



HARVARD SCHOOL OF PUBLIC HEALTH

Human Subjects Committee

Ichiro Kawachi, M.D., Ph.D., Co-Chair

Michelle Mello, J.D., Ph.D., M.Phil., Co-Chair

October 26, 2007

Jennifer Leaning, MD, SMH
c/o Gregg Greenough
Harvard Humanitarian Initiative
14 Story Street, 2nd Floor
Cambridge, MA 02138

1552 Tremont Street

Boston, Massachusetts 02120

Tel. (617) 384-5480 fax (617) 384-5484

hsc@hsph.harvard.edu

<http://www.hsph.harvard.edu/hsc/>

RE: Exemption of HSC Protocol #P15218-101
Measuring the Psychological Impact of Communities Affected by Landmines
PI: Jennifer Leaning, MD, SMH

Dear Dr. Leaning:

Thank you for submitting an application for initial approval of research with human subjects covering the above-referenced study. We have reviewed it and we find that this study is exempt from IRB review because it meets the criteria set forth in federal regulations at 45 CFR 46.101(b) (2). Specifically, you will be conduct population-based, household surveys and focus group in Angola, Kosovo, and Colombia in order to evaluate psychosocial and economic impact on communities affected by landmines. We understand that subjects may be indirectly identified through their participation in the household survey or focus group component; however, we find that disclosure of their responses, outside of the research arena, is not likely to put them at risk for criminal or civil liability or damage their reputation, financial standing, or employability.

Please note the following:

- When it becomes available, kindly submit the finalized focus group questions and introductory script.

I have enclosed the Department of Health and Human Services Certification form, showing that the Human Subjects Committee finds this study exempt. Please keep a copy of it and this letter for your records. This study will not require additional Committee review unless you change the protocol in a way that alters the above analysis; if this is the case, you must contact our office for clarification.

Important notice: research that has been deemed exempt must nevertheless be conducted in accordance with the Belmont Report. Download the Belmont Report at this link:
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

Feel free to contact me if you have further questions or concerns in this matter.

Sincerely yours,

Leslie Howes, MPH, CIP
Assistant Director

Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

| | | |
|--|---|--|
| 1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION | 2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____ | 3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. |
| 4. Title of Application or Activity <i>Measuring the Psychological Impact of Communities Affected by Landmines (P15218-101)</i> | | 5. Name of Principal Investigator, Program Director, Fellow, or Other Jennifer Leaning, MD, SMH |

6. Assurance Status of this Project (Respond to one of the following)

- This Assurance, on file with Department of Health and Human Services, covers this activity:
 Assurance Identification No. FWA00002642, the expiration date 03/21/10 IRB Registration No. 01
- This Assurance, on file with (agency/dept) _____, covers this activity.
 Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (if applicable)
- No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph 2.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
 by: Full IRB Review on (date of IRB meeting) _____ or Expedited Review on _____
 If less than one year approval, provide expiration date _____
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

Exempt under 45 CFR 46.101(b)(2)

| | | |
|--|---|----------------------|
| 9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided. | 10. Name and Address of Institution Human Subjects Committee Harvard School of Public Health 1552 Tremont Street Boston, MA 02120 | |
| 11. Phone No. (617) 384-5480 12. Fax No. (617) 384-5484 13. Email: hsc@hsph.harvard.edu | 15. Title Assistant Director | |
| 14. Name of Official Leslie Howes, MPH, CIP | | 17. Date 10/26/07 |
| 16. Signature | | |

Authorized for local Reproduction

Sponsored by HHS