CLIENT ALERTS & INSIGHTS

HHS and FDA Release Updated Guidance on Informed Consent

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On March 1, 2024, the US Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the US Food & Drug Administration (FDA) unveiled a preliminary guidance document named Enhancing Understanding in Informed Consent ("Draft Guidance"). This release signifies a progressive stride in HHS's ongoing endeavors to update and synchronize federal regulations concerning the safeguarding of human research subjects. The Draft Guidance furnishes sponsors, investigators, and institutional review boards with directives on the substance, arrangement, and delivery of pivotal informed consent information for FDA-regulated clinical investigations and HHS-supported human subjects research. Stakeholders, including sponsors, investigators, research institutions, institutional review boards, and other interested parties, are encouraged to assess the potential impacts of the Draft Guidance and submit comments by April 30, 2024

In 2017, OHRP revised the Federal Policy for the Protection of Human Subjects ("Common Rule") and introduced a novel requirement dictating that consent documents should commence with the primary information crucial for aiding prospective research subjects in comprehending and deciding whether to partake in a research study. Aligned with OHRP's directive under the 21st Century Cures Act to reconcile disparities between OHRP and FDA human subject protection regulations, the FDA proposed a rule in September of 2022. If enacted, this rule will incorporate similar primary information requests into the FDA's human subject protection regulations.

Acknowledging various approaches to providing essential information to prospective research subjects, the Draft Guidance underscores the importance of tailoring the approach to the unique attributes and design of each study, the characteristics of the prospective subject population, and the ailment under investigation. The Draft Guidance furnishes overarching recommendations for presenting this critical information.

Identifying Key Information

The Draft Guidance suggests that the key information section of a consent form start with an introductory statement outlining the key information and serve as a guide for the entire consent document. While stressing that not all informed consent elements need to be included in the key information section, the Draft Guidance emphasizes the inclusion of certain elements deemed "key" by prospective subjects, with the most crucial elements first. Additionally, the Draft Guidance recommends repetition of details in other parts of the consent form, along with providing page numbers or hyperlinks for cross-referencing more detailed information.

Examples Of Key Information

While acknowledging the variability of the key information section across studies, the Draft Guidance provides specific recommendations on elements of informed consent to be included in this section. The recommended statements are on voluntary participation, study purpose and protocol details, associated risks and benefits, alternative procedures or treatments, available medical treatments and compensation in case of injury, and any incurred costs or reimbursements related to study participation.

Supplemental Information To Include Within Key Information

Apart from basic and additional consent elements, the Draft Guidance deliberates on supplementary information that interested parties might consider including in the key information section. For instance, it suggests highlighting risks to non-participants and refers interested parties to recommendations from the Secretary's Advisory Committee on Human Research Protections for guidance on determining supplementary information.

Facilitating Understanding

The Draft Guidance concludes by recommending strategies for organizing and presenting consent forms to enhance prospective subjects' understanding. These strategies include structuring information within defined borders, employing formatting techniques such as two-column layouts and bullet points, utilizing visual aids, and presenting information in a tiered manner to cater to varying comprehension levels.

The Benesch Healthcare+ team monitors developments in this area of the law and may provide additional updates as they become available. Please contact the authors of this article for additional information or if you have any questions.

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