: Wednesday, April 19, 2006 1:33 PM
To: Stokes, Susan
Cc: Roy, Sharon L.; Youngblood, Laura; Beach, Michael J.; Human Subjects Review-OD
Subject: RE: 4583: request to modify exempt protocol

Thank you for the response. This action is now complete within HRPO.

Chad

From: Stokes, Susan
Sent: Wed, 2006 Apr 19 12:56
To: Heilig, Charles (Chad)
Cc: Roy, Sharon L.; Youngblood, Laura; Beach, Michael J.
Subject: FW: 4583: request to modify exempt protocol

Chad: Below responses to your questions on 4583. Thanks, Susan

From: Roy, Sharon L.
Sent: Wednesday, April 19, 2006 10:06 AM
To: Stokes, Susan
Cc: Youngblood, Laura; Beach, Michael J.
Subject: RE: 4583: request to modify exempt protocol

Good Morning,

In response to the questions below:

- Q6: There is no risk for civil liability for failing to follow the itinerary outlined in the permit.
- Q190: We do not believe that answering yes to any of these items could risk the participant's reputation.
- Q192: Inclusion of the under 18 category was an oversight and will be removed.
- Q200/201: We do not believe that responses to any of the questions could potentially jeopardize participants' employability.

Please let me know if you have any further questions.

Thanks,
Sharon

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

From: Heilig, Charles (Chad)
Sent: Tuesday, April 18, 2006 5:12 PM
To: Roy, Sharon L.
Cc: NCID DPD Human Subjects; Holtzman, Deborah; Human Subjects Review-OD; Stokes, Susan; Kovach, Gloria; Erickson, Lynn G.

Subject: 4583: request to modify exempt protocol

I have reviewed the request to modify exempt protocol 4583, "Internet-Based Survey of Illness and Injury Among Backcountry Users in Yellowstone National Park". I find that this modified research activity remains exempt under 45 CFR 46.101(b)(2). Changes to this protocol may not be implemented until they are reviewed and determined to be consistent with the exemption categories. The expiration date is 04/23/2007; you will be asked to confirm that no changes have occurred in the protocol or the related science that would affect the ethical appropriateness of the research or this exemption. Please be advised that the investigators remain responsible for appropriate human research protections even for research that is exempt from regulations for protecting human subjects.

Note: I would like to clarify a few points for the record, to ensure that exemption category 2 is appropriate. Please respond to these items so that we may add this information to the file.

- Q6 asks if the respondent followed the itinerary outlined in her backcountry permit. Please address whether answering yes could risk civil liability because it violates NPS procedures.
- Q190 asks about certain medical conditions. Please describe whether any of these items could risk the subject's reputation.
- Q192 allows a response of under 18 years of age. While persons under 18 years of age should have been screened out before the survey, I realize it is possible for one to have gotten past the screening. However, surveys of children are not exempt. I would recommend either removing the under-18 category or moving this item to the beginning and stopping the survey if the respondent is under 18.
- Q200/201 ask whether the respondent works or volunteers in Yellowstone, possibly even as an NPS employee. Please describe whether some of the responses (specifically Q6 or Q190, but really any of the others) could risk the subject's employability.

Chad

Chad Heilig, PhD

Manager, Human Research Protection Office
Office of the Chief Science Officer
Centers for Disease Control and Prevention
Mail: 1600 Clifton Rd MS D73, Atlanta GA 30333
Courier: 1600 Clifton Rd MS D73, Bldg 21 Rm 8206, Atlanta GA 30333
Voice: 404-639-4601
Fax: 404-639-4901