Published on *The National Law Review* https://natlawreview.com

# HHS and FDA Seek Comments on Informed Consent Draft Guidance

Article By:

Stephen W. Bernstein

Jiayan Chen

Jennifer S. Geetter

James R. Ravitz

Sam Siegfried

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Services (HHS) Office for Human Research Protections (OHRP) and the US Food & Drug Administration (FDA) released a draft guidance document entitled Key Information and Facilitating Understanding in Informed Consent (Draft Guidance). It represents the next step in HHS's continued efforts to modernize and harmonize federal human subject protection requirements and guidance. It also provides sponsors, investigators and institutional review boards with recommendations for the content, organization and presentation of key informed consent information in FDA-regulated clinical investigations as well as HHS-supported or conducted nonexempt human subjects research.

## IN DEPTH

When HHS finalized revisions to the Federal Policy for the Protection of Human Subjects (Common Rule) in 2017, it added a new requirement that – except for broad consent obtained in accordance with the Common Rule for certain secondary research activities – consent documents or other consent vehicles must begin with the key information most likely to assist a prospective research subject in understanding and determining whether to participate in a research study. Consistent with

HHS's mandate under the 21st Century Cures Act to harmonize differences between HHS and FDA human subject protection regulations, the FDA issued a proposed rule in September 2022 that, if finalized, will (among other things) add identical language to the FDA's human subject protection regulations.

In the Draft Guidance, OHRP and the FDA acknowledge that there are multiple strategies for providing key information to prospective research subjects that are consistent with the provisions of the revised Common Rule and the FDA's proposed rule. It is up to interested parties to develop an approach that takes into account certain relevant factors when developing and providing key information for any given study, including the distinctive attributes and design of the study, the prospective subject population, and the disease or condition being examined. The agencies offer several overarching recommendations for presenting this key information.

## IDENTIFYING AND PRESENTING KEY INFORMATION

The Draft Guidance opens with a general recommendation that the key information section of a consent form begin with an introductory statement to frame the key information included in the consent and serve as a roadmap for the entire consent document. The Draft Guidance is clear that each informed consent element does not need be included in the key information section, but elements that a prospective subject would consider "key" should be included, and the most important elements should appear at the beginning of the key information section. Even if an element is not selected for inclusion in the key information section, it must appear elsewhere in the informed consent form as required by the regulations.

The agencies also recommend that, where appropriate, details in the key information section be repeated in other parts of the consent form to help reinforce important considerations regarding participation in the study, and that the key information section include page numbers or hyperlinks to cross-reference more detailed information later in the form. In addition, for minimal-risk or certain other studies, the agencies note that the key information section may be the majority or even the entire consent document, so long as it provides sufficient information for the prospective subject to make an informed decision.

## SPECIFIC EXAMPLES OF KEY INFORMATION

While the key information section will vary from study to study, the agencies offer focused recommendations on specific informed consent elements that interested parties should consider including in the key information section. Among other information, parties should include:

- A statement that participation in the research is voluntary and that the decision to not participate, or later withdraw from participation, will not result in a penalty or loss of benefits to the prospective subject to which the individual is otherwise entitled.
- Information that provides a clear understanding of the purpose of the study and relevant details of the protocol (such as a description of the research and why it is being conducted, along with information about the study design, including expected duration, key procedures, the investigational product, any experimental procedures, and randomization and the use of placebos or sham procedures).
- Risks and discomforts associated with participation in the research (this should appear on the first page of the key information section):
    - If the key information section includes a discussion of some, but not all, risks and discomforts, the key information section should note this and include a reference to

the location of additional information later in the consent form. In addition, the information should clearly delineate between risks and discomforts associated with the investigational product or procedure itself, as well as risks and discomforts associated with other research interventions (*e.g.*, additional imaging studies not part of ordinary clinical care).

- Information about reasonably expected benefits from participating in the research, presented in simple and straightforward terms and without an inappropriate or overly optimistic representation of the facts.
- A clear and concise description of alternative procedures or courses of treatment:
    - The agencies recommend that interested parties consider informing prospective subjects about care they would receive if they were not enrolled in the study, followed by information to help them understand differences in the care they would receive if they were to participate in the study.
- An explanation of any medical treatments and compensation available to prospective subjects if an injury occurs as a result of participation.
- Any costs prospective subjects may incur by participating in the study, or whether they will be reimbursed for any study-related expenses (*e.g.*, travel, lodging, childcare).

## ADDITIONAL SUPPLEMENTAL INFORMATION

In addition to providing recommendations regarding which basic and additional consent elements to include in the key information section, the Draft Guidance also discusses other information interested parties might consider presenting to prospective subjects in the key information section. For example, the agencies suggest that interested parties may want to highlight risks, if any, to others not participating in the study (*e.g.*, risks associated with radioactive interventions or shedding of a virus in gene therapy studies). The Draft Guidance also recognizes that determining which supplemental information to include can be complex and directs interested parties to recommendations from the Secretary's Advisory Committee on Human Research Protections as one resource for making these determinations.

## FACILITATING UNDERSTANDING

- The Draft Guidance concludes with a discussion of and recommendations for how consent forms can be organized and presented to better facilitate prospective subjects' understanding of the reasons why they may or may not want to participate in the study. These recommendations include:
  Organizing information within a defined border (*e.g.*, rounded boxes, or "bubbles," that create distinct units of information) that separately addresses discrete topics and makes the content easy to read and understand.
- Formatting text into two columns, using bullet points and including sufficient white space to improve readability.
- Using visual aids and plain language techniques such as listing the most important points first, breaking complex information into smaller statements, using simple language, and providing background and context for technical terms or concepts.
- Providing information in a tiered manner; for example, a first tier with only key information, a second tier with the remaining consent elements not covered in the first tier (and divided into different topics), and a third tier that addresses other supplemental information or describes required information in more detail.
- Presenting information at a level that prospective subjects can comprehend, which may include an assessment of the needs and characteristics (*e.g.*, age, English language

proficiency, education level) of the prospective subject population or review by patient advocacy groups or other external parties.



National Law Review, Volume XIV, Number 82