Standard Operating Procedures (SOPs) for the
QIMR Berghofer Human Research Ethics Secretariat
(HRES)

Version 8: February 2017

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ACRONYMS

AE  Adverse Event
AHEC  Australian Health Ethics Committee of the NHMRC
CTN  Clinical Trial Notification
CTPC  Clinical Trial Protocol Committee
CTX  Clinical Trial Exemption
E-application  Electronic application
E-Form  Electronic Form
FWA  Federal Wide Assurance (USA)
GTRAP  Gene and Related Therapies Research Advisory Panel
HREC  Human Research Ethics Committee
HRES  Human Research Ethics Secretariat
HSSC  Human Scientific Sub-Committee
ICF  (Participant) Information Consent Form/s
IEC  Independent Ethics Committee (USA)
IPP  Information Privacy Principles (QLD State)
APP  Australian Privacy Principles (Commonwealth)
IRB  Institutional Review Board (USA)
IT  Information Technology
National Statement  NHMRC National Statement on Ethical Conduct in Human Research (National Statement 2007)
NEAF  National Ethics Application Form
NHMRC  the National Health and Medical Research Council
NPP  National Privacy Principles
OGTR  Office of the Gene Technology Regulator
PI  Principal Investigator
QH  Queensland Health
QIMR Berghofer  QIMR Berghofer Medical Research Institute
RAM  Regulatory Affairs Manager
RBWH  Royal Brisbane and Women’s Hospital
SAE  Serious Adverse Event
SECRETARY  Secretary to CTPC, HSSC and HREC
SOP  Standard Operating Procedure
TGA  the Therapeutic Goods Administration
TOR  Terms of Reference
E-form abbreviations
SC  Submitted to Committee
AR  Action Required
CA  Committee Approved
1. NEW APPLICATIONS FOR HUMAN RESEARCH ETHICAL REVIEW


1.2. Each project requiring approval by the QIMR Berghofer-HREC must be submitted using the Human E-Form via the QIMR Berghofer Electronic Forms (E-Forms) System (https://eforms3.qimr.edu.au/landing.aspx).

1.3. Documentation to be considered by QIMR Berghofer-HREC (e.g. Approach letter/s; advertising material; information brochure; questionnaire/s; Participant Information Consent Form/s [ICF]; research protocol; investigator’s brochure; copies of approvals from ethics committees from collaborating institutions etc.) must be submitted as attachments to the Human Ethics E-Form.

1.3.1. The human ethics E-form application is designed to ensure an accurate record is kept of all relevant documents required to be reviewed by the NHMRC National Statement (5.2.23 – 5.2.27), as well as essential study information. This includes:

- All recruitment material (NS5.2.23)
- (NS5.2.24)
  - name/s of the institution/s to which the research approval is provided
  - (b) project identification number/s (P# reference auto-assigned by e-forms)
  - (c) name/s of principal researcher/s (e-form q1)
  - (d) title of the project
  - (e) correspondence between the review body and the researcher about the review (via the “attachments” tab)
  - (f) acceptance or rejection of any changes to the proposal
  - (g) proposed date of completion of the proposal (e-form qPD004)
  - (h) formal advice of final ethical approval or non-approval, with date (via “History” tab and approval letter in “Attachments” tab)

1.4. Generally, amendments to approved protocols, termination reports, annual reports, completion reports and final reports are submitted to the QIMR Berghofer-HREC through the E-Forms System. [Note that a major modification of a research proposal previously approved by QIMR Berghofer-HREC may require the submission of new application, and where appropriate, closure of the previously approved project proposal.]

1.5. Human research ethics applications are normally reviewed by the Human Scientific Sub-Committee (HSSC) or the Clinical Trial Protocol Committee (CTPC) prior to review by the HREC. To ensure expeditious processing of applications, the HREC has scheduled meetings approximately once a month. These meetings are coordinated with subcommittee meetings to try to ensure that the majority of protocols can be approved when they are first presented to HREC. To assist investigators make best use of this process, deadlines for submissions of human proposals via the Human E-Form and dates of committee meetings are published on the QIMR Berghofer Human Ethics intranet site Research projects involving human participants.

1.6. An application should clearly state whether the proposed study would infringe the Privacy Act 1988 (Commonwealth): In particular, the Australian Privacy Principles (APPs) (http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles) and the Queensland Information Privacy Principles (IPP) (http://www.oic.qld.gov.au/guidelines/for-government/guidelines-privacy-principles/collection/basic-guide-to-ipps-1-3-collection-of-personal-information). If it does, the PI needs to identify within their application the relevant APPs and IPPs that would have been breached, and justify their use of this private information (The HREC is required to report this use of information to the NHMRC).

1.8. The Human Research Ethics Secretariat (HRES) will:-

1.8.1. Check new applications for obvious administrative errors and/or omissions.
1.8.2. For clinical trial applications, ensure that the following documents are attached:
   1.8.2.1. Clinical Trials Protocol
   1.8.2.2. Investigators Brochure
   1.8.2.3. Participant’s Consent & Information form

If these essential documents are not provided, then the e-application will be returned to Principal Investigator (PI) for attention, prior to review by CTPC and HREC.

1.9. The Secretary of the HSSC/CTPC/HREC (hereafter ‘the Secretary) in the HRES handles e-applications as per procedures set out in this document.

2. **NEW APPLICATIONS FOR HUMAN RESEARCH ETHICAL REVIEW – MULTICENTRES**

2.1. **Mutual Acceptance/Recognition Agreement/s**

2.1.1. The QIMR Berghofer and QIMR Berghofer-HREC may make a formal mutual acceptance/recognition agreement with a collaborating institution and its HREC. Where such an agreement exists, the ethics approval procedure will be set out in the agreement.

2.2. **Other Multicentre Projects**

2.2.1. Unless QIMR Berghofer and QIMR Berghofer-HREC has a formal mutual acceptance/recognition agreement applicable to the project, QIMR Berghofer investigators are required to submit human research ethics applications as per §1.

2.2.2. An application may be submitted to collaborating HRECs concurrently. The HRES and the QIMR Berghofer investigators may liaise to facilitate approvals of multicentre trials.

2.2.3. The HRES handles the e-application as per procedures set out in this document.

2.2.4. The HRES checks that the investigator has or will obtain approvals from HRECs of collaborating institutions. If appropriate, the project will remain *Action Required* (AR) until all approvals are received.

2.3 **Minimisation of duplication of ethical review – applications for a waiver from QIMR Berghofer-HREC review**

2.3.1 QIMR Council approved in February 2017 the following arrangements for handling applications for a waiver of the requirement for QIMR Berghofer HREC review:

2.3.1.1 Applications for a waiver will be considered by QIMR Council delegate. The current QIMR Council delegate is Dr Ian Wilkey.

2.3.1.2 A “waiver from QIMR Berghofer- HREC review” means that the Institute’s HREC does not need to provide ethical oversight of the research, because the study activities occurring at this site have already undergone ethical review from another HREC. Governance oversight in the form of an MTA may still be required.

2.3.1.3 PI will submit a research proposal to QIMR Council Delegate, via a completed e-form application, with a formal request to waive the requirement for QIMR Berghofer HREC review in line with Chapter 5.3 of the “National Statement”.

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2.3.1.4 Applications that are accepted as suitable for a waiver from QIMR Berghofer HREC review will be reviewed within 7 days of submission.

2.3.1.5 The submission will include:

2.3.1.5.1 Evidence of ethical approval for the project granted by another properly constituted HREC that operates in accordance with the National Statement. The approval letter should list the documents that are approved.

2.3.1.5.2 The other properly constituted HREC must be accredited with the NHMRC.

2.3.1.5.3 Evidence that the other HREC has reviewed the nature of the work occurring at QIMR Berghofer. This should be in the form of a Protocol detailing the work, or some other document approved and listed in the HREC letter of approval which fully details the nature of the work occurring at QIMR Berghofer.

2.3.1.5.4 Any other study documents approved by the external HREC as attachments to the e-form application.

2.3.1.5.5 The applicant should highlight the relevant QIMR Berghofer section of the approved application so the Delegate may easily see what activities have been approved by the external HREC.

2.3.1.5.6 The Council Delegate may request additional information or refuse a waiver if the work is considered to be initiated by QIMR Berghofer researchers, or significantly represented to the public as coordinated by QIMR Berghofer researchers.

2.3.1.5.7 QIMR Berghofer sponsored studies are not eligible for a waiver from QIMR Berghofer-HREC review.

2.3.1.6 Council Delegate will consider the request. Any exchange of relevant information and advice with another HREC(s) and/or the investigator will be facilitated by the QIMR Berghofer HREC Secretariat and documented in E-forms.

2.3.1.7 If appropriate, the Council Delegate will approve the request to waive the requirement for QIMR Berghofer HREC review on behalf of QIMR Council.

2.3.1.8 The decision will be documented in e-forms. The project status will be changed to “WR” (“Waived Review”) to reflect that the project was not reviewed by the QIMR Berghofer HREC. The decision will be communicated to the PI by email via e-forms.

2.3.1.9 Annual reports for waivered studies must be submitted.

2.3.1.10 All approvals to waive the requirements for QIMR Berghofer HREC review granted by Council Delegate on behalf of QIMR Council will be tabled for noting at the next QIMR Berghofer HREC meeting and included in the QIMR Berghofer HREC minutes, which will be submitted to QIMR Berghofer Directors Consultative Committee and QIMR Council.

2.4 Research involving use of commercially sourced cells

2.4.1 The NHMRC National Statement provides for alternative pathways for certain low risk research, as supported by QIMR Berghofer and the Regulatory Affairs Department.

2.4.2 For use of cells acquired from commercial companies, exemption from full HREC review may be suitable, if the PI can present information supporting that the research is low risk. The following provisions of the NS may be considered in applications for use of commercially acquired biospecimens:

2.4.2.1 NS 3.4.9 If the research involves no more than low risk, then the provisions of paragraphs 5.1.18 – 5.1.21 for non-HREC levels of review may apply.

2.4.2.2 NS 5.1.18 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.
2.4.2.3 **NS 5.1.20** The levels of ethical review referred to in paragraph 5.1.18 may include, but need not be limited to: (c) delegated review with reporting to an HREC; or (d) review by a subcommittee of an HREC.

2.4.3 The Regulatory Affairs Manager in consultation with the HREC Chairperson may choose to apply the NS clauses given above to applications for low risk use of human cells and/or biospecimens that are sourced from commercial companies.

2.5 QIMR Berghofer Human E-Form and the NHMRC National Ethics Application Form (NEAF)

QIMR Berghofer investigators who are collaborating with researchers from institutions which use the NEAF should normally be able to complete the QIMR Berghofer Human E-Form by copying relevant text from the NEAF and pasting it into the corresponding sections of the e-application. The completed NEAF can be attached to the E-Form.

The HRES handles the e-applications as per procedures set out in this document.

3. **CHECKLISTS FOR APPROACH LETTERS AND CONSENT DOCUMENTATION**

3.1. **General Recruitment Material**

3.1.1. The HRES should ensure that general recruitment material e.g. advertisements contain sufficient identification for the source and purpose of the advertisement to be readily ascertained.

3.2. **Approach Letters and Consent Documentation**

3.2.1. The HRES should ensure the following information is clearly included in approach letters, ICF and any other documents sent to individuals in the course of recruitment.

(a) QIMR Berghofer project reference number and project title;
(b) Contact persons (for research project and for concerns/complaints) clearly stated in all Approach and ICF documentation;

3.3. **Recruitment Documentation**

3.3.1. The HRES should ensure the following information is included in the application.

(a) The source/s of participant recruitment;
(b) Method/s of recruitment;
(c) Relevant details (e.g. Gender, age, control/case, etc.) of participants (approached and recruitment);
(d) If only data or previously collected tissue is to be used, the relevant prior consent for additional use in research.
(e) An application should clearly state whether the proposed study would infringe the Privacy Act 1988 (Commonwealth): In particular, the Australian Privacy Principles (APPs) (http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles) and the Queensland Information Privacy Principles (IPP) (http://www.oic.qld.gov.au/guidelines/for-government/guidelines-privacy-principles/collection/basic-guide-to-ipps-1-3-collection-of-personal-information). If it does, the PI needs to identify within their application the relevant APPs and IPPs that would have been breached, and justify their use of this private information (The HREC is required to report this use of information to the NHMRC).

3.4. **Inquiries and Complaints**
3.4.1. Where recruitment involves approaches to individuals identified from databases e.g. electoral rolls, disease registries or other databases the HRES may receive inquiries, concerns and/or complaints from research participants or their relatives concerning privacy infringement (refer to §12).

3.4.2. The HRES should encourage all QIMR Berghofer investigators, who are identified as the contact persons in the ICF, to maintain an immediately accessible database so that all such inquiries could be followed up promptly.

4. MODIFIED APPLICATIONS FOR HUMAN RESEARCH ETHICAL REVIEW

4.1. PI is required to submit a Modified Application via the E-Forms system if s/he wishes to make a change to a QIMR Berghofer-HREC approved project. The study Protocol must be updated and any changed documents must have the appropriate version controls and dates.

4.2. With the exception of minor administrative changes (e.g. contact numbers and/or addresses; correction of version control and/or page numbering; correction of minor errors etc.), modified e-applications and/or relevant attachments are handled by the HRES per procedures set out in this document.

4.3. In general, minor administrative changes as indicated in §4.2 do not need to be reviewed by the HSSC or the CTPC. These amendments may be accepted by the Secretary. If an amendment is minor but not simply a correction of an administrative error, the Secretary may submit the proposed amendment to the HREC Chair for executive approval. Amendment accepted by the Secretary or approved executively by the HREC Chair are to be listed in the HREC agenda for noting at the next HREC meeting.

5. EXPEDITED REVIEW OF RESEARCH PROPOSALS BETWEEN MEETINGS (EXECUTIVE APPROVALS)

5.1. Although in general all proposals must be submitted to the QIMR Berghofer-HREC for approval, the QIMR Berghofer-HREC has provision for the expedited review of research proposals between meetings.

5.2. Executive approval process may be used in the following circumstances:

5.2.1. Where a deficiency is identified by the QIMR Berghofer-HREC or additional information is required, the QIMR Berghofer-HREC may authorise the Chairperson or Delegate to approve the proposal executively when the Chairperson or Delegate is satisfied that the deficiency has been addressed, or the additional information has been provided.

5.2.2. Executive approval may be requested by the PI to expedite approval of non-controversial amendments to an approved protocol, for example to approve amendments requested by another HREC, to update personnel on a project, to improve trial associated procedures, or to make technical modifications to test procedures.

5.2.3. Executive approval may be requested to expedite approval of minor amendments of administrative nature e.g., changes of contact details, corrections of version control and/or page numbering, or correction of minor errors in approved documents.

5.3. Executive approval process is not appropriate for a new protocol or annual reports.

5.4. Requests for executive approval may be made through the Secretary to the Chairperson or Deputy Chairperson, or any HREC Member, who is acting as HREC Chair (“the Executive”).

5.5. If the Executive is satisfied that the circumstances justify urgent review, the Executive may:

5.5.1. Grant Executive Approval.
5.5.2. Refer the application to any other member or members of the QIMR Berghofer-HREC, the QIMR Berghofer-HSSC or the QIMR Berghofer-CTPC for comment to assist the Executive in deciding whether approval should be given.

5.5.3. Bypass the normal HREC review process by placing the request as a late item on the HREC agenda.

5.5.4. Request an out of session review by HREC (“Flying minute”).

5.5.5. Call a special meeting of HREC.

5.5.6. Require amendment of the proposal.

5.5.7. Refuse the request for executive approval.

5.6. An executive approval is final and does not require further approval. All executive approvals will be submitted to the next meeting of the QIMR Berghofer-HREC for noting.

6. QIMR Berghofer-HREC APPROVALS

6.1 Preparation, Updating and Signing of Approvals

6.1.1. To assist with timely approval notification to researchers, QIMR Berghofer-HREC Approvals and relevant TGA documentation (e.g. CTN, CTX forms) are normally prepared in advance of each HREC meeting, for the HREC Chair signature and date following the meeting (see §16.3.6).

6.1.2. The Approvals and relevant TGA documentation are prepared on the assumption that the research ethics applications listed for consideration by the HREC at the meeting will be approved with no concerns. If the decision of the HREC is inconsistent with the prepared approval or documentation, the relevant documents must be withdrawn and new documents prepared for the Chair’s signature.

6.1.3. Approvals must clearly state the following:
   (a) Condition/s or proviso/s;
   (b) Date of the QIMR Berghofer-HREC meeting;
   (c) Full listing of all documents reviewed and approved by the QIMR Berghofer-HREC;
   (d) Approved study sites;
   (e) Noting of advice such as SAEs, protocol deviations, etc. especially in relation to clinical trials are essential;
   (f) QIMR Berghofer-HREC Approvals are renewed annually. Renewal is normally granted when the Annual Report is noted;
   (f) Executive approval and the noting of the approval by the next HREC meeting are documented in the updated QIMR Berghofer-HREC Approval.

6.2 Distribution of Approvals

6.2.1 Original signed copies of the QIMR Berghofer-HREC Approvals are kept in the HRES Office.

6.2.2 QIMR Berghofer-HREC Approvals for new protocols should be withheld from PIs until all necessary Safety (mandatory), OGTR, GTRAP and/or Risk Management clearances have been received. The E-forms comment from the Secretary should state that ethical approval only is granted, and that final approval to commence the study is dependent on the safety approval.

6.2.3 Copies of the signed QIMR Berghofer-HREC Approvals and TGA documents (where relevant) are provided to the following via email:
7. **SERIOUS ADVERSE EVENTS (SAEs) AND ADVERSE EVENTS (AEs)**

7.1. **AEs and SAEs Involving QIMR Berghofer Sponsored Trials**

7.1.1 The reporting, handling and review of AEs and SAEs are described in the QIMR Berghofer-CTPC TOR as well as QIMR Berghofer’s Standard Operating Procedure for Adverse Events Reporting available on the QIMR Berghofer Intranet: [http://intranet.qimr.edu.au/intranet/corporate/ethics/SOPs/QIMRCTSOP013.pdf](http://intranet.qimr.edu.au/intranet/corporate/ethics/SOPs/QIMRCTSOP013.pdf)

7.1.2 The Clinical Trial Office is responsible for the administrative handling (recording, arranging review, follow-up, assists PI in posting notifications and reports into e-forms, etc.).

7.1.3 Once a notification or report is posted into E-forms, the Secretary should list it for consideration or noting by the CTPC and HREC, at their next scheduled meetings.

7.2. **AEs and SAEs Involving Non-QIMR Berghofer Sponsored Trials**

7.2.1 The reporting, handling and review of AEs and SAEs are described in the QIMR Berghofer-CTPC TOR

7.2.2 Once a notification or report is posted into the e-form, the Secretary should list it for consideration or noting by the CTPC and HREC, at their next scheduled meetings.

7.3. **AEs and SAEs Involving Studies other than Clinical Trials**

7.3.1 Once a notification or report is posted into E-forms, the HREC Secretary should list it for consideration or noting by the HSSC and HREC, at their next scheduled meetings.

8. **QIMR Berghofer-HREC ANNUAL REPORTS TO THE NHMRC-AHEC**

8.1 QIMR Berghofer-HREC is required to submit an annual report (calendar year) to the NHMRC-Australian Health Ethics Committee (AHEC) secretariat, usually early in the next year for the preceding year. The AHEC secretariat will send a notice when this report is required.

8.2 The Secretary prepares the draft Annual Report, in consultation with the HREC Chair and RAM.

8.3 Once the report is approved by the HREC Chair and RAM, it is signed and dated by QIMR Berghofer Director and HREC Chair. The Secretary then submits the completed Report to AHEC by the submission deadline. A copy of the Report is also tabled at the next scheduled HREC meeting, for members’ information and subsequently sent with the corresponding HREC minutes to Council, for information.

8.4 Forms for the prospective collection of statistics relevant for the NHMRC AHEC report can be found at: G:\ethics\HREC\Statistics. The HRES will enter the required data into these forms following each HREC meeting.

9. **BILLING FOR HREC REVIEW OF Q-PHARM TRIALS**

For each review period an invoice is generated for all Q-Pharm clinical trials which have received HREC review. The level of review being conducted by the HREC and/or its Chair (i.e. new protocol, amendment, or executive approval request) determines the fee being charged. Following the HREC meeting, the HREC Secretary is required to compile a list of Q-Pharm trials which have been reviewed.
in the given review period. This listing should include protocol number, protocol title, invoicing details and description of what has been reviewed (captured from minutes). The listing should then be forwarded to the Accounts Receivable Officer for invoice generation, with copies to Q-Pharm Operations Manager and Regulatory Affairs Manager.

10. LISTING OF ANNUAL REPORTS FOR NON-CLINICAL TRIALS, SUBMITTED FOR HREC REVIEW

In accordance with the National Statement (Section 5.5.5) researchers are obliged to provide the Institution with a report on progress to date, etc. ‘at least annually and at the completion of the project’. Reports for all projects approved by HREC are also reviewed by the Institution. For QIMR Berghofer projects, a reporting mechanism has been established whereby a standard form report must be submitted by the due date (the date 1 year from previous approval); the HREC secretary is tasked with compiling a list of annual reports submitted in a given review period. A table including protocol number, Project Leader and Lab Head details and protocol title should be compiled and forwarded to the Assistant Secretary for tabling at the next scheduled DCC meeting.

11. FEDERALWIDE ASSURANCE (FWA); INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC) REGISTRATION

11.1 A number of QIMR Berghofer investigators receive research funding from the USA. A condition of the American funding requires QIMR Berghofer-HREC registration with the Office for Human Research Protections (OHRP), United States Department of Health and Human Services (DHHS) as well as QIMR Berghofer providing an official assurance to OHRP.

11.2 The Secretary is responsible for the registration of QIMR Berghofer-HREC with OHRP, and submits a duly completed and signed FWA to the OHRP. Once approved and accepted by the OHRP, the IRB/IEC registration and FWA may need to be renewed and/or updated, from time to time.

11.3 As OHRP documentation may be updated from time to time, the Secretary refers to the OHRP website (http://www.hhs.gov/ohrp/) for current information and documentation.

12. INQUIRIES, CONCERNS OR COMPLAINTS - HANDLING

12.1 Inquiries, Concerns or Complaints from Research Participants or Their Relatives

12.1.1 Potential participants for research projects are often approached by investigators using pathology reports, electoral roll, cancer registers, etc. Some people who are approached to participate in these studies may be concerned that their privacy may have been breached and it is important that their questions are answered promptly and effectively (ref 3.4).

12.1.2 When a person contacts (by telephone or email) the HRES to inquire and/or complain about a research study, the Secretary will usually be able to handle the matter quickly and with authority using the documentation available in the QIMR Berghofer E-Forms system. The following process is used as a guide:

(a) Identify the project;
(b) Ascertain the nature of the inquiry, concern or complaint;
(c) If a complaint is being made, advise the caller how to submit a complaint in writing;
(d) Explain and/or clarify what the study is about, why they were contacted, how their details were obtained and how the contact complies with the privacy principles;
(e) If it turns out that the person approached should not have been contacted or there is some other problem or error, the caller can be informed of what the HRES will do to fix the problem (e.g. Secretary contacts PI/trial coordinator to notify him/her of the problem and request for appropriate assistance and action);
(f) Where appropriate, follow up by contacting the caller to ensure the inquiry, concern or complaint has been resolved/dealt with satisfactorily;

(g) If the caller/inquirer is not satisfied with the explanation and/or proposed action to resolve the matter, the Secretary may need to refer the matter to the HREC Chair for advice. The caller should be informed of the intention;

(h) The matter is not closed until the caller indicates satisfaction with the advice and/or action taken;

(i) The Secretary should keep a record of the matter, and where appropriate and required, report it formally to the HREC Chair, HREC, etc.

12.2 Complaints from Investigators

12.2.1 When a person contacts the HRES to inquire or complain about the HREC procedures, the Secretary should try to answer any questions about the procedures. The following process is used as a guide:

(a) Identify the project;

(b) Ascertain the nature of the inquiry, concern or complaint;

(c) If the caller is making a complaint, advise how to submit a complaint in writing;

(d) Explain and/or clarify the HREC procedures;

(e) If the caller/inquirer is not satisfied with the explanation and/or proposed action to resolve the matter, the Secretary may need to refer the matter to the HREC Chair for advice. The caller should be informed of the intention;

(f) The Secretary should report the matter to the HREC Chair, keep a record of the matter and report it formally to the next meeting of the HREC, etc.

12.3 Written Inquiries, Concerns or Complaints

12.3.1 If the inquiry, concern or complaint about a study is in writing, it should be brought to the attention of relevant persons (e.g. HREC Chair and Chair of the relevant subcommittee) as soon as possible. If the complaint is about the HREC, the written complaint should also be forwarded to the General Manager or Director.

12.3.2 The Secretary will assist the HREC Chair, and be guided by him/her in the resolution of the matter.

12.3.3 The matter will be: (1) Listed in the agenda for the next HREC meeting; (2) Included in formal report/s (e.g. QIMR Berghofer-HREC Annual Report to the NHMRC-AHEC); (3) Where required, reported separately to relevant person/s and/or authority/ies (Director, Council, etc.)

13 CONFIDENTIALITY

13.1 All applications and associated documents, as well as committee feedback to investigators, are kept electronically and confidentially in the E-form system:

13.1.1 This is ensured via password protected access from HREC and scientific subcommittee reviewers. All reviewing committee members are given access only to applications submitted to the committee via the E-form workflow. Applications not submitted to the committee cannot be viewed by members.

13.1.2 All HREC members sign confidentiality agreements upon appointment to the committee.

13.1.3 When agendas are sent to members, this is via courier direct to the recipient or via an electronic agenda where the login link to online E-forms is provided.

13.1.4 Members return paper copies of applications to the HREC Secretariat at meetings for confidential shredding/destruction.

13.1.5 Computer access to agendas and minutes is restricted to HREC support staff, and members of management also bound by confidentiality agreements upon employment.
14 MONITORING OF QIMR BERGHOFER-HREC APPROVED PROJECTS

14.1 Refer to Standard Operating Procedure available on the QIMR Berghofer Intranet:

13.
15 QIMR BERGHOFER CLINICAL TRIAL PROTOCOL COMMITTEE (QIMR Berghofer-CTPC) MEETINGS - [Refer to the Terms of Reference for QIMR Berghofer-CTPC

15.1 Membership
A copy of the current CTPC membership listing can be accessed from QIMR Berghofer’s “Research Involving Human Participants” intranet site. This document must be updated whenever there is a change of membership.

15.2 Agenda and Papers for CTPC Meetings

15.2.1 The Secretary prepares the draft agenda, based on protocols submitted to the subcommittee via the E-Forms System, serious adverse event reports, the previous meeting minutes and any other matters referred to the subcommittee. The Secretary may also need to check with the Regulatory Affairs Manager (RAM) to ascertain whether there are matters (especially in relation to QIMR Berghofer sponsored trials) for the agenda.

15.2.2 The Secretary sends the draft agenda and papers (normally electronically via email) to the committee Chair, for approval. The Chair may nominate to have a virtual meeting if there are no new applications to review.

15.2.3 Once the CTPC agenda and papers are cleared by the CTPC Chair, they are distributed (normally electronically via email) to committee members at least one (1) week in advance of the scheduled meeting.

15.2.4 In exceptional circumstances, with the agreement of the CTPC Chair, certain papers and/or protocols may be tabled at the meeting. The CTPC Chair may accept late submissions at his/her discretion.

15.2.5 As the CTPC reviews submissions online, in general, the Secretary does not need to photocopy papers for CTPC meetings. However, a set of new protocol submission documentation should be provided (in hard copy) to the CTPC Deputy Chair a week prior to the meeting.

15.3 Preparation for CTPC Meetings

15.3.1 If required by the Chair, invite PI/s to the meeting to clarify and present his/her protocols.

15.3.2 Prior to the meeting, the Secretary should confirm meeting venue (via the Boardroom booking calendar in Outlook), arrange catering and ensure there is quorum for the meeting. If quorum requirements may not be met, the Secretary liaises with the committee Chair as soon as practical for advice and action.

15.3.3 Parking for external member/s. All car spaces must be booked at the beginning of the year via Security. Where possible, 1-2 days before the meeting, confirm external members attending the meeting with reception and security services. Ensure there are enough prepaid parking vouchers for use at the nearby commercial parking facility (Cornerstone Car Park). Parking vouchers are provided at the meeting to any member who requests this.
15.4 Minutes of CTPC Meetings, Recording and Dissemination of CTPC Recommendations

15.4.1 To assist with the preparation of minutes, the proceedings of CTPC meetings may be recorded.

15.4.2 The Secretary prepares the minutes. In general, the draft minutes should be prepared and submitted to the Chair for clearance as soon as possible, and within 5 working days following the meeting.

15.4.3 Unconfirmed minutes of CTPC meeting. Once the Chair clears the draft minutes, the Secretary:
   (a) Notifies PI of CTPC decisions by posting these comments into the *Official Comments* box of the relevant E-Forms, as soon as practical;
   (b) Ensures a copy of the minutes are used for the preparation of the following HREC meeting agenda;
   (c) Follows up on other matters that require action and/or consideration;
   (d) If matters pertain to the E-Forms and/or IT related, provides a copy of the extract of the minutes to the IT Helpdesk, with a copy to QIMR Berghofer E-Forms Developer for information and/or consideration

   *Note:* With respect to multicentre studies, where appropriate, the Secretary may provide relevant extracts from the unconfirmed minutes (as cleared by the committee Chair) to collaborating HREC/s, subject to confidentiality and privacy restrictions.

15.4.4 Posting extracts of the minutes into E-Forms, and actioning E-Forms:
   (a) Important to note that CTPC is an advisory committee; it does not *approve* applications;
   (b) If CTPC does not have any concerns with the e-application, this should be noted in the E-Form and the E-Form is then *Submitted to Committee (SC)* for HREC review;
   (c) If CTPC has comments on the submission and recommends clarification and/or revision by the PI, comments are entered into the *Official Comments* box of the relevant E-Form and the E-Form should be AR for consideration and action by the PI.
16 QIMR BERGHOFER HUMAN SCIENTIFIC SUB-COMMITTEE (QIMR Berghofer-HSSC) MEETINGS [Refer to the Terms of Reference for QIMR Berghofer-HSSC (http://intranet.qimr.edu.au/intranet/scientific/ethics/humans/TOR-HSSC.pdf]

16.1 Membership

16.1.1 A copy of the current HSSC membership listing may be provided on request, and is located on the shared ethics drive. This document must be updated whenever there is a change of membership.

16.2 Agenda and Papers for HSSC Meetings

16.2.1 The Secretary prepares the draft agenda based on protocols submitted to the subcommittee via the E-Forms System, serious adverse event reports, the previous meeting minutes and any other matters referred to the subcommittee.

16.2.2 The Secretary sends the draft agenda and papers (normally electronically via email) to the committee Chair, for approval. The Chair may nominate to have a virtual meeting if there are no new applications to review.

16.2.3 Once the HSSC agenda and papers are cleared by the HSSC Chair, they are distributed (normally electronically via email) to committee members at least one (1) week in advance of the scheduled meeting.

16.2.4 With the agreement of the HSSC Chair, certain papers and/or protocols may be tabled at the meeting. The HSSC Chair may accept late submissions at his/her discretion.

16.2.5 As the HSSC reviews submissions online, in general, the Secretary does not need to photocopy papers for HSSC meetings.

16.3 Preparation for HSSC Meetings

16.3.1 If required by the Chair, invite PI/s to the meeting to clarify and present his/her protocols.

16.3.2 Prior to the meeting, the Secretary should confirm meeting venue (via the designated room booking calendar in Outlook); arrange catering and ensure there is quorum for the meeting. If quorum requirements are not met, the Secretary liaises with the committee Chair as soon as practical for advice and action.

16.3.3 Parking for external member/s. Usually all car spaces are booked at the beginning of the year via front reception. If not, where required, 2 days before the meeting reserve QIMR Berghofer parking bays (via QIMR Berghofer front reception) for external members attending the meeting. Ensure there are enough prepaid parking vouchers for use at the nearby commercial parking facility (usually at the Wilsons’ Car Park). Members who receive prepaid parking vouchers should sign for the vouchers with the Secretary at the conclusion of the meeting. The Secretary maintains a record for Accounts.

16.4 Minutes of HSSC Meetings and Dissemination of HSSC Comments

16.4.1 To assist with the preparation of minutes, the proceedings of HSSC meetings may be recorded.

16.4.2 The Secretary prepares the minutes. In general, the draft minutes should be prepared and submitted to the Chair for clearance as soon as possible, and within 5 working days following the meeting.
16.4.3 Unconfirmed minutes of HSSC meeting. Once the Chair clears the draft minutes, the Secretary:

(a) Notifies PI of HSSC decisions by posting these comments into the *Official Comments* box of the relevant E-Forms, as soon as practical;
(b) Ensures a copy of the minutes are used for the preparation of the following HREC meeting agenda
(c) Follows up on matters that require action and/or consideration;
(d) If matters pertain to the E-Forms and/or IT related, provides a copy of the extract of the minutes to the IT Helpdesk, with a copy to QIMR Berghofer E-Forms Developer for information and/or consideration

*Note:* With respect to multi-centre studies, where appropriate, the Secretary may provide relevant extracts from the unconfirmed minutes (as cleared by the committee Chair) to collaborating HREC/s, subject to confidentiality and privacy restrictions.

16.4.4 Posting extracts of the minutes into E-Forms, and actioning E-Forms:

(a) Important to note that HSSC is an advisory committee; it does not *approve* applications;
(b) If HSSC does not have any concerns with the e-application, this should be noted in the E-Form and the E-Form is then *SC* for HREC review;
(c) If HSSC has comments on the submission and recommends clarification and/or revision by the PI, comments are entered into the *Official Comments* box of the relevant E-Form and the E-Form should be *AR* for consideration and action by the PI.
17 QIMR BERGHOFER HUMAN RESEARCH ETHICS COMMITTEE (QIMR Berghofer-HREC) MEETINGS - [Refer to the Terms of Reference for QIMR Berghofer-HREC ]

17.1 Membership

17.1.1 A copy of the current HREC membership, contact addresses (including emails) and numbers is attached. This document must be updated whenever there is a change of membership.

17.1.2 The names of members of this Committee may be published in the Annual Report and other official documents of QIMR Berghofer.

17.2 Agenda and Papers for HREC Meetings

17.2.1 The Agenda will normally have the following headings:

- Apologies
- Conflict of Interest, Declaration by Members
- 1.0 Minutes of the Last QIMR Berghofer-HREC Meeting
- 2.0 Business Arising from Minutes
- 3.0 Sub-Committees
  - 3.1 Clinical Trial Protocol Committee (CTPC)
  - 3.2 Human Scientific Sub-Committee (HSSC)
- 4.0 Research Protocols For Review & Approval
  - 4.1 Clinical Trial Protocols
  - 4.2 Human Experimentation Research Protocols
- 5.0 Serious Adverse Events
- 6.0 Regulatory Affairs
- 7.0 Other Business

17.2.2 The Secretary prepares the draft agenda and sends the draft agenda and papers (normally by email) to the HREC Chair, for approval. The Chair may nominate to have a virtual meeting if there are no new applications to review.

17.2.3 Unconfirmed minutes (as cleared by the Committee Chair) of CTPC and HSSC are listed under item 3, and copies of these minutes are appended to the agenda.

17.2.4 Item 4 is the major item of business and it is in two parts. Within each part, protocols are considered under the headings – “New” protocols, “Amendments” (protocols for amendment with or without annual reports), “Reports” (annual, completion and final reports when no amendment is requested), “Items granted executive approval between meetings” and “waived” items. Clinical Trial Protocols for consideration by HREC will have been considered by CTPC and Human Experimentation Research Protocols will have been considered by HSSC. A protocol which has not been reviewed by the relevant committee should not be placed on the agenda without the approval of the HREC Chair. Where CTPC or HSSC has made a recommendation with respect to a protocol, the PI is given an opportunity to respond or to amend the protocol following that meeting. The Secretary may need to liaise with the relevant PI/s with regard to the re-submission of protocols in response to HSSC/CTPC comments.
17.2.5 Item 5 includes serious adverse events notified to the HREC via the E-Forms system. In general, as these notifications and reports would have been reviewed by the CTPC and/or HREC Chair prior to the HREC meetings, they are mainly listed in the agenda for noting by the HREC only.

17.2.6 For item 6, the Secretary will liaise with the RAM for any updates on relevant matters for the upcoming HREC meeting, where appropriate.

17.2.7 Items of other business (item 7) may be included in the agenda with the agreement of the Chair.

17.2.8 Confirmed minutes of the Safety Committee are appended to the agenda for noting.

17.2.9 Once the HREC agenda and papers are cleared by the HREC Chair, they are distributed (print copies via courier/express post to external members and internal members, who expressed preference for receiving hardcopy meeting papers, and via E-forms to remaining internal members) to committee members at least one (1) week in advance of the scheduled meeting.

17.2.10 In general:
(a) For members receiving print copies of agenda papers, the E-Form application, consent and information documents, approach letters, questionnaires etc are provided as Agenda papers;
(b) Some attachments to applications (e.g. investigator’s brochure,) are not sent as print copies with the Agenda papers, rather via email;
(c) Members may access all attachments to E-forms using the E-Forms system;
(d) Copies of all documents are available for perusal at the meeting, from the Secretary, or via projection of the electronic documents; and
(e) A member may request a printed copy of any attachment to a protocol.

17.2.11 Applications are not accepted for review by HREC unless they have been considered by CTPC or HSSC. However if an amendment requires urgent attention, the HREC Chair may agree to its inclusion as a late item.

17.2.12 Investigators may be invited to a meeting to clarify and represent their protocols or inform the HREC about their area of research as per 4.1.5.

17.2.13 The HREC may also invite other observers from time to time as required/desired, to discuss research matters with the HREC members (eg presentations on general areas of research by investigators who may not have applications before the committee at that immediate time).

17.2.14 Investigators may request to be present at a meeting for discussions of their proposed research.

17.3 Preparation for HREC Meetings; HREC Approvals

17.3.1 A program of meetings of HREC and its sub-committees together with closing dates for the following year is prepared by the Chair and Secretary in consultation with QIMR Berghofer and HREC for adoption at the HREC November meeting and promulgated to QIMR Berghofer staff on the intranet and noticeboards.

17.3.2 Prior to each meeting, the Secretary should confirm the meeting venue (via the designated room booking calendar in Outlook), and arrange catering. The Secretary should check that enough members will attend to constitute a quorum. If it appears that a quorum will not be met, the Chair should be notified as soon as practical for advice and action.

17.3.3 Quorum for QIMR Berghofer-HREC meeting: Chair or Deputy Chair, and half (50%) plus one of the total number of members, including at least two external members.
17.3.4 The quorum should include at least one member from each of the essential categories (viz. a lay man, a lay woman, a lawyer, a pastoral carer, a person with knowledge of, and current experience in, the professional care, counselling or treatment of people, and a person with current research experience that is relevant to research proposals regularly considered by the HREC). If no member of each of the essential categories is able to attend, it is important to ensure that the agenda and all papers for the meeting are received by the member/s prior to the meeting. These members are encouraged to comment prior to the meeting via written or oral advice to the Secretary or Chair. If no written or verbal advice is received from at least one member of each category prior to the meeting, the Secretary must check with these members whether they have any concerns. Minutes of the meeting should clearly record the absence, acknowledgement of agenda and papers, and which absent members have provided comments.

17.3.5 The Chair or any member of the HREC may invite or require a PI to attend a meeting of HREC to clarify and discuss his/her protocols. The Secretary should liaise with the invitee for a suitable time for their attendance.

17.3.6 HREC Approvals. As alluded in §6.1.1, to ensure prompt completion of the HREC approval process, HREC Approvals (new or updated) and other relevant documents (e.g. CTN/CTX forms) are prepared prior to the meetings, ready for signature by the Chair at the conclusion of the meeting.

17.3.7 Parking for external member/s. Where required, on the day before the meeting, reserve QIMR Berghofer parking bays (via QIMR Berghofer security) for external members attending the meeting, and ensure there is enough prepaid parking vouchers for use at the nearby commercial parking facility (usually at the Wilsons’ Car Park). Members receiving prepaid parking vouchers should sign for them. The HREC Secretary maintains a record for Accounts.

17.3.8 Notify Reception on the morning of the meeting of any external attendees so that name stickers can be ready and members feel welcomed and expected when they arrive.

17.4 Minutes of HREC Meetings, Recording and Dissemination of HREC Decisions

17.4.1 For the purpose of completing the minutes, the proceedings of HREC meetings may be recorded. If the meeting is being recorded, all attendees should be advised.

17.4.2 The Secretary prepares the minutes. The draft minutes should be prepared and submitted to the Chair for clearance as soon as possible, and within 5 working days following the meeting.

17.4.3 Unconfirmed minutes of HREC meeting. Once the Chair clears the draft minutes, the Secretary:
   (a) Releases the approvals and other documentation signed by the Chair following the HREC;
   (b) Notifies PI of HREC decisions by posting these comments into the Official Comments box of the relevant E-Forms, as soon as practical;
   (c) Follows up on other matters that require action and/or consideration;
   (d) If matters pertains to the E-Forms and/or IT related, provides a copy of the extract of the minutes to the QIMR Berghofer Helpdesk, with a copy to the QIMR Berghofer E-Forms Developer for information and/or consideration; and
   (e) Where appropriate, if HREC comments relate to multicentre studies, relevant extract/s from the minutes may be provided to the collaborating HREC/s for their information, subject to confidentiality and privacy restrictions.

17.4.4 Posting extracts of the minutes into E-Forms, and actioning E-Forms:
(a) If HREC approves the submission with no concerns, this should be noted in the Official Comments box of the E-Form. The status of the Human E-Form must not be changed to Committee Approved (CA) until PI has clearance for all other relevant safety applications, eg. Safety, OGTR/GTRAP and/or Risk Management;
(b) If the HREC has comments on the submission and it requires clarification and/or revision by the PI, comments are entered into the Official Comments box of the relevant E-Form and the E-Form should be AR for consideration and action by the PI.

17.4.5 It is not uncommon for investigators to contact the Secretary for clarification of HREC decisions. The Secretary should be in a position to assist investigators in this regard, and if necessary, seek advice from the HREC Chair.

17.4.6 Confirmed minutes of HREC meetings. Minutes are distributed via email to all members following approval by the Chair. Members are given a reasonable length of time to comment (2-3 days) after which time the minutes are considered fully approved. If HREC requires amendment of the minutes, the amendment should be incorporated in the final version which is signed and dated by the Chair. The Secretary provides a summary of the HREC minutes in a briefing paper to the Regulatory Affairs Manager, for tabling at the following Council and DCC meetings.

17.4.7 Discontinuation of Research Projects
In cases of non-compliance and/or where circumstances warrant that a research project should be discontinued, the QIMR Berghofer-HREC will recommend to QIMR Berghofer Director and QIMR Berghofer Management and the collaborating research institute/s that the research project be discontinued or suspended. The HREC and the Regulatory Affairs Office, including HREC Secretariat will ensure that the NHMRC NS guidance regarding withdrawal of approval is adhered to. Specifically:
NS 5.5.8 Where ethical approval for a research project is withdrawn:
(a) the researcher, the institution/s and, where possible, the participants (will) be informed of the withdrawal;
(b) the institution must see that the researcher promptly suspends the research and makes arrangements to meet the needs of participants; and
(c) the research may not be resumed unless either
   (i) the researcher subsequently establishes that continuance will not compromise participants’ welfare; or
   (ii) the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved.
If either QIMR Council of QIMR Berghofer HREC consider that urgent suspension of research is necessary before the process described above is undertaken, the instruction to stop will come via the Institute’s management.

17.5 Miscellaneous

17.5.1 Photocopying of E-Forms and attachments. HREC Secretary prints out one full set of agenda papers, which is then photocopied to the required number of attendees. Remuneration of essential and necessary expenses incurred by members (of HREC, HSSC and CTPC) in carrying out their QIMR Berghofer -HREC duties. The Secretary assists in the reimbursement of such expenses to members, e.g. reimbursement of mileage/travel expenses for external member to attend HREC meetings at QIMR Berghofer, internet access, etc.

17.5.2 The HRES retains a print copy of the complete agenda and papers from each HREC meeting (usually from a discarded set left behind by a HREC member who attended the meeting) in
the office. Usually only the most recent set is kept in the HRES office and the older papers archived off QIMR Berghofer Herston site. The service of RECALL is used for the archiving of papers. HRES needs to liaise with the Information Systems office when seeking to archive copies of HREC papers, or when needed to access past HREC documentation.

17.5.3 All business of the HREC is confidential. Committee members should be encouraged to leave behind all print copies of meeting papers when they have finished with the documents, for appropriate disposal (e.g. shredding) by the HRES. These papers must not be left unattended in open access areas.