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April 25, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Rm 1061
Rockville, MD 20852

Submitted via https://www.regulations.gov

Re: Docket No. FDA–2022–D–2997, "Key Information and Facilitating Understanding in Informed Consent."

Dear Dr. Califf:

America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 600 blood collection sites providing close to 60 percent of the U.S., and a quarter of the Canadian, blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration (FDA).

ABC appreciates FDA providing draft guidance for sponsors, investigators, and institutional review boards on "Key Information and Facilitating Understanding in Informed Consent," and applauds FDA's intent to "make informed consent easier to understand."[1]

I. FDA should ensure that key information is written at no higher than an eighth grade reading level, and preferably at a sixth or seventh grade reading level.

ABC is pleased that FDA is providing guidance to address the presentation of key information that "includes recommendations for the content, organization, and presentation of informed consent information in FDA-regulated clinical investigations of drugs, devices, and biologics… and in HHS-supported or -conducted nonexempt human subjects research." However, ABC is concerned that FDA does not address health literacy and the need for this key information to be at an appropriate reading level.

According to the Agency for Healthcare Research and Quality (AHRQ), "health literacy depends on both an individual's skills and the complexity of health information and the tasks needed to manage health. Thus, anyone—regardless of background—can experience limitations in health literacy at various times in their life. This fact, combined with controversies regarding conducting literacy testing in health care environments, led to a universal precautions approach to health literacy. In this approach, clinicians and health care systems assume that all patients are at risk of not understanding medical information, and they communicate with patients in ways anyone can understand. Health literacy universal precautions involve organizational health literacy strategies that will help patients to achieve health literacy

[1] "FDA Works to Make Informed Consent Easier to Understand," accessed April 5, 2024.

[including]…written materials should be at a 4th to 6th grade level…"[2] Additionally, the American Medical Association recommends that patient materials should be written at a sixth grade reading level, while the National Institutes of Health recommend these materials be written at an eighth grade reading level.[3] While FDA states in the draft guidance that "information should be presented in plain language at a level prospective subjects would likely comprehend," critical parts of the key information sample included in the appendix of the draft guidance, which is likely to be used as a template if the guidance is finalized as is, are close to a college reading comprehension level using Dale-Chall, the most accurate and reproducible analyzer available through Datayze.[4]

FDA should ensure that key information is written at no higher than an eighth grade reading level, and preferably at a sixth or seventh grade reading level. FDA should further recommend instruments that can be utilized to ensure these recommendations pertaining to reading levels are met.

II. FDA should provide clarity around the recommended length of key information.

The draft guidance recommends the "key information section of a consent document be relatively short (e.g., generally no more than a few pages)." ABC recommends that FDA provide further clarity around the recommended length of the key information, to ensure this information is understandable and consistent.

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ABC appreciates the opportunity to comment on the draft guidance. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

Thank you for your collaborative work to ensure a safe, adequate, and available blood supply.

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer

[2] "Personal Health Literacy," Deb Bakerjian, PhD, APRN, FAANP, FGSA, FAAN, August 30, 2023. AHRQ Patient Safety Network.
[3] Rooney MK, Santiago G, Perni S, Horowitz DP, McCall AR, Einstein AJ, Jagsi R, Golden DW. Readability of Patient Education Materials From High-Impact Medical Journals: A 20-Year Analysis. J Patient Exp. 2021 Mar 3;8:2374373521998847. doi: 10.1177/2374373521998847. PMID: 34179407; PMCID: PMC8205335.
[4] Readability Analyzer (datayze.com).