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Memo

Date: January 3, 2011

To: Jennifer Berktold, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Initial Approval of Deep Vein Thrombosis & Pulmonary Embolism, Project 8417.04**
FWA 05551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **Deep Vein Thrombosis & Pulmonary Embolism, Project 8417.04.** The Westat IRB reviews all studies involving research on human subjects. This project is sponsored by the Center for Disease Control and Prevention (CDC).

Westat and CDC will develop messaging concepts to be used in a public awareness campaigns to build knowledge and awareness about deep vein thrombosis (DVT) and pulmonary embolisms (PE).

Sixteen focus groups will be conducted; eight (8) formative focus groups and eight (8) message testing focus groups. Participants will include recently hospitalized patients and senior citizens. Participants will receive $75 in appreciation of their time in the session.

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.

As the Project Director you are responsible for the following:

- If you received a conditional approval, project activities (e.g., recruiting, enrolling) may not begin until your responses have been received by the IRB and final approval is granted.
- You are required to submit this study for a continuing review on or before January 3, 2012.
- 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
Adriana Brigatti