Baystate Health | UMass Chan Medical School

OHRP Participant-Centered Informed Consent Training

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Consider taking the Participant-Centered Informed Consent Training provided by the Office of Human Research Protections! This training is for anyone in the research community who plans, writes, or reviews consent forms for research involving human participants.

The goal of the training is to teach people how to improve consent forms by explaining common mistakes and suggesting ideas for better organization, wording, and design. For example, some common problems found in consent forms are:

- Too much information/unnecessary details.
- Overly complex language
- Dense formatting with minimal white space
- Jargon written for scientific reviewers.
- Disjointed content copied directly from research protocols or grant applications.
- Complicated legal-sounding language in passive voice.

Some suggestions from the training on how to use a participant-centered approach are to:

- Get input from intended participant population.
- Step away from the formal scientific writing style.
- Break down complex concepts.
- Provide context for understanding.

The OHRP training provides examples of these suggestions such as:

- Swapping medical terms/research terms for familiar words (even if it takes more than one word)
- Using readability tests to calculate readability scores and average grade reading level. Readability Scoring System (readabilityformulas.com)
- Write as if you were speaking to simplify text. Ask someone who is unfamiliar with your project to read your draft consent.
- Use shorter sentences and words.

The training also gives suggestions on how to organize the information in consent forms. Some examples are to:

- Separate ideas into sections. Address one general topic and divide the details up into short paragraphs, lists, tables, etc.
- Stick to the point. Avoid irrelevant details. Minimize unnecessary repetition.
- Rewrite section headings as questions. Such as “What Will Happen if I Participate?”
- Some details only become relevant after a person decides to participate. Consider providing those details in a supplemental document for actual participants.
- Use design elements such as graphics, color, tables, and pictures that make the document simpler and easier to understand.
- Help participants understand the content by highlighting content relevant to them and use visual cues.

It is the job of the IRB to make sure consent forms are clear and easy to understand. We aim to provide as many resources as possible as reference for these principles. Please check out the resources listed below and take the training if you have some time!

Participant-Centered Informed Consent Training | HHS.gov

Checklist of Strategies for Writing and Reviewing Consent Forms (hhs.gov)

Participant-Centered Informed Consent Resource List (hhs.gov)

Example of Part of a Key Information Section (hhs.gov)

Boilerplate Explanation of Randomization with Blinded Assignment (hhs.gov)