

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

FAX:
To: Basavappa, Ravikumar
OD
BG 1 RM 201B

Exempt #: 11311

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The proposed activity is to conduct a process evaluation of the NIH Director's Early Independence Award (EIA) Program. The information gathered will document the EIA program operations, and will be used to improve the program and guide future strategic and management decisions.

The EIA program a NIH Common Fund program was established in FY 2011. The NIH

Original Request Received in OHSR on: 2/10/2012

Responsible NIH Research Investigator(s): Ravikumar Basavappa, OD

OHSR review of your request dated Wed, Feb 8, 2012 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
- Other

Office Person HB Admin Assist. CB

Note:

2/17/12: This activity is a program evaluation intended for quality improvement (a systematic collection for non-research purposes) and is not research as defined by 45 CFR 45.102. hb



Lynnette Nieman, MD

Director, OHSRP

2/17/2012

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

OHSR Use Only

1 2 3 4 5 6

Biologic Material: No