INFORMED CONSENT: CONCISE PRESENTATION OF KEY INFORMATION

Emory IRB
2/14/2019
WHAT WILL BE COVERED IN THIS PRESENTATION?

• Common Rule’s New Requirements- Key Summary
• SACHRP Recommendations
• New Templates
• Questions
Informed consent must begin with a **concise and focused presentation of the 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. This part of the informed consent must be organized and presented in a way that facilitates comprehension, and provides sufficient **information that a “reasonable person” would want** to have. Informed consent as a whole must present information in sufficient detail relating to the research, and must be **organized and presented** in a way that **does not merely provide lists of isolated facts.**
WHAT IS “KEY INFORMATION”? 

More Info In Preamble

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

5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.
BUT NO OFFICIAL GUIDANCE YET

SECRETARY’S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTIONS (SACHRP)
Commentary on the New “Key Information” Informed Consent Requirements
October 17, 2018

The Secretary is responsible for regulatory oversight of the system for the protection of human subjects in biomedical and behavioral research supported or conducted by the Department of Health and Human Services (HHS).
Electronic consent, audio, or video presentations may best present key information.

Key information elements in preamble may not be sufficient: **Flexibility is key**

May need to include other elements or information.

May exclude elements that won’t help with subject understanding.
SACHRP COMMENTARY: BENEFITS

• If applicable, include a statement that there are no direct benefits

• Otherwise include an **accurate and specific** description of potential benefit
  
  • For clinical research, keep in mind the potential for therapeutic misconception—study’s primary goal is advancing knowledge and not delivering treatment

• Avoid unclear language

• Risks or potential benefits that would be used for decision on participation (in absence of more info) should be included
SACHRP COMMENTARY: RISKS

• Should refer to the most important risks with regard to frequency and magnitude
  
  • Avoid exhaustive lists

• Clinical research: include how risks differ from standard of care

• Discomforts and inconveniences, rather than risks, might be key information (in SHB studies)
SACHRP QUESTIONS TO HELP IDENTIFY KEY INFORMATION

➢ What are the main reasons a subject will want to join this study?
➢ What are the main reasons a subject will not want to join this study?
➢ What is the research question the study is trying to answer? Why is it relevant to the subject?
➢ What aspects of research participation or this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject’s expectations, or require special attention?
SACHRP QUESTIONS TO HELP IDENTIFY KEY INFORMATION

- What information about the subject is being collected as part of this research?
- What are the types of activities that subjects will do in the research?
- What impact will participating in this research have on the subject outside of the research? For example, will it reduce options for standard treatments?
- How will the subjects’ experience in this study differ from treatment outside of the study?
- In what ways is this research novel?
SACHRP COMMENTARY: LOGISTICS

- Key information requirement will add to length of informed consent documents
  - No sections have been taken away
- Key information **does not need to be repeated** in body of document
  - Unless repetition facilitates understanding
SACHRP COMMENTARY: LOGISTICS

- Studies with simple design may have a concise enough informed consent document
  - For now, if your study is **federally funded**, you are **required to complete this section**
  - For other studies not federally funded, the IRB will use discretion for documents that are only 1-2 pages
    - Document the highlights in summary: risks/benefits and reason for study
OPTIONS TO ENHANCE READABILITY
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