



## Revised Policy: External SAEs/IND Safety Reports

The University of Miami periodically reviews and updates its Written Policies and Procedures for the Protection of Human Subjects in Research. As of June 30, 2012, its policy on external SAE/IND Safety Reports has changed.

If an External SAE is **expected AND unrelated/unlikely to be related AND AEs have not occurred at a significantly higher frequency/severity than expected**, it does not require reporting to the UM IRB.

Any external SAE/IND Safety Report which does not meet the criteria of an unanticipated problem, as defined above, does not require submission to the UM IRB nor will it be reviewed by the UM IRB. 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 [section 14 of the University of Miami Written Policies and Procedures for the Protection of Human Subjects in Research](#) for additional details.