

v. date 6/4/2020

Policy 103, *Education Program* was implemented on June 1, 2019 (at that time it was numbered as Policy 201), and all NIH investigators were required to 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 originally issued in 2013. 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 courses as each one 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 of these courses as noted previously (no test out), unless they have completed one of these courses (no test out) since 1/21/19. Courses 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 issued by CITI at the time of course completion 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 were required to also complete or test out of the CITI Good Clinical Practice (US FDA Focus) Course by September 1, 2019 if they had never taken it before, or they should complete this CITI GCP (US FDA Focus) 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](mailto:IRB@od.nih.gov) if you have any questions.

**Human Subjects Protections Training Required for NIH Investigators Conducting Human Subjects Research (HSR) and those non-NIH Investigators conducting HSR on a protocol under the oversight of the NIH IRB**

	<b>NIH investigators who only conduct HSR that is exempt from IRB review</b>	<b>NIH Investigators conducting non-exempt HSR who have completed a Good Clinical Practice (GCP) course in past 3 years</b>	<b>NIH Investigators conducting non-exempt HSR who have NOT completed a Clinical Practice (GCP) training course in past 3 years</b>	<b>Non-NIH Investigators conducting HSR on a protocol under the oversight of the NIH IRB</b>
<b>CITI Basic HSR course: either CITI Biomedical 101 and/or CITI Social and Behavior Modules based on the type of research conducted by the investigator</b>	X (Complete by 9/1/2019)	X (Complete by 9/1/2019)	X	
<b>CITI GCP (US FDA focus)</b>		X (Complete when current GCP training expires: 3 years after completion of prior GCP)	X (Complete by 9/1/2019)	
<b>Optional or Just-In-Time Training as required by IRB, Clinical Director, or PI</b>		X	X	
<b>Training as required by their home institution (See Policy 103 for information regarding submission of required documentation in iRIS and possible additional IRB requirements for training for non-NIH investigators)</b>				X