APPLICATION FOR GOOD LABORATORY PRACTICE
FOR NON-CLINICAL LABORATORY STUDIES

Please complete this form if you are conducting a non-clinical laboratory study intended to be submitted to, or reviewed by, the Food and Drug Administration.

Title of the Study: ________________________________

Sponsor: ________________________________________

Principal Investigator: ___________________________ Title: ________________________________
Last   First   MI

Department: ___________________________ Phone: ____________ Fax: ____________
E-Mail: ______________________________________

Please complete this section if the PI is not the Study Director

Study Director: ___________________________ Title: ________________________________
Last   First   MI

Department: ___________________________ Phone: ____________ Fax: ____________
E-Mail: ______________________________________

Co-PI/ Contact: ___________________________ Title: ________________________________
Last   First   MI

Department: ___________________________ Phone: ____________ Fax: ____________
E-Mail: ______________________________________

This Study is for (Please check one):

☐ New drug application
☐ New animal drug application
☐ Research or marketing permit
☐ Notice of claimed exemption for a new animal drug
☐ Notice of claimed investigational exemption for a new drug
☐ A biological product license
☐ An investigational device exemption
☐ Permit approval of a medical device
☐ Product development protocol for a medical device

Is this study an

☐ In-Vitro
☐ In-Vivo

CAR Approval Number: ________________________________

Attach a copy of the approved protocol including all correspondence with the CAR regarding the application.
PERSONNEL

List all personnel involved in the study (include the PI, Co-PI and the Study Director. You may attach a copy of the CAR application personnel page, indicating training and GLP experience for each participant

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<th>Years (GLP experience)</th>
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QUALITY ASSURANCE PROGRAM

Describe your QA program in detail including the person responsible for your QA Unit.

FACILITIES

a) Animal housing

Bldg.       Room       Species

b) Test and control article handling (identify where test and control articles will be received or stored)

Bldg.       Room       Species       Purpose

c) Laboratory operation area (identify separate laboratory space for performance of the routine specialized procedure under this study)

Bldg.       Room       Species       Purpose

d) Specimen and data storage facilities (identify the location of archives for the storage and retrieval of raw data and specimens)

Bldg.       Room       Species       Purpose
EQUIPMENT

Do you have detailed written Standard Operating Procedures (SOP) describing methods and schedules for (check all that apply)

☐ Routine inspection, testing and calibration and/or standardization of equipment
☐ Remedial Action to be taken in the event of failure or malfunction of equipment
☐ Record keeping for function listed above
☐ Cleaning of equipment
☐ A designated person responsible for performance of each function
☐ Documentation of the training for responsible person(s)

FACILITY OPERATION

Do you have written Standard Operating Procedures (SOP) for (check all that apply):

☐ Animal room preparation
☐ Animal Care
☐ Laboratory tests
☐ Test system (animal, plant or microorganism) observation
☐ Collection and identification of specimen
☐ Histopathology
☐ Data handling, storage and archiving
☐ Transfer, proper placement and identification of animals
☐ Handling of animals found moribund or dead during the study
☐ Removal from the study of deteriorated, outdated or expired reagents and solutions
☐ Necropsy of animals or postmortem examination of animals
☐ Labeling of reagent and solutions in the laboratory area to indicate identity, titer or concentration, storage requirements and expiration date

Notes
1. All deviations from SOP must be authorized by the Study Director and must be documented in the raw data
2. Significant changes from established SOP must be approved in writing by management (e.g. Study Director, CAR, LARC Director as appropriate)
3. A historical file of SOP and all revisions, including dates of revisions must be maintained

ANIMAL CARE

☐ I will follow LARC SOP regarding animal care (contact LARC Director for details)
☐ I have attached equivalent SOP for review
CERTIFICATION

I hereby certify that the information submitted in this application is accurate and the study will be in accordance with the approved protocol.

Principal Investigator: ____________________________
Signature: ____________________________ Date: ________________

OR USE ONLY

Attending Veterinarian: ____________________________ Review Date: ________________
Comments: ______________________________________
Approval Date: ________________ Signature: ____________________________
AWAP Review: ____________________________ Review Date: ________________
Comments: ______________________________________
Approval Date: ________________ Signature: ____________________________
PI/Study Director Concurrence: ____________________________