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A Review of OHRP Compliance Oversight Letters

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The Office for Human Research Protections (OHRP), a component of the Department of Health and Human Services (HHS), is responsible for oversight of compliance with HHS regulations governing research with humans (HHS regulations).[1] Institutions that undertake human subjects research conducted or supported by HHS must sign a written Assurance committing them to compliance with these regulations. Many institutions extend the Assurance of Compliance to all human subjects research, regardless of the source of funding.

In carrying out its oversight responsibilities, OHRP evaluates all written substantive allegations or indications of noncompliance with HHS regulations. Sources of allegations or indications of noncompliance include research subjects or their loved ones, the institution itself, internal institutional whistle-blowers, patient/subject advocates, and OHRP staff who raise concerns based on published accounts of clinical trials in the scientific literature or the lay media.

If OHRP has jurisdiction over the human subjects research that is allegedly in noncompliance with HHS regulations, it notifies the relevant institution of the allegations and asks the institution to conduct an investigation. The institution is asked to provide OHRP with a written report on the outcome of the investigation accompanied by IRB documents and any other materials relevant to the inquiry. After reviewing these materials and, in certain cases conducting telephone interviews with key individuals at the institution, OHRP issues written determinations regarding whether research was reviewed and conducted in accordance with the HHS regulations, and may require corrective actions. In a limited number of cases, OHRP conducts on-site evaluations of an institution's program for protecting human subjects before making determinations.

Partly in response to a request by the Institute of Medicine for information about OHRP oversight activities involving human subjects research,[2] OHRP's Division of Compliance Oversight reviewed 269 compliance oversight determination letters issued to 155 institutions between October 1, 1998 and June 20, 2002 (fiscal year 1999 through fiscal year 2002).[3] The letters include those in which OHRP made a definitive finding of noncompliance with HHS regulations and/or expressed concern about apparent regulatory or other deficiencies that resulted in the institution taking corrective action. The institutions in the sample include state and private universities, private research institutions, medical schools, academic

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