



POLICY ON CONDUCTING RESEARCH STUDIES USING GOOD LABORATORY PRACTICES

Policy Number: 3.0.4

Classification: Compliance

Responsible University Office: Office of Research Compliance

Version Number: 001

Effective Date: July 1, 2018

1.0 Purpose

The purpose of this policy is to ensure that Clemson University has the necessary infrastructure to support any non-clinical laboratory studies that require Good Laboratory Practices.

2.0 Applicability

This policy applies to all faculty, staff and students at Clemson University.

3.0 Government Rules and Regulations

Sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

4.0 Definitions

Good Laboratory Practices - Standards for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products.

5.0 Policy

It is the policy of Clemson University that all investigators intending to conduct nonclinical laboratory studies as defined in Section 4.0 must first seek and receive the approval of the Vice President for Research prior to beginning the research study.

6.0 Responsibilities

It is the responsibility of the investigator of the proposed study to submit a request to the Vice President for Research for permission to conduct the study, prior to beginning any research activities.

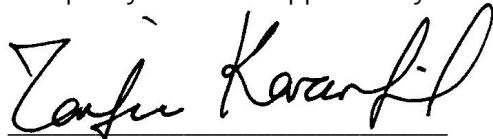
It is the responsibility of the investigator to contact the Office of Research Compliance for guidance in understanding the specific requirements of Good Laboratory Practices.

7.0 Sanctions for Non-Compliance

Non-clinical laboratory studies requiring the use of Good Laboratory Practices that have commenced without the approval of the Vice President for Research will be terminated immediately.

8.0 Approval Signatures

This policy has been approved by:



Tanju Karanfil
Vice President for Research

July 1, 2018
Date

REVISION HISTORY		
EFFECTIVE DATE	REVISION NUMBER	MODIFICATION
January 1, 2014		
July 1, 2018	1	New policy format and classification