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

From: Anne Klibanski, MD   Date: 12/1/16
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Re: Required GCP training: New NIH policy

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 now comply with a
new NIH policy that requires 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 has 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.

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/.

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.

What is the required timing of this training?
- Begin or complete the CITI GCP training 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 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.

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

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