University of Kentucky (UK) Consent Form Template FAQ

The UK ORI and IRB implemented a revised informed consent template December 2017 in preparation for the January 2019 effective date of the revised Protection of Human Subjects "Common Rule" regulations for protecting human subjects. The template is also consistent with FDA regulatory requirements. It is a tool for developing consent documents; however, the language and style should be tailored to meet the needs of the prospective study population. "Cookie-cutter" consent text is not conducive to facilitating understanding.

General Consent Template Information

1. The template is provided as a guide. It includes all the elements required by the regulations (purpose, risks, alternatives, etc.).

2. It includes verbiage for diverse types of research. Remove portions that don't apply to your specific study. Refer to specialty templates such the banking or survey cover letter template when applicable.

3. **Your consent does not have to use the exact language verbatim**. In fact, the revised regulations encourage writing and formatting the document to meet the needs of the prospective study population. For instance, the style of writing for young adults may differ from that created for seniors. You can tailor the language to fit the participants and use the ORI Consent Checklists to ensure it includes required elements and assess for regulatory compliance.

4. Use the tools on the ORI Informed Consent website to write in conversational style, and use lay terminology resources and "plain language" techniques to create a consent document that facilitates understanding. The Harvard Catalyst Sample Consent Language Library includes verbiage to describe risk implications for technical concepts such as cloud storage or text communications.

5. Choose formatting that facilitates understanding and don't duplicate information. In addition, remove the ***blue italicized instructions*** when formatting the final form.

Consent Template Frequently Asked Questions (FAQ)

Do I have to begin a consent document and presentation with a concise summary of Key Information? Generally, the answer is "yes". It is a regulatory requirement that potential subjects be first presented 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."* Sample Key Information sections are on the ORI Sample Application page. A single page is provided for key information in the consent template: however, if a consent form is sufficiently brief, the key information may be incorporated into the beginning of the consent and not separated on a single page.

Does the information provided in the concise summary have to be exactly what is in the UK template?
Not verbatim. The intent of the rule is to consider what key information a potential subject would need to know up front.

> **It is the most important information that would influence a potential participant to say "Yes" and the most important thing that would influence a potential participant to say "No" to participation.**

This allows the individual to weigh the key pros and cons of volunteering early in the process.

Isn't the reason someone would or wouldn't participate always going to be a risk or benefit?
In some cases, it will, but it depends. The most significant deterrent could be a serious potential risk or a

number of benign but unpleasant risks. In other cases, it may be merely inconvenience. The key reason to participate could be a personal gain or to help advance science. A proven alternative treatment may be considered more advantageous that an experimental treatment. The most influencing factor could be the implication of the risk. A breach of confidentiality may have minor repercussions for a survey study, while the same occurrence with genetic testing could affect family planning. The idea is not to present all considerations first but start with the most influential pros and cons to participation.

How do I know what information would be key to someone's decision to participate or not?
The choice may be based on the investigator's experience with the study population. Support groups or associations may provide insight into participant perceptions. You may also search for empirical research (e.g., *Participant perception of risks and benefits of genetic research;* or *Participant Perceptions on data sharing*). The patient-centered and participant-centered movements have prompted considerable research on subject perceptions of research consent.

When would I need to include the Medical Template, "Storing Your Information/Specimens for Future Research" Appendices?
If you plan to collect, store, and share information or specimens from a study, to use and share for future secondary research, include the applicable appendix in your consent. Formatting this as an appendix may help a potential participant understand the difference between the main study and other future secondary research with their stored material. If the study IS ONLY a bank or registry, incorporate the information from the "Storing for Future Research" Appendix into the Detailed Consent or use the ORI Sample Repository/ Data Registry/Specimen Bank Consent as a guide for designing your research repository consent document.

Do I have to put the risks, alternatives, etc. in the Appendices?
No. Only use appendices if they facilitate better understanding. The consent should be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates understanding. Consider the context of the study and decide if any information would be easier to understand in a table, illustration, or graphic format. For instance, some studies include superfluous information such as study schedules in the appendices, and include information central to making an informed decision for the body of the consent document. If they offer no value, delete the Appendices.

Does my consent have to use the template language verbatim?
No. The template has language for diverse types of research. Editing the language to fit the context of the study and the needs of the study population is permitted. However, be sure to present the Key Information first and be careful not to omit a required regulatory elements! The template offers flexibility to organize and present information in a format that facilitates understanding. For example, a limited number of risks in paragraph form may be fine in the Detailed Consent. However, lengthy or detailed risk information may be easier to understand in table format grouped by severity or incidence.

Does the language need to be readable and understandable to a layperson?
Yes. Strive to simplify and use plain, conversational language. For medical studies, use tools such as the NCI Lay Risk Language Database or the Side-Effect Database. Use resources such as the PRISM readability toolkit or the Multi Regional Clinical Trials (MRCT) Health Literacy Resources . Consider process enhancements such as use of videos or anatomic models, and practice confirming understanding through teach-back techniques. More tools are available at Tools for Developing Informed Consent Documents.

I thought the idea was to make consent forms shorter. Why is the UK template so many pages?
The template was designed to include formatting options and to provide sample language for diverse types of research. Not everything included will apply to all studies. Remove what does not apply including collapsed sections. Don't duplicate information. Use only what applies and makes sense in the context of your study.