

A Review of OHRP Compliance Oversight Letters-Update

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Problem/Issue Statement

The Office for Human Research Protections (OHRP), a component of the Department of Health and Human Services (HHS), is responsible for overseeing compliance with the HHS regulations governing research with human subjects (HHS regulations), and evaluates written substantive allegations or indications of noncompliance with the HHS regulations. In September 2003, OHRP's Division of Compliance Oversight reported on the review of 269 compliance oversight determination letters issued to 155 institutions between October 1, 1998 and June 20, 2002. Now we describe a similar report of a review of 235 compliance oversight determination letters issued to 146 institutions between August 1, 2002 and August 31, 2007. Research questions: What percentage of institutions were cited by OHRP for various noncompliance? What is the distribution of OHRP citations of noncompliance? What are the trends that have evolved since our previous analysis?

Description of Research

Research methods: We reviewed 235 compliance oversight determination letters issued to 146 institutions between August 1, 2002 and August 31, 2007. Compliance oversight determination letters included in the analysis include those in which OHRP made a definitive citation of noncompliance with the HHS regulations and/or expressed concern about apparent regulatory or other deficiencies that resulted in the institution taking corrective action (hereinafter "citation of noncompliance").

Results: The tables show the percentage of institutions cited by OHRP for various noncompliance and the distribution of OHRP citations of noncompliance. Table 1 shows that institutions were most frequently cited for noncompliance related to the initial IRB review process (56%), informed consent documents and/or informed consent process approved by the IRB (51%), IRB continuing review process (22%), and IRB policies and procedures (20%). Table 2 shows that the most common areas of noncompliance and deficiency involved informed consent documents and procedures (34%) and the process for IRB initial review of research protocols (20%). These were also the top two categories of citations in our previous review (27% and 25%, respectively). Table 3 indicates that almost two-thirds of the citations relating to IRB initial review of research protocols pertained to IRB failure to approve research protocols in accordance with HHS regulations at 45 CFR 46.111. This is a substantial increase over the percentage of these findings in our last review, which was about one third (153 citations vs 277 citations). Table 4 indicates that nearly a third of the citations of noncompliance involved matters related to informed consent, which is similar to our previous analysis. The most common informed consent citations were that consent documents failed to adequately describe the purpose, procedures, and duration of the research (23%) and the risks and discomforts of the research (23%).

Conclusions: Our current analysis demonstrates that, since our last analysis, there has been an increase in the percentage of institutions with citations of noncompliance regarding changes in research without prior IRB review and approval (25% in our previous analysis and 35% in our current analysis). Conversely, in our previous analysis, the number of citations of noncompliance in the category of written IRB policies and procedures was 88 (rank order #4), and in our current analysis it was 113 (rank order

#3). This increase is statistically significant (113/762 vs. 88/1120; Chi-Square=23.1; $p < 0.00001$). The analysis of these data provides OHRP with a reference point by which it may develop targeted guidance and educational programs to help strengthen protections for human subjects. Awareness of the most frequent problem areas identified by OHRP may allow institutions to take proactive measures before noncompliance occurs. Limitations: The letters examined only represent institutions that were involved with allegations or indications of noncompliance or underwent a not-for-cause evaluation ($n = 146$); the data do not represent a random sample of institutions that hold an OHRP-approved assurance. The vast majority of cases were for-cause evaluations by OHRP during the time period noted above. In addition, for many evaluations the scope of research assessed was small, focusing on a single complaint and involving a limited sample of an institution's human subjects research portfolio.