Guidance on Reporting Incidents to OHRP

Date: May 27, 2005

Scope: This document provides guidance about procedures institutions may use to file incident reports with OHRP. Incident reports include reports of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval. In particular, OHRP offers guidance on the following topics:

I. Applicability of incident reporting requirements;
II. Information to be included in incident reports;
III. Time frame for reporting incidents;
IV. OHRP focus on corrective actions when reviewing incident reports;
V. OHRP's response to incident reports; and
VI. Additional guidance.

Target Audience: IRBs, institutional officials, and institutions that may be responsible for review, oversight, or conduct of human subjects research covered by an OHRP-approved assurance.

Regulatory Background:

HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to research conducted under an OHRP-approved assurance are promptly reported to OHRP:

a. Any unanticipated problems involving risks to subjects or others;
b. Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
c. Any suspension or termination of IRB approval.

Guidance:

I. Applicability of incident reporting requirements

In general, these reporting requirements apply to all nonexempt human subjects research that is:
(a) conducted or supported by HHS;
(b) conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or