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**Institutional Review Board for the
Protection of Human Subjects
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State University of New York
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September 1, 2009

To Whom it May Concern:

Effective immediately the SUNY Upstate Medical University Institutional Review Board has changed its policy for reporting adverse events and unanticipated problems to the IRB. The Upstate IRB has made these changes based on the OHRP and FDA regulations regarding the reporting of unanticipated problems and adverse events and the recent OHRP and FDA guidance.

In general the Upstate IRB will now only accept reports of individual adverse events if these events meet the definition of an unanticipated problem involving in risk to subjects or others. Summaries of other adverse events can be included with the progress report during the continuing review process.

For a detailed explanation of the revised procedures please review the policy on the Upstate IRB website.

Thank you for your attention to this matter.

Marti Benedict, RN, BSN
IRB Administrator and Chief Compliance Officer for Research
SUNY Upstate Medical University IRB

Attachment: Summary of Related Regulations

Summary of Related Regulations

FDA:

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER D--DRUGS FOR HUMAN USE

PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION

Subpart D--Responsibilities of Sponsors and Investigators

Sec. 312.66 Assurance of IRB review.

An investigator shall assure that an IRB that complies with the requirements set forth in part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study. **The investigator shall also assure that he or she will promptly report** to the IRB all changes in the research activity and **all unanticipated problems involving risk to human subjects or others**, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL

PART 56 -- INSTITUTIONAL REVIEW BOARDS

Subpart C--IRB Functions and Operations

Sec. 56.108 IRB functions and operations.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

Please note that 312.66 does not state that adverse events have to be reported to the IRB. 312.66 only states that unanticipated problems must be reported to the IRB. Adverse events and unanticipated problems are defined the same. Also, 312.66 does not state that all adverse events must be reported to the IRB individually, or in real time.

OHRP (45 CFR 46):

HHS regulations for the protection of human subjects (45 CFR part 46) contain five specific requirements relevant to the review and reporting of unanticipated problems and adverse events:

(1) Institutions engaged in human subjects research conducted or supported by HHS must have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and any supporting department or agency head of any unanticipated problem involving risks to subjects or others (45 CFR 46.103(b)(5)).

(2) For research covered by an assurance approved for federalwide use by OHRP, HHS regulations at 45 CFR 46.103(a) require that institutions promptly report any unanticipated problems to OHRP.

(3) In order to approve research conducted or supported by HHS, the IRB must determine, among other things, that:

> (a) Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes (45 CFR 46.111(a)(1)).
>
> (b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result (45 CFR 46.111(a)(2)).
>
> (c) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111(a)(6)).

(4) An IRB must conduct continuing review of research conducted or supported by HHS at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research (45 CFR 46.109(e)).

(5) An IRB must have authority to suspend or terminate approval of research conducted or supported by HHS that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and any supporting department or agency head (45 CFR 46.113).