TITLE: Training of Comparative Medicine Staff for Contribution to GLP Studies

SCOPE: All Authorized Personnel

RESPONSIBILITY: Comparative Medicine GLP Study Personnel

PURPOSE: To Outline the Training Requirements of Comparative Medicine Staff Prior to Participation in Studies Conducted in Accordance with 21 CFR 58 Good Laboratory Practices

I. PURPOSE

1. To outline the training, education, and experience required of Comparative Medicine Staff participating in studies conducted at a GLP testing facility following Good Laboratory Practices (GLP), as delineated in Title 21 Code of Federal Regulations Part 58 Good Laboratory Practice for Non-Clinical Laboratory Studies (21 CFR 58).

II. RESPONSIBILITY

1. All staff that intend to contribute to the conduct of a GLP Study Protocol at a GLP Testing Facility (e.g., Center for Advanced Medical Learning & Simulation, CAMLS) must receive formal training regarding the unique requirements of studies conducted in accordance with 21 CFR 58 and must become certified as to the adequacy of their education, training, and experience to perform their assigned functions.

III. PROCEDURES

1. Prior to contributing to a GLP Study, staff must review and become familiar with 21 CFR 58.

2. Staff receive formal training regarding the requirements of 21 CFR 58, and the policies, practices, and procedures which govern the conduct of GLP study protocols within the GLP Testing Facility (e.g., CAMLS).

3. Staff are taught that these regulations govern the conduct of non-clinical laboratory studies that are intended to support applications for permits to the Food and Drug Administration (FDA).

4. Staff review definitions in 21 CFR 58 Subpart A, 58.3, including the meanings of the terms “act, test article, control article, nonclinical laboratory study, application for research or marketing permit, sponsor, testing facility, person, test system, specimen, raw data, quality assurance unit, study director, batch, study initiation date, and study completion date.”
5. Staff certify that they clearly understand the functions they are to perform, and have sufficient education, training, and experience to perform their assigned functions.

6. Staff are reminded that they are to wear clothing appropriate for the duties they perform, must take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems, and will report to their immediate supervisor any personal health or medical condition that may adversely affect the study and will exclude themselves from the study until the condition is corrected.

7. Staff are informed of who is the Director of the GLP Testing Facility (e.g., CAMLS CEO) and that the Director designates a Study Director for each GLP study and replaces the Study Director during the conduct of a study whenever necessary.

8. **Staff are taught that the Study Director has overall responsibility for the technical conduct of the study, represents the single point of study control**, and, as such, assures that the approved GLP study protocol is represented by a matching IACUC-approved protocol, that the protocol is followed, that all experimental data (including observations of unanticipated responses) are recorded, that any unforeseen circumstance that may affect the quality or integrity of the study is noted and corrective action is taken and documented, that all applicable regulations are followed, and that all data, documentation, protocols, specimens, and reports are archived with the GLP Testing Facility (e.g., CAMLS).

9. Staff are instructed that a separate and independent Quality Assurance Unit (QAU) monitors the GLP Testing Facility and its equipment, personnel, methods, practices, records, and controls so that they are in conformance with 21 CFR 58.

10. Staff are informed that the QAU monitors and inspects each study at intervals adequate to assure the integrity of the study.

11. Staff are reminded that documented actions are required to correct any deviation from 21 CFR 58 reported by the QAU to the Study Director.

12. Staff are taught that all equipment used in the generation, measurement, or assessment of data must be adequately tested, calibrated, or standardized and that all such calibrations, failures, or malfunctions with equipment, and the remedial actions taken to correct equipment defects, must be reported in writing to the Study Director and the GLP Testing Facility Management.

13. Staff are expected to have reviewed all relevant GLP Testing Facility SOPs, all relevant laboratory SOPs and manuals that describe standard methods for conducting the laboratory tests that have been assigned to them, and all animal care SOPs relevant to the test system(s) that they will assist regarding animal care, as part of their assigned duties.

14. Staff are reminded that all reagents and solutions in the laboratory must be labeled to indicate identity, titer or concentration, storage requirements, and expiration date.
15. Staff must know that the identity, strength, purity, stability, composition, and other characteristics that define the test or control article must be determined for each batch and documented in writing. A reserve sample must be retained.

16. Staff understand that any changes in or revisions of an approved protocol must be signed and dated by the Study Director, approved by the sponsor, the Director of the GLP Testing Facility (e.g., CAMLS CEO) and, when applicable, the IACUC. All changes in, or revisions of, an approved protocol and the reasons therefor shall be documented and must be maintained with the study protocol.

17. Staff understand that a GLP study must be conducted in accordance with the protocol, the GLP Testing Facility SOPs, Comparative Medicine SOPs, 21 CFR 58, and IACUC Principles & Procedures and will report any noncompliance to the Study Director and, when applicable, to the IACUC.

18. Staff are taught that all specimens collected during the study must be identified as to the test system, study, nature, and date of collection.

19. Staff are reminded that all data generated during the conduct of the study must be recorded directly, promptly, and legibly in ink, initialed by the person entering the data, and dated on the date of entry.

20. Staff are instructed that any change in data entries must be made so as not to obscure the original entry, must indicate the reason for the change, and must be dated and signed at the time of the change.

21. Staff understand that all raw data, documentation, protocols, final reports, and specimens generated as a result of a study must be retained and archived with the GLP Testing Facility (e.g., CAMLS).

22. Staff are expected to report all relevant education, training, and experience that has prepared them to perform their assigned functions.

23. Staff provide the GLP Testing Facility with a copy of their curriculum vitae or current job/position description.

24. Comparative Medicine staff contributing to GLP studies receive this training annually.

25. Training of staff is documented in CMDC #028 entitled “GLP Certification of Comparative Medicine Personnel” and the original provided to testing facility management.

26. Any additional required training will be provided by the GLP Testing Facility.

Approved:       Date: