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Office for Human Research Protections Extends Comment Period for Draft Guidance

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The **Office for Human Research Protections** (OHRP) is extending the comment period for its **Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care** (Draft Guidance). Parties interested in commenting will now have an additional 30 days – until January 23, 2015. As noted **previously**, the Draft Guidance "aims to clarify many of the issues…about the use of standard-of-care procedures in clinical research" and was initially published on October 24, 2014. Below is a look at some of the comments received thus far.

OHRP is extending the deadline in response to public requests to allow interested parties sufficient time to fully review and thoughtfully respond to the document. An extension was called for by organizations such as Public Responsibility in Medicine and Research (PRIM&R) and Rare Disease Legislative Advocates (RDLA), the latter of which solicited petitions to aid the request, citing the dramatic impact of the guidance on rare disease patients and families.

As of December 18th, the Draft Guidance has received 34 public comments. The vast majority of comments have been made by individual scientists, but with organizations chiming in such as the Federation of American Societies for Experimental Biology (raising concerns about impact to patient participation), the University of New Mexico Health Sciences Center (expressing agreement with the need for informed consent in research), and the New England Journal of Medicine (NEJM). NEJM's comment urges that an institutional review board determine, based on existing data, that clinical equipoise exists between the treatments being compared (i.e. that there is true medical uncertainty about which treatment is more effective). Further, NEJM argues that informed consent should include a discussion regarding this medical uncertainty and highlight to the participant that the purpose of the study is to determine which treatment is more effective. For more on NEJM's position, see the published editorial **here**.

Roughly two-thirds of the comments express concern about the proposed guidance, with many echoing concerns made by NEJM. More specifically, the majority focused on the document's lack of clarity, the potential chilling effect on research, the need for maximum flexibility in the consent process, and expression of adamant agreement with NEJM in its call for major change to the guidance to "reflect the day to day realities of clinical care." Presumably, several more organizations (including those that pushed for the extension) will weigh in with more detailed analysis of the issues raised by the Draft Guidance before the new deadline of January 23, 2015.

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