Resources for Simplifying Consent Forms

Please see the Forms & Templates section of our website for examples of adult consent and child assent forms. Below, we list some suggestions and resources to ensure that your consent materials are understandable for your research participants. Your goal should be to facilitate comprehension as much as possible.

- In 2017, the U.S. Department of Health and Human Services issued revisions to the regulations for human subjects protections regulations. These revisions included a new section that could be added to consent forms called “key information.” As indicated on the consent template available on our website, this section is not required. However, it may be helpful depending on the complexity of your project. This section provides a concise and focused presentation of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Please click here for a helpful presentation by David H. Strauss, MD on the key information section of consent forms.

- The University of Michigan Library has compiled an excellent plain language medical dictionary that allows users to enter medical terminology to search for a simplified substitute. For example, when the user enters “contusion,” the term “bruise” is suggested. For researchers proposing medical studies, this is an excellent resource to simplify the language in the consent form.

- PlainLanguage.gov is a federal resource providing a number of examples, checklists, and guidelines for using language that is understandable to the public. Although this website was created due to the Plain Writing Act of 2010, which requires federal agencies to use clear communication that the public can understand and use, many of the examples can be translated to consent forms and other research materials (such as recruitment materials). The CDC has also published a number of similar resources, as has the NIH.

- The PRISM Toolkit published by Kaiser Permanente aims to improve print materials used in communication with research participants. It includes a number of resources and strategies to create understandable consent forms. Page 21 of this toolkit includes a template for an informed consent form with a reading level ranging from grades 4 to 7.

- Children’s Hospital of Philadelphia has a simple checklist for developing easy-to-read consent forms.