

Human Subject Research Office

UNIVERSITY
OF MIAMI



Revised IRB Policy: Submission of External SAEs/IND Safety Reports for IRB Review

The University of Miami periodically reviews and updates its guiding principles (Written Policies for the Protection of Human Subjects in Research). As of December 5, 2013, its policy on external SAE/IND Safety Reports has changed.

The IRB transitioned to a new electronic protocol submission and tracking system and, no longer requires the submission of external SAEs/IND Safety Reports to the IRB for review. If submitted, they will not be reviewed by the UM IRB and must be discarded by the study team.

Instead, the IRB requires that a copy of the sponsor's analysis of these events or a recent DSMB report, and a summary of all external unanticipated problems must be submitted by the study investigator at the time of continuing review. Please refer to the Investigator Manual for additional details.

Sincerely,

Dushyantha Jayaweera, MD, FACP, CIP
Associate Vice Provost for Human Subject Research

Dated: 2/26/2014