Policy 201, *Education Program*, is being implemented on June 1, 2019, and all NIH investigators should be in compliance with its requirements by September 1, 2019. There are significant differences between requirements for this new education policy and those of the prior one. The changes specific to investigators are summarized below and the attached table provides a summarized overview. For complete requirements, please refer to this policy on the IRBO website at https://irbo.nih.gov/confluence/display/IRBO/Policies+and+SOPs

1. All investigators who conduct human subjects research (HSR) that has been determined to be exempt from IRB review or that is required to undergo IRB review (exempt and non-exempt HSR, respectively) must take an initial Collaborative Institutional Training Initiative (CITI) course (no test out) to include the CITI Biomedical 101 Basic Course or the CITI Social & Behavioral Educational Modules Basic Course based on the type of research that the investigator conducts. Investigators who conduct both types of research should complete both modules as each course has unique material. Please note that CITI has updated its content related to the revised Common Rule. All investigators must now complete one or both courses as noted previously (no test out), unless they have completed one of these courses (no test out) since 1/21/19. Tests completed after that date include the updated content relating to the revised Common Rule.

2. CRT and the in-person *Bioethics Ethical and Regulatory Aspects of Clinical Research* course will no longer meet the NIH requirement for a basic HSR protections course. The reasons for this change are: 1) the status of completion and expiration of CITI courses can be tracked in iRIS; 2) CITI offers automatic refresher options (testing out or re-taking the course) on their website at the time the training expires (every three years); and 3) this simplified requirement (a single on-line source for training and refreshers on a set schedule and easier tracking) should help to increase investigator compliance. Investigators should still continue to save training certificates as they may be requested by external sponsors and/or non-NIH external Reviewing IRBs.

3. In addition to the requirements in item number 1 above, all NIH investigators conducting non-exempt HSR must also complete or test out of the CITI Good Clinical Practice (US FDA Focus) Course by September 1, 2019 if they’ve never taken it before or complete this CITI GCP course whenever their current GCP certification (NIAID or CITI GCP) expires (at the three-year mark). Note that this requirement for GCP training is no longer limited to investigators conducting FDA-regulated research, and it applies to all investigators conducting non-exempt HSR.

4. The *Roles and Responsibilities of Laboratory Investigators (Lab AI)* course and quiz and the *Data Quality Management (DQM)* course and quiz will no longer be required courses for any investigator. The Triennial refresher (offered in 2016) and the DQM course will no longer be accepted as refreshers for the basic HSR protections or GCP courses, respectively.

Feel free to contact us at IRB@od.nih.gov if you have any questions.