

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

FAX: 301-480-3441
To: Massett, Holly
NCI
6116 Executive Blvd.

Exempt #: 12707

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The National Cancer Institute (NCI) Experimental Therapeutics Clinical Trials Network (ETCTN) is a new program that resides within NCI's Division of Cancer Treatment and Diagnosis (DCTD). The first funding cycle began in March 2014 and will continue for five years with an annual budget of \$10 million. The ETCTN was created to replace NCI's 50- year-old legacy system to conduct early phase cancer treatment trials. Grants were awarded to 13 academic cancer centers around the US. NCI is conducting a process evaluation

Original Request Received in OHSR on: 12/1/2014

Responsible NIH Research Investigator(s): Holly Massett, PhD NCI

OHSR review of your request dated Mon, Dec 1, 2014 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 JE

Admin Assist. CB

Note:
Quality improvement/quality assurance



Julie M. Eiserman

Policy Analyst, OHSRP

12/9/2014

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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