

APPENDIX 1:
OHSRP RECOMMENDATIONS

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX: 301-496-0760
To: Danis, Marion
CC
10/1C118

Exempt #: 5933

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

Cognitive testing of survey instrument. Involves showing questionnaire to 12-24 physicians and gathering responses to questionnaire to determine how well questions/items perform, understanding of survey instructions and if questionnaire successfully addresses scientific question of the survey.

Original Request Received in OHSR on: 8/30/2011

Responsible NIH Research Investigator(s): Marion Danis, MD CC

OHSR review of your request dated Wed, Aug 24, 2011 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Confidentiality Agreement
- Reliance
- Amendment 6/11/11 *ms*
- Other

Office Person SPC Admin Assist. CB

Note:
6/11/12 AMENDED: To proceed to the next phase of the project to survey approximately 5000 surgeons via the UVA Center for Survey Research. hb

Heather Bidge Jov.
Charlotte Holden, JD

Acting Director, OHSR

10/7/2011

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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