UCSF

University of California, San Francisco
Office of Research

# 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***

| Last | First | Title | Phone | e-mail | Years (GLP experience) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

## QUALITY ASSURANCE PROGRAM

**Describe your QA program in detail including the person responsible for you 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**
- ☐ **Receipt, identification, storage, handling and sampling method of test and control articles**
- ☐ **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**
- ☐ **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**

***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:** _____