Guidelines for monitoring animal welfare

Monitoring requirement

The *Australian Code for the care and use of animals for scientific purposes* (The Code) requires that animals be monitored to ensure any harm, including pain and distress, is promptly detected and managed (clauses 2.5.5 (ii), 3.1.20 (ii)). In line with the Code, Griffith University Animal Ethics Committee approval conditions clearly state that **experimental animals in captivity must be monitored daily including weekends and public holidays.** The methods and frequency of monitoring must be detailed in project applications to the Animal Ethics Committee (AEC) and approved by the AEC (Australian Code clause 2.7.4 (xv)). The appropriate methods used to monitor animals will vary with the species and type of research**.**

Level of monitoring

The level of monitoring refers to the degree of interaction with the animal. In some cases, it may be that the animals are monitored from outside the cage or enclosure, and observations noted. This can be referred to as 'indirect monitoring'. At other times, the animals may need to be handled for direct monitoring (e.g. physical health examination). Depending on the frequency of the monitoring, a combination of the latter two may be required throughout the protocol.

Monitoring personnel

Animals must be monitored by person deemed to be competent and knowledgeable about the normal behaviour and signs of pain and distress for the species, or a person under the direct supervision of a competent person. It is important to understand the normal behaviour of the species involved in the project, to recognise what is abnormal.

The animal husbandry checks done by Biosciences resources facility (BRF) staff are not considered part of the daily monitoring requirements. The animal husbandry check includes ONLY the following:

- Access to food
- Access to water
- Sufficient bedding
- Enrichment
- Animal looking obviously sick on a visual inspection.

Investigators must undertake the monitoring and assessment of animal wellbeing under experimental procedures. Where animal carers (BRF staff) are involved in the monitoring and assessment of animals, the investigators must ensure that the scope and responsibilities for day-

to-day monitoring are clearly outlined and communicated to all parties and clearly described in the ethics application.

An animal carer can be involved in monitoring procedures and all the below procedures must be followed to ensure the scope and responsibilities for day-to-day monitoring are clearly outlined and communicated to all parties:

- they have been given a copy of the approved AEC protocol
- they have had training in the procedure and are competent
- they have accepted the role
- they are named on the AEC application as co-investigators
- detailed information regarding procedures and level of monitoring by animal carer must be provided in the team member table and in the AEC application (specifically question 35: Will Biosciences Resources Facility staff be requested to perform technical work on animals in addition to routine husbandry)

Maintaining monitoring records

Monitoring visits must be documented in an animal monitoring scoresheet. These may be requested by the AEC and should also be attached to progress, annual and final reports for the protocol. Animal monitoring score sheets and other documentation relating to the monitoring of animal management and welfare in research are considered primary materials and are to be stored for at least seven years after the last action is taken on the research project.

Records of the monitoring and assessment of animal wellbeing must be:

(i) sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies

(ii) accessible to all people involved in the care of the animal

(iii) available for audit by the institution, the AEC and authorised external reviewers.

Clinical welfare monitoring guidelines to set humane end points for animals under experimental procedures

The Clinical welfare monitoring, and scientific observations (such as sample collections and behavioral recordings etc) are different entities. The Clinical welfare monitoring is performed by applying a score system to the monitoring sheet to ascertain humane end/intervention points and what actions should be taken if clinical signs develop. A scoring system directed at each

parameter to be monitored helps to make the procedure more objective across the whole team that is responsible for the animal's care.

The Clinical welfare monitoring frequency will depend on three main factors and should be considered and justified in the proposed clinical monitoring plan for the protocol:

1. *The intervention/invasiveness category of the proposed experiment*
2. *What are the known and expected adverse effects of the experiments* (likely or unlikely) and how quickly they can develop, causing the animals to be in distress. If an adverse effect is detected, the monitoring frequency must increase as per the decision tree/monitoring and intervention plan.
3. *How the disease model affects the animal's well-being and normal physiological state*. If these pathologies require more frequent monitoring on a regular basis, then it needs to be considered. Please clearly characterize the disease model, all the factors that will affect the animal wellbeing and the steps taken to mitigate them and justify the monitoring plan in the AEC application question* related to the balance of harms to benefits of the study to support the case of ethical acceptability of the proposed use of animals is requested.
   *

   12- Please explain the balance of harms to benefits in this study to support the case of ethical acceptability of the proposed use of animals. Please address whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits of the research.
   The Code defines well-being as the positive mental state of an animal, able to have positive experiences, express innate behaviours, and respond and cope with potentially adverse conditions. The Code also states that the wellbeing of animals must be considered in terms of the cumulative effects of an animal's lifetime experience. It is therefore necessary to weigh up the positive as well as the negative experiences of all animals involved, based on their will to survive and thrive, and to consider all alternative actions which could be maximise well-being and avoid harm to sentient beings. To answer this question, please refer to the Governing Principles of the Code (1.1, 1.3, 1.5, 1.6, 1.7 1.8).

   The description of how the animals will be monitored during a project must be outlined in a detailed monitoring plan, which is presented to the AEC as part of the ethics application. Please provide monitoring plan documents in response to the AEC application question* related to "animal monitoring and clinical score sheets".

Response must include:

1. Summary of the monitoring plan with **a clear pictorial representation** of daily and clinical monitoring in the proposed protocol.
2. Daily animal welfare observation sheet
3. Clinical monitoring score sheet

*

21- Daily animal monitoring is a condition of your ethics approval and should be documented in a monitoring scoresheet.

Additionally, a clinical welfare score sheet should be completed if any abnormalities are detected during daily monitoring, to define signs of pain and distress and where specific interventions will take place to relieve pain and distress and implement humane endpoints.

Upload a document titled 'Animal Monitoring and Clinical Score Sheets' to the Documents Tab. You may use your own score sheet or a template can be found here: This template MUST be modified with the criteria relevant to your specific project and animal model. It is important that you consider the likely clinical signs for your animal model. Each team member should be clear about what the signs are and how they are to be scored, and what interventions must occur.

The baseline frequency for clinical welfare monitoring of animals under experimentation:

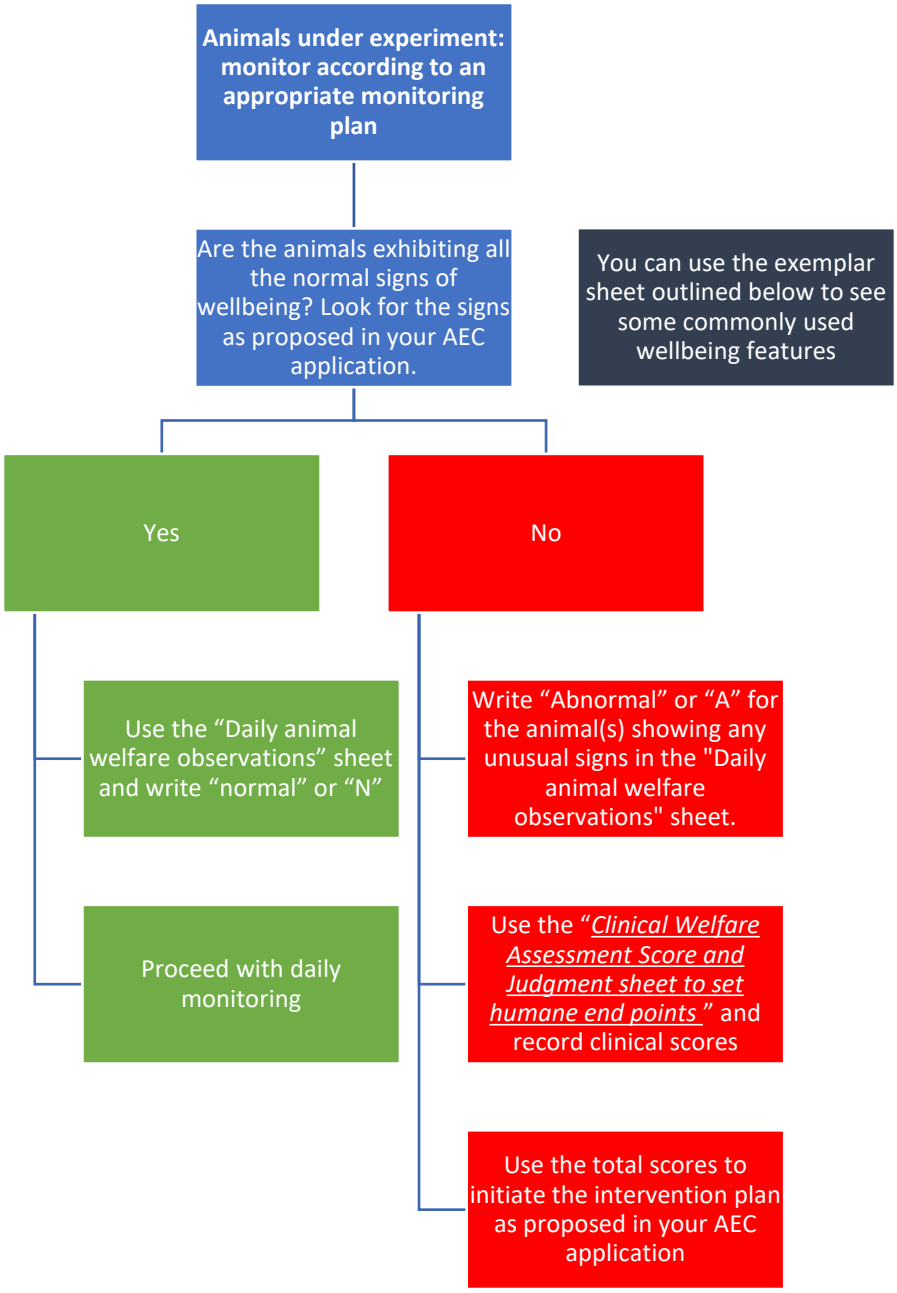
Invasiveness Category	Clinical welfare monitoring requirements	Examples
Observation Involving Minor Interference Animals are not interacted with or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.	Post and pre challenge checks must be carried out as per AEC approvals in the protocol	• Observational study only • Breeding animals for supply, where only normal husbandry procedures are used • Breeding or reproductive study with no detriment to the animal • Feeding trial, such as Digestible Energy determination of feed in a balanced diet • Behavioural study with minor environmental manipulation • Teaching of normal, non-invasive husbandry such as handling and grooming
Animal Unconscious Without Recovery Animal is rendered unconscious under controlled circumstances (i.e. not in a field situation) with as little pain or distress as possible. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal which is then killed without regaining consciousness.	Not applicable	• No experiments of living animals eg animals killed painlessly for dissection, biochemical analysis, tissue studies, etc • Collecting blood or plasma from anaesthetised dogs prior to euthanasia • Teaching surgical techniques on live, anaesthetised patients which are not allowed to recover following the procedure

Minor Conscious Intervention without Anaesthesia Animal is subjected to minor procedures that would normally not require anaesthesia or analgesia. Any pain is minor and analgesia usually unnecessary, although some distress may occur as a result of trapping or handling.	Close monitoring in the hour following intervention and once daily over the first 48-72 hours, and then checks must be carried out as per AEC approvals in the protocol	• Injections (not vaccination trials), blood sampling in conscious animal • Minor dietary or environmental deprivation or manipulation, such as feeding nutrient- deficient diets for short periods • Trapping and release as used in species impact studies etc • Trapping and humane euthanasia for collection of specimens • Stomach tubing, branding, dehorning young animals, shearing
Minor Operative Procedures With Recovery The animal may be rendered unconscious with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and post-operative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.	Post and pre-operative checks and close monitoring in the hour following intervention and then checks must be carried out as per AEC approvals in the protocol.	• Biopsies • Cannulations (minor) • Sedation/anaesthesia for relocation, examination or injections/blood sampling
Surgery With Recovery Animal may be rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal	close monitoring in the hour following intervention, 3 times a day in the intensive recovery period (48-72 hours) following surgery, 2 times a day for convalescence	• Orthopaedic surgery • Abdominal or thoracic surgery • Transplant surgery • Cannulations (major) • Mulesing, castration without anaesthesia • Other major surgeries

allowed to recover. Post-operative pain is usually considerable and at a level requiring analgesia.	period (usually requiring regular analgesic administration) and then checks must be carried out as per AEC approvals in the protocol. Surgical Intervention table must be included in the clinical welfare check protocol.	
Minor Physiological Challenge Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress or any pain/distress is quickly and effectively alleviated.	close monitoring in the hour following intervention and then checks must be carried out as per AEC approvals in the protocol. Detailed monitoring plan that explains and accounts for the natural progression of the disease/infection model must be included.	• Minor infection, minor or moderate phenotypic modification, early oncogenesis • Arthritis studies with pain alleviation • Prolonged deficient diets, induction of metabolic disease • Polyclonal antibody production • Antiserum production • Vaccination trials
Major Physiological Challenge Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated.	close monitoring in the hour following intervention, 2 times a day in the intensive recovery as well as convalescence period following the intervention, then checks must be carried out as per AEC approvals in the protocol. Detailed	• Major infection, major phenotypic modification, oncogenesis without pain alleviation • Arthritis studies with no pain alleviation • Uncontrolled metabolic disease • Isolation or environmental deprivation for extended periods • Total body irradiation and reconstitution • Monoclonal antibody raising in mice processes.

	monitoring plan that explains and accounts for the natural progression of the disease/infection model must be included.	
Production of Genetically Modified Animals This category is intended to allow for the variety of procedures which occur during the production of genetically modified animals. As animals in this category may be subjected to both minor and major physiological challenges and surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes ALL animals used in GM production other than the final progeny which are used in a different category of procedure.	As per BRF breeding protocol.	• Initial breeding of animals used for GM production including vasectomised males, donor and recipient females • Breeding and maintenance of GM colonies • Animals culled as part of the GM production process

Flow chart for monitoring animals under experimentation



Daily animal welfare observations

AEC Protocol No:	Group:	Investigator Name: Contact details:

The Animal cage and each animal it contains is observed/examined daily under experimentation for:

- Abnormalities and or clinical signs as appropriate. "Animals Natural activity and Appearance:" e.g. Observant, active, still, isolated or normal
- Contents of Cage and bedding: e.g. Wet, Dry, moist faecal contents.
- Normal signs are recorded as N or A for abnormal in the table (See *appendix 1* clinical sign determination).

"Any changes observed that deviate from normal signs within the cage require the investigator to complete a separate Clinical Welfare Score Sheet assessment for each individual animal that has displayed abnormalities (See *appendix 1*).

Observations

Day / Date	1		2		3		4		5		6		7	
Mouse #	Normal / Abnormal	Weight	Normal / Abnormal	Weight	Normal / Abnormal	Weight	Normal / Abnormal	Weight	Normal / Abnormal	Weight	Normal / Abnormal	Weight	Normal / Abnormal	Weight

Appendix 1

Exemplar Clinical Welfare Assessment Score and Judgment sheet to set humane end points for animals under experimental procedures

Please note: You must include all the categories as described below to assess the general health of the animal. You can choose some or all the parameters from each category depending on your disease and intervention model.

Animal ID:		**Date:**							
Category	**Parameters**	**Abnormality**	**Score**	**Day 0***	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**
General appearance	Activity / alertness	Abnormal posture	1						
		Huddled / inactive	2						
		Moribund / unconscious	9						
	Breathing	Rapid, shallow	1						
		Rapid, abdominal breathing	2						
		Laboured, irregular, skin blue	3						
	Coat	Coat rough	1						
		Unkempt, wounds, hair thinning	2						
		Bleeding or infected wounds, or severe hair loss	9						
	Eyes	Wetness or dullness	1						
		Discharge	2						
		Eyelids matted	3						
Hydration status	Signs of dehydration in skin	Skin less elastic / increased OR decreased intake over 24 hours	1						
		Skin tenting / increased OR decreased intake over 48 hours	2						
		Sluggish behaviour with skin tenting/ Not drinking over 24 hours	3						
	Urine output	Reduced volume	1						
		Abnormal colour	2						
		No urine 24 hours OR incontinent, soiled perineum	3						
Nutrition	Body weight	Weight loss 5-10%	1						
		Weight loss 10-14%	2						

		Weight loss ≥15%	9						
	Eating	Increased OR decreased intake over 24 hours	1						
		Increased OR decreased intake over 48 hours	2						
		In appetence over 48 hours	3						
	Faeces	Faeces moist	1						
		Loose, soiled perineum OR abnormally dry +/- mucus	2						
		Running out on handling OR no faeces for 48 hrs OR frank blood on faeces	3						
Altered sensorium/ Agitation	Self-mutilation	Skin breakage wound	1						
		Bleeding from wound site	2						
		Sub-dermal layers visible	3						
		Loss of an appendage	9						
	Vocalisation	Squeaks when palpated	1						
		Struggles and squeaks loudly when handled/palpated	2						
		Abnormal vocalisation	3						
			Score						
Intervention procedures (tick if provided)	**Use appropriate intervention plan to manage the clinical score observed**	Pain relief injection (Temgesic / Meloxicam)							
		Antibiotic injection (Baytril)							
		Fluids (Saline injection)							
		Mushy food							
		Wound treated							
		Antibiotic (Tricin) powder / Topical Savlon							
		Bandage or collar							
		Heating pad							

Judgement:

0-4 = Mild (increased monitoring)
5-8 = Moderate (follow intervention procedures)
9 + = Substantive (Euthanasia)

Appendix 1 Continued

Exemplar Intervention & Disease model Specific Score and Judgment sheet

Animal ID:	**Date:**							
	Abnormality	**Score**	**Day 0***	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**
Intervention related scoring sheet (Example provided below:)								
Injection site	Redness/ swelling	1						
	Discharge and bleeding	2						
	Open Ulcer	3						
Disease model Score and Judgment sheet (Example provided below:)								
Tumour growth	Tumour growth impeding upper limb movement	1						
	Tumour growth impeding head movement	2						
	Growth impeding regular daily activity such as movements and feeding	3						
Tumour appearance	Appearance of any skin inflammation/ change in colour	1						
	Loss of fur from the overlying skin	2						
	Indurated or ulcerated skin over the tumour site	3						
Tumour size	Mean diameter 20mm, volume 2000 mm^3	**9**						

Appendix 2

Exemplar Post-Interventional monitoring Incident & Endpoint Record

Animal ID _____

Date	Details of findings and action taken	Initials
	Sacrifice procedure	