



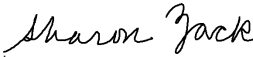
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Memo

Date: December 6, 2011

To: Adriana Brigatti, Project Director

From: Sharon Zack, Westat IRB Administrator


Sharon Zack
2011-12-06 03:24 PM
I am the author of this document

Subject: Exemption of NHLBI Clinical Studies Support Center (CSSC), Project Number 8687
FWA 00005551

The proposed survey qualifies for exempt from Human Subjects regulations for the following reasons:

This research aims to evaluate the CSSC pilot program and obtain feedback for improvement. No generalizable knowledge is expected to come from this activity.

Data gathered will not relate to the survey participants as human subjects but only their opinions regarding the CSSC program will be collected. As more than 30 participants are expected, the survey will be submitted for OMB.

Per 45 CFR 46 102 (f) and based on the information provided, this project does not include human subjects and is therefore exempt from further IRB review.

If activities change, please contact the IRB Office to ensure that the status is accurately reflected in our records. You are only required to submit the study for a continuing review on or before December 6, 2012 if activities change for this project. 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
Nancy Weinfield