Animal Ethics Complaints, Non-Compliance and Adverse Events Procedure

Section 1 - Purpose

(1) The purpose of this Procedure is to describe the procedure for addressing:

a. Complaints,
b. Non-Compliance and
c. Unexpected Adverse Events that are associated with the care and use of Animals for Teaching Activity and research purposes at Melbourne Polytechnic.

Section 2 - Scope

(2) This Procedure applies to:

a. all Melbourne Polytechnic staff or Students involved in the care and use of Animals for Teaching Activity and research purposes regardless of where the work is carried out,
b. all Project participants including Project Investigators (formally referenced as Project Co-ordinator) visitors and volunteer's;
c. all persons who identify an issue of concern relating to the care and treatment of Animals used at Melbourne Polytechnic for Teaching Activity and research purposes; and
d. Animal Ethics Committee (AEC) members.

(3) This procedure does not apply to Complaints;

a. about personnel outside the AEC; or
b. Teaching Activities or research that are not connected to the care and use of Animals for Teaching Activities, see Student Discipline Policy or Feedback and Complaints for details on how to lodge these types of Complaints.

Section 3 - Procedure

Complaints Associated with the Care and Use of Animals for Teaching Activity and Research

(4) Melbourne Polytechnic recognises that from time to time grievances may occur. This procedure sets out how Melbourne Polytechnic addresses its responsibilities to address Complaints and Non-Compliance relating to the care and use of Animals for Teaching Activity and research purposes.

(5) Complaints pertaining to the care and use of Animals for Teaching Activity and research, may be raised by any person or group, including Project investigators, Animal carers, AEC, AEC members, Students, Melbourne Polytechnic employees and members of the public.

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(6) Complaints may relate to the activities of any party or person involved in the care and use of Animals, including Project investigators, Animal carers, the AEC and governance officials. Complaints may relate to Conscientious Objection in the case of Teaching Activities (refer to Animal Ethics Conscientious Objection Procedure).

(7) Complaints can include but are not limited to:

a. Complaints concerning the care and use of Animals by Melbourne Polytechnic, including conscientious objection in the case of Teaching Activities;
b. Complaints concerning the AEC process of review of an application or report, including resolution of disagreements between AEC members, between the AEC and Project investigators, and between the AEC and Melbourne Polytechnic;
c. Complaints concerning the process for independent external review; or
d. Non-Compliance with the Code by any party or person involved in the care and use of Animals including Project Investigators, Animal carers, the AEC, governance officials, and external parties who are subject to agreements (as described under clauses 2.6.3 and clause 2.6.6 of the Code). Non-Compliance may also involve breaches of the Act.

(8) Melbourne Polytechnic staff, AEC members and Project Investigators/participants are required to comply with complaint and non-compliance responsibilities, as cited in the Code in Section 5.

(9) Any Compliant must be in writing and should be in as much detail as possible, such as the date and nature of the event resulting in the Complaint. Complaints should be lodged by email, contacting the Executive Officer AnimalEthics@melbournepolytechnic.edu.au.

(10) Melbourne Polytechnic will address Complaints while implementing the following principles:

a. giving priority consideration to the wellbeing of the Animals, and ensuring that activities with the potential to adversely affect Animal Wellbeing cease immediately;
b. Fair, equitable and consistent treatment will be observed when dealing with all staff, students and members of the public to ensure Complaints are resolved justly;
c. Complaints will be dealt with sensitively;
d. Complaints will be treated as confidential. The Complaint will be handled by as few people as possible to ensure active promotion of confidentiality;
e. promptly and structured processes will be implemented as described in the Procedure;
f. where possible, Complaints will be resolved at the local level;
g. adhere to governing principles as cited in the Section 5 of the Code; and
h. every effort will be made to resolve Complaints within Melbourne Polytechnic without involving agencies external to Melbourne Polytechnic and minimising any disruption to Melbourne Polytechnic operations.

(11) Where a Complaint alleges misconduct that falls outside the range of ‘animal teaching and research misconduct’, as described in the Australian Code for the responsible conduct of research, the complaint will be handled in accordance with Melbourne Polytechnic processes for dealing misconduct as set out in the:

a. the Code of Conduct Policy; and
b. the Student Discipline Policy.

Complaints made to the Animal Ethics Committee

(12) All Animal care and use for the purposes of Teaching Activities and research requires Animal Ethics approval. Animal Ethics approval delegations’ may only be exercised by the AEC. Approval is based upon the principle that the

intended animal use activities (Animal Ethics Projects), will comply with the Code and the Act. Animal Ethics approval by the AEC also requires consideration of the following:

(13) applying the Replacement, Reduction and Refinement (the 3Rs) principles at all stages of Animal care and use including:

a. the reduction in the number of animals used;
b. the replacement of Animals with other methods; and
c. the refinement of techniques used to minimise the adverse impacts on Animals.

(14) A decision made by the AEC regarding the ethical acceptability of any Project Proposal or activity involving animals in line with the Code cannot be overridden (see Conduct of Projects Procedure).

(15) The Complainant should contact the AEC and discuss their issues and concerns regarding any of the following:

a. Animal Ethics approved project conditions and requirements;
b. AEC feedback provided for an Animal Ethics Project; or
c. submit Complaints by contacting the AEC Executive Officer using the email address AnimalEthics@melbournepolytechnic.edu.au.

(16) Complaints are made by contacting the AEC Executive Officer using the email address AnimalEthics@melbournepolytechnic.edu.au.

(17) Melbourne Polytechnic will address Complaints while implementing the following principles:

a. Complaints will be resolved at the local level where ever possible;
b. Complaints will be dealt with sensitively.

(18) It is recommended that the Complainant meet with either the AEC chair or AEC representative, e.g. the AEC Executive Officer. Resolution of a Complaint with the AEC, is identified as local level resolution. The AEC should give priority consideration to the Wellbeing of the animals, and ensure that activities with the potential to adversely affect animal wellbeing cease immediately.

(19) Where resolution addresses the complaint issues and agreement is reached between the complainant and AEC, the Animal Ethics Project conditions should be reviewed and updated if required. The Project Investigator is responsible for:

a. detailing the changes to the Animal Ethics Project; and
b. submitting the updated Animal Ethics Project to the AEC for approval. Refer to the Animal Ethics Conduct of Projects Procedure for process.

(20) The AEC is responsible for approving the changes to the Animal Ethics Project (see Animal Ethics Committee Terms of Reference).

(21) If the Complaint is made by a Melbourne Polytechnic staff member, and the grievance cannot be resolved by the AEC the Complainant should notify their line manager and the Course Head of Program / Lead Teacher detailing the grievance and impacts to delivery and/or students.

(22) Where agreement cannot be reached between the AEC and the complainant, the Complainant can appeal. Melbourne Polytechnic will ensure that the Complainant has access to a person or agency external to the AEC for review of the processes followed.

(23) Where the grievance cannot be resolved at the local level (AEC), the Complainant may submit a complaint with Animal Welfare Victoria (within Agricultural Victoria, a portfolio within the- Department).

(24) The AEC will ensure that all parties, including the Complainant, are aware of the process and are informed of its progress and outcomes.

(25) All Complaints will be treated confidentially.

Non-compliance Procedure

(26) Non-compliance can include any instances as described in Section 5 of the Code but are not limited to:

a. Non-compliance with the Code by any party or person involved in the care and use of Animals including Project Investigators, Animal carers, the AEC, governance officials, and external parties subject to agreements; and
b. Non-compliance may also involve breaches of the Act.

(27) All activities that are Non-compliant or suspected to be Non-Compliant with the Code and or the Act, should be reported immediately to the AEC by contacting the Executive Officer AnimalEthics@melbournepolytechnic.edu.au.

(28) Non-compliance with the Code may be detected by:

a. Project Investigator, Project participant, volunteer, Melbourne Polytechnic staff member, Student or member of the public who can report the alleged non-compliance to the AEC by contacting the Executive Officer via email AnimalEthics@melbournepolytechnic.edu.au; or
b. the AEC as part of Monitoring Activity.

(29) If an AEC member detects activities that are Non-Compliant with the Code, the AEC is required to investigate, giving priority consideration to the Wellbeing of the animals, and to ensure that activities with the potential to adversely affect Animal Wellbeing cease immediately.

(30) The AEC Chair is responsible for assessing information provided to determine if a Non-Compliance with the Code has occurred and subsequently determining the severity (as defined in the following four steps and in the Code) of the Non-Compliance event.

(31) Non-compliance is ranked relative to how serious the issue is, as either,

a. minor,
b. moderate or
c. serious in nature.

(32) Minor Non-compliance may include:

a. an administrative error;
b. minor deviation from the approved protocol without impact to Animal Welfare;
c. failure to maintain adequate records with no potential impact on Animal Welfare;
d. failure to supply required notification to the AEC with no potential impact on Animal Welfare; or
e. failure to report an adverse event that had no impact on Animal Welfare.

(33) Moderate Non-compliance may include:

a. a deviation from the approved protocol minimally impacting Animal Welfare;
b. failure to report and maintain adequate records on Project progress as required by the AEC failure to provide

notification. To AEC regarding Unexpected Adverse Events;

c. failure to provide notification to AEC regarding Unexpected Adverse Events.
d. failure to supply required notification to the AEC with potential impact to Animal Wellbeing; or
e. Animal Facility environmental changes with minor or moderate impact on Animal Wellbeing.

(34) Serious Non-compliance may include:

a. deliberate or negligent deviation(s) from approved Project or activities that has potential for significant impact to Animal Welfare;
b. failure to comply with conditions of approval by the AEC with potential or actual impact to Animal Welfare;
c. failure to report an Unexpected Adverse Events impacting on Animal Welfare to the AEC;
d. Animal use outside of an approved protocol;
e. Animal use in premises or at a place not approved by the AEC; or
f. Animal use by persons not approved by the AEC.

(35) The classification of the severity of the alleged breach will determine the tasks and actions required. The determination of severity of the alleged breach is the responsibility of the AEC Chair.

Investigation of Alleged Minor Code Non-compliance

(36) Where an alleged Non-compliance with the Code and/or the Act has been categorised by the AEC Chair as Minor, the following tasks should be undertaken across three stages:

Stage 1: Review the Minor Non-compliance Allegation

(37) discuss at the next AEC meeting;

(38) all relevant staff (including the Project Investigator, Project participants, Facility staff and Melbourne Polytechnic teaching staff) should be invited to the AEC meeting and are required to attend meeting;

(39) the AEC should review the evidence and discuss issues arising from the alleged Non-Compliance. The AEC should consider if the evidence supports a find of a Minor Non-Compliance event; and

(40) the AEC should consider improvements that will reduce the likelihood of recurrence in the future.

Stage 2: Determine the Outcome of the Minor Non-compliance Allegation

(41) the AEC Chair will determine the outcome to the alleged misconduct implementing an evidenced based approach. Emphasis will be on Animal Welfare, compliance and reducing the risk of possible future Non-compliance;

(42) the AEC Chair will recommend rectification actions that will reduce the risk of possible future non-compliance. These actions are to be undertaken taken by the Project Investigators, Project participants and/or Melbourne Polytechnic staff;

(43) the AEC Chair will determine the timeline for implementation of the rectification actions; and

(44) Projects may continue while the changes are implemented.

Stage 3: Ratification Implementation Reporting and Review of Minor Non-compliance

(45) Project Investigators, participants and/or Melbourne Polytechnic staff will implement the changes in accordance with the rectification actions;

(46) the rectification actions are to be completed within the required timelines;

(47) Project Investigators will report to the AEC on the completion of rectification actions. This will be considered and discussed at the next AEC meeting; and

(48) the AEC and Project Investigators must maintain records (including reports) of all breaches of the Code in a dedicated Animal Ethics Complaints Teams site and managed in accordance with MP's Records Management Policy, Procedure and Guidelines.

Investigation of Alleged Moderate Code Non-compliance

(49) Where an alleged Non-compliance with the Code and/or the Act has been categorised by the Chair as Moderate, the following tasks should be undertaken across three stages:

Stage 1: Review Moderate Non-compliance Allegation

(50) the AEC Chair will establish an investigation team to review the Project. Members of the investigation team may include:

a. the AEC Chair;
b. Executive Officer;
c. a person with established experience in furthering the Welfare of animals and who is independent to Melbourne Polytechnic;
d. a person who has not engaged in Animal experimentation beyond undergraduate level studies and who is independent to Melbourne Polytechnic; and
e. Other.

(51) The investigation team will review alleged Non-compliant activities, records, speak with all relevant staff, inspect animals, Facility for housing Animals and if there is any impact to Animal Welfare.

(52) The investigation team will conduct the investigation within 10 working days of establishing the investigation team.

(53) Provide a report of the findings and ratification actions to address Non-Compliance and table for discussion at the next AEC meeting.

(54) The AEC will discuss the investigation team findings.

(55) All relevant staff (including the Project Investigator, Project participants, Animal care Facility staff and Melbourne Polytechnic teaching staff) should be invited to the AEC meeting and are required to attend meeting.

(56) The AEC should review the evidence and discuss issues arising from the alleged Non-Compliance. The AEC should consider if the evidence supports a Moderate Non-compliance event.

(57) The AEC should consider improvements that will reduce the likelihood of recurrence in the future.

Stage 2: Determine the Outcome of the Moderate Non-compliance Allegation

(58) the AEC Chair will determine the outcome to the alleged misconduct implementing an evidenced based approach. Emphasis on Animal Welfare, Compliance and reducing the risk of possible future Non-compliance will be made;

(59) the AEC Chair will recommend rectification actions that will reduce the risk of possible future Non-compliance. These actions are to be undertaken taken by the Project Investigators, Project participants and/or Melbourne Polytechnic staff;

(60) the AEC Chair will determine the timeline for implementation of the rectification actions;

(61) the AEC Chair should suspend approval of the projects where non-compliance has been determined. The AEC Chair will provide the reasons for the suspension.

(62) the timeline for implementing the ratification actions will be 5 working days.

(63) the AEC Chair will notify the following people upon Project suspension:

(64) Project Investigator;

(65) Melbourne Polytechnic Scientific Procedures Premises Licence nominee stating withdrawal of ethical approval;

(66) Executive Director Educational Excellence and Educational Directors (VET/HE); and

(67) Program and Animal Facility leadership (Managers).

Stage 3: Ratification Implementation Reporting and Review

(68) where a project has been suspended, no activity will be undertaken.

(69) Project Investigators, participants and/or Melbourne Polytechnic staff will implement the changes in the rectification actions, within 5 working days.

(70) the rectification actions are to be completed within the required timelines.

(71) Project Investigators will report to the AEC regarding competition of rectification actions. This will be considered and discussed at the next AEC meeting.

(72) the AEC and Project Investigators must maintain records (including reports) of all breaches of the Code in a dedicated Animal Ethics Complaints Teams site and managed in accordance with MP's Records Management Policy, Procedure and Guidelines.

(73) The AEC will review Project report(s) and approve reinstatement of Project where rectification actions have been successfully completed and the Project adheres to the Code.

Investigation of Alleged Serious Code Non-compliance

(74) Where an alleged Non-compliance with the Code event has been categorised by the chair as serious, the following tasks should be undertaken across three stages:

Stage 1: Review Serious Non-compliance Allegations

(75) The AEC Chair will halt the Project if there is a potential or actual impact on Animal Welfare while the matter is investigated.

(76) As a priority, consideration of Animal Welfare will be undertaken.

(77) The AEC Chair will notify the Melbourne Polytechnic Scientific Procedures Premises Licence nominee and the Executive Director Academic Operations that an alleged Serious Non-compliance event has taken place.

(78) The AEC Chair will establish an investigation team to review the Project. Members of the investigation team may include:

a. the AEC Chair;

b. Executive Officer;
c. a person with established experience in furthering the Welfare of Animals and who is independent to Melbourne Polytechnic;
d. a person who has not engaged in Animal experimentation beyond undergraduate level studies and who is independent to Melbourne Polytechnic; and
e. Other.

(79) The investigation team will review alleged Non-compliant activities, records, speak with all relevant staff, inspect Animals, Facility for housing animals and if there is any impact to Animal Welfare.

(80) The investigation team will conduct the investigation where possible within 5 working days and no later than 10 working days of establishing the investigation team.

(81) The investigation team will liaise with the Manager - Licensing and Audit (Agriculture Victoria – DJPR) to seek guidance in determining the appropriate action to be taken.

(82) Provide a report of the findings and ratification actions to address Non-Compliance and table for discussion at the next AEC meeting.

(83) The AEC will discuss the investigation team findings.

(84) All relevant staff (including the Project Investigator, Project participants, Animal care Facility staff and Melbourne Polytechnic teaching staff) should be invited to the AEC meeting and are required to attend meeting.

(85) The AEC should review the evidence and discuss issues arising from the Serious Non-Compliance allegation. The AEC should consider if the evidence supports a Serious Non-compliance event.

(86) The AEC should consider improvements that will reduce the likelihood of recurrence in the future.

Stage 2: Determine the Outcome of the Serious Non-Compliance Allegation

(87) The AEC Chair will determine the outcome to the alleged misconduct implementing an evidenced based approach. Emphasis on Animal Welfare, Compliance and reducing the risk of possible future Non-Compliance will be made.

(88) The AEC Chair will recommend rectification actions that will reduce the risk of possible future Non-Compliance. These actions are to be undertaken taken by the Project Investigators, Project participants and/or Melbourne Polytechnic staff.

(89) The AEC Chair will determine the timeline for implementation of the rectification actions.

(90) The AEC Chair should suspend approval of the Projects where Non-Compliance has been determined. The AEC Chair will provide the reasons for the suspension.

(91) The AEC Chair must report Serious Non-Compliance to Executive Director Educational Excellence, Education Directors (VET / HE), Managers, Program Leadership and the Manager - Licensing and Audit - DJPR.

(92) The timeline for implementing the ratification actions will be 5 working days.

(93) The AEC Chair will notify the following persons upon Project suspension:

a. Project Investigator;
b. Melbourne Polytechnic Scientific Procedures Premises Licence nominee stating withdrawal of ethical approval;

c. Executive Director Educational Excellence and Educational Directors (VET/HE);
d. Program and Animal Facility leadership (Mangers); and
e. the Manager - Licensing and Audit (Agriculture Victoria – DJPR).

Stage 3: Ratification Implementation Reporting and Review

(94) Where a Project has been suspended, no activity will be undertaken.

(95) Project Investigators, participants and/or Melbourne Polytechnic staff will implement the changes in the rectification actions, within 5 working days.

(96) The rectification actions are to be completed within the required timelines.

(97) Project Investigators will report to the AEC regarding completion of rectification actions. This will be considered and discussed at the next AEC meeting.

(98) The AEC and Project Investigators must maintain records (including reports) of all breaches of the Code in a dedicated Animal Ethics Complaints Teams site and managed in accordance with MP's Records Management Policy, Procedure and Guidelines.

(99) The AEC will review Project reports and approve reinstatement of Project where rectification actions have been successfully completed and the Project adheres to the Code and the Act.

Unexpected Adverse Event

(100) An Unexpected Adverse Event is an event that may have a negative impact on the Wellbeing of Animals and was not expected in the approved Project or Activity.

(101) When an Unexpected Adverse Event occurs, ensuring the animal welfare is addressed, is of the upmost priority. Alleviation of pain and distress of a severity that was not anticipated in an approved Project or activity must take precedence over an individual animal reaching the planned endpoint of the Project or activity, or the continuation or completion of the Project or activity. If necessary, animals must be killed humanely without delay. These measures must be performed by people who are competent or by people under the direct supervision of a competent person. When an animal dies unexpectedly, or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person (see Clause 2.1.5).

(102) It is the responsibility of all, particularly Project Investigators, to report all Unexpected Adverse Events to the AEC, as soon as practicable and after ensuring the Animal Welfare has been addressed. Unexpected Adverse Event reporting should:

a. describe the Unexpected Adverse Event in a report;
b. be submitted the Unexpected Adverse Event report to the AEC by email AnimalEthics@melbournepolytechnic.edu.au;
c. Unexpected Adverse Events reports should be submitted as soon as possible and within 10 working days of the event being detected;
d. Unexpected Adverse Events should be reviewed by the AEC with consideration to any improvements that can be made to reduce the likelihood of recurrence in the future;
e. the AEC should determine an outcome that is evidence based and supports Non-Compliance with the Code. Possible outcomes include one of the following:
    i. all necessary steps have been taken to prevent a recurrence and the project can continue without modification or additional conditions;
    ii. the Project can continue but certain actions must be taken;

iii. Project is suspended until modified conditions are met; and
iv. impact to the Animals is not outweighed by benefits of the Project and approval for the Project is revoked.

f. The AEC should maintain records of all Code breaches in a dedicated Animal Ethics Complaints Teams site and managed in accordance with MP's Records Management Policy, Procedure and Guidelines;
g. The AEC should determine any action to be taken by the staff member along with a timeline for implementing the changes within 5 working days of the decision by AEC. The Project Activity may continue while the changes are implemented, or the Project may be suspended until the changes are implemented;
h. the Project investigator has to implement the AEC recommended changes and submit a report to the next AEC meeting; and
i. the AEC is required to review the report, and where Projects meet the Code and the Act requirements, reinstatement of Project Activity.

(103) Any allegations of breach or misconduct, including evidence of Animal Activities conducted with AEC approval or without Ethics approval must be dealt with Melbourne Polytechnic's Misconduct Procedures and Rules.

Section 4 - Responsibility and Accountability

(104) All Melbourne Polytechnic staff, Project Investigators, Project participants, Students and AEC members must:

a. comply with the Code and the Act;
b. give priority consideration to the Wellbeing of the Animals, and ensure that activities with the potential to adversely affect Animal Wellbeing cease immediately; and
c. report Non-Compliance and Unexpected Adverse Events to the AEC.

(105) The AEC is responsible for:

a. detecting Activity that is considered Non-Compliant with the Code and the Act;
b. reviewing and considering;
    i. all Complaints;
    ii. Non-Compliance;
    iii. Unexpected Adverse Events response;
    iv. improvements to reduce the likelihood of recurrence in the future; and
    v. issues arising from Complaints, Non-compliance and Unexpected Adverse Events Response at meetings.
c. determining the outcome Complaints, Non-Compliance and Unexpected Adverse Events Response, where evidence supports Non-Compliance with the Code and Act, if required suspend approval of the Project or Activity;
d. providing a decision on all Non-Compliance and Unexpected Adverse Events Response as referenced in the Code where evidence supports Non-Compliance with the Code;
e. reporting Serious Non-Compliance breaches to Executive Director Educational Excellence, Educational Directors (VET / HE), Managers and Program Leadership - Licensing and Audit (Agriculture Victoria – DJPR);
f. suspending a Project due to Serious Non-Compliance, providing the reasons for the suspension and taking actions by the Project Investigator / staff member and implementing those changes within 5 working days of the decision by the AEC;
g. determining rectification actions to be taken by Project Investigators and staff to reduce the likelihood of Non-Compliance or Unaccepted Adverse Events;
h. reviewing Non-Compliant implementation report(s) and approving the reinstatement of project;

i. maintaining records of breaches of the Code all Complaints, Non-Compliance and Unexpected Adverse Events Response in a dedicated Animal Ethics Complaints Teams site and managed in accordance with MP's Records Management Policy, Procedure and Guidelines

j. noting a Project Investigator or staff member has the right to appeal within 20 working days of receiving the outcome, where they are dissatisfied with a decision of the AEC. Complaints about the conduct of the AEC will be addressed by the MP scientific licence holder nominee and CEO. Making themselves available and providing requested information in a timely manner if an appeal on Animal Ethics is lodged.

(106) The AEC Chair is responsible for:

a. meeting with Project Investigators, Project participants or Melbourne Polytechnic staff that raise grievances concerning AEC project conditions, Non-Compliance or other issues pertaining to the care of Animals in Teaching Activities and research;
b. Non-Compliant investigation and decisions including:
    i. detecting Activity that is considered Non-Compliant with the Code;
    ii. categorising Non-Compliant Activity (Minor, Major or Serious);
    iii. for Serious Non-compliance, halting the Project if there is a potential or actual impact on Animal Welfare while the matter is investigated;
    iv. For Moderate and Serious Non-Compliance establish an Investigation team to review the Project. Review activities, records, speak with all relevant staff, inspect animals, facility for housing animals and if there is any impact to Animal Welfare within 10 working days of establishing the investigation team;
c. for Serious Non-Compliance investigations, liaising with the Manager - Licensing and Audit (Agriculture Victoria – DJPR) to seek guidance in determining the appropriate action to be taken;
d. determining any action that has to be taken regarding the Non-Compliant activity along with timeframes;
e. determining the outcome of Non-Compliant Activity where evidence supports Non-Compliance with the Code and suspend approval of the Project;
f. for Moderate and Serious Non-Compliance provide a report of the findings of investigations and recommended actions to address Non-Compliance to the next AEC meeting and invite the relevant staff member and other staff (if required) to attend the AEC to discuss the findings;
g. where Project suspension is the outcome of a Non-Compliant review provide the reasons for the suspension and any action to be taken by the staff member along with a timeline for implementing the changes within 5 working days of the decision by the AEC;
h. advising on the outcomes to be communicated to the Project Investigator.
i. communicating Moderate Non-Compliance outcomes to the following (1) Melbourne Polytechnic Scientific Procedures Premises Licence nominee, (2) Animal Facilities Manager(s) and (3) Education Directors (VET / HE);
j. reporting Serious Non-Compliance to Executive Director Educational Excellence, Educational Directors (VET / HE), Managers, Program Leadership and the Manager - Licensing and Audit (Agriculture Victoria – DJPR).
k. assessing information provided to determine if a Non-Compliance has occurred and the severity of the Non-Compliance; and
l. informing the Melbourne Polytechnic Scientific Procedures Premises Licence nominee of Non-Compliance incidences.

(107) The Project Investigator is responsible for the following concerning Complaints:

a. contacting the AEC to follow up on queries or concerns regarding the outcome of an application. Where the outcome of discussions requires an update to the application, the Project Investigator will amend and resubmit applications to the AEC for approval;
b. Melbourne Polytechnic Project Investigators are to advise and discuss application resubmissions.

c. where Project Investigator concerns are not able to be resolved after AEC discussions, the Educational Director (VET or HE) should be contacted. A grievance should be submitted (appeal) where the matter remains unresolved; and
d. submitting a Complaint with Agriculture Victoria (DJPR) if not satisfied with the outcome of the investigation regarding AEC decision. Melbourne Polytechnic can support independent complaint processes and details will be provided from Educational Director (VET or HE).

(108) The Project Investigator is responsible for the following concerning Non-Compliance:

a. where Non-compliance with the Code is suspected, contact and discuss with the AEC; Invite the relevant Project/staff member(s) to attend the AEC to discuss alleged non- compliance;
b. where the AEC determines a project suspension decision (e.g. Serious Non-Compliance), the Project Investigator must stop all Project Activities immediately;
c. implement changes and submit a report to the next AEC meeting;
d. where the outcome of discussions requires an update to the application, the Project Investigator will amend and resubmit applications to the AEC for approval; and
e. Melbourne Polytechnic Project Investigators are to advise and discuss application resubmissions.

(109) Where Project Investigator concerns are not able to be resolved with AEC discussions the Educational Director (VET or HE) should be contacted. A grievance should be submitted where the matter remains unresolved.

(110) The Project Investigator is responsible for the following concerning Unexpected Adverse Events:

a. reporting all Unexpected Adverse Events to the Executive Officer as soon as practicable after ensuring the Animal Welfare has been addressed;
b. preparing and submit a report to the AEC detailing the Unexpected Adverse Events within 10 working days of the event being detected;
c. Implement changes within the AEC directed timeframes and submit a report to the next AEC meeting; and
d. the Project Investigator (1) has the right to appeal AEC decisions of Non-compliance/ Unexpected Adverse Events and Project approvals and is (2) responsible for lodging appeals, within 20 working days of receiving the outcome, if they are dissatisfied with a decision of the AEC. Appeals should be lodged to the Executive Director Educational Excellence utilising the Melbourne Polytechnic Complaints system.

(111) All Project participants are responsible for:

a. reporting Non-compliance, Unexpected Adverse Events and complaints in line with the Code requirements;
b. making themselves available if a Non-compliance, Unexpected Adverse Events or complaint is lodged and investigated. This includes commitments pertaining to attending AEC meeting when invited and prompt follow up to questions and providing information for reporting purposes; and
c. for making themselves available and providing requested information in a timely manner if an animal ethics appeal is lodged and investigated.

(112) All Project participants have a right to appeal where Complaint, Non-Compliance, Unexpected Adverse Events concerns are not resolved upon AEC consideration. Contact the Educational Director (VET or HE) for details. A grievance should be submitted (appeal) where the matter remains unresolved.

(113) All Melbourne Polytechnic staff involved in the care of Animals for the purposes of Teaching Activities and learning are responsible for:

a. reporting Non-compliance, Unexpected Adverse Events and Complaints in line with the Code requirements;

b. for making themselves available if a Non-compliance, Unexpected Adverse Events or complaint is lodged and investigated. This includes commitments pertaining to attending AEC meeting when invited and prompt follow up to questions and providing information for reporting purposes;
c. responding promptly (within 5 working days) to evidence requests for the purpose of Complaint, Non-Compliance, Unexpected Adverse Events investigations, that made by any of the following:
    i. AEC Chair;
    ii. AEC members;
    iii. Non-Compliant investigation team;
    iv. Project Investigators where Projects are subject to Complaint, Non-compliance and Unexpected Adverse Events allegations;
    v. Melbourne Polytechnic Scientific Procedures Premises Licence nominee stating withdrawal of ethical approval; and
    vi. Executive Director Educational Excellence and Educational Directors (VET/HE).
d. providing information a timely manner for the purpose of rectification Project AEC required reporting that pertain to either Complaint, Non-Compliance or Unexpected Adverse Events.

(114) AEC Executive Officer is responsible for:

a. detecting Activity that is considered Non-Compliant with the Code; and
b. supporting the AEC administration, including forming and reporting of investigation teams and AEC/AEC Chair outcomes.

(115) Melbourne Polytechnic Chief Executive and Scientific Procedures Premises Licence nominee are responsible for investigating Complaints about the conduct of the Animal Ethics appeals.

Section 5 - Supporting Documents and Templates

(116) Related Melbourne Polytechnic policies and procedures:

a. Animal Ethics Conscientious Objection Procedures
b. Animal Ethics Complaints, Non-Compliance and Adverse Events Procedure
c. Animal Ethics Policy
d. Animal Ethics Conduct of Projects Procedure
e. Code of Conduct Policy
f. Records Management Policy
g. Records Management Procedure
h. Student Discipline Policy

(117) Related Forms:

a. Planning Projects
b. Animal Ethics Project Proposal
c. Animal Ethics Project Summary Form
d. Animal Ethics Return Reporting Template

(118) Related Terms of Reference:

a. Animal Ethics Committee (AEC)

(119) Related Legislation and Regulation:

a. Australian code for the care and use of animals for scientific purposes 8th edition 2013
b. Australian code for the responsible conduct of research 2018
c. Prevention of Cruelty to Animals Act 1986 (POCTA)
d. Prevention of Cruelty to Animals Regulations 2008

(120) Related Guidelines:

a. Animal Ethics Use of Animals for Scientific and Teaching Purposes Guidelines
b. Records Management Guidelines
c. Student Code of Conduct Guidelines.

Section 6 - Definitions

(121) For the purpose of this procedure the following definitions apply:

a. Act: The Prevention of Cruelty to Animals Act 1986 (Vic).
b. Activity/Activities: 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'.
c. Animal: Any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.
d. Animal Ethics Committee (AEC): A committee constituted in accordance with the terms of reference and membership laid down in the Code.
e. 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.
f. Application: A request for approval from AEC to carry out a Project or Activity. An application may be for commencement of a Project or Activity, or an amendment to an approved Project or Activity.
g. Code: Australian Code for the care and use of animals for scientific purposes 8th edition 2013 (updated 2021).
h. Compliance: Acting in accordance with the Code and the Act.
i. Complaint: A statement that something is unsatisfactory or unacceptable, this may relate to the Activities of a department, AEC or person involved in the care and use of Animals, including Project Investigators and Animal carers.
j. Department/DJPR: Department of Jobs, Precincts and Regions.
k. Ethics: A framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when Animals are proposed for use, or are used, for Scientific Purposes.
l. Executive Officer: Person responsible for providing administrative support to the AEC.
m. Facility: Any place where animals are kept, held or housed, including yards, paddocks, tanks, ponds, buildings, cages, pens and containers.
n. Project Investigator: Any person who uses Animals for Scientific Purposes. This 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.
o. Monitoring: Measures undertaken to assess, or to ensure the assessment of, the Wellbeing of Animals in accordance with the Code. Monitoring occurs at different levels (including those of Project Investigators, Animal

carers and AEC).

p. Minor Non-Compliance: Has the meaning given in section 33 of this Procedure.
q. Moderate Non-Compliance: Has the meaning given in section 34 of this Procedure.
r. Non-Compliance or Non-Complaint: Failure to act in accordance with;
    i. the Code;
    ii. the Act;
    iii. any relevant regulations; and
    iv. approvals by Melbourne Polytechnic's AEC; or
    v. Projects and standard operating Procedures approved by the Melbourne Polytechnic's AEC.
s. Procedure: this Animals Ethics Complaint, Non-Compliance and Adverse Events Procedure.
t. Project: An Activity or group of activities using Animals for Teaching Activates or research purposes that have been given approval by AEC.
u. Reduction: Methods for obtaining comparable levels of information from the use of fewer Animals in Scientific Procedures or for obtaining more information from the same number of Animals.
v. Refinement: Methods that alleviate or minimise potential pain and distress, and enhance Animal Wellbeing.
w. Replacement: Methods that permit a given purpose pain and distress, and enhance Animal Wellbeing
x. Scientific Procedures: In accordance with the definition within the Act, this includes the use of Animals for:
    i. acquiring, demonstrating or developing scientific knowledge
    ii. acquiring, demonstrating, developing or exercising scientific techniques
    iii. developing or testing the use, hazards, safety, or efficiency of vaccines, substances, drugs, materials or appliances intended for use in connection with human beings or Animals.
y. Scientific Procedures Premises License nominee: As per the requirements under section 26(2) of the Act, a person that Melbourne Polytechnic has nominated to be responsible for the procedures to be carried out on the Melbourne Polytechnic premises and who is identified on the Scientific Procedures Premises Licence. The appointed Scientific Procedures Premises Licence nominee must have suitable authority to execute their obligations.
z. Scientific Procedures Premises Licence: A scientific procedures premises licence (SPPL) authorises the licence holder to use Animals for research, teaching or testing in Victoria, at the sites nominated on their licence, under the approval of a nominated AEC.
aa. 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.
ab. Serious Non-Compliance: Has the meaning given in section 35 of this Procedure.
ac. Teaching Activity/Teaching Activities: Any action or group of actions undertaken with the aim of achieving a scientific purpose, where the scientific purpose is imparting or demonstrating knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements.
ad. 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:
    i. death of an Animal, or group of Animals, that was not expected (e.g. during surgery or anaesthesia, or after a Procedure or treatment);
    ii. adverse effects following a Procedure or treatment that were not expected;
    iii. 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;

iv. a greater level of pain or distress than was predicted during the planning of the Project or Activity; and
v. 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.

ae. Wellbeing: An Animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an Animal's physical and psychological health and of the Animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions.

Status and Details

Status	Current
Effective Date	13th July 2022
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Policy Owner	Frances Coppolillo Chief Executive
Policy Implementation Officer	Nicola Cooley Director Higher Education
Author	Nicola Cooley Director Higher Education
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