

REQUIRED MSM GOOD CLINICAL PRACTICE (GCP) TRAINING

Good Clinical Practice (GCP) is an international, ethical, and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Morehouse School of Medicine will require, **as of January 1, 2017**, GCP training for all new NIH funded studies for investigators, co-investigators and study personnel listed on a MSM IRB application and involved in research, defined as follows by the NIH: *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.* <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

All investigators, Co-Investigators and study personnel have until January 1, 2017 to come into compliance with this policy.

Accepted training to meet the GCP training requirement will include one of the following:

1. CITI Good Clinical Practice (GCP) for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) found at [citiprogram.org/Morehouse school of medicine](http://citiprogram.org/Morehouse%20school%20of%20medicine).
2. NIH Clinical Research Training online from the Office of Clinical Research Training and Medical Education (5 hours)
3. Industry sponsored GCP Training approved by TransCelerate

Please note that the CITI Human Subjects Protections course does not fulfill the GCP Training requirement.

Investigators, co-investigators and study personnel who have taken an accepted training program on or after January 1, 2014 should notify us of the previously received training by sending in a copy of your certificate to josmith@msm.edu. You should also select a MSM approved recertification option and complete it within 3 years of your most recent training. If training is completed through the NIH or another external institution, you must follow the same notification process to the IRB office.

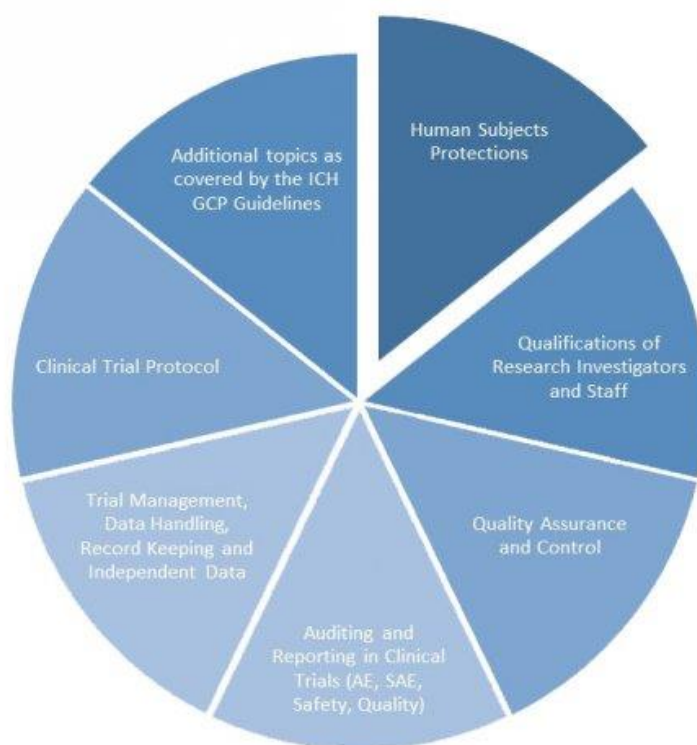
New investigators, co-investigators and study personnel (or those who have not had any GCP training since January 1, 2014) will be required to participate in one of the accepted training options by January 1, 2017.

GCP Training Facts

1. What is Good Clinical Practice?

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. While human subjects protections training requirements are one part of GCP, those training requirements do not meet the full spectrum of competencies GCP training requires.

Good Clinical Practice



2. Who does this new training requirement apply to?

Investigators, co-investigators and study personnel listed on the IRB application involved in research defined as follows by the NIH clinical trial definition:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

3. How often do I need to be trained?

You need to participate in an initial training and then be recertified every 3 years.

Individuals who have already taken the approved training do not need to participate in

the initial training but when their current training expires they should re-certify using one of the IRB approved options listed below.

Initial Training Date	Date for Initial Certification or Recertification	Training Available
Prior to January 1, 2014 or First Time Training	January 1, 2017	<i>Accepted Training</i> • CITI Good Clinical Practice (GCP) Course • NIH Clinical Research Training online from the Office of Clinical Research Training and Medical Education • Industry sponsored GCP Training approved by TransCelerate (please submit certificate to josmith@msm.edu to be added to your training profile)
January 1, 2014 and ongoing	Recertify every 3 years beginning on January 1, 2017.	<i>Accepted Training</i> • CITI Good Clinical Practice (GCP) Course • NIH Clinical Research Training online from the Office of Clinical Research Training and Medical Education • Industry sponsored GCP Training approved by TransCelerate (please submit certificate to josmith@msm.edu to be added to your training profile)

4. **Who should I contact if I have additional questions?** If you would like to speak with someone regarding any additional questions, please email pwinfield@msm.edu. **Please note that the IRB administrative office will be closed from Friday, December 22, 2016 – Monday, January 2, 2017.**