Special Notice

Common Rule Changes to the Consent Templates

Changes to the Common Rule, the primary rule regulating human subjects research, go into effect on January 19, 2018. A number of UVM IRB policies, procedures, and systems have been updated as a result of the changes to the rule.

Investigators will see a number of changes required under the new rule specific to the Consent Form:

“The informed consent must begin 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.”

Revised Common Rule: Federal Register Volume 82, Number 12 (issued, January 19, 2017)

- All medical and behavioral consent forms will now be required to include a concise summary of study activities, risks, and benefits presented to research participants, on page one of the consent document. The IRB will not require re-consent for previously enrolled subjects.

- To assist researchers in creating this new section a Plain Language Medical Dictionary has been added to the website to promote consent comprehension.

- Additional elements of informed consent (specific to biospecimens) are required to be included in consent forms – these are included in the Medical
Consent Template (DOCX) and Repository Consent Template (DOCX) and are highlighted in BLUE.

- Please note that only studies approved or altered after January 19, 2018 will be governed by the new rule; the IRB will grandfather all existing approved consent forms under the pre-2018 rule.

- IRB applications submitted shortly before January 19, 2018 may not be reviewed in time to qualify under the current human subjects protection regulations. Applications undergoing the review process at the time of transition may be returned to the study team to update the informed consent elements.

- The Research Protections Office has provided Concise Examples for the Web (DOCX) on how to apply this new element.

- If you have further questions about how to apply the new "key information" requirement for a particular study, contact your IRB Research Analyst for advice.