1.0   OBJECTIVE

   1.1   This document describes the procedures used for submitting, documenting, and
          archiving histopathology samples, tissues, slides tissue blocks and reports.

2.0   SCOPE

   2.1   This procedure applies to all samples generated and processed, or sent out by MMRI for
          histopathological evaluation.

3.0   POLICY

   3.1   It is the policy of MMRI to establish written and approved procedures to ensure that there
          is no bias in selection of animals for study procedures.

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   REFERENCES

   5.1   SOP# ANP017, Necropsy Procedures.

6.0   PROCEDURE

   6.1   Histopathology submission form.

      6.1.1   Completely fill out the histopathology submission form (Appendix I).

      6.1.2   Make two copies of the completed form. File one in the Histopathology Archive
               binder, and one in the study binder. The original will accompany the samples if
               samples are sent out.

   6.2   Samples Analyzed by MMRI

      6.2.1   Fix the samples in 10% formalin. Individual samples are placed in 50 mL or 15
               mL plastic tubes.

      6.2.2   Label each contained with the following: Fixation date, MMRI, study number,
               and type of sample.

6.3   Samples Analyzed by External Histopathology Lab.

6.3.1   Fix the samples in 10% formalin. Individual samples are placed in 50 mL or 15 mL plastic tubes.

6.3.2   Label each contained with the following: Fixation date, MMRI, study number, and type of sample.

6.3.3   Print out several Slide Box and Tissue Box labels. Print out a sample Received card. Fill in the study number, sample type, and sample number on the card. Place the card, the labels and the submission sheet (include a cover letter if necessary) in an envelope.

6.3.4   Pack the samples in an appropriate box, labeled for overnight shipping. Place a hazardous materials label on the box. Put all the sample jars in sealed plastic bags and pack them in the box with packing material.

6.3.5   Place the envelope containing the submission form on the top of the packed samples. Seal the box. Place a currently completed shipping label on box. Send to lab via overnight mail service.

6.4   Returned blocks and Slides

6.4.1   Unpack the slides and tissue blocks. File them by study and in numerical order, by sample, then by tissue number, in the slide and tissue block storage unit

6.4.2   Fill in the date blocks and slides are returned, on the histopathology submission form in <u>BOTH</u> the study binder and the Histopathology Archive. Make a note of the histopathology reference number on the submission form.

6.5   Documentation

6.5.1   Enter the study title and number on the list of studies submitted for histopathology

6.5.2   For samples sent to external histopathology labs make certain that two copies of the submission form are filed. One in the Histo-Archive binder, and one in the study binder. Maintain an electronic copy of the submission form in the study folder on the network.

6.5.3   When tissues are returned, enter the date returned and the histopathology lab's reference number on both copies of the submission form.

6.5.4   File the histopathology report in the histopathology archive binder and place a copy in the study binder.

6.5.5   Fill in the date of the report on the list of studies submitted for histopathology.

MMRI STUDY NO. PROJECT: PRINCIPAL INVESTIGATOR/CONTACT:	
PURPOSE OF STUDY:	
ANIMAL SPECIES	
DATE TISSUE FIXED	

Document Number: ANP036	Title: **HISTOPATHOLOGY ARCHIVES**	Effective Date: JANUARY 2005
Section: Animal Research		Supersedes Date: N/A

Subsection:
   Documentation
	CONFIDENTIAL INFORMATION
	MOLECULAR MEDICINE RESEARCH INSTITUTE
		Page:
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Number of containers		
Seq. Of numbered containers		
Total number of tissues		
TISSUES OR SAMPLES OF INTEREST		
Method of Fixation		
Required number of slides/tissue:		
Required no. of sections per slide:		
Sectioning instructions		
Special instructions		
Staining required (per tissue):	[ ] H&E	
	[ ] Unstained	
	[ ] Other stains	
	Specify:	
Name of Histopathologist: (for non-MMRI processing): Address: Phone no. Contact person:		
Date tissues to be processed (or sent to lab): Date tissues returned: Path. Lab reference no:		
MMRI:storage cross-reference: Tissue: Slides:		

MMRI HISTOPATHOLOGY TRANSMITTAL SHEET

Sample Type Submitted: ☐ Wet tissue cassettes ☐ Paraffin blocks

Number of Samples Submitted: _____

Study Number: _____ Study Director: _____

Comments: _____

_____

_____

Instructions: The laboratory submitting wet tissues or blocks to the Histopathology Lab will fill-in "Sample Number" and "Number of Samples Submitted" on the attached inventory sheet. Sample verification will be performed by the Histopathology Laboratory as follows:

Wet Tissue Cassettes – During embedding, the Histopathology Lab will verify the number of tissue cassettes on the inventory sheet and sign below when verification has been completed.
Paraffin Blocks - Upon receipt, the Histopathology Lab will verify the number of blocks on the inventory sheet and sign below when the verification has been completed.

When the blocks/slides are returned to the submitting laboratory, Histopathology Lab will fill-in "Number of Blocks Returned", "Number of Slides Returned", and "Final Histopathology Lab inventory by" and return the transmittal sheet and attached inventory with blocks and slides to the submitting laboratory.

Sample Inventory

Sample Number	Number of Samples Submitted	Verification (X)	Number of Blocks Returned	Number of Slides Returned

Samples Submitted by: _____ Date: _____

Samples Received by: _____ Date: _____

Samples Verified by: _____ Date: _____

Final Histopathology Lab Inventory by: _____ Date: _____

Comments from Histopathology Laboratory: _____

_____

_____

MMRI
INDIVIDUAL ANIMAL HISTOLOGY RECORD

STUDY NUMBER: XXXXXXXX

Species: Rat

Animal (Sample) Number: _____

Sex: _____

 Dose Group: _____

Stains Requested (X):

___   Hematoxylin & Eosin

___   Stain A

___   Stain B

Indicate (X) the following when completed. A Quality Control check of slides will be performed by technician before slides are given to pathologist. Slides will be recut as needed. ONLY those slides identified for recuts by the pathologist will be inventoried on this form.

Block Number	Tissue Description	Tissue Trimmed	Tissues Embedded	Number of Blocks (NB)	Slides Cut	Number of Slides (NS)	Staining (X and number) H&E B	A	Quality of Sections Checked	RECUTS Total Number of Slides (RC)	Total Slides Cut (NS+RC)
1	Tissue 1										
2	Tissue 2										
3	Tissue 3										
	TOTAL										

Sign and Date when animal completed:

Tissues Trimmed: _____   Cutting: _____

Embedding: _____   Staining: _____

Quality Control Check: _____

COMMENTS: