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Informed consent process review under revised Common Rule requirements

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On January 19, 2019, most provisions of the revised Federal Policy for the Protection of Human Subjects, also known as the Common Rule, went into effect, including new requirements related to the informed consent process for clinical research studies. The Common Rule sets forth guidelines for the protection of human subjects involved in clinical research. The Common Rule was published in 1991 and adopted by 15 federal departments and agencies, including the Department of Health and Human Services (HHS).[1] The Common Rule also sets forth processes for review of all human subjects research by an institutional review board (IRB). A revised Common Rule was published in the Federal Register on January 19, 2017, which set forth changes to many human subjects research requirements, including revisions and enhancements to the informed consent process.[2] Although certain requirements were delayed following publication of the revised Common Rule, the majority of provisions went into effect on January 21, 2019, including the informed consent-related requirements.

New informed consent requirements

The revised Common Rule enhances the informed consent process by making it more transparent to subjects. The revised Common Rule added a requirement that the informed consent process allow the subject to be "provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate."[3] Specifically, the Common Rule now requires that the informed consent form "begin with a concise and focused presentation of key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research" and "present information in sufficient detail relating to the research."[4] The language used must be comprehensible and must facilitate the individual's understanding of the reasons as to why one may want or not want to participate. According to HHS, to be understandable, the information must be "presented to subjects [...] in a language and at a level the subject can comprehend, including an explanation of scientific and medical terms."[5]

Although the precise level of detail to be described in the informed consent form will vary from study to study, the preamble to the revised 2018 Common Rule suggests the initial presentation of key information could include "a summary of relevant pieces of information that are explained in greater detail later in the consent form."[6] Specifically, the preamble suggests the following five elements currently required under 45 C.F.R. § 46.116(b) be included in the initial presentation of key information:

1. A statement that the project is research and participation is voluntary;
2. A summary of the research, including the purpose, expected duration of the subject's participation, and

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procedures that are a part of the research;

3. The reasonably foreseeable risks or discomforts that may result;
4. The benefits that could reasonably be expected to result; and
5. If applicable, any alternative procedures or courses of treatment that might benefit the subject.[7]

The revised Common Rule also requires that the informed consent form contain a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects and the conditions for such disclosure.[8] For studies involving biospecimens, the informed consent form must disclose whether the study will involve whole genome sequencing.[9] The informed consent form must also state whether biospecimens (even those for which identifiers are removed) may be used for commercial profit and, if so, whether the subject will share in that profit.[10]

In terms of documentation of informed consent, the revised Common Rule added a waiver in relation to the signature requirement on an informed consent form if the subject is a member of a distinct cultural group or community in which signing forms is not the norm, the research involves no more than minimal risk, and there is an alternative method for documenting that consent was obtained.[11]

Finally, the revised Common Rule requires that for clinical trials supported by the federal government, the informed consent form used to enroll subjects in the study must be publicly posted on a federal website established for such purpose, no later than 60 days from the last study visit for any subject.[12] On August 28, 2018, the HHS Office for Human Research Protections (OHRP) announced two publicly available federal websites that will satisfy the consent form posting requirement at this time: ClinicalTrials.gov and a docket folder on Regulations.gov.[13] OHRP also stated that it may identify additional federal websites that satisfy the posting requirement in the future.

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