TITLE: Handling, Storage, and Retrieval of Records and Data

SCOPE: All Animal Program Personnel

RESPONSIBILITY: Directors, Facility Managers, Veterinarians, All Animal Program Personnel

PURPOSE: To Outline the Proper Practices Which Govern Record and Data Handling, Storage, and Retrieval

I. PURPOSE

1. The following procedures are followed to ensure the identity, integrity, and expedient retrieval of all materials that document program activities, and those used to record observations, data, and summaries made regarding the animal care provisions of studies conducted by a GLP Testing Facility (e.g., Center for Advanced Medical Learning & Simulation, CAMLS) in accordance with 21 CFR Part 58-Good Laboratory Practices for Nonclinical Studies (GLP) (e.g., subpart C, 58.41-45, and subpart E, 58.81b, items 1, 2, 6, and 12), or academic research investigations.

2. These materials may include, but are not limited to, animal medical records for regulated species, IACUC semi-annual inspection reports, USDA inspection reports, USDA annual reports, USDA registrations, OPRR/PHS assurance, AAALAC program description, AAALAC findings and communications, DEA records, GLP study animal care-related materials/data, quality records, such as room status sheets, health and environmental concern forms, autoclave, cage wash and refrigerator monitoring logs, and instrument and equipment calibration records.

II. RESPONSIBILITY

1. All program staff contributes to the proper handling, storage and retention of all materials, reports, data, and findings associated with program-wide issues, and the animal care provisions of a GLP study protocol performed at a GLP Testing Facility (e.g., CAMLS).

2. The Assistant Director is ultimately responsible for and manages the archive files. The Director, Assistant Director, and archivist are authorized access to the archives.

III. PROCEDURES

General Procedures

1. Facility Managers are responsible for retaining the following records from the facility they manage for a period of 6 months:
   a. Animal Health and Environmental Concern Sheets (CMDC #077)
   b. Cagewash Temperature Monitoring Sheets (CMDC #081)
   c. Refrigerator/Freezer Temperature Monitoring Sheets (CMDC #020)
   d. Food & Bedding Room Temperature Sheets (CMDC #082)
   e. Autoclave Monitoring Records (CMDC #121)
   f. Rodent Medical Records for non-regulated species (CMDC #139)
   g. Pest Control Records
h. Rooms Status Sheets (e.g., CMDC #041)  
i. Sanitation Efficacy Logs (e.g., AccuPoint®)  
j. Bioquell HPV Decontamination Records  
k. Enrichment Records (CMDCs #177, #189, #190, #191)  
l. Progress Notes (for non-regulated species CMDC #013)  
m. Veterinary Clinical Notes (CMDC #057)  
n. Animal Concern Forms (CMDC #155)  
o. Thermometer/Hygrometer Calibration Record (CMDC #023)

2. Facility managers are responsible for submitting Sanitation Efficacy Logs (i.e. novaLum) quarterly and Bioquell HPV Decontamination Records monthly following decontamination procedures to the Microbiological Monitoring Program Manager. The MMPM maintains a copy of these records electronically for a period of 3 years.

3. **Facility Managers are responsible for maintaining records of division-owned equipment** inspections, calibrations, maintenance, and current inventory for their facility on the **Equipment Maintenance Log** (CMDC #192). The manager maintains the original records of these procedures and forwards copies to the Assistant Director as completed. These original records are maintained until the next calibration cycle is completed. Original equipment records relevant to a study conducted in accordance to 21 CFR 58 are provided to the GLP testing facility management at the time of recalibration/recertification and the facility manager will maintain an exact copy until the next calibration cycle is completed.

4. **The Assistant Director is responsible for maintaining the division’s Equipment Maintenance Log** (CMDC #192) for all facilities. This log summarizes records of division-owned equipment inspections, calibrations, maintenance, and current inventory for all facilities. An updated **Equipment Maintenance Log** is provided to Facility Managers at least quarterly to be updated and returned to the Assistant Director. Copies of records that have been provided by the managers are maintained by the Assistant Director until the next calibration cycle has been completed.

5. **The Assistant Director is responsible** for maintaining the following records/reports for the time indicated.
   a. USDA annual reports – 3 years  
   b. USDA registration – 3 years  
   c. OLAW/PHS assurance – 3 years  
   d. AAALAC program description – renewed every 3 years  
   e. AAALAC findings and communications – 3 years from date of resolution.

6. The **Veterinary Clinical Notes** (CMDC #057) and veterinary **Animal Health Concerns Forms** (CMDC #155) are maintained by the veterinary staff and retained for a period of at least 6 months by the Facility Manager.

7. **The Assistant Director is responsible for maintaining DEA records** to include inventory and other records required by 21 CFR Parts 1300-1399 to be kept by the registrant and be available, **for at least 2 years** from the date of such inventory or records, for inspection and copying by authorized employees of the DEA.

8. **Research Integrity & Compliance is responsible for maintaining all records relating to IACUC** applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC, IACUC meeting minutes and records of deliberation are held for **3 years after the completion of the activity**.
9. Records of unsuccessful **compatibility testing** for an individually housed social animal (i.e., a compatible cagemate cannot be found) are maintained in the housing **Room Log Book**. Compatibility records may be disposed of after the final disposition of the animal.

10. Facility Managers are responsible for maintaining the **animal medical records and per diem sheets** for all regulated species at their respective facilities until the final disposition of the animal (e.g., deceased, adopted, or relocated).

11. Animal Medical Records are maintained as required by the **Animal Welfare Regulations, Part 2, Subpart C, Section 2.35b**—for three (3) years from completion of the study (i.e., IACUC protocol closure)

**Archival of Animal Medical Records and Per Diems**

1. **Animal medical records are maintained and archived by federal year on the private shared drive** (P) in a Portable Document Format (PDF).

2. At the end of each month and prior to the 15th of the subsequent month, the facility manager ensures the records are complete and then scans the documents to their respective individual management area folder in the “KonicaMinoltaShared” folder in private shared drive (P).

3. Upon completing the document scan, the Facility Manager reviews the scanned files to ensure they are complete, legible, and properly oriented, and when confirmed, names the scanned document.
   a. Scanned animal medical records for nonrodent USDA species are identified with the animal’s unique intramural USF identification number (assigned upon arrival and described in **SOP #015 Animal Identification**).
   b. Scanned animal medical records for USDA rodent species are identified with either the animal’s unique intramural USF identification number or may be identified and maintained as batch records.
   c. Paper copies of scanned documents are maintained in the College of Medicine (COM) administrative office MDC 1034.

4. Beginning on the 15th and prior to the 30th of the subsequent month, clinical veterinarians will compare the scanned documents with paper copies, and when deemed accurate, move the electronic PDF copies into a **Medical Record** sub-folder in the appropriate species folder within the current federal year folder. At this time the paper copies of the scanned documents are transferred to MDC 1047.

5. For annual reporting purposes of regulated species, the facility manager will scan the completed September Per Diem sheets into the federal fiscal year folder within the “KonicaMinoltaShared” folder annually, prior to the end of October.

6. The Fiscal & Business Specialist maintains the **Animal Identification Log** for regulated species and scans this completed document into each regulated species folder within the federal fiscal year folder annually, prior to the end of October.

7. Beginning the 1st and prior to the 15th of November each year, the Assistant Directors will ensure the federal year folder is complete.

8. The complete federal year folder is copied to disc and all paper copies are disposed of.
Animal Care Records for Studies Conducted in Accordance with 21 CFR Part 58

1. All GLP-related materials, including the master schedule sheet, protocols, specimens, records of quality assurance inspections, raw data, data summaries, room and equipment monitoring records, interim and final reports, summaries of training and experience and job descriptions, records and reports of the maintenance and calibration and inspection of equipment must be archived by the GLP Testing Facility (e.g., Center for Advanced Medical Learning & Simulation, CAMLS) upon completion of the study for the following period of time, whichever is shortest:
   a. When the data supports a permit application to the Food and Drug Administration (FDA), records are archived for at least two years following the date on which the application for a research or marketing permit is approved by the FDA.
   b. When data supports investigational new drug (IND) applications, or investigational device exemption (IDE) applications to the FDA, records are archived for at least five years following the application date on which the results of the study are used in an application submitted to the FDA.
   c. In other situations (e.g. where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), all quality records are maintained for a period of at least two years following the date on which the study is completed, terminated, or discontinued.
   d. All finalized records of a specific GLP study must be stored as a unit and filed by the GLP Testing Facility. These files must be indexed by the GLP Testing Facility to facilitate retrieval, and shall include a list of all personnel responsible for study records.

2. Animal medical records for the test systems used in studies conducted in accordance with 21 CFR 58 are maintained as described below:
   a. Following the final disposition of the animal, the facility manager, or designee, makes exact copies of the animal's medical record (e.g., Arrival Status, surgical/procedural records, Progress Notes, necropsy report, etc.)
   b. The original animal medical records are delivered to the Study Director.
   c. The exact copies are annotated that they are an exact copy and are signed and dated by the facility manager, or designee.
   d. The exact copies are then archived as described above in the section of this procedure entitled “Archival of Animal Medical Records and Per Diems”

3. The Assistant Director for Training is responsible for maintaining a summary of equipment calibration/certification on the Equipment Maintenance Log (CMDC #192) for the animal care program. The animal facility manager will submit the original records of equipment associated with the conduct of the animal care provisions of a GLP study to the GLP Testing Facility for archiving as equipment is re-calibrated/recertified.

4. All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry (i.e., no write-overs, scratch-outs, or use of white-out). Changes in data entries shall be made using by a single line through the wrong entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.
5. Original records/data collected by Comparative Medicine and relevant to studies conducted in accordance with 21 CFR 58 are maintained as described below:
   a. The facility manager, or designee, makes exact copies of the records (e.g., Room Status Sheets, sanitation efficacy logs, autoclave monitoring logs, etc.)
   b. The original animal medical records are delivered to the Study Director.
   c. The exact copies are annotated that they are an exact copy and are signed and dated by the facility manager, or designee.
   d. The exact copies are then retained by the animal facility manager as described above in Section III Item 1 of this SOP.

6. All GLP original documents/materials must be retained in archives by the GLP Testing Facility in an orderly manner so as to facilitate expedient retrieval and to minimize deterioration. Materials checked out of the archives for review are recorded on the Master Log of Archived Materials and must include the name of the individual requesting the materials, initials of the individual removing the materials from the archives, the date materials are checked out and the initials and date when the materials are returned to the archive.

7. Only authorized personnel are permitted access to the GLP archives in each GLP Testing Facility.

8. The Director of the GLP Testing Facility (e.g., CAMLS CEO) is responsible for naming an individual who is responsible for the GLP archives.

9. Specimens and articles must be retained only as long as the quality of the preparation affords evaluation.