Frequently Asked Questions
NIH Policy on Good Clinical Practice (GCP) Training for
NIH Awardees Involved in NIH-funded Clinical Trials

Question 1. Why did NIH issue the GCP policy?

Answer: The NIH GCP training policy is part of a multi-faceted NIH initiative to enhance the quality, relevance, feasibility, efficiency, and transparency of NIH funded clinical trials through stewardship reforms (see Hudson KL, Lauer MS, Collins, FS. Toward a New Era of Trust and Transparency in Clinical Trials. *JAMA*. 2016; 316(13):1353-1354).

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials. NIH applauds institutions that promote even higher standards by requiring their clinical trial investigators to surpass the baseline GCP standard.

Question 2. Does NIH expect that all relevant investigators and clinical trial staff at an awardee institution will have been GCP trained by the good clinical practice policy effective date of January 1, 2017?

Answer: Institutions need not regard the policy's effective date as a deadline by which we would expect NIH-funded investigators and clinical trial staff involved in the design, conduct, oversight, or management of clinical trials to be GCP trained. Rather, as long as steps are being taken to meet the expectation, e.g., staff who have not yet been trained have signed up for a course, the training itself can be completed after the effective date.

Question 3. Does the GCP policy apply to personnel on grants and contracts awarded before the January 1, 2017 effective date?

Answer: The policy applies to all active grants and contracts, no matter what point they are in the life cycle of the trial.

Question 4. What is the scope of the GCP policy, i.e., who else besides the clinical investigator is expected to be GCP trained?

Answer: The policy applies to NIH-funded clinical investigators and clinical trial staff who are responsible for the design, conduct, oversight, or management of clinical trials. The policy describes the investigator as the individual responsible for the design and conduct of the clinical trial at a trial site or, if a team of individuals at a trial site are involved, the investigator leading the team. The policy describes clinical trial staff as those who are responsible for study coordination, data collection, and data management. It provides examples of the activities such individuals may carry out such as participant recruitment and enrollment, including obtaining informed consent, data collection and documentation, and regulatory compliance and reporting. It notes that clinical trial staff may be referred to variously as a research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

The policy also applies to investigators and clinical trial staff:

- Whose clinical trials are exempt from the Common Rule (exempt categories defined in 45 CFR part 46.101(b));
- Whose names are added on to non-competing progress reports; and,
- Who are on subawards, foreign awards, or foreign subcontracts.

The policy does not apply to those who may consult with the clinical trial team but have no role in the design, conduct, oversight, or management of a clinical trial (e.g., a biostatistician acting as an independent consultant). Nonetheless, since consultants would likely also benefit from an understanding of GCP principles, they should not be discouraged from taking GCP training. In addition, if institutions find it easier to take a broader approach and apply the GCP policy to everyone on a covered protocol, they may do so.

Question 5. Does the GCP policy apply to investigators who are conducting clinical research studies that are not clinical trials?

Answer: The policy applies to investigators and staff involved in clinical trials. At the same time, however, understanding the principles of good clinical practice may be helpful to clinical researchers generally. The definition of clinical trial and guidance about it are available at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials.

Question 6. Does the GCP policy apply to investigators who are not supported by NIH funds?

Answer: The policy applies only to investigators who are supported by NIH funds.

Question 7: In 2000, NIH issued the Required Education in the Protection of Human Research Participants policy. The 2000 policy applies to investigators submitting grant applications or contract proposals to NIH for research involving human subjects and to investigators receiving new or non-competing awards for such research, and it requires them to be educated in the protection of human research participants. How is the GCP policy different from the 2000 policy?

Answer: The 2000 policy pertains to all research involving human subjects. Its goal is to ensure that investigators conducting such research understand the goals and principles of human subjects protections as well as the relevant regulations governing such research. The GCP policy applies to NIH-funded investigators and staff who are involved in the design, conduct, oversight, or management of clinical trials. Its goal is to ensure that NIH-funded clinical investigators understand ethical and scientific standards for clinical trial design, conduct, recording, and reporting.

Question 8: The GCP policy indicates that investigators should be trained in GCP "consistent with the principles of the International Conference on Harmonization (ICH) E6 (R2)." Some of the elements of ICH (E6) seem to pertain specifically to trials of drug and device interventions. How would those elements apply to trials of behavioral interventions?

Answer: The principles of ICH (E6) apply generally to all clinical trials. Some measures, e.g., reporting of adverse drug reactions to regulatory authorities, are pertinent specifically to trials of interventions involving drugs and devices, rather than to trials of behavioral interventions. However, the underlying principle of safety monitoring and reporting is relevant to all clinical

trials and can be a guide to behavioral investigators in their monitoring and reporting of safety events to relevant oversight bodies, e.g., the Institutional Review Board.

Question 9. Does NIH expect investigators and clinical trial staff to take a particular GCP training program?

Answer: The policy does not specify that a particular GCP course or program be taken. The policy includes links to GCP training courses sponsored by NIAID and NIDA (see, respectively, https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx and https://gcp.nihtraining.com/about). In addition, NCATS has developed a GCP training program geared to behavioral clinical trial investigators (see https://obssr.od.nih.gov/training/web-based-learning/good-clinical-practice-for-social-and-behavioral-research-elearning-course/). These courses are free of charge. Other free courses as well as fee-based courses are available.

Question 10. Does the GCP policy expect investigators and clinical trial staff to retain documentation of their GCP training?

Answer: The policy expects investigators and clinical trial staff to retain documentation of their training and, as needed, provide it to NIH upon request.

Question 11. How often does the GCP policy expect clinical trial investigators and clinical trial staff to update their GCP training?

Answer: The policy expects investigators and clinical trial staff to maintain their GCP training through refresher courses in GCP topics every three years.