MUSC
Medical University of South Carolina

I. Policy

A. Introduction

The guidance for this policy is based on guidance on continuing review from OHRP dated January 15, 2007, in particular on item 2, "Additional considerations for continuing review of multi-center trials…..". In this guidance, OHRP acknowledges that local investigators participating in multi-center trials often are not able to prepare a meaningful summary of adverse events or may not have access to other communications from other sites. However, OHRP recommends that at the time of continuing review local investigators send their IRB a current report from the monitoring entity. This could include information from the research sponsor, a coordinating or statistical center or as data safety monitoring board or data safety monitoring committee.

B. OHRP Recommendations

OHRP recommends the report include, but may not be limited to the following:

1. A statement of what type of information was reviewed by the monitoring entity (e.g., recent published literature, interim findings, study-wide adverse events with aggregate data analysis blinded or un-blinded);

2. The date of this review;

3. The monitoring entity's assessment of the information reviewed; and

4. The local principal investigator should make judgment as to whether or not this information warrants changes in the local informed consent document and/or the research protocol.

Information obtained from multi-center trials by the local investigator should be reviewed for its relevance on the basic of safety, ethics and clinical implications. Any information that is received that is felt to be of a vital, timely or urgent nature should be forwarded to the appropriate IRB administrator without delay and without waiting for the next continuing

review. This information should be sent electronically by the principal investigator or his/her designee regarding this particular multi-center trial.

C. IRB Responsibilities

The report will be forwarded to the appropriate IRB administrator for initial review and then forwarded to the appropriate chair person, vice chair person or their designee. This IRB official may request further information from the local investigator, the originator of the communication or from the research sponsor. A host of actions or no action could be anticipated based on the nature of the information received in the report. The information could be passed to the next IRB meeting for further discussion and actions. The IRB chair person or vice chair could request the investigator provide a detailed report from the monitoring entity, a request for cessation of study recruitment could be requested at the local site, and reports to OHRP and/or the FDA could be applicable.