

GOOD LABORATORY PRACTICE FOR NON-CLINICAL LABORATORY STUDIES

The United States Food and Drug Administration (FDA) regulates all Good Laboratory Practices (GLP) under Code of Federal Regulations (CFR) 21. The FDA regulations specify a set of specific procedures that must be followed if the data generated during the study are to be acceptable by the FDA.

The following document is designed to provide the Investigators with guidance on how to meet the requirements of the regulations.

Roles and Responsibilities

The Associate Vice Chancellor, Research (AVC-R), in the **Office of Research**: has been delegated overall responsibility for compliance with the requirements of the GLP and has appointed specific individuals to be responsible for elements of the program.

Within the Office of Research:

- **Attending Veterinarian**: has been delegated responsibility for review and approval of GLP studies involving the use of animals.
- **Director of Animal Welfare Assurance Program (AWAP)**: has been delegated responsibility for oversight and approval of the overall Quality Assurance Program.

Principal Investigator: has the overall responsibility for the conduct of the study in accordance with the applicable regulatory and UCSF Policy requirements. These include:

- Submitting an Application, and obtaining an approval, for GLP to the Office of Research, prior to starting the study
- Notification to the Office of Research of any changes in the approved study, prior to their implementation
- Obtaining an approval form the Committee for Animal Research (CAR), if animals are used in the GLP study
- Providing adequate resources for the conduct of the study
- Review and Approval of Standard Operating Procedures (SOP) applicable to the study
- Review and Approval of all changes from established SOP

Study Director (if different from the Principal Investigator): responsible for conducting the study, in accordance with the provisions of the GLP study, approved by the Principal Investigator

Individual Users: responsible for complying with the provisions of approved study protocols, SOPs and other regulatory requirements.

Approval Procedure

In order to obtain approval for conducting a GLP study, the Principal Investigator must submit an Application for Good Laboratory Practice for Non-Clinical Laboratory Studies to:

**Office of Research
GLP Section
Box 0962 * New Box #**

Upon receipt of the Application:

- The completed Application will be reviewed by the appropriate personnel within AVC-R and may be followed by site visits to review specific SOPs, equipment and facilities described in the Application.
- After the review has been completed, a meeting will be set with the reviewers, the PI, and the study Director to assess the findings.
- After the completion of the meeting, and resolution of any outstanding issues, a signed copy of the approved Application will be returned to the PI.
- The Approved protocol will include details of additional, specific conditions which may have been agreed upon during the review process.

Periodic Inspections

The Office of Research will conduct periodic inspections of all approved studies to verify that they are in compliance with the provisions of the approved protocol. The inspections will include site visits, review of the records and procedures, adequacy of personnel training, and other pertinent elements of the study as appropriate.

Quality Assurance Program

UCSF does not have a central Quality Assurance (QA) unit. Therefore, each Principal Investigator must appoint an individual to be responsible for the overall QA elements of the study. This individual may be given responsibility for multiple studies.

As indicated above, the Director of AWAP will be responsible for oversight and coordination of the QA programs identified in each study proposal.