



WHAT ORI & IRB NEED TO KNOW REGARDING REVIEW OF THE NEW CONSENT TEMPLATE

The Effective and Compliance Date for the New Common Rule Regulations for the Protection of Human Subjects has been delayed for 6 months. However, institutions may move forward with implementation of any aspect of the new rule that is not contrary to the current rule. This allowance permits ORI to continue transitioning to the revised informed consent template, in order to ensure compliance by the new effective date (July 19, 2018).

Consent documents under the new rule must:

- be organized to facilitate understanding with key information presented first, and
- include new required elements (one basic and three additional elements to include when applicable).

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

UK has developed a template to assist investigators in complying with consent document requirements. The UK template was designed to include options for formatting and language for varied types of research. Using the template, investigators will need to:

- tailor the language to fit the context of the research;
- organize the format to facilitate understanding; and
- determine the most important '*Key Information*' to present first.

Based on the changes, we would not expect all consents to look alike or include language that exactly mirrors the template. Institutions most effective at implementing the 'spirit' of the new rule will have diverse informed consent documents that no longer look 'cookie cutter'. The **Key Information** could be presented differently and still be compliant as long as it is presented first and provides a concise summary of key reasons a participant would or would not choose to participate. In addition, the new template offers options for where or how to include required elements to best facilitate understanding. Since elements may not consistently appear in the same section, the attached General Requirements Basic & Additional Elements document or the *Color-Coded version* of the template may be used as tools for ORI to screen consent documents to ensure all Basic and Applicable Additional Elements are included.

To prepare to screen or review consent documents using the new template, please review the attached [New Template FAQ](#), the attached New Consent Template Slides and "Key Information" Examples, which will be added to the [ORI Sample Applications and Protocol Development Resources](#) webpage.

PLEASE NOTE: Several guidance documents regarding implementation and/or interpretation of the New Common Rule are pending release by the federal Office for Human Research Protections (OHRP). If new information adds to or contradicts the implementation of the new template, we will modify accordingly.