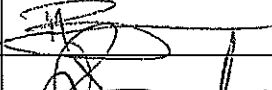
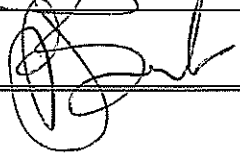
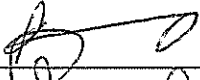
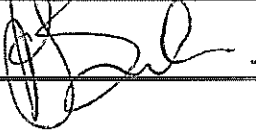


Title Determining Pain and Distress in Laboratory Rodents**SOP no** SOP Viv Anim 27 **Issue no** 1**Issue date** 04-08-2014 **Revision date** 04-08-2016**Effective date** 04-08-2014 **Page no** Page 1 of 4**1. COMPILATION AND AUTHORISATION**Uncontrolled copy
Superseded on 06-03-2015Controlled
Document

Action	Designated Person	Signature	Date
Compiled by:	Mr H Buntting		01-08-2014
Authorised by:	Mr CJJ Bester		01-08-2014

2. DISTRIBUTION

Department	Name	Signature	Date
PCDDP QA Manager	L Scholtz		04-08-2014
Head: Vivarium	CJJ Bester		04-08-2014

3. DOCUMENT HISTORY

Date	Issue no	Reason for revision
04-08-2014	1	First issue of SOP

Title	Determining Pain and Distress in Laboratory Rodents		
SOP no	SOP_Viv_Anim 27	Issue no	1
Issue date	04-08-2014	Revision date	04-08-2016
Effective date	04-08-2014	Page no	Page 2 of 4

Uncontrolled copy COPY
Superseded on 06-03-2015

4. POLICY and OBJECTIVE

Animals can experience pain and distress. It is the ethical and legal obligation of all personnel involved with the use of animals in research to reduce or eliminate pain and distress in research animals whenever such actions do not interfere with the research objectives.

5. SCOPE

To designate responsibility, recognize signs of, and alleviation of pain and distress in laboratory rodent.

6. REFERENCE DOCUMENTS

- SOP_Viv_Anim 7 – Necropsy and post mortem examination
- SOP_Viv_Anim 11 – Animal health and environmental surveillance

7. ABBREVIATIONS and/or DEFINITIONS

Abbreviation	Description
PI	Principle investigator
N/A	Not applicable
NWU	North West University
PCDDP	Pre-Clinical drug development platform
SOP	Standard operating procedure
FD	Found Dead

8. RESPONSIBILITIES

- The key points for fulfilling the responsibilities of both the Study director/ PI and the Vivarium staff are:
 - a) Understanding the legal requirements as laid out in the relevant legislation and internally by the research animal ethics committee.
 - b) Being able to distinguish pain and distress in animals from their normal state
 - c) To relieve or minimize the pain and distress appropriately.
 - d) To establish humane endpoints.
- All program staff contributes to the oversight and reporting of animal welfare status.



Title	Determining Pain and Distress in Laboratory Rodents		
SOP no	SOP_Viv_Anim 27	Issue no	1
Issue date	04-08-2014	Revision date	04-08-2016
Effective date	04-08-2014	Page no	Page 3 of 4

9. TEST PRINCIPLES

N/A

Uncontrolled copy **COPY**
Superseded on 06-03-2015

10. MATERIALS and EQUIPMENT

N/A

11. SAFETY

N/A

12. PROCEDURES

- Recognition of pain and distress:
 - a) Animals must be monitored by trained individuals as appropriate for the species, condition and procedure.
 - b) The ability to distinguish between normal and abnormal behaviour is critical to the accurate assessment of pain and distress.
 - c) See addendum 1: Potential Signs Associated with Pain or Distress in Rodents
 - d) Animals need to be monitored as per the protocol for the relevant study. Additional observations may be required on a case to case basis. Observations can be noted on check sheets as per Addendum 2: Pain and distress monitoring and score sheet.

- Intervention Strategies:
 - a) If pain or distress is observed, animal care staff/researchers review the contact sheet for any specific instructions from the research staff, and in addition to these instructions, report the animal's condition as described in (SOP_Viv_Anim 11).

NOTE: If at any time there is a medical emergency, the attending clinical veterinarian or designee is to be notified immediately.
 - b) Staff/researchers should immediately report all incidences of pain and distress, verbally, directly to the Facility Manager/Lab animal Technologist on duty.
 - c) When an animal is found in pain and/or distress, the Facility Manager must notify the attending research staff immediately of the animal's condition, and advise the research staff of the action to be taken as per the agreed humane endpoints for the given study.

Title	Determining Pain and Distress in Laboratory Rodents		
SOP no	SOP_Viv_Anim 27	Issue no	1
Issue date	04-08-2014	Revision date	04-08-2016
Effective date	04-08-2014	Page no	Page 4 of 4

advise the research staff of the action to be taken as per the agreed humane endpoints for the given study.

Uncontrolled copy
Superseded on 06-03-2015
COPY

- d) If the endpoint requires euthanasia, it will be performed by the lab animal technologist on duty at the time that it needs to be performed. Any animals observed to be in severe pain as per Addendum 2, will be immediately euthanised regardless of desired experimental endpoints. The welfare of the animal needs to take preference in this regard.
- If euthanasia is required a necropsy may be performed as per SOP_Viv_Anim 7 – Necropsy and post mortem examination
 - Concerns regarding a number of unanticipated signs of pain and distress associated with a particular research protocol and/or with a specific genotype of research animal should be addressed to the Clinical Veterinarians in writing. Clinical Veterinarians evaluate the alleged concerns, and take an appropriate course of action to resolve the concern.

13. ADDENDUM

ADDENDUM 1: Potential Signs Associated with Pain or Distress in Rodents.

[SOP_Viv_Anim 27 ad 1]

ADDENDUM 2: Pain and distress monitoring and score sheet. [SOP_Viv_Anim 27 ad 2]



SOP Addendum

Title	Pain and distress monitoring and score sheet		
SOP no	SOP_Viv_Anim_27 ad 2	Issue no	1
Issue date	04-08-2014	Revision date	04-08-2016
Effective date	04-08-2014	Page no	Page 1 of 1

COPY

Parameter	Animal ID -	Score						
Appearance	Normal	0						
	Lack of grooming	1						
	Dull coat, ocular and nasal discharge	2						
	Piloerection, hunched up	3						
Food and Water Intake	Normal	0						
	< 5% weight loss	1						
	Noted intake - 5-15% weight loss	2						
Clinical Signs	No food or water intake	3						
	Normal Respiration and Cardiac activity	0						
	Slight changes	1						
Natural behaviour	Respiratory increase \uparrow 30%	2						
	Respiratory increase \uparrow 50%	3						
	Normal	0						
Provoked behaviour	Minor changes	1						
	Less mobile alert, isolated	2						
	Vocalization, restless or still	3						
Natural behaviour	Normal	0						
	Minor depression	1						
	Moderate change	2						
	Reacts violently/weakly, precomatose	3						
	TOTAL	0-20						

0-4 = Normal
 5-9 = Monitor carefully, consider intervention
 10-14 = Suffering, provide relief, observe regularly. Seek second opinion from Technologist as per call out sheet. Consider humane euthanasia
 15-20 = Severe pain; Intervene immediately per humane endpoint, reconsider experimental protocol