Sample text that can be used to justify changes to IRB Key Information Templates

What is the purpose of this document?
Below we provide sample text that you can use in IRB applications or with Sponsors to provide the rationale for, and help justify, the changes we recommend you make to Key Information. This may be especially helpful if the changes deviate from templates provided by IRBs or Sponsors. We have included key references from the literature supporting these practices.

How can I use the text you provide?
You can use the text to support IRB applications or to justify to Sponsors the rationale for making changes to Key Information. For instance, you could use the text below in the "Background", "Rationale", or "Protocol" sections of the IRB application to justify the use of evidence-based communication strategies, such as formatting and plain language, in your Key Information. IRB applications may ask for relevant references, which we have also provided. This information can also be used for Sponsors to justify the rationale for changing Key Information, or other individuals or bodies who require further information on the practices.

Please note, most IRB and Sponsor templates specify what to include in Key Information. If your IRB or Sponsor has provided you with a template, we recommend that you present the information they require, while incorporating our tips on plain language and formatting.

**You have permission to use the text below verbatim,
or to adapt it as needed for your purposes.**

Suggested text and references to support changes to Key Information that are recommended in the Consent Practices Study

The revised (2018) federal regulations for the protection of human subjects (45CFR46) state that informed consent must begin with a "concise and focused presentation" of the key information that is most likely to assist a research participant in understanding the "reasons why one might or might not want to participate in the research."[1] The key information must be organized and presented in a way that facilitates comprehension." [2]

We have included all of the key information recommendations in the IRB template [*we recommend you ensure required information is included*], while adopting evidence-based communication best practices including [*insert relevant practices you have utilized: plain language, formatting, bullets, increased white space*] to maximize understanding of information [3-6] These practices make it easier for participants to understand and retain key information.

Improving the consent process using these techniques enhances respect for autonomy and ethical protections of research participants.[7] These communication best practices help meet the recommendations of federal agencies including the National Institutes of Health (NIH), Centers for Disease Control (CDC), and the Centers for Medicare and Medicaid Services (CMS).[8-11]

References

Common Rule References

1. Subpart A of 45 CFR 46 : Basic HHS Policy for Protection of Human Subjects (As revised on January 19, 2017, and amended on January 22, 2018 and June 19, 2018). In: Services US Department of Health and Human Service, Office of Human Research Protections, U. S. Department of Health Human Services, Office for Human Research Protections, Office of the Assistant Secretary for Health, eds 2018. https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
2. Menikoff J, Kaneshiro J, Pritchard I. The Common Rule, Updated. The New England Journal of Medicine. 2017;376(7):613-615. doi: 10.1056/NEJMp1700736

References regarding lack of understanding of informed consent by participants and practices that have been shown to improve understanding

3. Flory J, Emanuel EJ. Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review. Journal of the American Medical Association. 2004;292(13):1593-1601. doi:10.1001/jama.292.13.1593
4. Kim EJ, Kim SH. Simplification improves understanding of informed consent information in clinical trials regardless of health literacy level. Clinical trials. 2015;12(3):232-236. doi: 10.1177/1740774515571139
5. Agre P, Campbell FA, Goldman BD, et al. Improving Informed Consent: The Medium is Not the Message. IRB: Ethics & Human Research. 2003;Suppl 25(5):S11-S19. doi: 10.2307/3564117.
6. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: a comparison of print, video, and computer-based presentations. Patient Education and Counseling. 2004;53(2):205-216. https://doi.org/10.1016/S0738-3991(03)00162-9

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7. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report: Ethical principles and guidelines for the protection of human subjects of research. Washington, D.C.: United States Department of Health, Education, and Welfare; April 18, 1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Plain Language Guidelines provided by Federal Agencies

8. National Institutes of Health. Clear Communication. https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication, 2019.
9. The Plain Language Action and Information Network. Plain Language.; https://www.plainlanguage.gov/. 2019
10. Centers for Medicare and Medicaid Services. Toolkit for Making Written Material Clear and Effective. https://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index?redirect=/WrittenMaterialsToolkit, 2019.
11. Office of Disease Prevention and Health Promotion. Health Literacy Online: A Guide for Simplifying the User Experience. https://health.gov/healthliteracyonline/, 2019.