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Are you ready for January 21?

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The revised Common Rule[1] goes into effect on January 21, 2020, for general compliance. It is intended to reduce administrative burden on a research site so that an Institutional Review Board (IRB) can better serve the role they have in the research process. Another goal is to better protect human subjects. These are the first significant changes to human subjects research regulations since the Common Rule was established in 1991.

The change in the consent requirements is one that has been considered for months by sites across this country. Beginning with a more "concise and focused" presentation of key information in an informed consent, isolated facts cannot be just a laundry list. There needs to be enough detail to facilitate a subject's understanding of why they may want to participate in a clinical trial. The general improvement is for the information to be presented in "sufficient detail" and "organized and presented"in a way that facilitates the subject's understanding of why someone might or might not want to participate in a study.[2]

A task of this nature will not be easy for sites, because it will be a culture change. When a physician delivers a consent process to a subject, they must be concise and focused so the subject truly understands "clinically" what will occur. I've trained hundreds of clients to use language such as, "You may or may not receive a benefit from participating in this study," but I know the revised language will be more defined to facilitate the consent process. The consent will now need to have sharper wording, such as, "You may have reduced medical complications from this investigational procedure, which may lead to a better outcome." It remains to be seen how future consents will differ in the language and what it can mean for a subject's understanding of the clinical trial or research project they are participating in.

Therapeutic intent is an area of concern in billing compliance, given a consent should not negate the intent. With the new Common Rule, that takes on new meaning, because the subject is supposed to be granted concise information on why the research is being done, what the treatment involves, and what it means to be randomized, receive a placebo, or have a sham procedure. Ryan Meade has always said, "A consent form should be written so your grandmother can understand it." Today, that has greater meaning when explaining the clinical pieces of the clinical trial that involve complex areas.

On January 21, the consent process will change! Are you prepared?

1 45 C.F.R. § 46
2 45 C.F.R. § 46.116(a)(5)(ii)