

Why does [REDACTED] have a new consent form template?

The [REDACTED] and IRB implemented a revised informed consent template December 2017, along with newsletter announcements, FAQs, and Informed Consent Workshop offerings. This transition occurred a year in advance of the January 2019 effective date of the new Protection of Human Subjects "Common Rule" regulations for protecting human subjects. The revision has provided an opportunity for researchers and IRB members to become familiar with select requirements from the new rule.

The template is provided as a guide. Investigators are instructed to remove portions that don't apply to the research and choose formatting options that facilitate participant understanding. It includes all of the elements required by the regulations (purpose, risks, alternatives, etc.).

Use conversational style, lay terminology resources and "plain language" techniques to create a consent document that facilitates understanding. After drafting, use the Consent Checklists to assess for regulatory compliance.

When does the new "Common Rule" go into effect?

The general compliance date for the new Common Rule is January 21, 2019. [REDACTED] begin posting New Informed Consent Form templates based on the new rule [REDACTED] December 2017. Transitioning to the new template in advance has provided investigators, the [REDACTED] an opportunity to work with, provide feedback, and edit the template prior to the compliance date.

What is new about the new consent form template?

To comply with the new Common Rule, the template includes 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 different from lengthy text in paragraph form (i.e., reference listings, tables, charts, illustrations, photos).

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 are on the [REDACTED] page.

Does the information provided in the concise summary have to be exactly what is in the [REDACTED]?

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 than 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. [REDACTED] 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?

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. If not, 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 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, 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 Quorum Simplify Your Consent Guide. 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 [REDACTED] 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. Use only what applies and makes sense in the context of your study. Choose formatting that facilitates understanding and don't duplicate information. In addition, remove the *blue italicized instructions* when formatting the final form.