



STANDARD OPERATING PROCEDURE 810 MAINTAINING CLINICAL RECORDS

1. PURPOSE

This Standard Operating Procedure (SOP) describes procedures for maintaining clinical records for animal research models.

2. RESPONSIBILITY

Principal investigator (PI) and their research staff.

3. INTRODUCTION

- 3.1. Maintaining good clinical records is essential for providing adequate veterinary care to animal research models. The value of implementing a good documentation system is described below:
- 3.1.1. Maintains ongoing communication between all personnel managing the research, the primary care, and the health of research models.
 - 3.1.2. Assists the animal care staff in providing appropriate care relevant to the specifics of the research project.
 - 3.1.3. Supplies investigators with relevant information they can refer to when interpreting research data.
 - 3.1.4. Allow an easy method for tracking clinical history and accountability.
 - 3.1.5. Provides legal documentation of significant events related to the research study.
 - 3.1.6. Provides a tool to the institution for preparing the reports for Israel Council on Animal Experimentation inspections.
 - 3.1.7. This is a regulatory requirement.
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4. GUIDELINES

- 4.1. Maintain individual records for all animal species (i.e., rodents, fish, amphibians, rabbits, poultry, reptiles, and small ruminants).
- 4.2. Maintain group records for all birds, fish, amphibians, reptiles, and rodents.
- 4.3. For all birds, fish, amphibians, reptiles, and rodents, also use an individual record if an extensive procedure is conducted on an individual or if the research dictates a need.
- 4.4. Place the records in an area that is readily accessible to the research personnel and veterinary care staff.
- 4.5. Structure the record system, so the information is easily collected, gathered, analyzed, summarized, and available to the PI, veterinary care staff, and the BGU Animal Care Committee.

- 4.6. Avoid general terminology and acronyms. Enter only concise information, utilizing data to back up animal condition assessments.
- 4.7. Provide all relevant records whenever animals are transferred between institutions or sites within the same institution.
- 4.8. Write the date, time (if pertinent), initials of the person who documented the event, and contact information on all record entries. Write in ink only (no pencil).
- 4.9. Include all basic animal information on all animal records:
 - 4.9.1. Species
 - 4.9.2. Individual identification number or batch number
 - 4.9.3. Sex
 - 4.9.4. Date of birth or acquisition date
 - 4.9.5. Source
 - 4.9.6. Sire and dam identification when relevant
- 4.10. Record all significant clinical events on the clinical record:
 - 4.10.1. Clinical histories, including a history of surgical procedures and post-operative care.
 - 4.10.2. Any significant environmental changes include facility transfers, room-to-room transfers, and changes in caging or bedding used.
 - 4.10.3. Preventative medicine measures were taken, including dates of vaccinations, deworming, and parasite and sentinel screening.
 - 4.10.4. Details of experimental use or events that may cause pain, distress, or discomfort
 - 4.10.5. All drugs/test substances administered, including medication names, dosages, routes and volumes of administration, name of personnel that administered medication, and withdrawal times for any agents administered to livestock animals
 - 4.10.6. Blood collection volumes and sites.
 - 4.10.7. Observations of abnormal behavior or physical problems.
 - 4.10.8. Physical exams and veterinary checks, clinical signs, diagnoses, laboratory results, prognosis, treatments, and resolution of events.
 - 4.10.9. Follow up on the improvement or deterioration of the animal's condition and related treatments and interventions.
 - 4.10.10. Record of euthanasia, including the method and agent used.
 - 4.10.11. Necropsy observations and pathology results.
- 4.11. In addition to essential clinical records, specific records should be maintained for the following:
 - 4.11.1. Anesthesia monitoring
 - 4.11.2. Transgenic phenotype logs
 - 4.11.3. Breeding records
 - 4.11.4. Mortality logs
 - 4.11.5. Treatment logs

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Approved by the BGU Animal Policy and Welfare Oversight Committee