

Attachment 4
Office of Human Subject Research Response

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

FAX: 301-480-1729

Exempt #: 3212

To: Taffet, Richard

OD

2115 E. Jefferson Street

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

Survey, NIH applicants, potential applicants and those who recently rejected offers about their views on the new Conflict of Interest Regulations at the NIH, specifically relating to the regulations' impact on their decision to pursue employment with the NIH.

Original Request Received in OHSR on: 1/30/2006

Responsible NIH Research Investigator(s): Richard Taffet, OD

OHSR review of your request dated Mon, Jan 30, 2006 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. No further action is necessary.
- 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
- Other

Note:

OHSR views these surveys as part of NIH quality improvement work, not as human subjects research. Consequently approval pursuant to 45 CFR 46 is not required for this activity.

Amendment

OHSR has reviewed your request to amend Exemption 3212 to include two additional surveys, one survey for former NIH employees and one survey for potential applicants. Attached are the two additional surveys. OHSR understands that except for the difference in the surveys, the other information in the original submission to OHSR is the same.

OHSR views these two new surveys as part of NIH quality improvement work, not as human subjects

Amendment approved 12/15/06

Cherlotte Holder

Alison Wichman, M.D.

Acting Director, OHSR

2/15/2006

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material:

OHSR Use Only

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