DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

November 21, 2016

Anthony P. DeCrappeo
President
Council on Governmental Relations
1200 New York Avenue, N.W., Suite 460
Washington, DC 20005

Dear Tony:

Thank you for your letter of October 6, 2016, in which you raised concerns about the scope and applicability of NIH's Policy on "Good Clinical Practice (GCP) Training for NIH Awardees Involved in NIH-funded Clinical Trials." I want to thank you and Lisa Nichols for taking the time to discuss your concerns and perspectives with Mike Lauer and me on October 28 and for Lisa's follow-up email of November 8. Mike and I also hope our discussion and this letter will reassure you we intended to provide appropriate flexibility to implement the policy in a way that makes the most sense to the institutions.

We appreciate that institutions take training obligations seriously and that they want to be as careful and deliberate as possible when implementing the new policy. We understand that the first of the year is fast approaching, but we continue to believe that meeting the expectations of the policy will be manageable for institutions. Since GCP training can be beneficial at any point in the life cycle of the trial, we did not limit the policy to new awards. However, institutions should not regard the policy's effective date as a deadline by which we would expect all staff involved in the conduct, oversight, and 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 taken in a timely fashion after the effective date.

Your concerns about the applicability of the policy are well-taken. However, we thought it would make sense to tailor the policy to the subset of investigators and staff who are responsible for the conduct, oversight, and management of clinical trials. Thus, while the policy's definition of investigator is conceptually consistent with how the term is used in the FCOI regulation, they are not identical. If they had been, the policy would have applied more broadly than necessary. With regard to staff to whom it applies, we thought it made most sense for the policy to cover the individuals who are involved in coordinating the trial and collecting and managing data. You pointed out that the Required Education in the Protection of Human Research Participants policy applies to "key personnel," which refers to "all individuals responsible for the design and conduct of the study." It is difficult to see how those responsible for study coordination, data collection, and data management would not be considered key personnel, so the approaches

should not be far apart. We believe the policy applies to the appropriate staff, and that it is neither overly broad nor more narrow than appropriate. However, if institutions find it easier to take a broader approach and apply it to everyone on a covered protocol, they may do so.

With regard to the added effort that will be needed to ensure compliance, we hope institutions will be able to ease the burden by adapting systems they already have in place for tracking those who are required to take training in responsible conduct of research and human subjects' protections. Since GCP training is widely considered to be a baseline standard for clinical investigators and support personnel, we also think that many, if not most NIH-funded investigators and staff involved with clinical trials, are likely to already be GCP trained. We know, too, that such training is currently required by some institutional policies, e.g., the University of Southern California and Johns Hopkins University. We recognize that some institutions may want to see their clinical trial investigators surpass the baseline GCP standard, and we would certainly applaud those institutions for promoting even higher standards.

NIH appreciates COGR's perspectives and your willingness to engage in discussion of your concerns. We hope these points and clarifications will be helpful. We also intend to issue a set of FAQs that we hope will be helpful in clarifying the intent of the policy for the community.

Sincerely,

Carrie Wolinetz, Ph.D.
Associate Director for Science Policy
National Institutes of Health

cc: Michael Lauer, M.D., Deputy Director for Extramural Research, NIH