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Institutional Review Board (IRB)

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Consent Guidance Key Information (45 CFR 46.116):

Key Information Guidance from the Preamble to the Revised Common Rule posted in the Federal Register:

The Federal Register identifies 5 key factors that are suggested to be key information.

1. A statement that the project is research and participation is voluntary
2. A summary of the research including purpose, duration, and a list of procedures
3. Most important reasonable foreseeable risks or discomforts (The remainder of risks or discomforts can be addressed later in the consent form.)
4. Reasonable expected benefits
5. Alternative procedures or course of treatment (if any)

These factors should be a summary of the sections that come up later in the consent document.

What the Federal Register Says:

To help understand the spirit of the new requirement of Key Information, review the exact language in the Preamble of the Revised Common Rule posted in the Federal Register:

In general, we would expect that to satisfy § __.116(a)(5)(i), the beginning of an informed consent would include a concise explanation of the following: (1) the fact that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. As a general matter, a brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research, as required by § __.116(a)(5)(i) and § __.116(a)(4). However, we recognize that this determination is necessarily fact-specific and that IRBs and institutions may require that somewhat different (or additional) information be presented at the beginning of an informed consent to satisfy § __.116(a)(5)(i).

https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects