MEDICAL COLLEGE OF WISCONSIN

January 21, 2019

Sponsors, Clinical Research Organizations, and others:

As you likely are aware, institutions that review federally-funded research must comply with the revised Common Rule effective January 21, 2019. Additionally, the Medical College of Wisconsin (MCW) has opted to transition all ongoing research to comply with the revised Common Rule, which includes updating the consent forms for all ongoing projects to reflect the revised requirements for consent.

The transition to the consent form must occur at the time of the next submission for each project, and exceptions to this rule will not be granted. A submission, therefore, will *not* be reviewed unless the consent form has been updated to reflect the requirements of the revised Common Rule.

The MCW consent form template has been updated to comply with the revised Common Rule. Please note that no other content-related changes were made with this revision. The changes that were made to the consent form per the change in federal regulations are detailed below and must be implemented to avoid a lapse in approval.

Section/*Added Language*	Rationale	Federal Regulation
Consent Form Introduction	The revised Common Rule requires that the consent form 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.	.116(a)
Use of Data or Biospecimens *Once all personal identification is removed from your health information and/or biospecimens, the information and/or*	The revised Common Rule requires additional language if the research involves the collection of identifiable	.116(b)(9)

Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, Wisconsin 53226-0509

MEDICAL COLLEGE OF WISCONSIN

biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.	private information or identifiable biospecimens.	
Identifiable Biospecimens *Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor <PI> will pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your <health information/ specify biospecimens>.*	The revised Common Rule requires the addition of language describing that subjects will not receive any profit if profit is gained by the Sponsor or Investigator from the subject's biospecimens.	.116(c)(7)
Clinically Relevant Research Results Two sections have been added in Section D4 of the consent form to reflect when clinically relevant research results will or will not be released to subjects.	The revised Common Rule requires that subjects be informed of whether or not clinically relevant research results will be released.	.116(c)(8)
Whole Genome Sequencing *Whole genome sequencing will be included as part of the genetic testing for this research.*	The revised Common Rule requires that subjects be informed if a project will or might involve whole genome sequencing.	.116(c)(9)

It is understood that the changes detailed above may not apply to every project, but the updated language must be included when applicable.

Please direct any questions regarding this memo to IRBOffice@mcw.edu.

Thank you.

David C. Clark, PhD
MCW Human Research Protections Program Director

Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, Wisconsin 53226-0509