Ethics at Melbourne

Consultation Paper
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Background

Robust ethics review is recognised internationally as the cornerstone of high-quality research. Although people, animals and the environment may benefit from research activities, those who participate are subject to an inherent element of risk. The role of ethics review is to consider and manage that risk so that the rights and interests of research participants are respected and given precedence. During the 20th century, particularly following the Second World War and the violations of human rights that occurred in concentration camps in the name of research, recognition of this risk placed even greater emphasis on ethical research. Governments and organisations intensified their efforts to protect the rights of the vulnerable, formalising their expectations in legislation, requirements and guidelines that would mitigate the risk of harm to research participants, be it deliberate, negligent or an unfortunate mistake. These documents situate ethics review within the overall context of research governance and emphasise the responsibility of institutions for its implementation. Penalties for non-compliance are harsh, reflecting the fundamental importance attributed to research ethics, and include fines and litigation as well as loss of funding, publication opportunities, credibility and reputation.

The University of Melbourne (the University) is a comprehensive, research-intensive university committed to advancing research that enriches and transforms Australian and global society. To support these ambitions, the University is committed to having the highest ethical standards. This requires appropriate time and resource allocation to ensure robust, high-quality ethical review. Finding a balance between high-quality review and timeliness is a well-documented concern for research ethics committees.

The University’s ethics review systems have evolved organically over time, in response to changes in research methods as well as external and internal requirements, including compliance measures and associated administrative processes to support ethics review. A current tension exists between ensuring high-quality and time-intensive ethics review and allowing research to proceed in a timely and efficient manner. A balanced approach is required that allows ethics committees to perform the functions for which they were established while also allowing users to have confidence in the effectiveness and efficiency of the system. This remains a key challenge as we strive to balance the pressures of a ‘faster’ approval time with a ‘quality’ review process that does not compromise the ethical standards of research at the University.

Key objectives

This consultation paper seeks to establish the preferred models for animal and human research ethics review at the University.

Research ethics at the University

Research ethics review at the University meets the requirements of the relevant regulations and legislation. In Australia, all research conducted with or about people (or their data or tissue) must follow the current revision of the National Statement on Ethical Conduct in Research (updated 2015) (the National Statement). Similarly, the use of animals for research and teaching is directed by State legislation and regulations – the Prevention of Cruelty to Animals Act 1986 (Vic) and the Prevention of Cruelty to Animals Regulations 2008 – as well as the Australian Code for the Care and Use of Animals for Scientific Purposes 2013 (the Code). These codes, regulations and legislation have changed over time to reflect society’s expectations of what it means to promote ethical and responsible research.

Development of human ethics review at the University

Human ethics review was formalised in Australia in 1966 when the NHMRC issued its first Statement, with the University establishing a Human Research Ethics Committee (HREC) in 1979. There was a large increase in human ethics applications in the following years, partly attributable to a growing awareness of the value of ethics review, which is reflected in the NHMRC’s 1985 requirement that to be eligible for funding, applications must have undergone institutional ethics committee review. To deal with the rising number of applications and the broadening range of research methods without compromising the integrity of the review process, and to take a leading role among research institutions, a number of changes were adopted at the University. These included the establishment of a risk classification system, devolution of low risk application review to departmental advisory groups (now known as the Human Ethics Advisory Groups, HEAGs) and constitution of Human Ethics Sub-Committees (HESCs). Each HESC and HEAG developed their own processes within a given framework or Terms of Reference to ensure a common approach to procedures but to avoid overregulation. This is in line with the current National Statement that sets out the
Responsibilities of institutions in establishing good working procedures for ethical review bodies. Changes were regularly made to the system, with the number, composition and processes of the HEAGs fluctuating in response to the changing needs of departments. At the beginning of 2018 one HESC was split into two in order to better manage the volume of work, thus leading to the current system of four HESCs supporting applications from cognate disciplines. These are complemented by 23 HEAGs established at either the department or faculty level.

The human research ethics system at the University is under pressure from the burgeoning numbers of small student research projects – Masters minor theses, Honours theses and Doctor of Medicine research projects. The bulk of these applications are low-risk and are handled and approved at HEAG level. Consequently, HEAG workloads in some areas have been increasing (refer to number of applications in 2017, p. 8).

Development of animal ethics review at the University

Encapsulated in Victorian legislation and the Code is the standard harm minimisation of the ‘3Rs’ (replace, reduce, refine), aimed at reducing adverse impacts of research involving animals. In line with the legislation and the Code, in 1986 the University became licenced with the now Department of Economic Development, Jobs, Transport and Resources (the Department) to use animals in scientific procedures. The University also established Animal Ethics Committees (AECs), an Animal Welfare Ethics Committee to oversee the AECs, and the position of Animal Welfare Officer. Over time, a better understanding of animal welfare concerns developed within the wider community, bringing with it revisions to the Code, the Act and regulations.

Although these amendments were valuable in ensuring that the welfare of research animals was considered and that high-quality ethical review would occur, they also resulted in an increased administrative burden due to the added regulatory reporting required both at an institutional level and from individual researchers to the regulator. In response, the University modified requirements, application forms and guidance material to better meet the needs of researchers and the committees. Even so, the number of applications reviewed annually by the AECs continues to rise (e.g. 443 applications in 2017 compared with 402 in 2016 and 339 in 2015; 103 applications in Q1 2018 compared with 73 in Q1 2017 and 64 in Q1 2016), with the result that the workloads of AEC members and Secretaries is increasing.

During 2018, pre-submission review of applications will be implemented progressively. One or two academics experienced in successful submission of applications (not current members of an AEC) will review the application prior to submission and offer comments on content, meeting of legislative requirements and readability. The Faculty of Science has been trialling this process and the feedback is that it has improved the quality of the submission and reduced the burden on the AEC, including fewer major resubmissions. Significantly, pre-submission review is a suggestion of the NHMRC Best Practice Methodology released in December 2017.\(^9\)

Requirements governing ethics committees

Human ethics committees

HESC membership follows the recommendations of the National Statement (5.1.29–5.1.33). The minimum membership is eight, with equal numbers of men and women (as far as possible) and at least one-third of the members from outside the University. Each HESC should comprise: a chairperson with suitable experience, whose other responsibilities will not impair its capacity to carry out its obligations; at least two lay people; at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; at least one person who performs a pastoral care role in a community; at least one lawyer; and at least two people with current relevant research experience. No member may be appointed in more than one category. HEAGs also follow the recommendations of the National Statement for ‘Research involving no more than low risk’ (5.1.18–5.1.21).

The responsibilities of institutions, human ethics committees, other ethical review bodies and researchers are set out in Section 5 of the National Statement.\(^2\) These include that:

- ‘Institutions should regularly assess all their ethical review processes, including the criteria for allocating research to different levels of review, to ensure that those processes continue to enable the institution to meet its responsibilities under this National Statement’ (5.1.13).
- ‘Institutions that establish any non-HREC levels of ethical review for low risk research must have the resources and capacity to carry out such review competently and professionally’ (5.1.18).
• the institution is responsible for ensuring that ‘members have relevant experience and/or expertise’ (5.1.28(a)) and that members undertake ‘appropriate induction’ and ‘continuing education’ (5.1.28(b)).

• ‘Institutions that individually or jointly establish HRECs should adequately resource and maintain them’ (5.1.26).

• ‘Decisions by an HREC about whether a research proposal meets the requirements of this National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership (see paragraph 5.1.30). This exchange should, ideally, take place at a meeting with all those members present’ (5.2.29).

Animal ethics committees

AEC membership is prescribed by the Code. The Code requires that each AEC comprise representatives from a broad range of community and employment categories so as to have the necessary level of expertise while being representative of the wider community and its values. According to the Code, AECs must include the following categories of membership: Category A, a qualified veterinarian; Category B, a practising scientist, working with animals; Category C, a representative of an animal welfare organisation; and Category D, a layperson who is independent of the institution (and who is none of the above). Animal Welfare Officers and animal facility staff members regularly attend AEC meetings to provide guidance and expertise.

The responsibilities of institutions, animal ethics committees, animal carers and investigators are set out in Section 2 of the Code. These include that institutions that establish an AEC must:

• ‘ensure that the AEC membership will allow the committee to meet its responsibilities. Membership must comprise at least four people, one from each of the four categories of membership’ (2.2.1(i)).

• ‘provide the AEC with the resources required to carry out its responsibilities (see Chapter 2.3) and to maintain the AEC, and to respond effectively to recommendations from the AEC regarding resources and workloads’ (2.2.19).

• ‘establish procedures for the effective governance and operation of the AEC that will enable the AEC to meet its responsibilities under the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use’ (2.2.20).

• have documented meeting procedures that include ‘the conduct of quorate AEC meetings, including circumstances where face to face meeting is not possible – for example, through the use of videoconferencing and webconferencing or, in special circumstances, teleconferencing’ (2.2.26(ii)).

These also include that AECs must:

• ‘provide competent, fair, consistent and timely review of applications and reports related to the care and use of animals’ (2.3.3).

• ‘monitor the care and use of animals by inspecting animals, animal housing and the conduct of procedures, and/or reviewing records and reports’ (2.3.17).

Consultation on the preferred ethics review model

The following pages outline three options each for animal ethics and human ethics review processes, which have been considered within the context of the University’s expectations for responsible ethical review. Option 1 outlines the current process at the University. Options 2 and 3 have been developed with attributes aimed to better support the review process. No option is perfect. The main attributes of each option are stated, followed by a diagram and written description of the process. Each of the three options will have both positive and negative features, which have been listed in table format. The advantages and disadvantages of each option assume adequate resourcing for academic and professional support will be provided.
For animal ethics options 1–3 it is important to note that due to the legislative requirements around animal ethics and the Code, no option:

- is able to resolve the tight timeline required for revisions to be returned to the AEC.
- can wholly guarantee quorum.
- can consist of membership outside of the legislated make up.
- can allow responsibility for projects/applications to be shared across multiple AECs.

As part of the consultation, we ask that you review the options described and add your voice to the consultation. Visit the consultation page (https://staff.unimelb.edu.au/research/ethics-integrity/ethics-@-melbourne/) and provide your response through the survey portal (either individually or as the nominated respondent on behalf of a group). Individual responses may be provided anonymously, although you will be asked to identify what part of the ethics review process you are primarily associated with (e.g. researcher, student). At the end of the consultation period feedback will be collated for and considered by the Research Ethics and Integrity Strategy Committee (REISC) who will then make a recommendation to the DVC(R).
Options for a University ethics review model
Human ethics option 1: maintain current processes

Attributes

- The current model with no significant changes.
- HEAGs are located within departments/faculties. HESCs are centralised.
- Greater than Low Risk (GTLR) applications undergo review by HEAGs and HESCs.
- Low and Negligible Risk (LNR) applications undergo review by HEAGs, with the decisions ratified by HESCs.

Description

Pathway for Low and Negligible Risk applications

For Low and Negligible Risk (LNR) applications (the University’s Minimal Risk and Project with Program applications), researchers submit their application through Themis. The HEAG Administrator (located within the department/faculty) compiles the applications and creates the meeting documents. Each HEAG meets according to its own schedule, with meeting frequency and format (e.g. face to face or electronically, including by email circulation) varying according to the needs of that particular HEAG. Although HEAGs operate within a common Terms of Reference and the National Statement, they are free to modify their processes to meet their own needs. HEAGs have the delegated authority to approve Minimal Risk and Project within Program applications, and work may commence when the researcher is notified. These outcomes must also be referred to the relevant HESC for formal ratification (to meet National Statement monitoring requirements).

Pathway for Greater than Low Risk applications

For Greater than Low Risk (GTLR) applications (the University’s Standard Project and Program applications), researchers submit their application through Themis. The application goes first to the relevant HEAG meeting, where it is considered according to the processes of that HEAG. HEAGs vary in how detailed their review of a Standard Project is. Once approved by the HEAG, the application is submitted to the relevant HESC (deadline is 15 days prior to the meeting date). Discipline-specific HEAG–HESC relationships are shown here by matching colours. The HESC Secretary (located centrally in Research Ethics and Integrity) allocates key reviewers to each application, prepares the meeting documents and makes these available electronically. During the ensuing 9 days, all HESC members read the
applications. On the 10th day, the monthly HESC meeting is held face to face. The key reviewers lead the discussion around each application and HESC members consider the associated ethical issues.

Following deliberation, the HESC members determine an outcome for each application: approved (not common); not able to be approved (rare); or revision required (most outcomes fall within this category). Where an application is approved, the researcher is notified by the HESC Secretary and work may commence. Where revision is required, the HESC Secretary liaises with the researcher and, depending on the level of revision required and the decision of the HESC, seeks approval from the HESC, HESC Chair or others outside of the meeting schedule. Approval may be provided before the next HESC meeting or, alternatively, the revised application is considered at the next meeting. Once approved, the researcher is notified and work may commence. If the HESC decides that an application is not able to be approved, the researcher is notified and the process ends for that submission.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>All applications (LNR and GTLR) are reviewed at the local level by a HEAG, which has expertise relevant to the applicant’s research field.</td>
<td>There is no consistent HEAG process, leading to varying degrees of efficiency and researcher experience.</td>
</tr>
<tr>
<td>Departments and schools decide on their own HEAG processes/arrangements, allowing them to meet local needs.</td>
<td>Some HEAGs receive far too many applications to provide thorough and timely review for all. This is because the researcher population that they serve is too large.</td>
</tr>
<tr>
<td>HEAGs have delegation to approve LNR (Minimal Risk and Project within Program) applications, reducing the review workload of the HESCs who only need to ratify these approvals.</td>
<td>The workload of each HEAG comprises review of LNR (Minimal Risk and Project within Program) applications as well as pre-review of GTLR (Standard Project and Program) applications. Therefore, the HEAGs have two workload streams.</td>
</tr>
<tr>
<td>Standard Projects (GTLR) are reviewed twice: at HEAG and HESC levels. This is appropriate in some cases, but in other cases can lead to duplication/contradictory advice, lengthy time to approval and additional workload spent reviewing.</td>
<td>Each HEAG Administrator is appointed by the department or area, with FTE determined by that area according to available resources. There is little consistency around resourcing, with HEAG Administrators facing varying workloads and expectations from their departments or areas.</td>
</tr>
<tr>
<td>As faculties establish HEAGs to meet their own needs, it is difficult to evenly distribute the volume of applications.</td>
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Human ethics option 2: streamlining the process for Greater than Low Risk applications

Attributes

- HEAGs and HESCs are both centralised with greater consistency around resourcing.
- GTLR applications undergo pre-review at department/faculty level before being submitted for review by HESC.
- LNR applications undergo review by HEAGs, with the decisions ratified by HESCs.

Description

**Pathway for Low and Negligible Risk applications***

Researchers submit their ethics applications to the HEAG through a central submission portal. The HEAG membership remains composed of academics from cognate disciplines and the HEAG Administration is centralised. The HEAG Administrator compiles the LNR applications and distributes them to the relevant HEAG. The HEAG process for review is then followed, as in the current model (option 1). HEAGs have the delegated authority to approve LNR applications, and work may commence when the researcher is notified. These outcomes must also be referred to the relevant HESC for formal ratification (to meet National Statement monitoring requirements), as in option 1.

*Note that although fewer HEAGs are envisaged in this model, the number of HEAGs and the HEAG–HESC relationships are outside of the scope of this consultation and have not been determined. Resourcing requirements are similarly outside of the scope of this consultation and have not been determined.*

**Pathway for Greater than Low Risk applications**

GTLR applications are pre-reviewed at the department/faculty level, replacing the current HEAG preliminary review. Pre-reviews will provide advice to researchers on technical and ethical considerations to strengthen their application prior to formal submission. After pre-review, the applications are submitted directly to the relevant HESC. From this point on, the process follows the same steps as in the current model (option 1).
<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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</thead>
<tbody>
<tr>
<td>HEAG workload is reduced by approximately 40%.</td>
<td>HESC workload remains unaltered as LNR applications still need to be ratified and GTLR applications reviewed.</td>
</tr>
<tr>
<td>There is a single committee review for GTLR applications, reducing duplication as they do not go to the HEAG.</td>
<td>The time taken for pre-review will vary between applications, depending on the reviewers and the complexity of the application.</td>
</tr>
<tr>
<td>Pre-review of applications frees up HEAG resources to focus on ethical review of LNR applications.</td>
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<tr>
<td>HEAG Administration is centralised, with greater consistency and capacity around resourcing and access to information.</td>
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<tr>
<td>There is greater efficiency and consistency of process among HEAGs, leading to more consistent expectations and better researcher experiences.</td>
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<tr>
<td>Greater support and access to mentoring and training could be provided for HEAG Administrators as part of one team.</td>
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</tr>
<tr>
<td>For GTLR applications, pre-review at department/faculty level may proceed more quickly than some of the current HEAG timeframes because there is no longer a preliminary review that involves waiting for a set meeting date (provided that departments/faculties allow sufficient resources).</td>
<td></td>
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</tbody>
</table>
Human ethics option 3: aiming to reduce time to approval for Low and Negligible Risk applications

Attributes

- HEAGs and HESCs are both centralised with greater consistency around resourcing.
- GTLR applications undergo pre-review at department/faculty level before being submitted for review by HESC.
- LNR applications are reviewed by virtual HEAGs on a rolling basis rather than at set face to face meetings.

Description

Pathway for Low and Negligible Risk applications*
Researchers submit their ethics applications through a central submission portal. As LNR applications are received, the HEAG Administrator (located centrally) allocates them to HEAG members for review by circulation within a prescribed timeframe. All HEAGs will exist virtually rather than meeting face to face. The HEAG Administrator compiles the review feedback, liaises with the HEAG Chair who evaluates and adjudicates the feedback or decision, and the HEAG Administrator notifies the researcher. As in option 1, HEAGs have the delegated authority to approve LNR applications, and work may commence when the researcher is notified. These outcomes must also be referred to the relevant HESC for formal ratification (to meet National Statement monitoring requirements).

*Note that as in option 2, although fewer HEAGs are envisaged in this model, the number of HEAGs and the HEAG–HESC relationships are outside of the scope of this consultation and have not been determined. The objective is to provide more consistent resourcing across HEAGs rather than to remove resourcing, but resourcing requirements are similarly outside of the scope of this consultation and have not been determined.

Pathway for Greater than Low Risk applications
GTLR applications follow the process as outlined for option 2.
Applications are pre-reviewed at the department/faculty level, replacing the current HEAG preliminary review. Pre-reviews will provide advice to researchers on technical and ethical considerations to strengthen their application prior to formal submission.
After pre-review, the applications are submitted directly to the relevant HESC. Discipline-specific HEAG–HESC relationships are shown here by matching colours. From this point on, the process is the same as in the other options (options 1 and 2).

<table>
<thead>
<tr>
<th>Advantages</th>
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<tbody>
<tr>
<td>HEAG administration is centralised, with greater consistency and capacity around resourcing (as in option 2).</td>
<td>HESC workload remains unaltered as LNR applications still need to be ratified and GTLR applications reviewed (as in option 2).</td>
</tr>
<tr>
<td>There is no duplication of committee review for GTLR applications as they do not go to the HEAG (as in option 2).</td>
<td>The time taken for pre-review will vary between applications, depending on the reviewers and the complexity of the application (as in option 2).</td>
</tr>
<tr>
<td>Pre-review of GTLR applications frees up HEAG resources for review of LNR applications (as in option 2).</td>
<td>The HEAG Chair time fraction is significantly increased because they are more involved in decisions and provision of feedback to researchers. This is not an appropriate task for the HEAG Administrator to do on their own.</td>
</tr>
<tr>
<td>For GTLR applications: pre-review at department/faculty level may proceed more quickly than some of the current HEAG pre-review timeframes because pre-review no longer involves waiting for a set meeting date (provided that departments/faculties allow sufficient resources) (as in option 2).</td>
<td>Quality of HEAG review may be compromised if fewer people are reviewing the application (with the possibility of less expertise) and the process around providing one consistent response to the researcher falls to the Chair in terms of evaluating and adjudicating the review responses.</td>
</tr>
<tr>
<td>For LNR: Because HEAGs operate virtually on a rolling basis and are not constrained by monthly meeting dates, there is the potential for review to proceed more quickly.</td>
<td>Without set meeting dates and clear timelines there is a risk that time to outcome will not be reduced, and may even blow out, if HEAG review by circulation results in some reviewers not responding in a timely fashion or the allocation process fails to find researchers able to review.</td>
</tr>
<tr>
<td>There is greater efficiency and consistency of process among HEAGs, leading to more consistent expectations and better researcher experiences (as in option 2).</td>
<td>For LNR: This option is not in line with 5.2.29 of the National Statement stating that exchanges of opinions about whether a proposal meets the requirements of this National Statement should ideally take place at a meeting with all those members present.</td>
</tr>
</tbody>
</table>
Animal ethics option 1: maintain current processes

Attributes

• The current model with no significant changes.
• Applications are reviewed by committees with discipline-specific expertise.
• The opportunity to review applications occurs once per month.

Description

Animal ethics option 1 comprises the current model of four AECs associated with specific disciplines, with no significant modifications. Researchers lodge their ethics applications, which is then signed off by the project supervisor and submitted through Themis (the submission deadline is 15 days prior to the meeting date). The AEC Secretary (located centrally) compiles the applications and liaises with researchers to resolve any administrative issues. They then prepare the meeting papers and agenda and make these available electronically 7 days prior to the meeting. During the ensuing days, AEC members read the applications. Each of the four AEC meets monthly such that there is one AEC meeting occurring each week. Meetings are held face to face and may be lengthy, depending on the number and complexity of applications reviewed at each AEC meeting. It is a legislative requirement that each Category is represented at each AEC meeting, otherwise the meeting must be cancelled.

When deliberation of each application concludes, the AEC members determine an outcome from one of the following: approved; approved with conditions; revisions required; or not approved. Where an application is approved, the researcher is notified by the AEC Secretary and work may commence. Where an application is approved with conditions, the researcher must meet these conditions and submit their response. The AEC Secretary confirms receipt of their revised application and work may commence. Where revisions are required, the AEC Secretary liaises with the researcher and, depending on the level of revision required (determined by the AEC), one of the following processes may ensue: the revised application is circulated via email to the Executive (Chair and nominated committee members) who recommend an outcome that is then presented at the next AEC meeting; or the revised application is submitted for review at the next AEC meeting. If approved, work may commence. Where an application is ‘not approved’, the researcher is notified of the reasons and the process ends for that submission.
<table>
<thead>
<tr>
<th>Advantages</th>
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</thead>
<tbody>
<tr>
<td>The expertise necessary to address relevant ethical issues is more likely to be provided within AECs whose membership is associated with specific faculties/disciplines.</td>
<td>Researchers have limited access to AEC meetings for review of their ethics applications (11 annually).</td>
</tr>
<tr>
<td>Having AECs associated with specific faculties/disciplines helps with the retention of corporate knowledge of scientific procedures common to those areas of research.</td>
<td>If major revisions are required, researchers must make their revisions within 7 days and resubmit to make the next meeting. If this deadline is not met, wait times can be substantial.</td>
</tr>
<tr>
<td>AEC members inspect animal facilities associated with the applications that they review to ensure compliance with approval conditions, documentation and condition of animals.</td>
<td>If an AEC meeting does not proceed because quorum cannot be reached, applications often wait an additional month for review, with the number of applications for review at the next meeting approximately doubled.</td>
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<td></td>
<td>The strict association between AECs and specific faculties/disciplines does not allow flexibility to evenly distribute AEC applications, leading to meetings of excessive length and workload, especially for volunteer AEC members.</td>
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</table>
Animal ethics option 2: increasing access to meetings while maintaining discipline-specific expertise

Attributes

- Applications are reviewed by AECs paired into cognate disciplines.
- The opportunity to review applications occurs twice each month.

Description

Animal ethics option 2 comprises four AECs paired into cognate disciplines: two focussed on research with small animals and two focussed on research with large or exotic animals. Researchers submit their ethics application, which is allocated to the next scheduled meeting of either relevant AEC. With AECs paired into cognate disciplines, the AEC will likely contain a member with expertise aligned to that application. The overall process follows that outlined for option 1. Because of the volume and complexity of applications being reviewed by each AEC, a fifth AEC should be considered to future-proof the system.

With general AECs, the AEC will not necessarily contain a member with expertise aligned to that application, so researchers are more likely to be required to attend the AEC meeting to speak to their application. It is more likely that overall meeting time will increase for each committee. Because of the complexity of applications being reviewed by each AEC, a fifth AEC should be considered to future-proof the system.

In order to maintain the integrity of the decision-making process and align with the regulator’s expectations, applications cannot be allocated to a different AEC after initial review. The AEC that conducts the initial review must also review any revisions or amendments to that application for the life of the project.
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Researchers have increased access to AEC meetings for review of their ethics applications (22 rather than 11 annually).</td>
<td>AEC members may be approving applications for research performed in facilities that they are not familiar with and do not inspect.</td>
</tr>
<tr>
<td>Applications would be discussed at the next available meeting when meetings are cancelled because quorum is not met, likely reducing that wait by at least 2 weeks.</td>
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<tr>
<td>Overall AEC meeting length can be reduced as there is an increased ability to manage applications and workflows, freeing up members’ time to focus on thorough ethical review.</td>
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<tr>
<td>A level of relevant discipline-specific expertise is retained within AECs whilst flexibility is increased.</td>
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</table>
Animal ethics option 3: increasing access to meetings

Attributes

• Applications are reviewed by non-specialist general committees.
• The opportunity to review applications occurs four times each month.

Description

Animal ethics option 3 comprises generalist AECs that do not include specific expertise aligned with particular disciplines. Researchers submit their ethics application, which is allocated to the next scheduled meeting of an AEC (with at least one available each week rather than monthly). The overall process follows that outlined for option 1.

With general AECs, the AEC will not necessarily contain a member with expertise aligned to that application, so researchers are more likely to be required to attend the AEC meeting to speak to their application. It is more likely that overall meeting time will increase for each committee. Because of the complexity of applications being reviewed by each AEC, a fifth AEC should be considered to future-proof the system. With this option, pre-review would be mandatory.

As for option 2, in order to maintain the integrity of the decision-making process and align with the regulator’s expectations, applications cannot be allocated to a different AEC after initial review. The AEC that conducts the initial review must also review any revisions or amendments to that application for the life of the project.
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<tr>
<td>Researchers have increased access to AEC meetings for review of their ethics applications (44 rather than 11 annually).</td>
<td>Greater responsibility is placed on the researcher to explain their methods as discipline-specific expertise is spread over AECs, and researchers would need to attend AEC meetings to speak to their application.</td>
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<tr>
<td>Applications would be discussed at the next available meeting when meetings are cancelled because quorum is not met, likely reducing that wait by at least 3 weeks.</td>
<td>Pre-review at the department level would need to be mandatory to ensure that the application is reviewed by peers with scientific expertise in that area.</td>
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<td>Overall AEC meeting length can be reduced as there is a greatly increased ability to manage applications and workflows, freeing up members’ time to focus on thorough ethical review.</td>
<td>Breaking the direct link between area of expertise and the responsibility for research in that area could lead to a lack of ownership and responsibility in the decision-making process.</td>
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<td></td>
<td>It is almost certain that AEC members would be approving applications for research performed in facilities that they are not familiar with and do not inspect.</td>
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References


