

## External Review Report: QIMRB15092016

### Summary



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## Executive Summary

This independent external review has been undertaken and the report prepared by Scientific Auditing Services Pty Ltd., as commissioned by the Council of the Queensland Institute of Medical Research as part of its obligations under section 6 of the Australian code for the care and use of animals for scientific purposes - 8th Edition (the Code).

The independent external review is to assess the institution's level of compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities as identified in the Code.

The objectives of this review are to:

- evaluate and provide information, through independent external review, regarding the level of conformity by Queensland Institute of Medical Research Berghofer (QIMR Berghofer) with the requirements of the compulsory Code.
- contribute to QIMR Berghofer's promotion of animal wellbeing, principles of best practice and application of high standards of scientific integrity within the QIMRB's animal ethics framework by highlighting any non-conformance with the Code and providing recommendations to support conformance with the Code.

The Scope of the review is limited to:

- Information collected during the time period identified for the independent external review of 20 October 2016 to 31 December 2016 and during the agreed extension period of 01 January 2017 to 16 January 2017.
- QIMR Berghofer's Animal Ethics Administrative Framework - Overall Guidance Documentation - including but not limited to procedures, policies, forms and records that make up the QIMR Berghofer Animal Ethics system.
- Operation of the QIMR Berghofer AEC and its relationships - Administrative and Actual Operation - including but not limited to forms, policies, procedures (e.g. dealing with conflict of interest, complaint handling, member resignation etc.), meeting structures, authorities, minutes, training, membership composition, meeting frequency and dynamics. Attendance by the External Review Panel at a QIMR Berghofer AEC meeting held on 08 December 2016.
- QIMR Berghofer's Central and Bancroft Animal Holding Facilities situated at the Herston campus.
- Selected QIMR Berghofer Animal Use Activity - Provided by QIMR Berghofer - a currently approved research project that has been underway for at least 12 months.
- All documentation relating to the approved project, including annual/completion reporting, adverse events reporting, amendments and related correspondence.

The criteria used for the review process are:

- NHMRC - Australian code for the care and use of animals for scientific purposes - 8th Edition [<https://www.nhmrc.gov.au/guidelines/publications/ea28>] Scientific Auditing Services Pty Ltd.
- Documents associated with the care and use of animals within the QIMR Berghofer, the sample documentation, were provided by Office of Regulatory Affairs and Ethics.

The method used for review was the assessment of the sample documentation and observations collected during the review period by the independent review panel in relation to the Australian code for the care and use of animals for scientific purposes - 8th Edition 2013.

Areas which did not conform with the Code requirements were identified as:

- Major non-conformances - applied when there is non-conformance to Code requirements that seriously compromises the operational effectiveness of the animal ethics system to support the ethical, humane and responsible care and use of animals used for scientific purposes. Corrective action is required promptly to resolve the non-conformance issue.
- Minor non-conformances - applied when there is non-conformance to Code requirements that has a lesser impact and does not pose a serious compromise to the operational effectiveness of the animal ethics system to support the ethical, humane and responsible care and use of animals used for scientific purposes. Corrective action is required within a reasonable timeframe to resolve the non-conformance issue.
- General comments are made in relation to observations that may have a negative impact on the structure and operation of the animal ethics system and its ability to conform to the Australian code for the care and use of animals for scientific purposes - 8th Edition 2013.

These classifications have been developed using the definitions for types of non-conformance outlined for regulatory review on page 11 of the Queensland Government Monitoring Program for the Scientific Use Code developed by the Department of Agriculture and Fisheries (formerly Department of Primary Industries and Fisheries) and the information contained in the Australian code for the care and use of animals for scientific purposes 8th Edition 2013. They have been modified for use in a conformance review and have no regulatory power.

Preliminary findings were outlined and discussed with QIMR Berghofer staff from the Office of Regulatory Affairs and Ethics and the Office of Scientific Services resulting in the production of this report.

The review identified:

- the level of conformance with Code requirements
- a list of commendations to highlight the high level of commitment by the institution, its staff and volunteers to ensure conformance to Code requirements and the ethical, humane and responsible care and use of animals used for scientific purposes.
- the extent to which the Governing Principles have been promoted and applied within the institution to guide the decisions of all people involved in the care and use of animals for scientific purposes.
- sixteen (16) minor non-conformances that require corrective actions to ensure conformance with Code requirements.
- evidence to support the application of non-conformance reports with Code requirements.
- recommendations to correct issues of non-conformance (corrective actions).
- a list of general comments based on a knowledge of the Code requirements, that may not necessarily be considered non-conformances however they may be useful in identifying potential areas of concern that may impact on the ability of the institution to meet Code requirements.
- In conclusion the review of QIMR Berghofer's animal ethics framework demonstrated that the institution maintains a high level of conformance with the Australian code for the care and use of animals for scientific purposes - 8th Edition. Some minor non-conformances were identified in the overall system and require corrective action to ensure a high level of conformance with the Code is maintained. In addressing these non-conformances within the framework and actively promoting the governing principles within the institution the ongoing improvement in the stability, adequacy and effectiveness of its procedures to provide oversight will allow QIMR Berghofer to meet its responsibilities under the Code.

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Signed on behalf of the External Review Panel for QIMRB15092