Wildlife and Small Institutions Animal Ethics Committee

Procedures for:

- Unexpected adverse event
- Complaint
- Non-compliance

2019
Definitions

**Activity:** any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the animal ethics committee. See also ‘Project’.

**Animal welfare:** an animal’s quality of life, which encompasses the diverse ways an animal may perceive and respond to their circumstances, ranging from a positive state of wellbeing to a negative state of distress.

**Assistant Director – Governance:** The Assistant Director of the Governance Team, Animal Welfare and Agriculture Regulatory Policy, Department of Jobs, Precincts and Regions. The team responsible for administration of the WSIAEC. May be contacted via the WSIAEC executive officer.

**Australian code:** the *Australian code for the care and use of animals for scientific purposes, 8th Edition 2013*.

**Chair:** Chair of the WSIAEC

**Complaint:** a statement that something is unsatisfactory or unacceptable, this may relate to the activities of any party or person involved in the care and use of animals, including investigators, animal carers, the WSIAEC and governance officials.

**Complainant:** person lodging a complaint.

**Department:** Department of Jobs, Precincts and Regions.

**Eligible Institution:** any natural person or incorporated entity meeting the eligibility criteria determined by the department, and as amended from time to time, to access the services of the WSIAEC.

**Executive Officer:** person responsible for providing administrative support to the WSIAEC.

**Investigator:** any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

**Licensing and Audit:** Licensing and Audit Team; Animal Welfare Victoria; Agriculture Victoria; Department of Jobs, Precincts and Regions. The regulator for the use of animals in research and teaching in Victoria. May be contacted on Sp.Licensing@ecodev.vic.gov.au

**Monitoring:** measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Australian code. Monitoring occurs at different levels (including those of investigators, animal carers and animal ethics committees).

**Non-compliance:** failure to act in accordance with relevant legislation or with projects and standard operating procedures approved by the WSIAEC.

**Person with ultimate responsibility:** person who is responsible for the overall management and conduct of an individual project, and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified.

**POCTA ACT:** *Prevention of Cruelty to Animals Act 1986*

**Project:** an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose WSIAEC, upon approval by the WSIAEC the project becomes the ‘approved project’.

**Scientific purposes:** all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.
**Scientific procedure**: definition in accordance with the definition within the *Prevention of Cruelty to Animals Act 1986*.

**Standard operating procedure (SOP)**: detailed description of a standardised procedure or process.

**Unexpected adverse event**: an event that may have a negative impact on the wellbeing of animals and was not predicted in the approved project or activity. An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment, or during or after capture and restraint)
- adverse effects following a procedure or treatment or capture that were not expected
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study
- a greater level of pain or distress than was predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

**Wildlife and Small Institutions Animal ethics committee (WSIAEC)**: a committee constituted in accordance with the WSIAEC terms of reference and membership as prescribed by the Australian code.

### General

All scientific procedures and breeding of specified animals must be conducted under a licence issued under part three of the POCTA Act and in compliance with relevant legislation including the Australian code and conditions of WSIAEC approval.

Animal use for scientific purposes under a wildlife scientific permit by eligible institutions, where an exemption from a licence issued under part three of the POCTA Act applies, must comply with all relevant legislation, conditions of WSIAEC approval including full compliance with the WSIAEC approved project and SOPs, and the Australian code.

### Purpose

The following procedures for complaints, managing non-compliance and unexpected adverse events have been developed in accordance with Victorian legislation, the Australian code and department policy.

These procedures provide mechanisms for reporting between the eligible institution, the WSIAEC and as necessary Licensing and Audit.

### Natural justice

When considering complaints, non-compliance and adverse events the principles of:

- responsiveness;
- integrity;
- impartiality;
- accountability;
- respect;
- protection of whistleblowers;
- right of appeal; and
- confidentiality will apply.

### Executive officer

The WSIAEC Executive Officer is responsible for maintaining complete records of all correspondence and matters relating to these procedures.

Email: wsi.aec@ecodev.vic.gov.au
Telephone: 03 9217 4190
Unexpected adverse event procedure
1. Unexpected adverse event

1.1 Introduction

An unexpected adverse event is an event that may have a negative impact on the wellbeing of animals and was not predicted in the approved project or activity. An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment, or during or after capture and restraint)
- adverse effects following a procedure or treatment or capture that were not expected
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study
- a greater level of pain or distress than was predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

Unexpected adverse events are reviewed by an AEC to assist in determining the cause of the event, and to consider mitigations that reduce the likelihood of a recurrence.

1.2 Responding to an unexpected adverse event

When animal wellbeing is no longer consistent with AEC approval, immediate action must be taken by the person that first notices the problem. The investigator or their delegate should be notified and direct the response. Alleviating unanticipated pain and distress to the animal(s) must take precedence over an individual animal reaching the planned endpoint of the project, or the continuation or completion of the project. If necessary, animals must be humanely killed without delay.

The investigator is expected to try to establish the cause of the event and identify any changes that will reduce the likelihood of recurrence.

1.3 Reporting

Investigators are required to report all unexpected adverse events to the WSIAEC Executive Officer as soon as possible after attending to the animals. As soon as possible means as soon as access to an appropriate communication device such as phone or computer is available. Eligible institutions are required to ensure reporting occurs.

The adverse event report form must be submitted to the WSIAEC as soon as all relevant information is available but no later than two weeks after the adverse event has occurred.

Where there is information that has yet to be received at the time of submission of the report (such as results of pathology tests) an interim report must be submitted with a final report submitted on receipt of all information.

1.4 WSIAEC review procedure

In consultation with the WSIAEC Chair, the Executive Officer will review the report, and reconcile it with the approval granted by the committee. Reports of events with significant or ongoing impact to animal welfare will be circulated to the WSIAEC for immediate consideration. Other events will be reviewed at the next ordinary meeting, unless an urgent request for review or modification is made. Requests for out-of-session review will be managed in accordance with the Terms of Reference.
If the unexpected adverse event has occurred due to non-compliance with the approved application and/or the Australian code, the WSIAEC non-compliance procedure will be followed.

The WSIAEC will consider the adverse event report, the investigator’s conclusions and steps already taken in response. The committee may request further information or consult with relevant people if necessary, to prevent further impact to animals. Approval may be suspended while the review proceeds.

The WSIAEC may determine that:

- all necessary steps have been taken to prevent a recurrence and the project can continue/resume without modification or additional conditions; or
- the project can continue but certain actions must be taken (e.g., reporting, servicing of equipment), which will be specified as conditions of approval; or
- continuation of the project is suspended until specified conditions are met, e.g., modification of the original application; or
- the impact to the animals is not outweighed by the benefits of the project and approval for the project is withdrawn.

The WSIAEC Executive Officer will record and file all deliberations and decisions in relation to an unexpected adverse event and will maintain a register of unexpected adverse events.
Complaint procedure
2. Complaint procedure

2.1 Overview

The following procedure applies to complaints made to the WSIAEC regarding:

- animal care and use
- conscientious objection to teaching activities involving animals by students
- the function of the WSIAEC, including the process for review of applications and reports.

2.1.1 Principles of complaints handling

The WSIAEC acts in accordance with the Victorian Ombudsman’s guiding principles by:

- acknowledging and dealing with complaints in a timely way
- providing transparent information about how complaints are handled
- protecting the privacy of information as far as possible
- treating everyone involved in a way that is objective, respectful and fair
- considering and respecting human rights
- promoting accountability for decisions.

2.1.2 Making a complaint

Complaints may be raised by any person or group, including investigators, animal carers, WSIAEC, WSIAEC members, students, eligible institutions and employees, and members of the public.

A student may elect, at any time, to notify a teacher of a conscientious objection to participating in teaching involving the use of animals.

Complaints may relate to the activities of any party or person involved in the care and use of animals, including investigators, animal carers and governance officials. Complaints may relate to the WSIAEC process of review of an application or report.

Complaints must be lodged through the WSIAEC Executive Officer. The complaint may be made verbally in the first instance, however an investigation will only commence after it is confirmed in writing. The written complaint must detail the project application number(s) if known, the nature and basis of the complaint including, as applicable, and if known, the species and number of animals involved.

The complainant should provide their contact details so that they may be contacted for further information. Anonymous complaints will be accepted and investigated as far as practical, based on the information provided.

2.1 Complaints concerning animal care and use

Eligible institutions must develop procedures for receiving, investigating and addressing complaints. Where complaints relate to activities that would normally require AEC approval, the complaints must be referred to the WSIAEC to investigate whether such activities are conducted in accordance with AEC approval.

2.1.1 Procedure

In consultation with the WSIAEC Chair, the Executive Officer will review the complaint, and reconcile it with the approval(s) granted by the committee.

Immediate assessment and actions

The Chair, with assistance from WSIAEC members and the Assistant Director – Governance as required, will make an assessment of the urgency and seriousness of the complaint and determine the next course of action. The assessment will include consideration of actual or potential impact to animal welfare.

Complaints involving significant or ongoing impact to animal welfare will be circulated to the WSIAEC for immediate consideration. Other complaints will be reviewed at the next ordinary meeting.
If a complaint alleges adverse impact to the welfare of animals, the WSIAEC may contact the person with ultimate responsibility for the animals, or the eligible institution, to establish whether animals require immediate treatment or euthanasia to alleviate pain and distress. The WSIAEC may direct the eligible institution to take these actions and / or to cease all activities with the potential to adversely affect animal welfare, pending the outcome of an investigation.

**Investigation**

The WSIAEC will consider the complaint and establish an investigation plan. The plan will include:
- a determination of the nature of the complaint - whether it relates to an unreported adverse event in an approved project, unapproved animal use, or other potential noncompliance with the Act, Australian code, WSIAEC approval, policy or procedures
- a summary of the information available and whether it is verifiable
- a list of people from whom the WSIAEC wishes to seek further information
- the member(s) or delegate responsible for gathering the information and reporting back to the committee.

Eligible institutions and investigators will be notified of any complaint made against them. They must cooperate with the WSIAEC and representatives to provide assistance in establishing the circumstances relating to the complaint. Provision of information, access to facilities, records and personnel and attendance at meetings may be required in order to resolve a complaint.

**Decision**

The WSIAEC will determine if the complaint is supported by the information available to them. The complaint may be dismissed, unable to be resolved due to insufficient information, or upheld. The WSIAEC will communicate its deliberation and decisions to the person raising the complaint, the eligible institution and the investigator in writing.

If a complaint is upheld, the WSIAEC may:
- initiate the unexpected adverse event procedure and / or the non-compliance procedure
- refer the matter to the eligible institution with recommendations for action
- require modification to a project or activity
- suspend or withdraw approval for a project or activity.

Eligible institutions must have procedures for addressing recommendations from WSIAEC.

### 2.1.2 Investigation outcome

Where complaints raise the possibility of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint will be handled in accordance with procedures specified in that document. In the absence of any negative impact to animal welfare, the WSIAEC will refer the complaint to the eligible institution who will be responsible for such acting on the complaint.

The WSIAEC will determine if:
- immediate or remedial action is required
- approval for the project or activity should be suspended or withdrawn
- approval for the investigator to conduct other research projects is suspended or withdrawn
- it is necessary to review other similar projects or activities
- there are strategies that can be employed to ensure such events are not repeated in the future
- the matter is referred to Licensing and Audit and or the eligible institution.

### 2.1.3 Right of appeal

If any person is dissatisfied with the outcome of the WSIAEC investigation of a complaint, that person has one month from receipt of written confirmation of the outcome to appeal the decision.
A formal submission to the WSIAEC via the Executive Officer should be provided in the first instance. The Executive Officer will refer this submission to the Assistant Director - Governance.

The Assistant Director - Governance will review the submission and may uphold the decision of the WSIAEC or may determine to review the investigation and decision and make recommendations in accordance with section 2.1.2 of this procedure.

2.2 Complaints concerning conscientious objection to the use of animals in teaching activities

A student may elect, at any time, to notify a teacher of a conscientious objection to participating in teaching involving the use of animals. Such a notification must be communicated to the WSIAEC by the teacher in writing in order to allow the WSIAEC to consider the ethical aspects of the teaching project in light of the reasons for the conscientious objection.

Projects using animals for teaching approved by the WSIAEC will be approved with the following condition applied:

- procedures must be in place for conscientious objection, by a student, to teaching activities involving animals in this project. The WSIAEC must be notified when a student conscientiously objects to a teaching activity involving animals in an approved project.

In accordance with section 5 of the Australian code, eligible institutions using animals for teaching activities must have a policy regarding conscientious objection by students.

On receipt of the notification of the conscientious objection, the WSIAEC will review the reason for the objection and the approved project to consider the ethical aspects of the teaching project in light of the reasons for the conscientious objection. The WSIAEC may request additional information from the eligible institution or investigators.

Depending on the reasons for the objection, the WSIAEC may determine that the general procedure for complaints to the WSIAEC concerning animal care and use is to be followed.

The WSIAEC will inform the person with ultimate responsibility (teacher) of the outcome of the review of the objection.

2.3 Complaints concerning the function and decisions of the WSIAEC

An eligible institution, or its representatives, may make a complaint concerning the function of the WSIAEC including the process for review of applications and reports or irreconcilable differences between the AEC and an investigator.

Where an eligible institution or investigator is dissatisfied with the function or decisions of the WSIAEC all efforts should be made to communicate directly with the WSIAEC, via the Executive Officer, to seek a resolution prior to submitting a formal complaint.

If the complaint cannot be resolved by direct communication, the complaint may be made directly to the Assistant Director – Governance via the Executive Officer.

2.3.1 Responsibilities

Chair and Executive Officer

The Chair or Executive Officer, upon receipt of a formal written complaint concerning the function or decision making of the WSIAEC, must advise the Assistant Director - Governance.

The Chair or Executive Officer will, on receipt of a complaint, request information from the complainant to determine if the complainant is satisfied the complaint is to be managed by communication with the WSIAEC or if the complaint is to be referred to the Assistant Director - Governance.
Complainant

The complainant, in order to submit a formal complaint must do so in writing, outlining the basis of the complaint.

Assistant Director - Governance

When receiving a complaint regarding the function or decision making of the WSIAEC, the Assistant Director - Governance will review the complaint and determine if the complaint is:

a. Dismissed: there is no basis for the complaint to be investigated, the complainant will be informed
b. Upheld: the complaint will be investigated.

2.3.2 Investigation

The Assistant Director - Governance will investigate the complaint and determine if relevant legislation, codes, policy and procedure have been followed. This may include reviewing WSIAEC procedure, meeting minutes, correspondence and meeting with WSIAEC members and representatives of the eligible institution.

After the investigation, the Assistant Director – Governance will determine if the complaint is:

- Dismissed: the complainant will be informed
- Upheld: recommendations to the WSIAEC will be made.

The Assistant Director – Governance will provide written communication of any relevant details of the investigation to the WSIAEC.

The WSIAEC will take into consideration recommendations by the Assistant Director – Governance and reach agreement regarding any change to process or procedure. The WSIAEC may need to re-evaluate its decision-making procedures in terms of the subject of the complaint.

The ultimate decision regarding the ethical acceptability of an activity lies with the WSIAEC and must not be overridden.

The complainant will be advised in writing of the outcome of the investigation, including recommendations to the WSIAEC if applicable.

2.3.3 Right of appeal

Where a complainant is not satisfied with the outcome of an investigation regarding WSIAEC function or decisions that person may lodge a complaint in accordance with the Department of Jobs, Precincts and Regions external complaints policy.

The form to lodge a complaint is found at https://djpr.vic.gov.au/about-us/contact-us/complaints-form

The DJPR complaints process is summarised in the following flow chart.
Non-compliant event procedure
3. Non-compliant event procedure

3.1 Purpose

The purpose of this procedure is to ensure appropriate investigation and management of any non-compliant events for activities for which the WSIAEC has responsibility for oversight.

The aim of the WSIAEC in undertaking investigations of alleged or suspected non-compliance is to return to compliance. Improvements to procedures or processes may be required.

3.2 General

Eligible institutions must have a procedure for managing non-compliance. This procedure must include the mechanisms for reporting all non-compliance in terms of animal use approved by the WSIAEC to the WSIAEC.

It is the responsibility of anyone working with animals at eligible institutions under WSIAEC approval to report non-compliant events in writing, using the non-compliant event reporting form to the WSIAEC Chair, via the WSIAEC Executive Officer. Whilst it is not anticipated non-compliance will occur, reporting of non-compliance is encouraged and is consistent with a functional internal compliance management process.

The WSIAEC may require reporting of a non-compliant event:
- in accordance with the animal use complaint procedure or animal use adverse event procedure
- as a result of independent external review findings
- for any other relevant reason.

The WSIAEC Executive Officer will record and file all deliberations and decisions in relation to a non-compliant event and will maintain a register of breaches of the Australian code and events of non-compliance. This register will inform education and communication to eligible institutions and investigators.

Where there has been an unexpected adverse impact to animal welfare, the adverse event procedure must be followed and the unexpected adverse event form completed.

3.3 Investigation process

The process of investigation of a non-compliant or suspected non-compliant event involves the following steps.

3.3.1 Categorisation of the event

Upon notification, the WSIAEC Chair, Executive Officer or their delegate will determine the severity of the non-compliance or alleged non-compliance (this may be in consultation with members of the WSIAEC, eligible institution and/or Assistant Director - Governance) in accordance with the following categories:

A. Minor non compliance

Definition: negative impact to animal welfare unlikely

Examples of minor non-compliant events in the context of the above definition include:
- an administrative error
- deviation from the approved protocol without impact to animal welfare
- failure to maintain adequate records
- failure to supply required notification to the WSIAEC
B. Moderate non compliance

Definition: actual minor or moderate negative impact or potential negative impact to animal welfare of minor to moderate nature likely

Examples of moderate non-compliant events in the context of the above definition include:
   a. deviation from the approved protocol
   b. failure to report on project progress as required by the WSIAEC
   c. failure to maintain adequate records
   d. failure to report unexpected adverse event required notification to the WSIAEC.

C. Serious non compliance

Definition: actual serious negative impact or potential serious negative impact to animal welfare likely

Examples of serious non-compliant events in the context of the above definition include:
   a. deliberate or negligent deviations from the approved project or activities
   b. failure to comply with conditions of approval by the WSIAEC with potential or actual impact to animal welfare
   c. failure to report an unexpected adverse event impacting on animal welfare to the WSIAEC
   d. animal use outside of an approved protocol
   e. animal use in premises or at a place not approved by the WSIAEC
   f. animal use by persons not approved by the WSIAEC.

3.3.2 Action

The action taken by the WSIAEC will be determined by the severity of the non-compliance or alleged non-compliance. Consideration will be given to the action taken by the eligible institution and investigator upon identification of the non-compliance.

In all cases, the eligible institution and or person with ultimate responsibility will be required to provide a report, using the WSIAEC non-compliant event reporting form, to the WSIAEC outlining the circumstances of the non-compliant event, or suspected non-compliant event and the action taken to date in response.

While the person with primary responsibility for the welfare of animals allocated to a project is the person with ultimate responsibility, consideration will be given to requiring information from all persons involved in the event.

All investigators involved in the event must provide required information to the WSIAEC in an accurate and timely manner. Prompt response to all enquiries from the WSIAEC and attendance at any scheduled meetings is expected.

Where there has been non-compliance, resulting in an unexpected adverse event the adverse event procedure will be followed in addition to this procedure.

A. Minor non compliance

The WSIAEC Chair or Executive Officer will report to the WSIAEC the non-compliance or alleged non-compliance. The WSIAEC will review the relevant information, including the non-compliant event report at the next WSIAEC meeting.

In order to facilitate timely resolution of the matter the person with ultimate responsibility and other relevant persons will be notified of the date of the WSIAEC meeting at which the matter is to be discussed. All efforts should be made by the person with ultimate responsibility to be available should the WSIAEC wish to meet to discuss the matter.

The WSIAEC will:
   a. assess the information provided to determine if a non-compliant event has occurred
   b. determine any actions to be taken by the person with ultimate responsibility or other persons
c. ensure the focus of investigation and review is on improvements in processes or protocols that will enhance animal welfare

d. inform the eligible institution and relevant investigators of the outcome of the assessment of the event, any actions required to return to compliance and reduce the risk of future non-compliance

e. consider an appropriate time point to review the project and all related projects. Where the WSIAEC is satisfied with the management of the non-compliance by the eligible institution, this may be review of annual reports for approved projects

f. consider the effectiveness of the management of the non-compliance by the eligible institution and may make recommendations for improvement to the eligible institution’s non-compliance procedures.

The WSIAEC may:

a. choose to require additional information, review of records, and submission of a request for amendment to approved projects or other documentation to satisfy the committee that such an event will not occur in the future.

b. review other approved projects with which the person with ultimate responsibility is also involved.

The focus of investigation and review should be on improvements in processes or protocols that will enhance animal welfare, and reduce the risk of such an event occurring in the future.

There are three possible outcomes of the WSIAEC determination as to whether a non-compliant event has occurred:

• no evidence to support a finding of non-compliance

• insufficient evidence to make a recommendation

• evidence to support a finding of non-compliance.

See 3.4 for examples of sanctions that may be considered by the WSIAEC where a finding of non-compliance is made.

B. Moderate non compliance

All steps in the minor non-compliance described will be followed. In addition:

a. the WSIAEC Chair may determine that the event is to be considered by an out of session executive of the WSIAEC prior to the next scheduled meeting of the WSIAEC

b. the eligible institution and or license nominee will be informed of the event and kept up to date with progress of any investigations or decisions

c. the WSIAEC or executive will establish an investigation team which will include at a minimum the WSIAEC Chair and the Executive Officer or delegate(s) to review the project under investigation and all related projects

d. the investigation team will work to determine the circumstances of the non-compliant event including who was responsible, any impact to animal welfare and any corrective action taken. This may be by:

• review of the project and, as necessary, related projects

• meeting with all relevant personnel involved

• review of records

• inspection of animals.

e. the investigation team will make all efforts to complete the review in a timely manner and ideally present the findings at the next meeting of the WSIAEC

f. the investigation team will make recommendations to the WSIAEC regarding actions required to address the non-compliance

g. where the investigation team finds non-compliance to have occurred the person with ultimate responsibility will be required to attend the WSIAEC meeting at which the matter is reported to discuss the findings and any required actions with the WSIAEC.

C. Serious non compliance

All steps in the minor and moderate non-compliance process will be followed, however the Chair will immediately inform the WSIAEC and:
a. where there is a potential or actual impact to animal welfare the WSIAEC may instruct the person with ultimate responsibility that all work on the project, other than ongoing maintenance of the animals, stop, pending the outcome of the investigation
b. where the alleged non-compliance relates to one person nominated on an approved project the WSIAEC Chair may restrict access to the animals for that person and allow other approved persons to continue work on the approved project pending the outcome of the investigation
c. the WSIAEC chair and or an executive of the WSIAEC may allow, in certain circumstances, for work using remaining animals in a project to continue if there is no ongoing potential impact to animal welfare due to the non-compliant event pending the outcome of the investigation
d. the WSIAEC will establish an investigation team consisting of an executive of the WSIAEC and as relevant other members with specific expertise; a representative of the eligible institution may be required by the WSIAEC to be part of this team
e. the investigation team may liaise with the Assistant Director - Governance to seek assistance in determining appropriate actions to be taken.

On completion of the investigation, if it is determined that a serious non-compliant event has occurred, the WSIAEC will inform the Manager - Licensing and Audit.

3.4 Examples of non-compliance and possible sanctions applied by the WSIAEC

The WSIAEC will consider the event and determine the appropriate action to reduce the risk of impact to animal welfare and with the goal of a return to compliance and prevention of future non-compliance. The recommendations of the investigation team and actions required by the WSIAEC will be determined on a case-by-case basis and consider the nature and extent of the event and any extenuating circumstances such as previous warnings by the WSIAEC or previous audit findings.

In determining an appropriate course of action, the WSIAEC should consider the following hierarchy of responses:

- warnings
- directions by the WSIAEC (training, restoration, improvements in facilities or equipment)
- temporary suspension of the project (while directions are carried out)
- reporting to the department
- increased inspection or reporting frequency
- review of other related projects
- withdrawal of project approval
- referral to the eligible institution for formal discipline.

The following are provided as examples only, the individual circumstances for each event of non-compliance must be considered.

A. Minor non-compliance

Non-compliance:
- Failure to submit annual return for an approved project.
  Action: Principal Investigator to submit the annual return and implement an internal reminder system.

Non-compliance:
- Failure to apply to the WSIAEC for approval to reduce the number of times a procedure is undertaken, scientific outcomes still met by the change.
  Action: Principal Investigator to submit a modification to the approved project for approval by the WSIAEC before undertaking any more work in the project.
B. Moderate-non compliance

Non-compliance:
- Failure to report on projects as required by the WSIAEC despite reminders.

Actions:
- WSIAEC will not consider any new applications from the eligible institution until reports are received and reviewed.
- WSIAEC suspend approval for current projects until reports are received and evidence of effective internal reminder system has been provided.

Non-compliance:
- Failure to submit an unexpected adverse event report where the impact to animal welfare was moderate and animals responded to treatment.

Actions:
- Education of investigator by requiring attendance at a meeting
- Eligible institution to implement training schedule to ensure all investigators understand responsibilities.

C. Serious non compliance

Non-compliance:
- Experienced investigator named on multiple approved projects for eligible institution undertakes work on project where not nominated.

Actions:
- Education of investigator by requiring attendance at a WSIAEC meeting
- Eligible institution to implement training schedule to ensure all investigators understand responsibilities.
- Eligible institution to implement system to restrict access only to those named within an application.

Non-compliance:
- Surgical procedure undertaken in an approved project that was not described within the approved project. Investigator has previously been cautioned by the WSIAEC about ensuring approval is in place for all procedures. Non-compliance identified as a result of regulatory compliance monitoring (audit).

Actions:
- Suspension of the project, and all other projects for this eligible institution for a period of three months in order for the eligible institution and principal investigator(s) to complete a review of procedures and implement changes.
- Principal investigator(s) to review all projects to ensure all procedures are described and resubmit for consideration by the WSIAEC.
- Education of investigator by requiring attendance at a WSIAEC meeting.
- Eligible institution to implement training schedule to ensure all investigators understand responsibilities.
- Eligible institution to review internal compliance monitoring program and satisfy WSIAEC that measures are in place to prevent a recurrence, but also to identify non-compliance promptly should this occur.
- On lifting the suspension three monthly reporting of animal use to the WSIAEC by the eligible institution on all approved projects.

3.5 Appeal process

If any person is dissatisfied with the outcome of the WSIAEC investigation of an event of non-compliance, that person has one month from receipt of written confirmation of the outcome to appeal the decision.

That person is encouraged to make a formal submission to the WSIAEC via the Executive Officer in the first instance.
The Assistant Director - Governance will review the submission and may uphold the initial decision or may determine to review the initial investigation and decision.