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Memo

Date: March 5, 2018

To: Grace Huang, Project Director

From: Sharon Zack, Westat IRB Administrator

Sharon Zack
2018-03-05 10:55 AM
I agree to the terms defined by the placement of my signature. cosign

Subject: **Initial Approval of CDC Distress Screening, Project Number 6282.07**
FWA 00005551

As Administrator of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **CDC Distress Screening, Project Number 6282.07.** The Westat IRB reviews all studies involving research on human subjects. This project is funded by Centers for Disease Control and Prevention.

The purpose of this study is to examine the extent to which disparities exist in distress screening and follow-up among cancer treatment facilities and programs across the country.

Westat, the subcontractor on the project, is responsible for the following activities:

- Receive a de-identified dataset with information from adult (age 18 and older) lung and ovarian cancer patients related to patient demographics, cancer diagnosis, and treatment, and receipt of distress screening and follow-up care
- A 60-minute key informant interview by telephone with a hospital administrator about the administrative decisions related to the implementation of the distress screening policies.
- A 90-minute focus group with direct service providers, such as physicians, nurses, social workers, psychologists, psychiatrists, at selected hospitals.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110]. This study can be considered minimal risk and is approved under expedited authority. Per 45 CFR 46 116 (d), a waiver or modification of informed consent is approved as this research is no more than minimal risk, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver and whenever appropriate, subjects will be provided with additional pertinent information about the participation. Per [45 CFR 46.117], a waiver of documentation of informed consent is also approved for the telephone interviews and focus groups as the research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

Please note the following:

- This research is due for a continuing review before March 5, 2019.

- IRB approval is required before any new or modified research activities are conducted or when there is a problem involving risks to human subjects. Submit amendment requests to the Horizon IRB Office.
- Upon learning of an incident, you must contact the Westat IRB Office within 24 hours via telephone (301-610-8828) or email (IRB@westat.com) and to the Horizon IRB Office.

cc: Institutional Review Board
Alicia Sutherland