



Guidance for AAHRPP Organizations that Comply with the Common Rule

After a long process, final revisions have been published to the Common Rule, with a new compliance date of January 21, 2019. Organizations who conduct or review research covered by the existing Common Rule must continue to comply with existing regulations until January 21, 2019, with the exception of three burden-reducing provisions:

- The revised definition of “research,” which deems certain activities not to be research;
- The allowance for no annual continuing review of certain categories of research; and
- The elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research.

With that backdrop, the purpose of this Guidance is to explain what to expect from AAHRPP. Please rest assured that, as with all our activities, we will endeavor to work closely with our accredited and not-yet-accredited organizations to facilitate smooth and reasonable processes related to AAHRPP accreditation.

AAHRPP standards are broad, and the vast majority of Standards and Elements are not affected by the revised regulations. That said, if the new rule stands, we recognize that in the areas that may need to be updated, it will take time to revise policies, forms, and electronic systems, conduct education, and transition to the revised Common Rule. We will track federal regulatory and guidance activities closely and develop further AAHRPP guidance (including but not limited to a revised Evaluation Instrument) in a transparent, timely process designed to give our organizations ample time to understand and integrate the new requirements.

For organizations that comply with the Common Rule:

- **Organizations whose complete process occurs prior to January 21, 2019:**
 - **Organizations whose entire accreditation process will occur and be completed (including Council determination) prior to January 21, 2019 will be evaluated for compliance with existing regulations using the February 2018 version of the Evaluation Instrument.**
- **Organizations whose Step 1 application is submitted prior to January 21, 2019 but whose site visit occurs on or after January 21, 2019:**
 - **Although the Step 1 application will be evaluated for compliance with existing regulations using the February 2018 version of the Evaluation Instrument, organizations need not have written materials in their applications that address the new requirements of the revised Common Rule, which do not become effective until January 21, 2019.** Rather, policies, forms, and other materials designed to comply with the revised Common Rule may optionally be submitted as part of the application. AAHRPP will provide comments, but organizations will not be asked to make revisions to written materials to address the revised Common Rule. (Note, however, that organizations submitting applications after July 19, 2018 and who are planning to implement the three burden reducing provisions which are eligible for implementation on July 19, 2018, should, in fact, describe this in written materials, which will be evaluated as part of the Step 1 application review.)
 - **The site visit agenda will be developed to ascertain from the organization how it is planning to address new regulatory requirements.**



- Organizations whose entire accreditation/reaccreditation process occurs after January 21, 2019:**
The entire process will be conducted in accordance with the new regulations and AAHRPP’s revised Evaluation Instrument (version January 2019 or after). Applications will be reviewed to ensure policies and procedures meet requirements in the revised regulations. The Step 1 Review report provided by AAHRPP will specify any additions or changes that need to be made to policies to comply with the revised regulations. The revised regulations will be in force at the time of the site visit, and site visitors will evaluate compliance with the revised regulations.
- Existing accredited organizations that do not have an application due should describe plans for implementing the revised regulations at the time of your Annual Report starting in September of 2018.**

Applicant	Evaluation Instrument version	Site Visit
Process completed before January 21, 2019	February 2018	Will not evaluate compliance with revised Common Rule, unless requested
Applicants whose applications are submitted before January 21, 2019 and whose site visit will occur on or after January 21, 2019	February 2018	Will not evaluate compliance with revised Common Rule in Step 1, unless requested. Will discuss compliance with new rule during 2019 site visit
Applicants whose entire accreditation process occurs after January 21, 2019	January 2019 (planned)	Will evaluate compliance with revised Common Rule

Please feel free to contact AAHRPP’s Director of Accreditation, Dr. Robert Hood (202-783-1112 or rhood@aahrpp.org) with any questions you may have regarding implementation of this AAHRPP guidance.