



## **AUSTIN HEALTH AEC (2020) GUIDELINE FOR ETHICS SUBMISSIONS DURING THE COVID-19 PANDEMIC**

Approved 20 March 2020  
Revised 28 August 2020

### **SUMMARY OF CHANGES – REVISION DATE 28 AUGUST 2020**

<b>Topic</b>	<b>Summary</b>	<b>Page Number</b>	<b>Effective Date</b>
Review and approval of new projects	Restriction for reviewing projects has been lifted.	3	April 2020
Commencing low impact projects	Low impact projects can recommence as long as researchers comply with the BRF policy and researchers have their own contingency plan in place.	4	May 2020
Animal orders in the BRF	Please contact the BRF Manager for further advice on animal orders if low impact projects are to commence.	4	May 2020
Review of SOPs	Restriction for reviewing SOPs has been lifted.	4	April 2020
Review of all other amendments	Restriction for reviewing all other amendments has been lifted.	6	April 2020

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## **1. PURPOSE**

Austin Health has provided this guidance document to support our researchers conducting animal research projects at Austin Health. This document is to help guide researchers in submitting documents to the Austin Health Animal Ethics Committee (AEC). It also provides information relating to animal orders in the BioResources Facility (BRF). This document will be updated and reviewed regularly as required.

COVID-19 has and will continue to bring about considerable changes to how we conduct our daily activities, with further changes anticipated over the coming weeks. As a result, all researchers that have projects underway must ensure that they have appropriate contingencies in place to ensure that the safety and wellbeing of animals and researchers is upheld, and that researchers are not unnecessarily placed in harm's way or researchers unduly expended during these challenging times.

This guideline is to ensure that ethics submissions to Austin Health's AEC are dealt with in a timely, consistent and appropriate manner during the COVID-19 pandemic.

## **2. GENERAL**

The Austin Health AEC meetings will be held via video/teleconference call as per the current planned meeting schedule. Please see the Austin Health website for a list of submission cut-off dates and meeting dates.

All submissions are to be submitted in electronic format and emailed to the AEC Secretary at [aec.ethics@austin.org.au](mailto:aec.ethics@austin.org.au).

## **3. REVIEW AND APPROVAL OF NEW PROJECTS DURING COVID-19**

The Austin Health AEC has now **lifted the restriction** on reviewing and approving new research projects. As of April 2020, the AEC **will be reviewing** new AEC projects. Please see the Austin Health [website](#) for a list of submission cut-off dates and meeting dates.

Should you require any further information, please contact Research Ethics on [aec.ethics@austin.org.au](mailto:aec.ethics@austin.org.au).

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#### **4. COMMENCEMENT OF HIGH RISK PROJECTS DURING COVID-19**

Any current AEC-approved projects involving **high intensity** animal care or **high risk** procedures are not to commence as of the 20<sup>th</sup> of March 2020 until further notice. This includes projects which involve an expected **high mortality** and/or **high morbidity** rate. This action has been taken to mitigate risks to animals and staff. It is possible that there may not be sufficient resources to support the currently approved AEC projects. This includes researcher and BRF staff oversight of animals, access to treatments/compounds, and any other necessary resources to effectively conduct research projects.

Researchers are to discuss their action plan with the BRF Manager if there are animals currently in the facility which are allocated to their projects.

#### **5. COMMENCEMENT OF LOW IMPACT PROJECTS DURING COVID-19**

As of May 2020, the AEC **will allow** the recommencement of low impact research as long as researchers comply with the BRF policy and Austin Health's policy. Please contact Julia Fyfe for a copy of the BRF policy ([Julia.Fyfe@austin.org.au](mailto:Julia.Fyfe@austin.org.au)). Researchers must have their own contingency plan in place which outlines the actions that will be taken in the event that researchers are unable to enter the facility. This includes a plan for the following circumstances, but is not limited to:

- Monitoring animals;
- Administering compounds/treatments; and
- Accessing necessary equipment and rooms.

If a researcher would like to commence their project, they must receive endorsement by the head of their laboratory, and receive approval by the BRF Manager who will provide regular updates on animal numbers and ordering to the Manager at the Office for Research.

Please obtain written approval by the head of the laboratory and the BRF Manager. Please email this to [aec.ethics@austin.org.au](mailto:aec.ethics@austin.org.au) along with a copy of your contingency plan. This request will be reviewed by the Manager at the Office for Research.

#### **6. ANIMAL ORDERS AT THE BRF DURING COVID-19**

Please contact the BRF Manager for further advice on animal orders and ensure that sections 4 and 5, above, are reviewed before animal orders are placed.

#### **7. REVIEW OF NEW STANDARD OPERATING PROCEDURES (SOPs) DURING COVID-19**

The Austin Health AEC has now **lifted the restriction** on reviewing new SOPs. As of April 2020, the AEC **will be reviewing** new SOPs. Please see the Austin Health [website](#) for a list

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of submission cut-off dates and meeting dates.

Please ensure that sections 4 and 5, above, are reviewed. Researchers must not begin a new technique or procedure on animals which has a high welfare impact or which involves frequent monitoring.

## **8. REVIEW OF URGENT PROCEDURAL AMENDMENTS DURING COVID-19**

Urgent amendments relating to COVID-19 can be reviewed out-of-session by an executive of the AEC. Examples of urgent amendments may include, but are not limited to:

- Changing the treatment/injection/surgery timeframe; or
- Changing the animal monitoring schedule.

Please contact the BRF Manager to obtain advice for urgent amendments relating to COVID-19. Please send an email to the AEC Secretary at [aec.ethics@austin.org.au](mailto:aec.ethics@austin.org.au) outlining the change in the approved protocol.

The amendment form **is not required** for urgent amendments relating to COVID-19. Please ensure the email is clear that the change in protocol is only relevant during the COVID-19 crisis.

If the change will be permanent and ongoing for the duration of the project, please ensure an amendment form is submitted on the template found on the Austin Health [website](#) along with an updated protocol and updated animal monitoring sheets, if required.

## **9. ADDITION OF INVESTIGATORS DURING COVID-19**

The Austin Health AEC **will accept** the submission of a delegation log outlining the researcher's competencies. Multiple amendments are not required to add researchers onto projects effective from the 20<sup>th</sup> of March 2020 until further notice.

Please ensure this delegation log is kept up-to-date including information such as the:

- AEC reference number;
- Researcher's name;
- Techniques/procedures to be performed;
- Their level of competency; and
- When they commenced on each project.

**Please note the Office for Research or BRF staff may request this document at any time.**

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## **10. OTHER AMENDMENTS DURING COVID-19**

As of April 2020, the AEC will be reviewing all new amendments. Please see the Austin Health [website](#) for a list of submission cut-off dates and meeting dates.

Examples of other amendments include, but are not limited to:

- Addition of new strain/s;
- Increasing the total number of animals;
- Including a sub aim; or
- Changing any procedure/technique which is not related to the COVID-19 crisis.

## **11. REPORTING UNEXPECTED ADVERSE EVENTS DURING COVID-19**

The Austin Health AEC **will accept** unexpected adverse event reports to be submitted via a table format (see example on page 7).

Only COVID-19 related adverse events should be reported using the table. Any unexpected adverse events **unrelated** to COVID-19 must be reported on the template found on the Austin Health [website](#).

Please submit one table per Principal Investigator at the end of every month and list each AEC reference number with the total number of animals affected.

Please note due to the current circumstance, unexpected adverse event reports may be submitted outside the usual 24-hour period.

**Please note upon request by the AEC Secretary, the researcher may be required to submit an unexpected adverse event report on the template found on the Austin Health [website](#) for all COVID-19 related adverse events. This will be advised at a later date.**

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## Unexpected Adverse Event Reports

Please submit one report per Principal Investigator to [aec.ethics@austin.org.au](mailto:aec.ethics@austin.org.au) at the end of every month until further notice

Date the Event Occurred	Principal Investigator	AEC Project Number	Description of Incident	Action: Euthanised, Found Dead, Culled, etc.	Total Number of Animals

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## **12. SUBMITTING ANNUAL REPORTS DURING COVID-19**

Annual reports are to be submitted for each calendar year for Austin Health AEC-approved projects. The due date for the 2019 calendar year was the 23<sup>rd</sup> of March 2020. Ethical approval is contingent on receipt of annual reports.

## **13. REPORTING NON-COMPLIANT EVENTS DURING COVID-19**

Please ensure the BRF Manager is aware of all non-compliant events and email the AEC Secretary at [aec.ethics@austin.org.au](mailto:aec.ethics@austin.org.au) to inform the AEC of the non-compliant event. This report does not need to be submitted on the usual template. An email will suffice until further notice.

**Please note upon request by the AEC Secretary, the researcher must submit a non-compliant event report on the template found on the Austin Health [website](#). This will be advised at a later date.**

## **14. CONTACT INFORMATION**

The person you may need to contact will depend on the nature of your query.

If you require any further information about the ethics submission process or if you have any concerns or questions in general, please contact:

<b>Name</b>	Bernadette Nguyen
<b>Position</b>	Research Ethics Officer
<b>Telephone</b>	(03) 9496 4099
<b>Email</b>	<a href="mailto:aec.ethics@austin.org.au">aec.ethics@austin.org.au</a>

If you would like advice about the welfare of animals or advice on any projects currently being conducted at the Austin Health BioResources Facility (BRF), please contact:

<b>Name</b>	Julia Fyfe
<b>Position</b>	BRF Manager
<b>Telephone</b>	(03) 9496 5581
<b>Email</b>	<a href="mailto:Julia.FYFE@austin.org.au">Julia.FYFE@austin.org.au</a>

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If you have any complaints or concerns and would like to discuss this with the Manager of the Office for Research, please contact:

<b>Name</b>	Dr Sianna Panagiotopoulos
<b>Position</b>	Manager, Office for Research
<b>Telephone</b>	(03) 9496 5088 or 0419 884 715
<b>Email</b>	<a href="mailto:research@austin.org.au">research@austin.org.au</a>

## **15. GENERAL INFORMATION – TYPES OF ETHICS SUBMISSIONS**

The Austin Health AEC reviews the following types of submissions at an ethics committee meeting:

### **New Protocols**

All research involving animals carried out at Austin Health's BioResources Facility requires the prior approval of the Austin Health AEC. The AEC is constituted in accordance with the requirements of *The Australian Code for the Care and Use of Animals for Scientific Purposes 8<sup>th</sup> Edition 2013* (the Code).

### **Standard Operating Procedures**

A Standard Operating Procedure (SOPs) which outlines specific requirements to perform a procedure on an animal requires the prior approval of the Austin Health AEC. SOPs will provide detail on the purpose of the procedure, the impact to animals, the materials and personal protective equipment required, a step-by-step instruction of the procedure, waste disposal considerations, and any safety and risk to personnel and animal care staff.

### **Amendments**

An amendment to an approved project requires the prior approval of the Austin Health AEC before it can be implemented. Amendments may be reviewed by an executive subcommittee of the AEC only upon justification of **urgency**. All amendments approved by an executive on behalf of the AEC must be ratified by the full committee at the next AEC meeting.

Some changes are minor, whereas others are more difficult to assess and may need to be considered by the full committee. The AEC will determine if the change is significant enough to require a new application. In every case, the welfare of the animals must be the first consideration.

For more information about the type of amendments which can be submitted, please see

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the *Austin Health Animal Ethics Committee Amendment Submission [Guideline](#)*.

### **Unexpected Adverse Events**

An unexpected adverse event is defined as an event that **was not** expected or anticipated within the approved AEC protocol that has, or has the potential to have, a negative impact on animal welfare.

For more information about unexpected adverse events, please see the [Austin Health AEC \(2019\) Guideline for Management of Adverse Events](#).

### **Annual Reports**

An annual report is required to be submitted to the AEC each calendar year for review at an AEC meeting. These reports outline:

- The current status of the project (e.g. ongoing, on hold, completed or abandoned);
- The progress which has been achieved against the aims of the project;
- The number of unexpected and/or anticipated adverse events;
- If there were any non-compliant events;
- The total number of experimental and training animals used during the reporting period; and
- Whether any investigators had left the project during the reporting period.

Ethical approval is contingent on receipt of annual reports.

### **Non-Compliant Event Reports**

A non-compliant event is a failure or refusal to comply with the currently approved AEC project. It is the responsibility of all researchers and staff members to report any non-compliant event or suspected non-compliant event to the AEC.

For more information about non-compliant event reports, please see the [Austin Health AEC \(2017\) Procedure for Non-Compliant Events](#).

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