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 or not to participate in the research.

With the pending implementation of the changes to the Common Rule on January 19, 2018, ORI is making the required changes to research forms and the Informed Consent Form templates. 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 such as Risks, Treatment Options, Registry, and Biorepository information in a format that facilitates understanding rather than using lengthy text.

*When relevant, Appendices will be used to inform participants how their information or biospecimens will be used or shared in the future after the study is complete.

It is a federal requirement that all studies approved by the IRB after January 19, 2018 use this new format. The new Informed Consent Form templates will be available on the ORI website December 20, 2017.

Unless the federal guidance changes, the Rule states that currently approved studies may continue to use the consent form previously approved by the IRB.

Additional announcements and education opportunities will be provided as we implement changes based on the new Rule.