



January 22, 2010

RE: Revised IRB Policy on Adverse Events that Require Reporting to the IRB

To The Research Community:

Spectrum Health IRB has recently revised its reporting policy. It is consistent with the Office of Human Research Protection's (OHRP) *Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subject or Others and Adverse Events* and with the FDA guidance document titled *Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting Improving Human Subject Protection* which was finalized by the FDA in January of 2009. This revised policy is intended to reduce unnecessary burden on our IRB and move the focus to reports that are of significance to its role in overseeing the protection of the rights and welfare of subjects enrolled in research.

Spectrum Health IRB-approved investigators are not required to report adverse events/serious adverse events unless:

- The harm experienced by a subject or other individual in the opinion of the local investigator are unexpected and at least probably related to the Human Research procedures and suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.
 - (1) A harm is "unexpected" when its specificity and severity are not accurately reflected in the consent document and/or current investigator brochure.
 - (2) A harm is "at least probably related to the Human Research procedures" if in the opinion of the local investigator, the research procedures more likely than not caused the harm (greater than 50% probability).

Please refer to the [Spectrum Health IRB Investigator Manual](#) for additional information on reporting requirements or contact the Office of the IRB at 616-486-2031 with any questions. All Spectrum Health forms and policies can be found on our website at www.spectrum-health.org/research.

Sincerely,

Jeffrey S. Jones, M.D., Chair
Spectrum Health Research & Human Rights Committee (IRB)