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Memo

Date: December 23, 2008

To: Melissa King, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: Full Approval for **The Prevalence and Incidence of HIV Molecular Variants, and their Correlation with Risk Behaviors and HIV Treatment in Blood Donors, Project 8067.99.03.02**
FWA 0551

On October 14, 2008, **The Prevalence and Incidence of HIV Molecular Variants, and their Correlation with Risk Behaviors and HIV Treatment in Blood Donors, Project 8067.99.03.02** was presented to the full Board.

Per 45 CFR 46 the Board determined that this project met criteria for classification as minimal risk and was assigned a conditional approval. In order to grant a full approval, the Board requested that the research team respond to several conditions. This memo includes the Board's conditions followed by your responses.

1. Clarify the correct amount of blood to be collected in the study.

- **Response:** The investigators in Brazil and at UCSF determined that there was an error in the blood collection protocol. The amount of blood collected should be 30 mL and not 10 mL. We have revised all the relevant documents to reflect this change. This modification will be submitted to the IRBs in Brazil and at UCSF.

2. Remove the word "strictly confidential" and replace with "confidential" from all consent forms and protocol documents.

- **Response:** Strictly confidential has been replaced with confidential in the letter to the cases and controls, information card for cases and the enrollment script for the control group.

3. Submit Brazil Blood Centers' documentation of procedures to be used to protect the confidentiality of data to the Board.

- **Response**: To maintain the confidentiality and privacy of the research subjects all data and study related forms will be kept in a locked file cabinet at the blood center. The file

cabinet itself will be kept in a locked office or suite. All electronic data will be coded and protected with a password and finally, data will be stored on a secure network.

Recommendations:

1. Change the name of the post-card to more closely represent materials being used.

2. Ask participants if they agree to have letters and other forms of communication that include the term "HIV positive" in materials sent to their homes.

3. Specify who's return address should be on the envelop.

4. Add language to the consent form that includes the phrase "without penalty or loss of benefits to which the subject is otherwise entitled" after the phrase "if the participant chooses to withdraw from the study".

5. Add a statement that the participant will have a choice to complete the interview using pencil and paper.

6. Add examples about what is meant by "personal information" in the statement "there is a small risk that your personal information may not be kept confidential".

7. Simplify the language when describing the ELISA test results at the end of page 40 and the top of page 41.

8. Use consistent measures/metrics when referring to blood draw collection (e.g., 2- 3 tsp on page 28 and 10 ml. on page 40).

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. I am therefore assigning a full approval as all of the above conditions have been met for this study. Your obligation to submit this study for a continuing review on or before October 14, 2009 remains unchanged. In the interim, you are responsible for notifying the Office of Research Administration 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
Karen Della Torre
Hilary Kruger