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Memo

Attachment 6

Date: January 28, 2010

To: Steve Riordan, Project Director

From: Kerry Levin, Chair Westat IRB

Subject: **Expedited Initial Approval of Cancer Trials Support Unit, Project Number 8339 FWA 0551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **Cancer Trials Support Unit, Project Number 8339.** The Westat IRB reviews all studies involving research on human subjects. This project is funded by the Cancer Therapy Evaluation program at the National Cancer Institute.

Westat will collect three customer satisfaction surveys; for the Help Desk, website, and patient registration. Particpants are invited by email and directed to an automated system to complete the surveys. Incentive gift cards will be distributed randomly to 10 selected participants in the study.

The IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk and is approved under expedited authority. A request for a waiver of documented informed consent was also approved (45 CFR 46 117 c. 2) as the study is minimal risk and involves no procedure for which written consent is normally required outside of the research context.

If activities change, please contact the IRB Office to ensure that the status is accurately reflected in our records. You are required to submit the study for a continuing review on or before January 28th, 2011. In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Jennifer Bryant

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

FAX: **Exempt: #:** 5314

To: Montello, Michael
NCI
EPN - Executive Plaza North, 7024

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The reporting of information through this resource is not a research activity but rather an infrastructure development project that will be enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009, P.L. 111-5. The National Cancer Institute (NCI) is developing an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database, which is intended to serve as a single, definitive source of information about all NCI-supported clinical research, thereby enabling the NCI to

Original Request Received in OHSR on: 6/1/2010

Responsible NIH Research Investigator(s): Michael Montello, NCI

OHSR review of your request dated Fri, Jun 4, 2010 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 SPC Admin Assist. CB

Note:
PI Changed from John Spearman OHSR #4722 to Mike Montello under 5314.

Charlotte Norton, MD — Acting Director, OHSR — 7/14/2010
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐1 ☐2 ☐3 ☐4 ☐5 ☐6