STANDARD OPERATING PROCEDURE FOR IMPLIED PROTOCOL ROLES AND RESPONSIBILITIES FOR ETHICAL ANIMAL CARE

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1 Explanatory Notes

1.1 INTERPRETATION

The following defined terms, abbreviations and acronyms are used in this SOP:

- ACS  Animal Care Services
- AEC  UWA Animal Ethics Committee
- AFMSAB  Animal Facility Manager of a School of Animal Biology facility
- ‘animal’  An animal used for scientific purposes
- Animal Care Personnel  See definition in 2.1.3
- Animal Monitor  A person designated in a written project protocol as being responsible for animal monitoring during a study
- AWO  Animal Welfare Officer
- CI  Chief Investigator
- Code  Australian Code for the Care and Use of Animals for Scientific Purposes, 8th edition (Canberra: NHMRC, 2013)
- Committee  UWA Animal Ethics Committee
- DACS  Director, Animal Care Services
- IEA  International Epidemiologic Association
- NHMRC  National Health and Medical Research Council
- ObM  Outbreak Manager; see definition in 4.2.4
- Outbreak  See definition in 4.2.1
- Outbreak Investigation  See definition in 4.2.2
- Outbreak Manager  See definition in 4.2.4
- Outbreak Response  See definition in 4.2.3
- Preventive Veterinary Intervention  See definition in 3.2.2
- SAB  School of Animal Biology
- SOP  Standard Operating Procedure
- Therapeutic Veterinary Intervention  See definition in 3.2.1
- University  The University of Western Australia
- Upsurge  See definition in 4.2.5
- UWA  The University of Western Australia
- WA  Western Australia
1.2 REASONS FOR THIS SOP

The competent and effective care of animals at UWA requires that a range of husbandry, veterinary care, housing and other support services are provided as part of the University’s animal ethics system. This infrastructure creates the context within which it is possible for the AEC to approve research, teaching and breeding protocols in the knowledge that access to, and appropriate use of, these high quality support services are implied conditions of every protocol. It is unnecessary and impracticable for these services to be detailed in each protocol, not least because many facets of ethical animal care are either of a routine nature or, if responsive to special animal needs as they arise, cannot be known in advance. For these reasons, most husbandry, veterinary care, housing and other support services are provided to animals as roles and responsibilities that are not explicitly stated but are implied in the relevant protocols.

This SOP clarifies the nature and extent of support services that are granted prior approval by the AEC and which are implied into every protocol where these support services are relevant from the outset or become relevant during the course of the protocol. It also clarifies accountability and the standards of documentation and reporting that must occur.
2 Animal Care Personnel as Investigators

2.1 POLICY BACKGROUND, PURPOSE AND SCOPE

2.1.1 Animal Care Personnel are employed or contracted by the University as technicians, veterinarians and administrators to provide husbandry, veterinary care, housing and other support services to animals used for scientific research, teaching and breeding purposes at a wide range of UWA facilities. Thus Animal Care Personnel are involved with the housing and care of animals used in the majority of protocols. Such care is mandated by the NHMRC Code (8th edition 2013), where paragraph 2.5.15 places on the manager of an animal facility “with support as required from the institution and other staff members, and advice from veterinarians” a set of duties, including day-to-day animal care, monitoring, veterinary services, record keeping and quality management.

2.1.2 The purpose of Part 2 of this SOP is to clarify when it is a requirement for Animal Care Personnel to be named investigators (co-investigators or a chief investigator) on an AEC full application or amendment.

2.1.3 The principles embodied in Part 2 apply to Animal Care Personnel, meaning employees and contractors who provide husbandry, veterinary care, housing and other support services to animals used for scientific purposes, at facilities or project settings (including field studies) managed or serviced by the ACS, the SAB, or Australian Cancer Research Foundation Cancer Imaging Technologist (who hold a valid Permission to Use Animals). The appropriateness of any wider application of this part is to be determined by the AEC on a case by case basis.

2.2 SITUATIONS THAT DO REQUIRE NAMED INVESTIGATOR STATUS

2.2.1 The following duties performed by Animal Care Personnel are grounds for mandatory nomination as an investigator on an AEC approved protocol:

- Performance of research-related activities within a protocol on which an Animal Care Personnel member (employee or contractor) is the CI; e.g., research to determine optimal standards of animal care.
- Designation as a responsible Animal Monitor on a protocol.
- Designation as a person responsible for animal euthanasia as an experimental end-point on a protocol.
- Where the Animal Care Personnel member (employee or contractor) assumes primary responsibility for a significant or technically demanding procedure or component of the research, or contributes to the intellectual capital of the project, as distinct from merely assisting one or more others who carry that responsibility.

2.2.2 In borderline or complex situations where the need for named investigator status is unclear or in dispute, it is the responsibility of the AEC Chair to make the relevant determinations and to report these decisions to the next meeting of the AEC.
2.3 SITUATIONS THAT DO NOT REQUIRE NAMED INVESTIGATOR STATUS

2.3.1 The following duties performed by Animal Care Personnel are not grounds for mandatory nomination as an investigator on an AEC approved protocol:

- Husbandry, transport or routine care of animals.
- Routine veterinary care delivered by appropriately qualified and competent Animal Care Personnel (employees or contractors), including assisting and anaesthetising during procedures, post-operative care or minor support procedures (including those specified in the research protocol) such as blood or other specimen collection, injections or cannula insertions.
- Therapeutic Veterinary Interventions or Preventive Veterinary Interventions delivered by an appropriately qualified and competent Animal Care Personnel member (employee or contractor) who is a veterinary surgeon or is acting under the direction of a veterinary surgeon in the delivery of such interventions.
- Euthanasia of animals as required for the purpose of animal colony management or as authorised by the AWO, DACS, AFMSAB or a veterinary surgeon.

2.3.2 For the avoidance of doubt, an Animal Care Personnel member (employee or contractor) who assumes primary responsibility for the administration of anaesthesia does not need to be named as an investigator.
3 Veterinary Interventions and Protocol Amendment

3.1 POLICY BACKGROUND, PURPOSE AND SCOPE

3.1.1 The ethical scientific use of animals relies on the provision of professional advice and services from qualified veterinary surgeons, who are registered under the Veterinary Surgeons Act 1960 (WA). Thus a number of veterinary surgeons are employed by the University or contracted as consultants to provide veterinary care to animals used for scientific purposes on protocols approved by the AEC.

3.1.2 Veterinary surgeons may also become involved in advising on or directing modifications to procedures covered in approved protocols, where the changes are considered necessary to redress an emergent health or welfare problem affecting a group of animals such as an Upsurge in animal disease, injury or mortality that does not warrant the declaration of an outbreak in accordance with Part 4 of this SOP.

3.1.3 The primary purpose of Part 3 is to clarify when it is necessary for a CI to apply for amendment to an approved protocol as the result of professional veterinary interventions and advice. A further purpose is to set out the administrative steps to be followed when such a protocol amendment is required.

3.1.4 Part 3 applies to veterinary surgeons employed or contracted by the University with agreed terms of contract to provide veterinary care to animals used for scientific purposes on protocols approved by the AEC. Nothing is Part 3 implies that a person who is a registered veterinary surgeon is by that fact alone empowered to provide such veterinary care.

3.1.5 Nothing in Part 3 affects the ability of the AWO, DACS/AFMSAB or nominated ObM to undertake an animal Outbreak Investigation or Outbreak Response in accordance with Part 4 of this SOP.

3.2 THERAPEUTIC VS PREVENTIVE VETERINARY INTERVENTION

3.2.1 Therapeutic Veterinary Intervention means a veterinary surgeon’s provision of diagnosis, treatment or aftercare services in response to an individual research animal’s health problem that is co-incidental to or a complication of scientific activities in an approved protocol.

3.2.2 Preventive Veterinary Intervention means instructions or services from a veterinary surgeon that apply proactively to a group of research animals (such as those remaining on a protocol, about to undergo a procedure or belonging to a particular phenotype) and intended to diminish the likelihood of health problems or complications into the future.

3.2.3 For the avoidance of doubt, where a veterinary measure is applied to an individual research animal following initial treatment with the aim of preventing a recurrence in that specific animal, this is construed as a continuation of the Therapeutic Veterinary Intervention, and not as a Preventive Veterinary Intervention in terms of the meanings given above.
3.3 REQUIREMENTS FOR PROTOCOL AMENDMENT

3.3.1 The provision of a Therapeutic Veterinary Intervention does not require a protocol amendment. However, comprehensive records of all Therapeutic Veterinary Interventions delivered to research animals must be created, maintained and available to the AEC.

3.3.2 The provision of a Preventive Veterinary Intervention does require an amendment to the approved protocol, except in the following circumstance: a protocol amendment is not required to enact veterinary instructions to modify routine animal husbandry; for example, changes to housing conditions or routine diet of a group of research animals. Here the meaning of the word ‘routine’ includes the caveat that the housing conditions or dietary composition are not part of the design of the experiment.

3.3.3 In borderline or complex situations where the need for, or appropriate method of, protocol amendment to accommodate a Preventive Veterinary Intervention is unclear or in dispute, it is the responsibility of the AEC Chair to make the relevant determinations and to report these decisions to the next meeting of the AEC.
3.4 METHODS OF PROTOCOL AMENDMENT

3.4.1 Provided that the preventive measure imposes merely a low level of impost on the animal (e.g., short term administration of a standard or accepted drug regime by simple routes or topical preparation), the correct course of action is for the CI to submit a minor amendment application for delegated approval by the AWO.

3.4.2 For a Preventive Veterinary Intervention of a minor nature, if in the opinion of the supervising veterinary surgeon the use of the preventive measure is so urgent that it must not wait for an ordinary minor amendment process to be completed, a minor amendment may be approved and confirmed in writing by the AWO in advance of the necessary paperwork, which must then be completed retrospectively at the earliest reasonable opportunity.

3.4.3 Rarely a preventive measure will involve an additional animal burden sufficient to warrant the need for a major amendment application to the full AEC. Examples might include surgical correction of entropion in a group of animals; or caesarean section, where a group of animals was found to be pre-disposed to a particular risk of natural birth.

3.4.4 For a Preventive Veterinary Intervention of a major nature, if in the opinion of the supervising veterinary surgeon the use of the preventive measure is so urgent that it must not wait for an ordinary major amendment process to be completed, a major amendment may be approved by the AEC Chair with the concurrence of one category C or D member of the AEC. A formal major amendment application must then be reviewed by the full AEC at the first reasonable opportunity, usually the next scheduled meeting.

3.4.5 In all circumstances, the veterinarian should make reasonable efforts to consult with the CI or nominated emergency contact person to ensure that the proposed veterinary intervention does not interfere with the research design or scientific outcomes.

3.4.6 Preventative Veterinary Interventions that are relevant to animal use within a wider range of projects or UWA facilities should be addressed in the longer term by the promulgation of appropriate SOPs.
4 Outbreak Investigation and Response

4.1 POLICY BACKGROUND, PURPOSE AND SCOPE

4.1.1 A number of provisions of the NHMRC Code (8th edition 2013) require a proactive approach to animal Outbreaks of disease, injury or mortality. These include requirements for clear lines of responsibility, communication and accountability, such that Outbreaks are promptly detected and effectively managed [paragraphs 2.1.7(i)(c), 3.2.1(iii)]; and AEC guidelines providing approval, in advance, for the immediate use of animals for the diagnosis of unexplained and severe disease Outbreaks, or morbidity/mortality, in animals or people [2.1.5(v)(e)].

4.1.2 Situations may arise where it is important that key UWA personnel responsible for animal care and welfare are empowered with executive authority to act urgently to characterise and contain an Outbreak through rapid investigation and response.

4.1.3 The purpose of this statement is to clarify the basis and extent of executive authority in relation to Outbreak Investigation and Outbreak Response, who may exercise this authority and how accountability for its use is achieved.

4.1.4 The use of Part 4 of this SOP is limited to circumstances of sufficient gravity to warrant the assumption of executive authority that goes beyond that required for more usual veterinary interventions in accordance with Part 3 of this SOP.

4.2 MEANINGS OF TERMS

The following definitions are adapted from the IEA Dictionary of Epidemiology for use in this part:

4.2.1 Outbreak means an actual or grave potential for an abnormal cluster of animal deaths or serious adverse health events with features in common, affecting a population of animals such as those on the same or related protocols, housed in the same area or housed under similar conditions. The causes of an outbreak (when known) may include a microorganism, chemical substance (including a drug, toxin or nutritional deficiency) or radiation.

4.2.2 Outbreak Investigation means activities undertaken to establish the existence of an Outbreak and to identify the source, causal mechanism and contributing factors as a basis for Outbreak Response.

4.2.3 Outbreak Response means activities undertaken to prevent further occurrence of the disease, injury, mortality or other adverse event.

4.2.4 Outbreak Manager (ObM) means the officer responsible for Outbreak Investigation and Outbreak Response.

4.2.5 Upsurge means an abnormal cluster of animal deaths or adverse health events with features in common that is of insufficient gravity to warrant a formal Outbreak declaration.
4.3 DECLARATION OF AN OUTBREAK

4.3.1 The AWO, DACS or AFMSAB may declare that an Outbreak has occurred. However, a formality is required such that the declaration takes effect from the time that the declarant notifies the following officers: AWO, DACS/AFMSAB, relevant CI and AEC Chair.

4.3.2 There is no minimum number of affected animals necessary before an Outbreak is declared. In making the decision to declare an Outbreak, the declarant may take into account the severity of disease, injury or other events; any unusual features; potential for spread and wider impact; the number of animals already affected; and the time frame in which the cluster has occurred. A single subclinical finding of a particularly dangerous microorganism in a sentinel surveillance animal can be a sufficient basis for declaration of an Outbreak. In most instances, however, there will be an actual cluster of affected animals with clinical manifestations.

4.3.3 There is no compulsion to declare an Outbreak for every set of circumstances that is consistent with the definition of an Outbreak. In most instances an Upsurge in disease, injury or mortality can be appropriately and effectively managed by usual veterinary interventions in accordance with Part 3 of this SOP.

4.3.4 If the declarant of an Outbreak has knowledge before the appointment of the ObM that the Outbreak involves a reportable animal disease under the Biosecurity and Agriculture Management Act 2007 (WA), it is the responsibility of declarant to ensure that a statutory notification of reportable animal disease has been or is immediately completed.

4.3.5 The AEC Chair shall direct the AEC Secretary to inform members of the AEC that an Outbreak has been declared at the earliest reasonable opportunity.

4.4 OUTBREAK MANAGER

4.4.1 As soon as an Outbreak is declared, the powers of Outbreak Investigation and Outbreak Response come into effect. The declarant will initially exercise these powers.

4.4.2 Within 72 hours of the Outbreak declaration (and sooner for a severe Outbreak), the AWO and DACS/AFMSAB must confer and jointly designate an ongoing ObM. This designation takes effect from the time that the original declarant notifies the following officers that the ObM has accepted the role: AWO, DACS/AFMSAB, relevant CI and AEC Chair.

4.4.3 The AEC Chair will be responsible for resolving any disagreement that arises between the AWO and DACS/AFMSAB on the designation of the ObM.

4.4.4 The primary consideration in managing an Outbreak must be the preservation of animal welfare with priority given to the utilitarian objective of achieving the greatest good for the greatest number of animals even if some animals must be sacrificed to achieve that end.
4.5 OUTBREAK INVESTIGATION AND RESPONSE

4.5.1 The ObM may authorise the following actions on behalf of the AEC for the purpose of an Outbreak Investigation:

- additional or altered monitoring of the health or welfare of animals;
- collection of biospecimens directly from or arising from animals for laboratory analysis;
- collection of environmental specimens for laboratory analysis or other environmental measurements;
- sacrificing animals by humane euthanasia for post mortem examination or tests;
- temporary suspension of scientific research, teaching or breeding activities;
- use of animals, including selection of different subgroups, as sentinel animals, who may be exposed to circumstances suspected to cause or prevent the adverse event under investigation; or
- any other reasonable action with the concurrence of the AWO, DACS/AFMSAB and AEC Chair. This may include a trial of variations to scientific activities on the protocol to test a causal hypothesis about the Outbreak.

4.5.2 The ObM may authorise the following actions on behalf of the AEC for the purpose of an Outbreak Response:

- cessation or part cessation of scientific research, teaching or breeding activities;
- quarantining or selected quarantining of animals;
- controlling human contact with the animals;
- culling or selected culling by humane euthanasia of animals;
- changes in husbandry practices, housing, dietary formulations or other animal care procedures based on evidence that such changes are likely to be necessary to control the Outbreak; or
- any other reasonable action with the concurrence of the AWO, DACS/AFMSAB and AEC Chair. This may include variations to scientific activities on the protocol based on evidence that such changes are likely to be necessary to control the Outbreak.

4.5.3 The authorised actions of Outbreak Investigation and Outbreak Response in 4.5.1 and 4.5.2 are applicable to any animal within any protocol and are in addition to usual veterinary interventions authorised in accordance with Part 3 of this SOP.

4.5.4 If the ObM acquires new knowledge during the investigation that the Outbreak involves a reportable animal disease under the Biosecurity and Agriculture Management Act 2007 (WA), it is the responsibility of ObM to ensure that a statutory notification of reportable animal disease has been or is immediately completed.
4.6 ACCOUNTABILITY, REPORTING AND RATIFICATION

4.6.1 All communications that report results or direct actions in relation to Outbreak Investigation and Outbreak Response must be made in writing or confirmed in writing at the earliest reasonable opportunity.

4.6.2 The AWO, DACS/AFMSAB and ObM (if different) are jointly accountable to the AEC for the competent management of an Outbreak. They are also professionally responsible for achieving high standards of communication during the course of an Outbreak, including with each other, the relevant CI and the AEC Chair in bringing the issue to resolution.

4.6.3 The powers of Outbreak Investigation and Outbreak Response must be used proportionally and judiciously with due consultation. In particularly serious circumstances, the ObM must convene an Outbreak task force to coordinate the investigation and response, which must include the ObM, AWO, DACS/AFMSAB and may include the relevant CI where appropriate.

4.6.4 During the course of an Outbreak, the ObM must provide regular progress reports to the AWO, DACS/AFMSAB, relevant CI and AEC Chair on the status of the Outbreak and actions taken to investigate it and respond. The frequency of reports will be proportional to the circumstances.

4.6.5 A summary report on progress must be tabled for review at each AEC meeting that occurs during the course of the Outbreak. Review of the management of the Outbreak may occur at any routine meeting of the AEC or the AEC Chair may convene one or more special meetings for this purpose.

4.6.6 Upon review of the management of the Outbreak, the AEC must either ratify the actions authorised by the ObM or direct any change in the approach to managing the Outbreak that the Committee considers necessary, which may vary from minor strategy adjustments to the appointment of a different ObM if warranted by unusual circumstances.

4.7 RESOLUTION OF AN OUTBREAK

4.7.1 The ObM is responsible for declaring when an Outbreak has been resolved. Usually this will occur after the cause has been identified and a sufficient response has been enacted to render any resurgence unlikely. However, an Outbreak may also resolve spontaneously or by other mechanisms. The ObM must inform the AWO, DACS/AFMSAB, relevant CI and AEC Chair when there are sufficient grounds to conclude that a resolution has occurred.

4.7.2 Following the resolution of an Outbreak, the ObM must table a final report on the Outbreak Investigation and Outbreak Response at the next scheduled meeting of the AEC for final review and ratification.
4.8 REQUIREMENTS FOR PROTOCOL AMENDMENT

4.8.1 No protocol amendment is necessary for the purpose of an Outbreak Investigation performed in accordance with Part 4 of this SOP unless the AEC directs that an amendment is required.

4.8.2 No protocol amendment is necessary for the purpose of an Outbreak Response performed during the course of an Outbreak in accordance with Part 4 unless the AEC directs that an amendment is required.

4.8.3 Following the resolution of an Outbreak, any consequential ongoing modifications to a research, teaching or breeding protocol must be the subject of an application for protocol amendment at the earliest reasonable opportunity in accordance with 3.3 and 3.4 of Part 3 of this SOP where applicable.

4.9 INVESTIGATION OF NON-COMPLIANCE OF ANIMAL ETHICS

4.9.1 Any grounds discovered during an Outbreak that raise the possibility that a non-compliance of animal ethics has occurred must be reported immediately to the AEC Chair and the AWO and, where applicable, in accordance with ACS or SAB communication policies.

4.9.2 The subsequent investigation should proceed in accordance with the Standard Operating Procedure for Non-Compliance of Animal Ethics, except that where a choice must be made between progressing the investigation of non-compliance and progressing the investigation of and response to the Outbreak, precedence must be given to the management of the Outbreak.