New UK Consent Form Template FAQ

Why does UK have a new consent form template?
The Federal Policy for the Protection of Human Subjects (the Common Rule), has updated regulations including revised requirements for the informed consent process. The intent of these consent changes is to facilitate a prospective subject’s comprehension by presenting information in a format that helps him/her decide whether to participate in the research. The template is provided as a guide. It includes all of the elements required by the regulations (purpose, risks, alternatives, etc.). It prompts investigators to think about what Key Information to include first in the consent form and the presentation.

What is new about the new consent form template?
To comply with the new Common Rule, the template was revised to include a few new required elements and the format was changed to begin with the Key Information described below. It also includes options that give flexibility to the investigator to design a form that best fits the context of the study and the study population’s needs. The revised consent form contains three sections:

• **Key Information Page** - a concise summary of key information a person would want in order to make an informed decision about whether to participate;
• **Detailed Consent** - the main body of information about the study; and
• **Appendices** - may be used to present information in a format that facilitates understanding rather than using lengthy text (i.e., reference listings, tables, charts, illustrations, photos).

As a whole, informed consent must present information in sufficient detail that is organized and presented in a way that does not merely provide lists of isolated facts, but facilitates understanding.

Do I have to begin a consent document and presentation with a concise summary of Key Information?
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 will be posted on the ORI Sample Application 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 instead of dispersed in the document.

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 pros and cons of volunteering.

The preamble describing the new Common Rule described 4-5 items that could be “key” to the decision whether to participate. The Key Information section of the UK Template includes those concepts; however, the idea is for the investigator to tailor this section to fit the study and the study population.

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 the number of benign but unpleasant risks. In other cases, it may be merely inconvenience. A proven alternative treatment may be considered more advantageous than an experimental treatment. Also, consider and include 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 insurability or employability. The same goes for reasons why one would agree to participate. It may be potential personal benefit, or it could be altruistic reasons. The idea is to present both so the individual can weigh the most important pro and con to participation. For instance, would increase life expectancy outweigh a diminished quality of life?
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 Consent Perceptions in Comparative Effectiveness Research). The patient-centered and participant-centered movements have prompted considerable research on subject perceptions of research consent.

Do I have to use the “Future Use” Appendices? If you plan to use or share information or biospecimens for future research after the study is complete, you should include the information from the future use appendices in your consent. Formatting this as an appendix may help a potential participant understand the difference between the main study and the plans to store, use, or share information or specimens for future research. If the intent of the study is to create a repository, then combining the information in the Detailed Consent and Future Use Appendices may be more logical.

Do I have to put the risks, alternatives, etc. in the Appendices? Only if it facilitates 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. If so, use the Appendices to present in that format.

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 element! 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 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 Quorum Simplify Your Consent Guide. Consider process enhancements such as use of videos or anatomic models, and practice confirming understanding through teach-back techniques.

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. Use only what applies and makes sense in the context of your study. Choose formatting that facilitates understanding.

EFFECTIVE & COMPLIANCE DATES:
When does the new Common Rule go into effect? The new rule goes into effect July 19, 2018.

The Office of Research Integrity (ORI) begin posting New Informed Consent Form templates based on the new rule on the ORI website December 2017. This was done to begin the transition and facilitate early compliance in the event that a study submitted prior to the effective date is not approved until after the effective date.