

Document Number: ANP010	<b>DOCUMENTATION OF OBSERVATIONS AND ACTIVITIES</b>  <u><b>CONFIDENTIAL INFORMATION</b></u> <b>MOLECULAR MEDICINE RESEARCH INSTITUTE</b>	Effective Date: JANUARY 2005
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## 1.0 OBJECTIVE

- 1.1 The objective of this procedure is to describe the procedures for documenting observations and activities considered to be raw data, and the proper correction of raw data errors by Animal Research and Animal Care personnel.

## 2.0 SCOPE

- 2.1 This procedure applies to raw data generated in the Animal Care facility at MMRI.

## 3.0 POLICY

- 3.1 It is the policy of MMRI to establish written and approved procedures to ensure raw data is properly recorded.

## 4.0 RESPONSIBILITIES

- 4.1 It is the responsibility of Manager of Animal Research or designated alternate to implement this procedure and revise it when necessary.

## 5.0 PROCEDURE

### 5.1 Definitions

- 5.1.1 Raw Data: Any record, laboratory worksheets, memoranda, notes or exact copies thereof that are the result of original observations or activities that could be necessary for the accurate reconstruction and evaluation of a study. Examples are as follows:

Clinical Observations  
 Daily Body Weights  
 Animal Cage Cards  
 Animal Room Comment Sheet  
 Animal Room Maintenance Log  
 Individual Animal Records  
 Purchase Orders for Animals  
 Animal Diet Records  
 Pesticide Application Records  
 Surgery Records

- 5.1.2 Protocols for studies may specify additional records to be kept.

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- 5.2 Record data on appropriate documents. Record date and time (if appropriate), sign (or initial) using a black water-proof ink pen.
  - 5.2.1 Where data has been recorded directly by computer, a printout of the final saved version of the data should be made immediately following the observations. The printout should be checked, initialed and dated.
  - 5.2.2 If the observation or activity was recorded by someone other than the person who performed the activity or made the observation, the performer/observer must verify, sign (initial) and date the record as soon as practical after its completion.
- 5.3 Correct data by making one line through the incorrect data, write in the correct data next to the incorrect data or footnote the correct data. Indicate a reason for the correction, initial and date the correction using a black water-proof ink pen.
- 5.4 Incorrect data must not be made illegible and correction fluid may not be used.
- 5.5 Data sheets should be filed and stored in Animal Research Study binders or Animal Care Facility Records as appropriate.