



VCU Office of Research and Innovation

[2018 Common Rule]

Summary of Changes and Impact

The 2018 Common Rule goes into effect on January 21, 2019 and will impact all human subjects research at VCU.



[Impact for Researchers]


- 1. No Continuing Review for Minimal Risk Research**
Under the 2018 Common Rule, research the IRB determines to be minimal risk does not automatically require continuing review. The Office of Research Subject Protection will instead request a once annual status update.
- 2. Broader Scope for Exempt Research**
The 2018 Common Rule expands the scope of certain exempt categories and introduces others. This means that some research that would previously have required expedited review may be exempt under the new rule.
- 3. No Grant Congruency Review Requirement**
The requirement for grant review by the IRB is removed in the 2018 Common Rule. IRBs will only review grants when required by funding agencies.


Learn more!

Check out the ORSP website and blog for more information and resources on the 2018 Common Rule.

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[What Changed]

- 1. New Definitions**
The 2018 Common Rule adds new definitions and revises the definitions of research and human subjects.
- 2. Grant Congruency Review Not Required**
- 3. New and Revised Exempt Research**
The new rule adds an exempt category for “benign behavioral” interventions and expands exemption criteria for certain survey, interview, and secondary data research activities. Some exempt research will require “limited IRB review: under the new rule. The IRB already meets this requirement under current procedures.
- 4. Continuing Review Requirements**
Research that is greater than minimal risk still requires continuing review but most minimal risk research will not require continuing review.
- 5. Consent Form Requirements**
The 2018 Common Rule requires a summary of key information as part of the informed consent document. The rule also adds four new elements of consent.
- 6. Consent Waiver Requirements**
Waivers or some/all elements will address a new criterion to justify the waiver. The rule adds a new option to justify a waiver of documentation. Lastly, consent waivers are no longer required for most recruiting and screening activities.
- 7. Consent Form Posting Requirements**
The new rule requires that all clinical trials post a copy of the consent form on a federal website.