

1.18.2018

TO: Oberlin College and Conservatory of Music Faculty and Staff
FROM: Daphne John, Associate Dean
RE: DELAY in Federal IRB Common Rule Changes

Regarding Human Subjects research, the U.S. Federal Government has DELAYED until July 19, 2018, the implementation of changes to the Common Rule (Federal Policy for the Protection of Human Subjects) scheduled to become effective January 19, 2018. Therefore, we are obligated to follow the Common Rule that currently is in place. That is, there are NO CHANGES in IRB review practices until the new regulations go into effect. At Oberlin, this mostly affects ORAL HISTORY research, which was to be removed from IRB regulations and classified as “non-research” in the new “Final Common Rule”. Please note that oral history research still falls under the purview of IRB review until the implementation of the new regulations in July. If you currently have an outstanding protocol regarding oral history research, you must act on this. If you have questions regarding IRB review, please contact Daphne John, Associate Dean and Chair of the Oberlin IRB (x58410, djohn@oberlin.edu).

Included below is the text of the notification of the delay from U.S. Office of Research Protections.

The U.S. Department of Health and Human Services and 15 other federal departments and agencies have announced an Interim Final Rule (IFR) that delays by six months the effective date and general compliance date of the revisions to the “Federal Policy for the Protection of Human Subjects” (also known as the Common Rule) originally published in the Federal Register on January 19, 2017 (82 FR 7149). Most provisions in the revised Common Rule were scheduled to go into effect on January 19, 2018.

The IFR delays the effective date and general compliance date to July 19, 2018, providing regulated entities additional time to prepare to implement these revisions.

The IFR has been put on public display by the Office of the Federal Register and can be accessed at: <https://www.federalregister.gov/documents/2018/01/22/2018-00997/federal-policy-for-the-protection-of-human-subjects-delay-of-the-revisions-to-the-federal-policy-for>.

Until July 19, 2018, regulated entities will be required to comply with the pre-2018 Common Rule as published in the 2016 edition of the Code of Federal Regulations (i.e., the Federal Policy for the Protection of Human Subjects, originally published on June 18, 1991, and subsequently amended on June 23, 2005) that can be accessed at: <https://www.gpo.gov/fdsys/pkg/CFR-2016-title45-vol1/pdf/CFR-2016-title45-vol1-part46.pdf>. This means that before July 19, 2018, institutions may only begin implementing provisions of the revised Common Rule that do not conflict with the pre-2018 Common Rule. An example of a revised provision that does not conflict with the pre-2018 rule is one that addresses new elements of informed consent (revised rule at §__.116(b)(9), (c)(7)-(9)). It is permissible to incorporate these new elements of consent now because the pre-2018 rule does not prohibit including these elements in informed consent.

An example of a revised provision that conflicts with the pre-2018 rule, and thus could not be implemented prior to July 19, 2018, is the provision eliminating the requirement for continuing review in certain circumstances (as described in the revised rule at §__.109(f)). Because the pre-2018 regulations require continuing review at least annually for all ongoing non-exempt human subjects research, halting continuing review for such research before that date would be considered non-compliance.

The IFR does not delay the compliance date for the cooperative research provision of the revised Common Rule (found at §__114(b)), which remains January 20, 2020.

Federal departments and agencies listed in the IFR are also in the process of developing a notice of proposed rulemaking (NPRM) seeking public comment on a proposal for further delay in the required implementation of the revised Common Rule (for example, until January 21, 2019). If such an NPRM is published, after consideration of the public comments, the federal departments and agencies will determine whether a final rule to further delay the revised Common Rule will be issued.