

**Memorandum**

Date August 5, 2015

From LaShonda Roberson, DHSc, MPH
LCDR, USPHS
Acting Senior IRB Administrator
Human Research Protection Office

Subject HRPO Approval of Amendment to CDC Protocol #6009, "Knowledge, Attitudes, and Practices about Travel Health among Travel Consultants and Aid Agencies"

To Carmen Perez-Guerra, PhD
NCEZID/DVBD

The CDC Human Research Protection Office has received your submission for review of changes to exempt protocol #6009, "Knowledge, Attitudes, and Practices about Travel Health among Travel Consultants and Aid Agencies." I find that this research activity remains exempt under 45 CFR 46.101(b)(2). The amendment includes the following changes:

- Changed the range of participants from 30-90 to 18-90 because we expect that at least 6 respondents participate in each focus group session, in at least 3 group sessions.
- Modification 2. Page 4 lines 98-101 - Included that participants will be screened for age and experience during telephone calls. We included the Attachment A- "Script for Telephone Calls to Screen and Recruit Participants of Focus Groups with Staff and Missionaries of Sending Agencies".
- Modification 3. Page 7 lines 184-186 - Updated timeline.
- Modification 4. Page 7 lines 194-201 - Included that focus groups participants will receive a copy of consent prior to participation and that moderator will read the consent form along with the participants before verbal consent.
- Modification 5. Page 8 lines 206-213 - Included paragraph stating that CDC moderators will brief participants on the focus groups process and included Attachment C- "Instructions for the Participation in Focus Groups".
- Modification 6. lines 216-217, 221 - Indicated that group discussions will be digitally audio taped and transcribed at verbatim.
- Modification 7 Page 11 and over. Included new attachments in English and Spanish. Focus groups will be conducted with adult participants only.

As a reminder, additional changes to this protocol may not be implemented until they are reviewed and determined to be consistent with the exemption categories. Also, 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 no later than three years from the current expiration date of **10/11/2016**.

Please be reminded that the investigators remain responsible for appropriate human research protections even for research that is exempt from regulations for protecting human subjects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-7570 or by e-mail at huma@cdc.gov.

cc:
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