

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS) (MC 672)
Office of the Vice Chancellor for Research
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

To Whom It May Concern:

RE: Policy on UPIRSOs and Adverse Events that Require Prompt Reporting – Information for Study Sponsors

The University of Illinois at Chicago's (UIC) Office for the Protection of Research Subjects (OPRS) will no longer accept adverse event or safety reports for IRB review that do not meet the definition of an unanticipated problem involving risks to subjects or others (UPIRSO). This letter outlines OPRS's policies for reporting UPIRSOs.

Federal regulations require institutions to establish written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and applicable regulatory or federal agencies of any unanticipated problems involving risks to subjects or others [45 CFR 46.103 (b)(5); 21 CFR 56.108 (b); 38 CFR 16.103 (b)(5)]. Recent federal guidance (January, 2007) reaffirms that only serious adverse events (SAEs) that meet the definition of an UPIRSO, including adverse unanticipated device effects, require submission to the IRB.

The UIC policy regarding the reporting of UPIRSOs establishes what types of events require prompt reporting to the IRB and will be accepted for review by the UIC IRB.

UPIRSOs are any incident, experience, or outcome that meets *all* of the following criteria:

- a. are not expected either in terms of nature, severity or frequency;
- b. are related or possibly related to participation in the research; and
- c. suggest that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

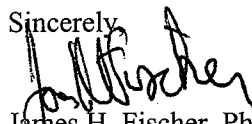
To qualify as an UPIRSO, an adverse event must either be:

1. **serious, unexpected** (in terms of either the **nature, severity or frequency** of its occurrence), and **related or possibly related** to participation in the research, or
2. not serious, but unexpected, related or possibly related to the research and suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

Adverse events not meeting the definition of an UPIRSO will be returned without IRB review and with an explanation as to why they are not UPIRSOs and do not require submission and/or IRB review. For additional information please refer to UIC UPIRSO policy at:

<http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/upirso.shtml>

Sincerely,


James H. Fischer, PharmD
Director, Office for the Protection
of Research Subjects

UIC