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Client Alert

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OHRP Issues Revised Guidance and New FAQs

On October 14, 2009, the Office of Human Research Protections (OHRP) of the Department of Health and Human Services (HHS) issued revised Guidance on OHRP's Compliance Oversight Procedures for Evaluating Institutions that use human subjects in research. The revised Guidance supersedes OHRP's October 19, 2005 guidance on this subject. The revised Guidance summarizes the procedures used by OHRP in performing compliance oversight evaluations of institutions conducting human subjects research, which are under OHRP's jurisdiction. The revised Guidance is available at here.

The revised Guidance provides further clarification regarding OHRP's compliance process on the following points:

- OHRP has discretion to choose other mechanisms to address allegations or indications of noncompliance;
- If OHRP and another agency have jurisdiction over an allegation of noncompliance, OHRP and the other agency will confer as to what arrangement to utilize in responding to the allegation;
- OHRP will use external expert consultants for assistance in compliance evaluations as needed;
- OHRP is available for assistance in developing a corrective action plan;
- Complainants, as well as institutions, may request that the Director of OHRP reconsider any determinations;
- Institutions are free to implement, or not implement, OHRP's recommendations; and
- One possible outcome of an OHRP oversight evaluation is that OHRP determines that the IRB Review (or IRB records related to the review) or conduct of one or more specific research projects, as well as the institution's policies and procedures for protecting human subjects in general, are not in compliance with one or more requirements of the HHS regulations.

In addition to the revised Guidance, on October 15, 2009, OHRP also posted on its website a new set of Frequently Asked Questions and Answers (FAQs) on research that would be exempt for institutions conducting research involving human subjects. Although the HHS regulations do not specify who at an institution may determine research is exempt from the requirements under 45 C.F.R. § 46.101(b), OHRP recommends that investigators should ***not*** be given the authority to make the independent determination that certain human subjects research is exempt because of the potential for conflict of interest. The FAQs state that "institutions should implement exemption policies that

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most effectively address the local setting and programs of research." Among other things, such policies should identify clearly who is responsible for making exemption decisions. Recognizing that institutional policy that allows investigators to make their own exemption determinations would likely risk inaccurate determinations, OHRP notes that "institutions may be able to craft policies that build in protections which lead to accurate determinations by appropriately dealing with investigator conflicts of interest and lack of detailed knowledge of the regulations."

The Exempt Research Determination FAQs are available here.