Quick Reference Guide to Common Rule Updates

On January 21, 2019, changes to the regulations under which human subjects research is conducted ("The Common Rule," found at 45 CFR 46) go into effect. These changes have been delayed twice already, but another delay does not appear to be in store at this time. While the changes to the Common Rule are numerous, they should not have a substantial impact on most human subjects research at the University of Notre Dame. Please review a summary of the changes below, and contact ND Research Compliance with any questions you have about the Common Rule and your research.

	Pre-2018 Common Rule	New Common Rule	PI Action
Continuing Review for "Minimal Risk" Studies (Expedited)	Expedited research required review annually to remain active	Continuing review is only required for Expedited research when an IRB reviewer notes a specific cause for it (e.g.: concern about a vulnerable population)	At least one more renewal will be required for already-approved Expedited studies. The IRB will determine if continuing review will be required after this initial review. Please note any expiration dates provided in the eProtocol system.
Continuing Review for "Minimal Risk" Studies (Full Board)	Full Board research required review annually to remain active	If Full Board decides research is minimal risk, it may also determine if continuing review is necessary	When reviewing a new study that is "greater than minimal risk" or does not fit in Exempt/Expedited categories, the IRB will determine if continuing review will be required after the initial review. Please note any expiration dates provided in the eProtocol system.
Exempt Research Categories	Research falling under five (5) categories could be submitted for Exempt review	Research under seven (7) categories may be submitted for Exempt review, with two (2) original categories revised and two (2) new categories added	When submitting a new study, take time to review the new categories of research to determine if your project qualifies for Exempt review.
Elements of Informed Consent	Informed consent required the inclusion of certain language	Informed consent must emphasize key information, and several new elements	When submitting a new study, use the new Informed Consent form templates available in the Resource Library.

Please note that most of these changes affect new studies approved after January 21, 2019. While the protocol submission form is largely unchanged in substance, be careful to review the level of review paragraphs to determine the best fit for your research. If you are unsure, or would like assistance with that determination, please contact ND Research Compliance at compliance@nd.edu or (574) 631-1461.