CMU
CENTRAL MICHIGAN UNIVERSITY

Office of
Research &
Graduate Studies

December 3, 2018

To Whom It May Concern:

As required by the National Institutes of Health (NIH), effective January 1, 2017, all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials will be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).

I certify that the enclosed **Central Michigan University Good Clinical Practice (GCP) Training Implementation Plan** is in place to meet the GCP training requirements for all NIH-funded investigators and clinical trial staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials.

Sincerely,

David E. Ash
Vice President for Research and Dean of Graduate Studies

Office of Research & Graduate Studies
Phone: 989-774-6777
Fax: 989-774-3439
orgs@cmich.edu
251 Foust Hall
Central Michigan University
Mount Pleasant, MI 48859

# Central Michigan University
# Good Clinical Practice Training Implementation Plan

This implementation plan is in response to NOT-OD-16-148, the NIH policy that establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials will be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH)E6(R2).

Any Central Michigan University (CMU) investigator and staff, as stated above, are required to follow the plan outlined below in ensuring GCP training requirements are met on all NIH-funded awards involving NIH-funded Clinical Trials.

***Federal Funding – non-NIH***

This implementation plan applies to all federal sponsors requiring GCP training. If the federal sponsor has additional requirements not listed within this plan, the Office of Research and Graduate Studies (ORGS) will work with the Principal Investigator (PI) to ensure the necessary GCP training requirements are fulfilled.

***PI Responsibility***

It is up to the PI to inform all investigators and staff involved in the conduct, oversight, or management of clinical trials of their GCP training requirement and to ensure that they complete it in a timely fashion and prior to engaging in funded clinical trial research. The training must be completed every three years.

***Training Mechanism***

CMU is an institutional member of the Collaborative Institutional Training Initiative* (CITI) and has worked with them to provide an online course, *Good Clinical Practice*, through their web site: https://www.citiprogram.org.

The PI or Co-PI must receive a score of at least 80% on the overall CITI *Good Clinical Practices* course in order to successfully complete this training requirement. If a PI or Co-PI receives an overall course score equal to or greater than 80%, but receives a score of less than 80% on an individual module, an email from ORGS will be sent to the PI or Co-PI. The email will notify the PI or Co-PI of the individual module(s) that was not successfully completed, and ask the PI to re-read the module and send a confirming email to ORGS that they have done so. If an email back to ORGS is not received **within one week** of notification, the associated grant account may be blocked.

A staff member, not including Principal Investigators (PI) and Co-PIs, must receive a score of at least 80% on the overall CITI *Good Clinical Practice* course, in order to successfully complete this training requirement. If a staff member, not including PIs and Co-PIs, receives an overall course score equal to or greater than 80%, but receives a score of less than 80% on an individual module, an email from ORGS will be sent to the PI. The email will notify the PI of the individual module(s) that was not successfully completed, and ask the PI to discuss the module's content either with the staff member to ensure a clear understanding or direct the individual to retake the related module.

Any individual that does not complete the course with an overall score equal to or greater than 80% will be required to retake the course succesfully prior to engaging in funded clinical trial research.

*Updated December 3, 2018*

**Please note that the CITI GCP modules are separate from the CITI course modules available for Human Subjects training, required for all personnel involved in human subject research. The GCP course may not be used to satisfy CMU's requirements for training in human subjects and vice versa.*

***Training Timeline***

The CITI *Good Clinical Practices* course must be completed every three years.

All investigators and staff involved in the conduct, oversight, or management of clinical trials must successfully complete the *Good Clinical Practices* course prior to engaging in funded clinical trial research.

If training is not completed in a timely manner, the associated grant account may be blocked.