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IRBs, Informed Consent, and New Consent Language for Studies

In this leading article we do something we seldom do. We're excerpting key highlights from a recent NIH Notice. We usually don't do this for two reasons. First, many -- if not most -- of our HRR readers are likely to have been apprised already of any IRB-related NIH Notice.

Second, even if an IRB member is unaware of the particular notice, individual researchers not on the IRB may be aware of the Notice and may modify their protocols appropriately anyway before submitting them for IRB review.

However, the NIH Notice in question does warrant our special attention, again for two reasons. First, it addresses a highly significant topic for IRBs; namely, informed consent. Second, there is still time (until September 29) for the research community to respond to this NIH proposal.

In our brief preliminary "heads up" about this proposal in last month's "IRB Compliance Comment Deadlines & Notices" feature, we incorrectly listed the comment deadline as October 1. It is actually September 29.

Focus Is On Sharing of Research Data

The Notice is titled "Request for Information: Developing Consent Language for Future Use of Data and Biospecimens" [emphasis added].

> "NIH is requesting information from stakeholders on the utility and useability of sample language developed for use in informed consent documents for data and biospecimen sharing ….
>
> Responsible sharing of data and biospecimens derived from human participants relies on robust informed consent practices that uphold the principles of autonomy and trust in biomedical research. Fundamental to these practices are clear and efficient communication strategies for conveying potential risks and benefits of sharing.
>
> NIH has heard from its stakeholders that there is a strong interest in sharing best practices for developing informed consent language to support [data] sharing. To assist in this endeavor, NIH has worked to develop sample language that may be used in informed consents when data and biospecimen

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc. However, we will on occasion insert words or edit text/formating in brackets [ ] to make the material easier to read, or to add an underline emphasis.

NOTE #2: Emphases are added to articles by HRR by underlining or adding ***bold/italics*** to selected text, unless stated otherwise.

NOTE #3: Articles **To Be Continued** in subsequent issues are marked at the end of the article with **{TBC}**.

Also In This Issue

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sharing may occur, as well as 'points to consider' for investigators and Institutional Review Board[s] (IRB[s]) when using or modifying the language.

NIH is interested in input on 1) the sample consent language [as it appears later in the NIH Notice], 2) the 'points to consider,' and 3) any gaps or additional components that should be included.

NIH is also interested in input on any hurdles or barriers to the voluntary use of the sample language and 'points to consider' by the community.

NIH welcomes input from research investigators, institutional review board members, study participants, professional organizations, associations with a focus on research oversight, and other interested members of the public" (NIH Notice No. NOT-OD-21-131, July 1, p. 2 of 7; on the Web at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-131.html).

Informed Consent Changes Are Specific

The "sample language" presented by NIH in its Notice is detailed and frequently contains options, depending on the nature of the research, the study timeframes involved, etc. The following excerpt is a representative example for the initial consent component.

"***Component 1: Introduction - Description***

Considerations for those responsible for study conduct and oversight: The Introduction-Description component is meant to provide prospective research participants with an introduction to, and description of[,] the storage and sharing of data and biospecimens in the study.

- If participants may be re-contacted to collect new or replacement data or biospecimens, include language to address re-contacting.
- Those responsible for study conduct and oversight will need to consider the appropriate timeframe for data and biospecimen storage based on their study and anticipated uses. For some, the appropriate timeframe may be indefinite, while others may have a clear, limited timeframe.

Instructions for those responsible for study conduct and oversight: See sample language below for the Introduction-Description component. If using the sample language, include the first three paragraphs then choose either Option #1 or Option #2. Replace embedded instructions identified in **[bold, bracketed text]** with specific information pertaining to the study and remove **[Option #1 and #2 text]**" (supra at p. 4).

NIH Wants Input on Consent Proposals

As can be seen from the excerpt above, the NIH Notice contains quite detailed sample consent language, with various options. This is true for the following sections as well: "Component 2: Voluntary Participation," "Component 3: Discontinuation/Withdrawal," "Component 4: Risks and Benefits," and "Component 5: Commercial Application."

Similarly, NIH has the following specific instructions for IRBs and anyone else wishing to comment upon the agency's proposals for new informed consent language, as follows in part:

"Comments should be submitted electronically by September 29, 2021, using the form at https://osp.od.nih.gov/rfi-comment-informed-consent-sharing/.

You may provide comments to one or all of the topics in the comment boxes. Comments received will be posted at https://osp.od.nih.gov/clinical-research/informed-consent/ without changes after NIH has reviewed all of the comments received. Please do not include any proprietary, classified, confidential, or sensitive information in your response ….

Please direct all inquiries to: NIH Office of Science Policy, OD/Division of Clinical and Healthcare Research Policy, Telephone: 301-496-9838, Email: SciencePolicy@mail.nih.gov" (supra at p. 7). ©