

EXTERNAL REVIEW OF THE QIMR ANIMAL ETHICS COMMITTEE

THURSDAY 11 OCTOBER, 2012

REVIEW COMMITTEE REPORT

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I. INTRODUCTION

An external review of the Animal Ethics Committee at the Queensland Institute of Medical Research (QIMR) was conducted in accordance with the NHMRC *Australian code of practice for the care and use of animals for scientific purposes*, 7th edition, 2004 (the Code). A **full schedule** for the review is provided in Appendix 1. The review involved auditing of a range of operational documentation including the AEC Terms of Reference (Appendix 2), inspection of two of QIMR's three animal holding facilities (one rodent, one zebrafish; Appendix 3), observation of the conduct of an AEC meeting (Appendix 4), and interviews with groups of stakeholders in the QIMR animal ethics system (Appendix 5).

The **review committee** consisted of Professor Peter Koopman (Chairperson), Executive Director, Research Ethics and Integrity, the University of Queensland, and Ms Jude Larking, an independent community member who serves as a Category D member of the University of Queensland AEC that deals with health sciences. Both have experience and knowledge relating to animal welfare matters pertaining to research and teaching institutions, and administration of animal welfare systems appropriate to QIMR with its focus on medical research.

The **aim of the review** was to validate that the welfare of animals used at QIMR for scientific purposes is safeguarded to a level appropriate both to the legal requirements of the Institution to comply with the provisions of the Code, and to maintenance of QIMR's reputation as a world-class research Institution that conducts its business in a socially and morally responsible manner.

The **primary focus of the review** was to establish whether the QIMR AEC is operating effectively in terms of its role in safeguarding the welfare of animals and evaluating the merits of research and teaching outcomes in relation to impacts on animal welfare.

To that end, the review committee sought specific insights relating to:

- **Quality of animal care**, including cleanliness and operations of animal care facilities, attitude and morale of animal carers, level of Institutional support, degree of veterinary oversight, feedback from researchers, frequency of adverse events, and mechanisms for dealing with adverse events that may impact on the welfare of animals;
- **AEC systems and support**, including quality and quantity of paperwork, level of administrative support, conduct of meetings, fairness and transparency of proceedings, user (ie. researcher) feedback, recognition and turnover of AEC members, effectiveness of communication between AEC, researchers and management, and ability to monitor the "3Rs".
- **Appropriate balance** between advancing medical research and the need to minimize welfare impacts on animals, taking into account a range of stakeholder views including animal welfare advocates and researchers themselves.

Commendations are provided to highlight aspects of AEC operations and Institutional support that the external review committee feels are of a notably high standard.

Recommendations are provided to enable QIMR management to evaluate and, if necessary, modify processes to ensure they conform to the provisions of the Code and/or best practice in animal welfare embodied in the principles of the Code.

All discussions, audits and site visits were conducted in strict confidence. Specific points of view expressed by individuals are not identified in this report, in order to maintain confidentiality.

2. COMPLIANCE WITH THE CODE

- i. All requested documentation was provided in an organized and timely manner to allow the review committee to conduct its business without impediment.
- ii. The review committee considers, based on evidence gathered, that:
 - The AEC is operating effectively according to the requirements of the Code;
 - AEC processes are fair and transparent to all involved;
 - There is effective communication between that AEC and researchers, and the AEC and senior management;
 - The AEC is a committee of standing within the Institution;
 - The AEC is receiving necessary support to meet its responsibilities;
 - The involvement of external members in the AEC is actively supported and facilitated;
 - There are effective strategies to promote and monitor implementation of the 3Rs by the Institution;
 - There is effective monitoring of the welfare of animals; and
 - Facilities used to house animals are managed to achieve high standards of animal welfare.

3. COMMENDATIONS

- i. Inspection of AEC documentation, activities of the AEC, and stakeholder interviews gave a very positive impression of the system in place at QIMR for handling animal ethics that is user-friendly and enables it to fulfil its obligations under the Code. The use of an AEC Executive and vetting of applications by an Institutional Scientific Subcommittee ensured that consideration of applications was both thorough and expedient. Electronic means of communication and feedback were used effectively. The *Handbook for the AEC, ASSC, Animal Ethics Secretariat and Notes for AEC Chairs* was commendable for its clarity and codification of procedures.
- ii. QIMR's AEC members evidently feel a sense of purpose and fulfilment, and show a high level of mutual respect; these are considered important contributors to effective committee operation.
- iii. The AEC receives a high level of support, independence and authority from QIMR management. Administrative support is efficient and of high quality. The Review Committee commends QIMR management on the recent increase in resources allocated to veterinary oversight. The planned expansion and refinement of the electronic application forms system is also commended.
- iv. AEC business is conducted to a high level of professionalism, inclusiveness, supportiveness and fairness. All members, including community volunteer members, are treated with respect and their viewpoints are clearly valued. AEC discussions focus on substantive matters of animal welfare and the AEC appropriately recognizes the need for a balance between research/teaching activities and impacts on animal welfare in order to generate important advances in medical research.
- v. Animal facilities are of an exceptionally high standard in terms of infrastructure, operations, staff and management. Animal facility staff and management were

enthusiastic, knowledgeable, and dedicated to task. Procedures were in place to deal with adverse events and emergencies quickly and appropriately. These procedures were clear to all and widely embraced.

- vi. The passion and commitment of all parties with whom we interacted were both evident and commendable.

4. RECOMMENDATIONS

- i. The committee recommends a revision of the AEC Terms of Reference, perhaps following the release of the next (8th) edition of the Code of Practice anticipated in 2013.
- ii. Because of the potential usefulness of the internal operations document *Handbook for the AEC, ASSC, Animal Ethics Secretariat and Notes for AEC Chairs*, it is recommended that this document be progressed out of draft phase into a mature form for distribution and reference.
- iii. The committee recommends expedited release of the next version of the electronic application forms, given that the version currently in used is widely considered to be outdated and cumbersome. This updated version should include a request for a lay description of not only aims and benefits, but also experimental approach
- iv. The use of Institutional SOPs for experimental procedures involving animals should be considered.
- v. A pro-active approach to AEC member recruitment and turnover should be considered, to ensure a sustainable, quorate membership.

5. FINAL COMMENTS

We thank Professor Peter Parsons and Ms Jo Chow for their invaluable assistance in carrying out this review, and the staff, students and AEC members who participated in interviews and inspections. Their co-operation and support were greatly appreciated.

* * *

Signed on behalf of the review committee:



Peter Koopman, PhD, FAA
Chair

Friday, 12 October, 2012

APPENDIX I: REVIEW SCHEDULE

Thursday 11 October, 2012

08:30 – 09:00 Entry meeting: Professor Peter Parsons meets with external review committee

09:00 - 09:45 Animal facility inspection (1 mouse, 1 zebrafish)

09:45 - 10:45 AEC meeting audit

10:45 - 11:00 Private review panel consultation

11:00 - 11:30 Interviews with QIMR researchers

11:30 - 12:00 Interviews with animal facility manager, animal carers

12:00 - 12:30 Interviews with Category C and D AEC members

12:30 - 13:00 Interviews with Category A and B AEC members and AEC Chair

13:00 - 13:30 Interviews with Animal Welfare Co-ordinator and Consultant Veterinary Officer

13:30 - 14:00 Private review panel consultation, consolidation, exit meeting

APPENDIX 2: DOCUMENTATION AUDIT

The following documentation was requested, supplied and considered:

| Document type | Purpose/issue | Committee notes |
|---|--|---|
| 1. Brief overview of the QIMR animal ethics setup - number of committees, names of key staff etc. | Process, systems, structures, communication | Effective and clear procedure in place, processes are transparent, likely to lead to consistent outcomes. Two-step approach to scientific review noted. |
| 2. Statistics on the volume of applications considered in 2010, 2011, 2012 | Workloads, resourcing | System does not appear overloaded; difficult to tell whether volume is genuinely increasing; explore further at interview. |
| 3. List of AEC members, their categories and length of service | Membership category compliance, turnover | Compliant. Perhaps some turnover of membership would help bring fresh and varied perspectives to AEC deliberations. Committee noted an Executive system is in place (good, but why so large? – explore at interview). AEC in urgent need of more Category D members. |
| 4. AEC Terms of Reference | Regulatory compliance | Adequate; could perhaps benefit from a refresh, perhaps with the release of the 8 th Edition of the Code in 2013. Were not able to identify procedures for dealing with emergencies – explore at interview. Policy on COIs needs to be discussed at interview. |
| 5. Most recent AEC animal facility inspection report | Animal welfare | On paper, facility appears to be of high standard. Some operational/procedural issues noted (some problems with ear tags on a minority of animals, some ill mice, size of rat cages) that will be explored at interview and inspection. |
| 6. Sample of an animal monitoring scoresheet | Ability to monitor animal welfare adequately | Sample supplied was adequate and showed a high standard of consideration of welfare. |
| 7. One sample animal ethics application | Process, systems, compliance | The forms appeared to be compliant with the Code but were cumbersome – questions, help text, explanatory text, answers and administrative notes were hard to distinguish from each other. |
| 8. List of SOPs | Process, systems, user support | Appeared to be mouse house SOPs – suggest a broader range including fish SOPs and research SOPs. |
| 9. A "typical" SOP (the SOP for genotyping transgenic mice was requested at random) | Process, systems, user support | Committee noted that the supplied SOP was an application rather than an approved SOP. The SOP requested (Genotyping) apparently does not exist. Discuss at interview. |

| | | |
|--|--|--|
| 10. Minutes of most recent AEC meeting 23 Aug 2012 | Process, systems, compliance, welfare monitoring | Revealed a high level of diligence of both AEC and AEC secretariat. Further comments to arise from AEC meeting audit. |
| 11. Most recent external review report (Review 6 March 2008) | Process, systems, compliance | Satisfactory, recommendations from the last review generally implemented – eg. policy on COIs – explore at interview. |
| 12. Agenda for the next AEC meeting | Process, systems, compliance | Compliant and high-standard. Very large volume of reading called for in some applications (especially modification application). |
| 13. Handbook for SEC, ASSC, Secretariat, Notes for AEC Chair (Draft) | Additional information not requested | This seems extremely useful. |
| 14. Glossary of terms | Additional information not requested | This is a useful document. |

APPENDIX 3: ANIMAL FACILITY INSPECTIONS

| Issue | Committee notes |
|-------------------------------|--|
| Cleanliness of facilities | Fish: adequate at best; room for improvement. Mouse: exceptionally high. Best we have seen. |
| Attitude and morale of carers | Fish: none encountered. Mouse: outstandingly knowledgeable, motivated and accessible. |
| Veterinary oversight | Satisfactory. System of delegation of emergency euthanasia to animal carers. |
| Cage cards system | Identified researcher, date(s), ethics approval number(s). |
| Other observations | Environmental enrichment to a very high standard. No-fragrance policy in mouse facility. Extremely favourable impression gained of a clean, efficient, best-practice mouse facility. Sick mice monitored very closely. Emergency euthanasia policy very clear. |

APPENDIX 4: AEC MEETING AUDIT

| Issue | Committee notes |
|-----------------------------|---|
| Focus on substantive issues | Achieved. |
| Adherence to Code | Achieved; quorate. Respect for animal welfare demonstrated. |
| Professional conduct | Achieved. Mutual respect evident. |
| Facilitative approach | Achieved; not adversarial, all comments relevant and appropriate. |
| Inclusive discussions | Achieved. |
| Effective chairing | Achieved. |

APPENDIX 5: STAKEHOLDER INTERVIEWS

** denotes key areas of focus.

| 1. QIMR researchers | |
|---|--|
| Present: 1x Senior Research Officer, 1x Research Fellow, 1x Research Assistant | |
| Questions | Committee notes |
| **Overall impression of the AEC systems from a user viewpoint | Executive system works well. SSC pre-review system is helpful. Some aspects cumbersome – which mice belong in which project? |
| **Are AEC deliberations fair and consistent? | Some inconsistency, possibly when members change. AEC takes an overly dim view of minor overuse at times. |
| **Is the form clear and straightforward to use? | Not presently – much repetition in the form. |
| **Are there SOPs available? | Not currently; would be helpful to the researcher. |
| **Comment on quality of animal care at QIMR | Excellent. High professional quality of animal carers was noted. |
| **Frequency of adverse events? | Infrequent. |
| **Do you know what the emergency treatment procedures at QIMR are? | Yes, these are very clear. Very positive comments about how animal house deals with these. |
| Are you familiar with the Code? | Generally not so much. |
| **Does QIMR achieve an appropriate balance between regard for animal welfare and ability to advance medical research? | Feeling that the AEC is a bit harsh at times, but overall the balance is generally pretty good. |
| Other comments? | System to track animal numbers for reporting would be extremely useful. |

| 2. Animal facility manager, senior animal carer, junior carer. | |
|--|---|
| Present: Manager, junior tech, senior tech | |
| Questions | Committee notes |
| Overall impression of animal welfare at QIMR | “It’s all about the animals.” Sick animals are very closely monitored. |
| **Is the animal house well supported by QIMR? | Yes, all necessary equipment is provided. |
| **Degree of veterinary oversight? | Adequate. |
| Do researchers take a responsible approach? | Yes; good relationship between researchers and animal support staff. |
| How are requests for additional resources dealt with? | Positively. |
| Is there a staff training program? | Yes – TAFE courses etc. |
| Is career development considered? | Was slow at first but is now better – systems in place for additional training and certification. |
| Do you know what the emergency treatment procedures at QIMR are? | Yes (these were clear at all levels). |
| Are you familiar with the Code? | Yes, this is one of the first things they are taught. |
| ** How have the outcomes of the most recent inspection been implemented? | Yes, all acted on. |
| What do you make of the monitoring scoresheets? | Generally very happy. |

| 3. Category C and D AEC members | |
|---|--|
| Present: 2x C, 1x D | |
| Questions | Committee notes |
| Overall impression of the AEC system from a member viewpoint | AEC tries hard to abide by the spirit of the Code, not just the letter. All suggested changes at QIMR are enacted very quickly. |
| Do you feel you have adequate input to the process? | Yes. |
| **Is adequate support available for AEC members? | Yes – admin systems, help with parking, lunches etc. |
| Is the workload manageable? Increasing? Decreasing? | Fluctuates a lot, increases at the end of the year. |
| What's your view of the AEC Executive system? | Only used for minor mods, as intended. Works well, saves time, no hassle. |
| How do you find the application forms? The TORs? | Currently clunky, far too complicated, researchers provide far too much information, too long, too complex. Often have to wade through 12 pages before you reach the lay summaries to start understanding what the application is about. It is helpful to have the QIMR publicist reviewing and helping draft the lay descriptions (this seems to be done as part of SSC pre-review). It is helpful to have a statistician check over the statistical soundness (this also seems to be done as part of SSC pre-review). |
| **Are you able to monitor the 3Rs adequately? | Yes – numbers are firmly tracked. Stats are checked. Replacement – not much scope given the nature of the research. |
| **Do you feel you are appropriately recognized? | Yes – not patronized by other AEC members, very well treated. |
| **Do you feel there is too much or too little turnover of AEC members? | Perhaps to little, but recruitment is currently in progress. |
| **Does QIMR achieve an appropriate balance between regard for animal welfare and ability to advance medical research? | Yes (unanimously) – emphasis on humane treatment at QIMR. Much progress has been made in this area. |

| 4. Interviews with Category A and B AEC members and AEC Chair | |
|--|--|
| Present: Chair, 2xB | |
| Questions | Committee notes |
| Overall impression of the AEC system from a member viewpoint | Good Institutional support. AEC Chair reports to Council. |
| Do you feel you have adequate input to the process? | Yes. |
| **Is adequate support available for AEC members? | Yes. |
| Is the workload manageable? Increasing? Decreasing? | Will increase with the new building coming online. Need to plan for this. |
| What's your view of the AEC Executive system? | Works very well. |
| How do you find the application forms? The TORs? | Application forms – “Everybody complains about them.” New system on the way – need to roll that out asap. |
| **Do you feel you are appropriately recognized? | They don't expect recognition, but do their work out of a sense of duty and wanting to facilitate research. |
| **Do you feel there is too much or too little turnover of AEC members? | Some stability is good, but need more turnover. Need a pro-active turnover system. |

| 5. Animal Welfare Co-ordinator and Consultant Veterinary Officer | |
|---|--|
| Present: Regulatory affairs officer, animal welfare officer (=CVO) | |
| Questions | Committee notes |
| Overall impression of the AEC system from a your viewpoint | Electronic comments-gathering system streamlines things enormously. Executive works well, involves a wide cross-section of AEC members. |
| Are AEC deliberations fair and consistent? | Members are very committed. Standards seem to have changed, generally more stringent than in years gone by. |
| ** Does QIMR support the animal welfare system adequately? | Yes; seen to be on par with UQ. Support for SSC vetting system and online applications. |
| ** Is there effective communication between AEC, researchers and senior management? | Yes. |
| ** Is there effective monitoring of animals? | Not at present – but increasing the AWO position from 20% to 50% will be a great help. |
| Why are there no research SOPs? | They don't agree with the use of SOPs as they feel SOPs allow people to not think about what procedure they are using and whether it is the best procedure for them. Instead they advocate descriptions of procedures being available for others to see, so people can modify those to suit their own purposes. |
| **Recruitment/sustainability plan for AEC members? | OK. |
| **Frequency of adverse events? | Very few. |
| Other comments? | Increasing the AWO position from 20% to 50% will be a great help; will allow autopsies to be carried out – not enough resources to do that presently. |