PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

To: Principal Investigators, Investigators, and Department/Grant Administrators

From: Anne Klibanski, MD
Paul Anderson, MD, PhD
Harry Orf, PhD
Kerry Ressler, MD, PhD
Ross Zafonte, DO

Date: 12/21/16

Re: NIH GCP Training Requirement – Memo #2 – Update

We are writing in follow-up to inquiries we have received about the GCP training requirement and additional options available to meet the requirement. New information is highlighted in yellow.

If you are currently receiving NIH funding for clinical trials research or will be applying for NIH funding to support a clinical trial, you must complete training in Good Clinical Practice (Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials; NOT-OD-16-148.) Like the human subjects research training requirement, GCP training must be renewed every three years. The NIH set a compliance date of 12/31/16. Investigators and study staff subject to the NIH policy are expected to have completed training by the end of the year or, at a minimum, to have registered for training and maintain documentation of registration.

Please review the following FAQs to determine whether this policy applies to you and options available to comply with the requirement.

What research is covered by this policy?

NIH defines clinical trial as a study "in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control; need not be randomized) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." Please see the following examples to help you determine whether your research meets the NIH definition.

GCP Required

- Open label study of behavioral interventions for smoking cessation.
- Study of whether return of genetic results to patients influences healthcare costs and uptake of standard clinical interventions such as statin therapy.
- Study of yoga for depression.

- Study of vitamins for knee osteoarthritis with goal of improving symptoms of osteoarthritis and function.
- Study of iPhone exercise apps for weight loss.

GCP NOT Required

- Survey/questionnaire studies not intended to modify a health outcome.
- Observational studies involving only phlebotomy and data, with no intent to return results to subjects or influence health outcomes.
- Studies limited to the use of coded samples and data from the Partner's Biobank, or RPDR if no additional interactions with human subjects.

What if my study does not fit into any of the situations listed above? How do I determine whether the GCP education requirement applies to my study?

We recommend you consult your Program Officer. If your Program Officer determines the education requirement does not apply, we recommend you secure documentation of the decision.

Who must complete this training?

Everyone listed on the IRB protocol is required to complete GCP training.

What specific training will fulfill the requirement?

- Prior to 1/1/2017, any GCP course completed within the past 3 years with appropriate documentation of completion will fulfill the requirement.
    - Submit your documentation to the PHS CITI Mailbox at citiprogram@partners.org.

- As of 1/1/2017, only the following GCP training will fulfill the requirement:
    - In-person GCP training offered by Partners (MGH and BWH courses).
    - In-person GCP training offered by a professional association with documentation of training completion; or
    - On-line CITI GCP course https://www.citiprogram.org/.
        - CITI GCP login instructions https://partnershealthcare-public.sharepoint.com/ClinicalResearch/GCP%20Instructions.pdf
    - National Drug Abuse Clinical Trials Network (NIDA) on-line course https://gcp.nihtraining.com/
        - Upon completion submit your documentation to the PHS CITI Mailbox at citiprogram@partners.org.
    - NIAID GCP Learning Center on-line course https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx
        - This course requires personal registration through a Google or PayPal account.
        - Upon completion submit your documentation to the PHS CITI Mailbox at citiprogram@partners.org.

Does the CITI Basic Biomedical Research for Investigators and Key Personnel course accepted by the IRB for human subjects research training satisfy the NIH requirement for GCP training?

No. Additional GCP training is required.

After 1/1/17, will Investigators and Study Staff conducting NIH-supported clinical trials be required to complete both the CITI Basic Biomedical Research AND the CITI GCP training before engaging in human subjects research?

No. The CITI GCP education fulfills both requirements.

For a new investigator, who has not completed ANY human subjects training, what is the most efficient way to complete necessary training?

We recommend the CITI GCP course as best option which fulfills both requirements. The BASIC biomedical CITI course AND ONE OF THE NIH courses is another option.

What is the required timing of this training?

- Begin or complete the CITI GCP training or other acceptable on-line courses by 12/31/16
- Register for an in-person training by 12/31/16 and maintain documentation of registration in the event the NIH requests this information.
- CITI, NIDA or NIAID on-line courses or in-person GCP training must be completed no later than 7/1/17 for current NIH awards.

How will training be tracked?

GCP training will be tracked in the Insight Admin module training tab. This can then be used by both the IRB and Research Management to check compliance. Insight currently generates reminders when updated human subjects research training is required and will similarly generate reminders for GCP refresher course requirements.

Please note, completion of CITI training through BWH or MGH is automatically updated by IRB staff in Insight the next business day. If you elect to fulfill the requirement through another institution (e.g., DFCI) or by enrolling in an in-person class or the NIDA or NIAID on-line course, you must send your documentation to citiprogram@partners.org.

Do I have to report GCP training to the NIH?

The policy does not include an NIH reporting requirement; however, this does not preclude NIH from adding such a requirement in the future.

For new applications, Research Management Pre-Award will be verifying training completion as part of the Just-in-Time Process.

What training will be acceptable for the NIH every three year "refresher" requirement?

The CITI GCP Refresher course or in-person GCP course offered by Partners or other professional association with documentation of training completion.

If you have any questions, please send them to irb@partners.org