PCD DST#NWU Preclinical Drug	DP Development Platform	St	Standard Operating Procedure				
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COMPILATION AND AUTHORISATION



Action	Designated Person	Signature	Date
Compiled by:	Mr H Buntting	E STATE OF THE STA	20.06.2014
Authorised by:	Mr CJJ Bester	Reb	20.06.2014

DISTRIBUTION

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Department	Name	Signature	Date
PCDDP QA Manager	L Scholtz	9-2	24-06-2014
Head: Vivarium	CJJ Bester	@21-	24.06.2014

3. DOCUMENT HISTORY

Date	Issue no	Reason for revision
11-04-2013	Draft 1	First draft of SOP based on initial process
25-10-2013	Issue 1	First issue of SOP
25-02-2014	Issue 2	Addition of Test Principles
23-06-2014	Issue 3	Training Removed

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4. POLICY and OBJECTIVE

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- 1. To outline the proper procedures for performing a necropsy and post mortem examination.
- 2. Circumstances that may warrant necropsy performance include research diagnostic purposes, or colony health diagnostic purposes.

5. SCOPE

This SOP encompasses all post mortem examinations of animals found dead, as well as animals euthanised for humane reasons.

REFERENCE DOCUMENTS

7. ABBREVIATIONS and/or DEFINITIONS

Abbreviation	Description
DST	Department of Science and Technology
GLP	Good laboratory practice
N/A	Not applicable
NWU	North West University
PCDDP	Preclinical Drug Development Platform
SOP	Standard operating procedure
SPF	Specified Pathogen Free

8. RESPONSIBILITIES

- Research staff or veterinarians conduct necropsies and post mortem tissue examinations of research animals.
- Necropsies must be performed by investigators and staff when unexpected morbidities or mortalities are observed that are not attributable to the research protocol in order to assess animal colony health status.

9. TEST PRINCIPLES

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10. MATERIALS and EQUIPMENT

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- Sharp pointed scissors
- Scalpel
- Forceps
- Syringe with 21 gauge needle
- Necropsy cutting board
- Bottles
- 10% Neutral buffered formalin
- Disposable gloves and nitrile gloves for handling formalin
- · Safety glasses and face mask or face shield
- Eye wash station
- Respirator mask suitable for use with formaldehyde

11. SAFETY

11.1. Required Qualifications

All personnel performing necropsy must be appropriately trained and the training recorded. The sponsor may require a trained veterinary pathologist to conduct a necropsy.

11.2. Required Safety Equipment

Formalin should only be used in a properly ventilated room, preferably in a fume cupboard. Asthmatics or those exposed to fumes (*i.e.* the person opening and closing formalin bottles) in a poorly ventilated room should wear a respirator mask. All personnel directly involved in necropsy procedures should wear protective clothing, safety glasses and facemasks (or a face shield), and gloves to protect against splashes of formalin and potentially infectious organisms.

11.3. Emergency Procedures

If formalin is splashed onto the skin or into an eye, it will be rinsed off with copious amounts of water for at least 15 minutes. Seek medical attention and notify the IVABS safety officer.

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11.4. Reagents and Chemicals

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Formalin is potentially very harmful and needs to be handled appropriately, according to its MSD sheet notification. Before working with formalin, read the appropriate MSDS, paying particular attention to protective equipment and emergency and first aid procedures.

11.5. Hazards

Formalin is a poison and may cause cancer. It causes burns, is harmful if absorbed through skin, and may be fatal if swallowed or inhaled. Avoid contact with eyes, skin and clothing, and avoid breathing vapour.

Care must be taken when working with sharps to avoid cuts and stab wounds. All needles, syringes, and scalpels must be disposed of in an appropriately labelled sharps container.

All material in contact or consisting of biological materials may be harmful and must be disposed of in an appropriately labelled biohazards container or autoclaved before discard.

12. PROCEDURES

- Animal necropsy is performed in areas specifically designated for that purpose.
- Cork boards used during necropsy must be covered with a clean, impervious disposable pad and the surface decontaminated after each use.
- Necropsy should be performed in a manner that avoids the occurrence of artefacts or post mortem change in the collected tissues, and as soon after death as possible to insure tissue integrity.
- Animals that cannot be necropsied immediately should be identified and refrigerated, and the attending research staff notified.
- Proper personal protective equipment and attire must be worn when performing necropsy.
 - a. Disposable gloves, shoe covers, and gown must be worn when conducting a necropsy.

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- b. Full protective clothing must be worn when handling animals infected with bio hazardous materials or chemical carcinogens and includes double gloves, cap, disposable gown, shoe covers, mask (or respirator if required), and eye protection.
- Specimens for microbiological assessment must be collected using sterile instruments and aseptic technique.
- All specimens, whether collected for submission to a laboratory for analysis or for archival purposes, must be placed in a suitable container and labelled as to the PI, animal ID, date of collection, the tissue or sample collected when appropriate, and the fixative or specific storage requirements when necessary.
- All tissues submitted for histo-pathological assessment by a pathologist for studies conducted in accordance with Good Laboratory Practices (GLP) must be accompanied by a completed study specific GLP form, that includes all of the necessary information to completely identify the specimen, including the PI, animal ID, date of collection, tissues submitted, fixative used or specific storage requirements, any special laboratory tests or procedures requested, and the name of the person conducting the necropsy.
- When possible, the necropsy should be planned in advance to insure that the evaluation is thorough, efficient, and appropriate to the aims of the study protocol. The purpose of the study, applicable SOPs, and precedent data should be considered when determining which tissues are to be evaluated, collected, and/or weighed, and what if any specific procedures or tests are required.
- Small specimens should be placed in labelled tissue cassettes, wrapped in lens paper or placed on a tissue sponge.
- When conducting a necropsy for a GLP study:
 - a. Confirm the identification of the animal.
 - b. Determine and record the animal's body weight. Scales used for weighing animals or organs must be calibrated.
 - c. Verify and record the animal's sex and age.

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- d. Conduct a thorough external examination by reviewing the body surface and orifices for abnormalities. Palpate for superficial swellings, or for enlarged organs or masses within body cavities.
- e. Examine organs and tissues *in situ* before dissecting or collecting tissues and record any abnormalities.
- f. Label all containers and tissue cassettes with the animal's ID number, and any protocol-relevant information.
- g. All lesions that were observed during the study, or that are observed during the necropsy must be recorded on the appropriate necropsy form, and include a complete description (e.g., size, number, color, shape, texture, severity, and weight or volume as appropriate).

13. ADDENDUM

N/A