ROYAL ADELAIDE HOSPITAL

HUMAN RESEARCH ETHICS COMMITTEE

MASTER POLICY AND PROCEDURE DOCUMENT

Contents

Created 5 September 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: AUDIT AND QUALITY ASSURANCE

Determining the nature of the study

Quality assurance, audit and research are not distinct activities but form a continuum [Ref 1]. The NHMRC have developed a guidance document to assist committees to determine whether a study is to be considered as research, audit or quality assurance [Ref 2]. A decision tree has been issued to define decision processes [Ref 3].

NHMRC determined that an activity falls under the heading of quality assurance if it is:

> *"An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a quality assurance study. QA should be an integral part of all health care delivery." [Ref 2].*

The RAH HREC determines that a study falls under the heading of audit if it meets the following criteria:

- Poses no risk or burden for patient/participants over and above those of routine care.
- Involves only the collection of data from routine clinical practice.
- Does not involve an intervention other than one that could be considered as routine care.
- Meets the NHMRC criteria for waiver of consent [Ref 4].

The RAH HREC determines that a study falls under the heading of quality assurance if it meets the conditions of audit in and the following criteria:

- Is undertaken for a valid purpose and its outcomes are used to improve health care
- Is conducted by a person normally involved in the patient/participant's care.
- Uses only information that is collected as part of routine clinical care.
- Is intended for use within the institution (RAH)

Determining whether ethical review is required

Quality assurance activities (in particular) are an expected function of a health care service provider which values quality. The NHMRC document [Ref 2] provides advice about whether ethics review is required:

> *"AHEC therefore advises that an appropriately planned activity can proceed without review by an HREC if:*
>
> *Both*
> *(a) the activity is undertaken with the consent of the patients, carers, health care providers or institutions involved;*
> *or*
> *is consistent with National Privacy Principle 2.1(a), which states:*
> *'An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless' …*
> *'both of the following apply:*
> *(i) the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;*
> *(ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose';*
> *and*
> *(b) it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social)."*

Notwithstanding the waiving of the need for ethical review, any audit or quality assurance activity must meet the ethical principles of integrity, respect for persons, beneficence and justice. It must

also adhere to any appropriate privacy and confidentiality principles and State, Territory and Commonwealth legislation.

An activity which is intended to be published in a peer reviewed journal is likely to require approval by an HREC. Where a full or expedited review is not considered necessary, this approval may take the form of a statement advising a journal editor that it is satisfied that the activity has been undertaken according to ethical principles. This will obviate any need for requests for retrospective approval.

Despite these guidelines and those of the recently published decision tree [Ref 3], the investigator should seek review of the HREC if he/she is uncertain of the need for ethical review. The need for subsequent review will then be determined by the Chairman or delegate.

Approval of audit or quality assurance

If the investigator and the Ethics Committee determine that an audit or quality assurance activity requires ethical review, the approval of an audit or quality assurance activity will be notified to the investigator by the use an Audit Approval Letter [Ref 5]. ~~The approval differs from a normal ethical approval process in that:~~

- ~~It will not be allocated a study number~~
- ~~It will be exempt from annual reviews~~

Notwithstanding, any changes to the nature of the study or study documentation must be communicated to the committee and the study must be conducted according to the principles of the NHMRC National Statement on Ethical Conduct in Human Research.

If audit and quality assurance require ethical review this would almost always be conducted under an expedited review process. Approved audits will be listed on the agenda of an HREC meeting. The Chairman's decisions will be subject to review at a full committee meeting.

Monitoring of audit or quality assurance

Audit and quality assurance activities are by definition low risk, have no direct impact on patient safety and generally involve routine clinical practices. They are often of a defined duration. As a result, the decision has been taken that monitoring and reporting requirements for audit and quality assurance are less stringent than for research studies. Investigators are not required to provide annual reports and are only required to notify the committee if there are any changes to the nature of the study or study documentation.

Research Governance and audit or quality assurance

The Research Governance office will be notified of any activity which undergoes ethical review. If the activity is of low or negligible risk in terms of impact on the institution, the Research Governance Officer may waive the need for a full review. The Research Governance Office should be contacted before assuming this.

Revision Details

Version 1.0 A. Thornton, 23 July 2010
Version 1.1 A. Thornton, 12 January 2014

References

[1] Wade DT. Ethics, audit, and research: all shades of grey. BMJ 330: 468-71 (2005)
[2] NHMRC When does quality assurance in health care require independent ethical review? NHMRC 2003.
[3] NHMRC Considerations in determining if an activity such as quality assurance requires ethical review. NHMRC 2010.
[4] NHMRC National Statement on Ethical Conduct in Human Research. NHMRC 2007
[5] Form: Audit Approval Letter

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: CHARGES FOR ETHICAL REVIEW

Determining Fees

The Schedule of fees is determined by the HREC from time to time. The fees schedule must be accepted by the committee at an appropriately constituted meeting.

Billing - Sponsored trials

Since February 1992, fees have been levied for consideration of applications for ethics committee consideration of *drug* related protocols by the Research Ethics Committee. Funds generated have supported both the Investigational Drugs Subcommittee and the Research Ethics Committee.

From September 2007, the Research Ethics Committee has introduced the same level of fee charges for the consideration of *device* protocols.

A scale of charges has been determined [Ref 1] depending on the complexity of the protocol and the phase of clinical investigation which the drug/device has reached. In addition, protocol amendment fees apply. A tax invoice will be forwarded to the Sponsor after full evaluation of an application has been completed.

The Executive Officer of the Human Research Ethics Committee (HREC) in conjunction with the Executive Officer of the Investigational Drugs Subcommittee (IDSC) decide upon the fee level to be charged. The Chairperson of the HREC may adjudicate in the event of dispute and reserves the right to reduce fees in appropriate circumstances.

In the event of dispute, the Chairperson of the REC will decide which trials are classified as sponsored and which as non-sponsored.

Billing - Amendments

The Chairperson determines the level of fee to be levied for amendments. This may be administrative, minor or major. The level of fee is determined by the amount of work required to process the amendment.

Billing - Non-sponsored trials

Charges are not levied for trials that are conducted without a commercial sponsor.

Billing - Independent Evaluations

When an independent evaluation is required to be performed this is charged to the trial sponsor on a cost only basis.

Incidental Fees

The Chairperson reserves the right to negotiate with Investigators a fee for other ethical review process under exceptional circumstances.

Variations to scheduled fees

The fees defined in Reference 1 are the maximum fees charged. The Chairman of the Ethics Committee reserves the right to reduce fees charged.

References

[1] Form: Charges for Ethical Review

Revision history

Version 1.0	M James 2005
Version 1.1	M James September 2007
Version 1.2	A Thornton 1 June 2009
Version 2.0	A Thornton 6 February 2010
Version 2.1	A Thornton 23 July 2010

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: COMMITTEE MEMBERSHIP

Constitution of the Committee

The Human Research Ethics Committee attempts to ensure that its membership continues to meet the principles of the NHMRC "National Statement on Ethical Conduct in Human Research" relating to the composition of the committee (Reference Clauses 5.1.29-5.1.33).

> *"(a) there should be equal numbers of men and women; and*
> *(b) at least one third of the members should be from outside the institution for which the HREC is reviewing research."*

From time to time due to attrition and extended absences the composition of the committee may vary from this but as far as possible the membership will be adjusted on resignation to meet this principle. This requires the Chairperson to review the composition with regard to the requirements to maintain a broad cross-section of expertise and meet the specific requirements of NHMRC clause 5.1.30.

Where possible clinical members of the HREC and its subcommittees should be or should have been actively engaged in research.

The membership of the Committee and Subcommittees is published on both the Royal Adelaide Hospital intranet and internet websites.

Membership in Special Categories

The Human Research Ethics Committee complies with section 5.1.30 of the National Statement in ensuring that appropriate members are appointed in the mandatory categories. The Committee also recruits, as needed, proxy members in mandatory categories.

Term of Membership

Members shall be appointed for a term of three years with approximately one third of the committee being re-nominated or replaced each year. There shall be no limit to the maximum term of a committee member. The Chairperson shall be re-nominated or replaced each years.

Investigational Drugs Subcommittee Membership

The IDSC is a committee of technical experts in pharmacology and pharmacy who are able to provide a detailed expert review of the pharmacology associated with research involving the administration of drugs. Whilst the primary responsibility of IDSC is to review pharmacological issues it may make recommendations on any other ethical or safety issues associated with the research. The IDSC may recommend that HREC not approve a protocol if it considers the proposal involves unacceptable risk in terms of the safety of participants. Whilst the opinion of IDSC is critical in the review process the approval of the research is the responsibility of HREC. The HREC considers that IDSC need not comply with the requirements of the NHMRC statement in relation to composition because:

- All IDSC decisions are subject to further review by HREC
- The specialist technical expertise expected of members of IDSC would make it impossible to comply with clauses 5.1.29-5.1.33.

The Chairmen of HREC and Cancer Subcommittee observe at the meetings of IDSC.

Cancer Subcommittee Membership

The Cancer Subcommittee (CSC) is a committee including technical experts in oncology who are able to render an expert opinion on relevant research proposals. Cancer research proposals involving the use of drugs are also subject to IDSC review which occurs before the CSC meeting. The CSC may recommend that HREC not approve a protocol if it considers the proposal involves unacceptable risk in terms of the safety of participants. Whilst the primary responsibility of the CSC is to review oncological issues it may make recommendations on any other ethical or safety issues associated with the research. Whilst the opinion of CSC is critical in the review process the approval of the research is the

responsibility of HREC. The membership of CSC is carefully managed to avoid conflict of interest and as such may not achieve full compliance with clauses 5.1.29-5.1.33 of the NHMRC statement.

- For review of haematological malignancy research, medical oncologists are co-opted to serve on the subcommittee.
- For the review of gynaecological malignancy research, medical oncologists and/or haematological oncologists are co-opted to serve on the subcommittee.
- For review of solid organ malignancy research other than gynaecological oncology, haematological oncologists are co-opted to serve on the subcommittee.
- For radiation oncology research, medical oncologists and/or haematological oncologists are co-opted to serve on the subcommittee.

The HREC considers that CSC need not comply with the requirements of the NHMRC statement in relation to composition because:

- All CSC decisions are subject to further review by HREC
- The specialist technical expertise expected of members of CSC would make it impossible to comply with clauses 5.1.29-5.1.33.

The Chairman of HREC observes at the meetings of CSC.

Proxy Members

Where a member is unable to attend a meeting the attendance of a proxy member is encouraged. This proxy member is an appointed member of the committee and shall have the same professional skills and experience as the committee member. Proxy members must complete the Conflict of Interest Declaration.

If a proxy is not available the member may provide the committee with written notes to be considered in the ethical review process.

Access to Specialist Expertise

Where the HREC or Chairperson of HREC determines that the committee's deliberations could be assisted by the referral of the research to an expert not a member of the committee, this may be done. The external reviewer(s) must complete a Conflict of Interest declaration. Specialist advice will be reviewed by the committee in the course of its deliberations but HREC is not bound by the recommendation contained within that review.

Interview with Researcher

Where the HREC or Chairperson of HREC determines that the committee's deliberations would be assisted by interview with the researcher, this may be scheduled for an upcoming HREC, IDSC or Cancer Subcommittee meeting.

Recruitment and Appointment of Members

Upon notification of resignation of a member, the Chairman shall commence a recruitment process for new members of the HREC. Members shall be appointed in a fair and transparent manner via the Chief Executive of the Central Adelaide Local Health Network (CALHN). Members shall receive a formal notice of appointment and an assurance that CALHN will provide legal protection for their activity as members of the committee.

Induction and Training of Members

New members are provided with resources at induction and are expected to attend one meeting as an observer for orientation purposes. SA Health or CALHN will also make available to members and officers of the HREC sufficient training opportunities to meet the continuing education requirements of the NHMRC National Statement of a minimu of one attendance each three years.

Reference

National Statement on Ethical Conduct in Human Research. NHMRC 2007

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 19 July 2010
Version 1.2 A Thornton 3 April 2012
Version 1.3 A Thornton 14 January 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: COMMUNICATION WITH RESEARCHERS

The Royal Adelaide Hospital Human Research Ethics Committee (HREC) recognises the importance of prompt, efficient and open communication with researchers. The HREC employs various means of communication as discussed in this document.

NHMRC National Statement

Section 5.2 of NHMRC National Statement on Ethical Conduct in Human Research [Ref 1] discusses the responsibilities of HRECs and in particular communication with researchers;

5.2.13 Good ethical review requires open communication between review bodies and researchers, and a shared commitment to the review process. The process should not be adversarial. Institutions should encourage this shared commitment by promoting:

(a) awareness of this National Statement among researchers; and
(b) ready accessibility of review bodies and their staff to researchers.

5.2.14 Misunderstandings can often arise when only written communication is used. From the outset review bodies should encourage informal communication with researchers, and should consider face-to-face meetings to resolve issues about research proposals that have not been resolved by written or telephone communication.

Communication to the Committee

In person: The HREC office is staffed during working hours. The Executive Officer is available and has delegated authority [Ref 2] to discuss the processes of application and the progress of individual applications. In person interviews with the HREC Chairman are encouraged where appropriate and are available by appointment. Researchers are encouraged to attend the meeting of the HREC or its subcommittees where they feel that this may facilitate the approval process.

Telephone: The HREC office is staffed during working hours. The phone number of the Executive Officer is widely available on all email and written communication from the HREC office and is available through the website and the hospital switchboard. The Executive Officer has delegated authority to discuss the processes of application and the progress of individual applications. Telephone interviews with the HREC Chairman are available by appointment. The Chairman has a mobile phone which is accessible through the hospital switchboard in the case of an emergency.

Email: Use of email is the preferred method of written contact with the HREC. Use of email has replaced the large majority of hard copy communication which is inefficient and costly to maintain. Email correspondence is sent to the Executive Officer directly or to the ethics mailbox at RAH.ethics@health.sa.gov.au. These email addresses are very widely available. To facilitate email communication the committee has developed an electronic Request to Review Updated Documentation form [Ref 3] which should accompany any document which is submitted. This form requests the researcher to provide:

- The exact title and reference number of the study;
- The status of the study in terms of enrolment;
- The impact of the submitted documentation on the ongoing acceptability of the study;
- A list of the documents to be reviewed; and
- Invoicing details.

If the electronic documents are too large to email they may be submitted on CD/DVD or USB memory device.

On-line: Applications to the committee may be made on line through the on-line forms website https://www.ethicsform.org/Au/SignIn.aspx. To facilitate this process for researchers who are unfamiliar with the system the Executive Officer is available for assistance and the HREC holds Ethics Forums approximately twice a year where the processes of application are communicated to researchers. The content of the Ethics Forum is posted on the RAH HREC website.

Hardcopy: Applications to the committee may be made through traditional hardcopy but this is not necessary and researchers are strongly encouraged to provide an electronic copy in addition to the hard copy. A list of the required submission documents for various types of application [Ref 4] is included on the RAH HREC website.

Communication from the Committee

In person: The Executive Officer or Chairman may request a face to face interview with researchers if it is expected that this will facilitate an approval process. The HREC and its subcommittees may also request a researcher to attend the HREC or IDSC meeting if the Chairman feels this would be of benefit to the committee or would facilitate the process.

Telephone: The Executive Officer may contact researchers by telephone for clarification of submissions. Email is however the preferred method of communication relating to any approval process because of its capacity to maintain a communication trail.

Email: Email is used extensively by HREC to communicate with researchers. The Executive Officer or Administrative Assistant will communicate from their named email account on a range of issues. The following types of communication are managed through email:

- Approval or rejection of a research study – template email with PDF attachment which is electronically signed by the Chairman or Executive Officer according to the delegations [Ref 2].
- Approval or rejection of an amendment – template email with PDF attachment which is electronically signed by the Chairman or Executive Officer according to the delegations.
- Approval or acknowledgement of regular reports or safety updates – email template
- Request for further information – committee review – template email with PDF attachment which is electronically signed by the Chairman.
- Request for further information – LNR review – template email with Chairman's comments included.
- Delay in review process – template email with inclusions from Chairman or Executive Officer explaining the reason for delay.

Hardcopy: The committee does not routinely provide hardcopy documentation except where a third party form such as TGA CTN form or EOA Notification Form is required to be signed. A hard copy of an approval letter may be provided upon request of the researcher.

Timeline of HREC Decisions

HREC expected timelines are documented [Ref 5]. Time frames may vary due to unexpected work pressures. The maximum total time for a review (excluding investigator/sponsor time) is 60 days. In brief the timelines from submission to initial HREC review are:

- Drug studies requiring subcommittee and HREC review – 22 days
- Non-drug studies requiring HREC review – 15 days.
- Low and Negligible risk submissions – may be submitted at any time.
- Amendments and other documents – may be submitted at any time.

The timeliness of HREC approval decisions is tracked using a clock mechanism provided by the ethics database AURED. The clock sums the time from submission to approval, rejection or the sending out of a request for further information and any subsequent review time taken by the committee in assessing further information provided by researchers.

References

[1] National Statement on Ethical Conduct in Human Research. NHMRC 2007 as updated from time to time.

[2] HREC Form – Delegations – Research Ethics Committee Office. Available on the RAH website at http://www.rah.sa.gov.au/rec/downloads/REC_Delegations_July_2013.pdf

[3] HREC Form – Request to Review Updated Documentation. Available on the RAH website at http://www.rah.sa.gov.au/rec/downloads/REC-Request-for-Review-of-Updated-Documentation-version2dated16May2013.doc

[4] HREC Form – Required Submission Documents. Available at http://www.rah.sa.gov.au/rec/downloads/RAH_Required_Submission_Documents.pdf

[5] HREC Policy – Research Ethics Committee Approval Timelines. Available at http://www.rah.sa.gov.au/rec/downloads/REC_Review_and_Decision_Timelines.pdf

Revision history

Version 1.0 A Thornton 1 August 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: CONFLICT OF INTEREST

Background

Members of the Human Research Ethics Committee and its subcommittees are charged with the responsibility of deciding whether research conducted at the Royal Adelaide Hospital meets acceptable ethical standards and defined by the "National Statement on Ethical Conduct in Human Research" (Reference 1).

"A conflict of interest in the context of research exists where:

- *a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or*
- *an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations."*

A conflict of interest may be financial or non-financial and members are responsible for conscientious self-assessment to determine both in general and specific terms whether any issue before HREC may be a conflict of interest. Perceived conflicts of interest may in some cases be as important as an actual conflict of interest if the process to support the declaration is not sufficiently rigorous and transparent.

Conflict of Interest – Institution

The Royal Adelaide Hospital is a South Australian Government Agency operating under SA Health. It has no commercial interest that is construed as influencing the Ethical Review process. The Royal Adelaide Hospital has established the Human Research Ethics Committee under Terms of Reference which provide appropriate levels of autonomy to ensure that ethical review is free of external influence.

Conflict of Interest – Committee

Conflicts of interest of HREC members in the research being reviewed by the HREC are rigorously managed. Conflicts of interest of a committee member may include:

- personal involvement or participation in the research
- personal involvement in competing research
- financial or other interest in organizations funding the research
- financial or other interest in organizations funding competing research.

The HREC has implemented policies to manage these conflicts of interest and to ensure that where such a conflict arises neither the committee nor the individual members are compromised. These policies include:

- Annual completion of the HREC/IDSC Conflict of Interest Form (Reference 2). This form will be completed at or before the first committee meeting of the calendar year or when a new or proxy member joins the committee for the first time.
- Completion of the single meeting HREC/IDSC Conflict of Interest Form (Reference 2) for any person who attends a meeting without having completed the annual declaration.
- Exclusion from the review process of any committee member with a conflict of interest in the research being reviewed
- Delegation to the Deputy Chairperson of all matters relating to the review where the Chairperson has a conflict of interest.
- Publishing the names and affiliation of members of the committees on an externally viewable internet website.

Conflict of interest declarations will not be made public but may be reviewed by the Medical Director of the Royal Adelaide Hospital in the event of an appeal by a researcher (see below).

Conflict of Interest – Researchers

Researchers may have a conflict of interest in the conduct of the research which is before the committee for ethical review. Whilst the researcher makes the submission to the HREC and may provide supporting statements or arguments, the process of review is conducted independently of the researcher. Researchers publishing or presenting their research findings are subject to the conflict of interest provisions of the relevant professional societies. The HREC considers that these policies are sufficient to manage conflicts of interest in reports of research.

Researchers are required to operate under the principles of ICH-GCP requiring them to manage personal conflicts of interest. The HREC considers breaches of ICH-GCP to be extremely serious and may require researchers to take appropriate remedial action is such breaches are detected by or reported to the HREC. Notwithstanding the HREC reserves the right to limit the level of involvement of the researcher with a research project in which there is clear conflict of interest. Requirements that may be imposed include:

- Declaration in the Patient Information Sheet of the conflict of interest
- HREC oversight of Informed Consent process
- Review of research documentation
- Review of research publications

Conflict of Interest – External Reviewers

Where an external reviewer is engaged to assist the HREC in the review of research the External Reviewer or Organization will be required to complete a confidentiality agreement and statement of conflict of interest relating to the research being reviewed. These declarations will be reviewed by the Chairperson, made available to the HREC committee and filed with the application for future reference.
Conflict of interest declarations will not be made public but may be reviewed by the Medical Director of the Royal Adelaide Hospital in the event of an appeal by a researcher (see below).

Rights of Appeal

Where a researcher considers that the research proposal has been managed inappropriately in relation to conflict of interest they may approach the Medical Director of the Royal Adelaide Hospital who will review the issues of conflict of interest on behalf of the researcher and make appropriate recommendation to the Committee.

Reference

1) National Statement on Ethical Conduct in Human Research. NHMRC 2007
2) IDSC/HREC Form – Conflict of Interest

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 19 July 2010

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: ETHICAL REVIEW OF MULITCENTRE RESEARCH

Background

The Royal Adelaide Hospital Human Research Ethics Committee recognises the challenges facing medical research in Australia. It is claimed by the Pharmaceutical Industry that the ethical review process is a major impediment and expense to the conduct of research in Australia. To address this, the RAH HREC has prioritised the prompt evaluation of research applications but recognises that the perception is likely to result in pharmaceutical trails being diverted from Australia to countries where trials can be conducted in a more economical way. Informal discussions with pharmaceutical industry have revealed that decisions about where to conduct trials are heavily influenced by the time taken to implement the research, of which ethical review is one part [Ref 1]. This has been recognised by the Australian Health Ministers Advisory Committee which has charged the NHMRC to facilitate the ethical review process. In October 2013 the South Australian Government signed a Memorandum of Understanding with Queensland, New South Wales and Victoria to accept ethical reviews conducted by a public health institution's human research ethics committee in any of the four states.

Researchers at the RAH are involved in a significant number of multicentre trials and it is apparent that a simplification of the review process would reduce the work that they need to do to obtain ethical approval for their trial. It may also improve the competitiveness of the RAH as a site to undertake such trials.

The RAH HREC is supportive of moves to simplify the process whilst maintaining as its first priority the safety and protection of RAH patients involved in research trials.

SA Health Policy

It is the policy of SA Health to encourage South Australian HRECs to pursue certification for the review of multicentre research under the NHMRC's HoMER process [Ref 2].

The SA Health policy embraces the principles of the NHMRC National Statement (sections 5.3.1 and 5.3.2) [Ref 3]:

> *"5.3.1 Wherever more than one institution has a responsibility to ensure that a human research project is subject to ethical review (see paragraph 5.1.1, page 77), each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review.*
>
> *5.3.2 Different institutions that regularly have review responsibilities for the same research (for example, universities and related teaching hospitals) should agree on a single review body to review the research."*

SA Health Single Ethical Review Model

The public health institutions within SA Health agreed to a single ethical review model which commenced in July 2011. The principles of this agreement are contained within the SA Health Research Ethics Operational Policy [Ref 4]. In brief:

- The SA Health model applies only to South Australia.
- The SA Health model applies only to all research not only clinical trials of a drug or device.
- The SA Health model applies only to research first reviewed on or after 1 July 2011.

- The research is reviewed according to the coordinating HRECs standard policies and procedures.
- Every research study which is to be conducted at one or more sites under the jurisdiction of SA Health will be ethically and scientifically reviewed once only by a SA Health HREC (the lead HREC).
- The review will be accepted by all other SA Health institutions.
- The choice of the lead HREC will be left to the main investigator (Coordinating Principal Investigator – CPI) but would normally be the employing institution of the CPI.
- Studies involving children must be reviewed by the Women's and Children's HREC.
- Studies involving Aboriginal or Torres Strait Islander persons must have a subsequent review by the Aboriginal Health REC.
- Studies which primarily involve access to centrally held databases, eg OACIS, ISAAC, Cancer Registry should be review by the SA Health HREC.
- Clinical trials must be submitted on the National Ethics Application Form (NEAF).
- Low and negligible risk studies may be submitted using the SA Health LNR Ethics Form.
- All studies must be recorded on the AU-RED database.
- Before commencement all research must undergo a site specific assessment process at each institution which intends to conduct the research.

National Mutual Acceptance Ethical Review Model

SA Health has signed a Memorandum of Understanding to support a national system of streamlined ethical review of clinical trials across participating public health organisations (National Mutual Acceptance).

Under this system, a NHMRC certified HREC provides the single ethical and scientific review of a multi-centre clinical trial application. The RAH HREC was certified to undertake this review on 27 August 2012.

The principles of operation are contained within the Standard Principles for Operation. In brief:

- The NMA applies only to South Australia, Queensland, New South Wales and Victoria.
- The NMA applies only to clinical trials of a drug or device.
- The NMA applies only to research first reviewed on or after 1 November 2013.
- The research is reviewed according to the coordinating HRECs standard policies and procedures.
- Every research project which is to be conducted at one or more sites covered by NMA will be ethically and scientifically reviewed once only by a certified committee.
- The review will be accepted by all other health institutions covered by NMA.
- Public health institutions with South Australia accept reviews only from other public health HRECs – this excludes privately run ethics committees.
- The choice of the lead HREC will be left to the main investigator (Coordinating Principal Investigator – CPI) but would normally be the employing institution of the CPI.
- In South Australia Phase 0 (first time in human) and Phase 1 clinical trials will not be accepted under the NMA.
- Approval from the Aboriginal Health Research Ethics Committee (AHREC), South Australia, will be required where is required where the research involves ATSIC persons.
- A time frame of 60 days is required to be met for the review process.
- The lead HREC will be responsible for the monitoring of the clinical trial, throughout the life of the trial.
- All studies must be submitted on the National Ethics Application Form (NEAF).
- All studies must be recorded on the AU-RED database.
- Before commencement all research must undergo a site specific assessment process at each institution which intends to conduct the research.

Monitoring Studies Under the SA Health Model or NMA

Only the lead HREC is in a position to provide ongoing monitoring for a research study and hence must accept this role as part of the review process. Monitoring is directed to all

participating sites through the Coordinating Principal Investigator. The Coordinating Principal Investigator communicates with the lead HREC. The responsibilities of the lead HREC, the CPI and other PIs are contained within the NHMRC Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research [Ref 6].

Site Specific Assessment processes

Acceptance of the ethical review does not guarantee that the RAH has the resources or expertise to conduct this research or that it can be conducted in an effective or efficient manner. Establishing these conditions is the role of the Research Governance Office who will liaise with HREC over issues which may involve decisions of an ethical nature.

Regardless of the ethical approval process undertaken (Single Site, SA Health Single Ethical Review, NMA), a site specific assessment must be completed before an ethical review will be considered for adoption at the RAH. Information required is in accord with section 5.3.3 of the National Statement:

> *"5.3.3 Where an institution decides to rely on ethical review by a body it has not established, it should undertake:*
>
> *(a) to identify any local circumstances relevant to the ethical review of its research, disclose these circumstances to the review body/ies, and provide for their management;*
>
> *(b) to exchange relevant information and advice with the review body/ies;*
>
> *(c) not to duplicate an existing, duly authorised scientific/technological/methodological assessment of the research;*
>
> *(d) to establish the roles, if any, the institution and the review body/ies may have in monitoring the research;*
>
> *(e) to inform participants if the research is discontinued; and*
>
> *(f) to adopt any other administrative procedures that will avoid unnecessary duplication of ethical review.*
>
> *Research approved under these guidelines will be listed on the agenda of the next HREC meeting for information."*

References

1. Clinically competitive: boosting the business of clinical trials in Australia (2011), Commonwealth Government.
2. National Certification Scheme for Institutional Processes related to the Ethical Review of Multi-Centre Research.
3. National Statement on Ethical Conduct in Human Research. NHMRC 2007
4. SA Health Research Ethics Operational Policy V2.0 from 1 November 2013.
5. Standard Principles for Operation - National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Clinical Trials
6. Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research.

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 19 July 2010
Version 2.0 A Thornton 13 January 2014 (Rewritten, no tracked changes)

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: EXPEDITED APPROVALS

Expedited approval process

The NHMRC National Statement on Ethical Conduct in Human Research [Ref 1] identifies mechanisms by which low and negligible risk research may undergo an expedited review process, thereby avoid the requirement for a review by a full committee process.

The NHMRC statement requires that:

> *"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.*
> *5.1.19 Where institutions establish such non- HREC levels of ethical review for low risk research, that review must:*
> *(a) be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;*
> *(b) be informed by Section 1: Values and Principles of Ethical Conduct, Section 3: Ethical Considerations Specific to Research Methods or Fields and Section 4: Ethical Considerations Specific to Participants;*
> *(c) take account of researchers' judgements as to whether their research is suitable for review by a non-HREC process;*
> *(d) have due regard to relevant privacy regulation."*

In recognition of this, the Research Ethics Committee has agreed that in general, the categories of research listed in the HREC *Form – Expedited Approvals [Ref 2]* may be approved by the Chairperson of the Research Ethics Committee and reported to the following meeting of the full Committee.

Applying for expedited approval

The Chairperson of the committee is responsible for the decision about whether a particular study satisfies the criteria for expedited approval. The researcher may request that expedited approval be considered but although that request will be noted, but the outcome will be based on a consideration of the types of research described in Attachment 1 and a consideration by the Chairperson as to whether the approval raises any ethical issues. If the chairperson considers that the study is potentially not approvable through an expedited process, despite attempts at resolving issues, the study must be referred to the full committee.

Monitoring of research under expedited approval

Monitoring and reporting requirements for studies which have been granted an expedited approval remain the same as for studies which have been reviewed by a full committee. Given the low risk nature of expedited approvals, some latitude may be allowed in terms of reporting administrative and other changes to the protocol which do not impact on the safety of participants. Annual reports and other significant trial related information must be provided in line with HREC reporting requirements.

Reviewing expedited approvals

To ensure that the expedited approval process retains integrity a full committee audit is conducted twice each year. The audit requires members of HREC to review an approval granted in the previous year against the criteria established for expedited review. In the absence of the Chairperson and under the chairmanship of the deputy chairperson, the HREC discusses the study and decides whether it meets the criteria.

Single centre ethical review

Low and negligible risk research is excluded from the National Mutual Approach but may be accepted under the SA Health Single Ethical Review Model. Any LNR study that has been approved by a SA Health HREC, irrespective of the nature of the approval process, may be accepted at another SA Health Institution. This applies to all studies submitted on or after 1 July 2011. Further information is contained within the policy document "Ethical Review of Multicentre Research".

References

[1] NHMRC National Statement on Ethical Conduct in Human Research. NHMRC 2007
[2] Form – Expedited Approvals
[3] Policy - Ethical Review of Mulitcentre Research

Revision Details

Version 1.0 A. Thornton, 23 February 2010
Version 1.1 A Thornton, 20 July 2010
Version 1.2 A Thornton, 13 January 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: INFORMED CONSENT

Background

The process of informed consent is central to the recruitment of participants to clinical trials. The Informed consent process includes:

- the provision of full and detailed information to potential participants in a style which is simple and understandable (Participant/Patient Information Sheet – PIS);
- the opportunity for the participant to ask questions of researchers before consenting;
- the opportunity for the participant to discuss involvement in the research with family members or third parties
- the signing and witnessing of the Consent Form.

The RAH HREC has produced a guidance document which addresses some of the difficult areas of the Informed Consent Process. [Ref 1]

Content: Participant Information Sheet

The HREC requires certain clauses to be included in the PIS for use in all research conducted at the RAH. These are derived from the NHMRC National Statement on Ethical Conduct in Human Research [Ref 2]. The RAH HREC supports the use of the NHMRC model Information Sheets which are available on the NHMRC website [Ref 3]. Deviations from these forms may be allowable provided that in the opinion of the Chairperson or HREC they do not compromise the informed consent process. See Attachment 1.

Content: Consent Form

The HREC promotes a standard Consent Form for use in all research conducted at the RAH. Deviations from this forms are allowable provided that in the opinion of the Chairperson or HREC they do not compromise the informed consent process. See Attachment 2.

Guidelines for selection of volunteers

Researchers should be aware of the possibility of exploiting subjects who are in a dependent relationship of any sort. These would include patients, fellow employees, students. Care must be taken to ensure that no subtle coercion is applied to encourage research participation.

Guidelines for payment of volunteers

The Policy document “Payment to Volunteers” [Ref 4] includes information about when it is appropriate to offer payment to volunteers. In general, payment in excess of *bona fide* expenses would potentially compromise the informed consent and voluntary nature of participation.

References

[1] Guidance Document – Informed Consent
[2] National Statement on Ethical Conduct in Human Research. NHMRC 2007
[3] Standardised Participant Information and Consent Forms available at http://hrep.nhmrc.gov.au/toolbox/standardised-forms
[4] RAH HREC Policy – Payment to Volunteers

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 20 July 2010
Version 1.2 A Thornton 13 January 2014

ATTACHMENT 1: Information sheets for research subjects guidelines on content and use

The Research Ethics Committee requires an Information Sheet to be given to potential research subjects to assist them in their decision about involvement. An Information Sheet must accompany each Consent Form. In order to assist researchers in preparing Information Sheets the following guidelines on content and use have been prepared. The Royal Adelaide Hospital must be identified on the header of the first page of the documents and the above logo is optional.

General

1. The Information sheet is one aspect of providing information so that people may come to informed decisions about their involvement in research. It must not replace personal communication between the investigator and the potential subject.

2. The investigator should ensure that the potential subject has the mental capacity and English comprehension necessary and is given sufficient time to consider the verbal and written information provided, and to discuss it with other people, before being asked to give consent to involvement.

3. The Information Sheet is to remain the property of the subject and a copy of the signed Consent Form should also be provided on request.

Style and Content

4. Use simple language with minimal technical terminology or jargon.

5. The sheet must be translated if non-English speaking subjects are to be recruited.

6. The following items will usually be included:-

   (i) Purpose of the study.

   (ii) If possible benefits from the study, to the subject and/or the Community are outlined, a statement indicating that these benefits are by no means assured.

   (iii) All procedures that involve the subject, including the use of drugs or radioisotopes.

   (iv) Alternative procedures or treatments for patients, if they elect not to enter the study.

7. The following statements must be included at an appropriate place:

   (i) This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. *(include this at or near the beginning of the information sheet).*

   (ii) Compliance with NHMRC National Statement.
   The research will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research, 2007.
   (include this at or near the end of the information sheet).

   (iii) Chairperson statement and phone number.

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, Royal Adelaide Hospital on 8222 4139.
(include this at or near the end of the information sheet).

8. The following issues must be addressed at an appropriate place:

   (i) Foreseeable risks, side effects, discomforts, inconveniences and restrictions, both immediate and late (especially after leaving hospital) that will be involved, eg. travel, absence from work.
   (ii) A comparison of the likelihood and probability of adverse effects from other procedures (or drugs) used for the same purpose.
   (iii) An explanation that random allocation and/or placebos may be used (where relevant).
   (iv) Assurances of confidentiality.
   (v) Measures that will be taken in case of an adverse event.
   (vi) The name and telephone numbers (work and after hours) of all members of the research group who can be contacted if any problems arise.

9. In protocols that involve the use of Radiation, there needs to be information about the extra radiation, using the examples of wording contained in the *Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes, 2005 – Annex 2*, according to the dose of radiation.
   RAH Intranet → Resource → Safety → Radiation Safety → Code of Practice - pdf file Annex 2 (p24 of 36)
   or *www.arpansa.gov.au/rps8.htm*

10. In protocols involving significant drug therapy or devices the following information should be included. (i-ix)

   (i) name of medicine(s) / device - generic mandatory, trade name(s) if necessary to study design.
   (ii) conditions in which the medicine/device should not be taken - e.g pregnancy.
   (iii) whether the drug/device is meant to treat the disease or to relieve symptoms and therefore how important it is to take the medicine.
   (iv) how to tell if the medicine/device is working and what to do if it appears not to be working.
   (v) when, how and how long to take the medicine/device, before or after meals etc.
   (vi) what to do if a dose is missed and the implications of ceasing the medicine/device use for any length of time.
   (vii) important side-effects and what to do about them, including effects on driving, work etc.
   (viii) interactions with alcohol and other drugs (generic and trade names).
   (ix) storage and disposal of medicines/devices.

ATTACHMENT 2: Consent form for research subjects RAH template.

PROTOCOL NAME: _____

_____

INVESTIGATORS: _____

_____

1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part.

2. I understand that I may not benefit from taking part in the trial.

3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

4. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.

5. I understand that I should not become pregnant during the course of this trial. In the event of a pregnancy occurring, I agree to notify the investigator as soon as is practically possible.

6. * I understand the statement concerning payment to me for taking part in this study, which is contained in the Information Sheet.

7. ** I have not been a volunteer in any other research projects which have involved radiation exposure in the last twelve months.

8. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

Name of Subject: _____

Signed: _____

Dated: _____

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

Signed: _____

Dated: _____
(Investigator)

*Investigators are responsible for including an appropriate statement regarding payments to subjects on the information sheet. If not applicable, please delete.

**For protocols involving radiation exposure to volunteers. If not applicable, please delete

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: MONITORING ETHICAL CONDUCT AND SAFETY OF RESEARCH

Background

The NHMRC National Statement on Ethical Conduct in Human Research [Ref 1] defines the documentation and reports required by the HREC to effectively monitor the ethical aspects of the research. These requirements are contained within section 5.5 of the National Statement.

HREC requirements for monitoring

The documentation required for monitoring is defined within the Procedure – HREC Committee Reporting Guidelines. The Procedure defines the nature of the document, the timeline for submission and whether the HREC expects to acknowledge or approve this document.

For studies reviewed under a single ethical review process such as National Mutual Acceptance (NMA) or SA Health Single Ethical Review processes where RAH is the lead HREC, monitoring is conducted for all sites which are included under the approval. However, communication related to monitoring remains the responsibility of the Coordinating Principal Investigator (CPI) who would normally be an employee of the RAH if the study has been reviewed by the RAH HREC. The exception to this would be an urgent safety notification from a Principal Investigator at another site when the CPI is not available. Details of monitoring arrangements for trials conducted under NMA are available in the NHMRC document *Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research* available on the NHMRC website [Ref 2].

Responsibility of HREC

The HREC will acknowledge all documentation provided to the committee. It will approve the documents defined as such in the *Procedure - HREC Committee Reporting* Guidelines [Ref 3]. All submitted documentation will be filed in a Protocol Specific File and retained as defined by the *Policy – Record Keeping* [Ref 4].

Responsibility of the researcher

Notwithstanding the responsibilities of the HREC in defining the documentation required to monitor the research, it is the responsibility of the researcher to take affirmative action to ensure that this occurs. All communication with the HREC must be forwarded by the researcher: Direct communication between sponsor and HREC is not acceptable except where the researcher must remain blinded to the information. In forwarding this documentation, the researcher must also be aware of the need to review the documentation submitted. For each document which requires review by HREC the researcher must provide an opinion as to whether this documentation materially impacts on the risk benefit characteristics of the trial or whether it has implications for safety of subjects enrolled in the trial. This includes amendments, reports of SAEs, SUSARS and revisions of the Clinician Information Brochure. Failure to provide this information may result in the documentation being returned to the researcher for such review.

A form: *Request to Review Updated Documentation* [Ref 5] has been developed to accompany any document for review.

Responsibility of the sponsor including DSMB

Sponsors are bound to conduct research under ICH-GCP guidelines which ensure a degree of responsibility in regard to the monitoring of clinical trials. Where research involves significant safety concerns, the sponsor would be expected to institute an appropriately constituted Data Safety Monitoring Committee or Board (DSMB). When a DSMB is involved in monitoring of the research project the HREC will, except in unusual circumstances, give strong consideration to the recommendation of the DSMB in relation to the conduct of the study. Notwithstanding this, the HREC reserves the right to make a decision which is contrary to that of the DSMB.

Research which has received expedited HREC review

There is no distinction between research receiving a full approval by HREC or an expedited approval in terms of the reporting requirements to adequately monitor the research. However, where the nature of the research is such that the level of risk is low, concessions may be made in relation to the reporting requirements. Examples of this type of research include observational studies, epidemiological studies and studies not involving interventions.

Audit or quality assurance review

Audit and quality assurance activities are by definition low risk, have no direct impact on patient safety and generally involve routine clinical practices. They are often of a defined duration. As a result, the decision has been taken that monitoring and reporting requirements for audit and quality assurance are less stringent than for research studies. Investigators are not required to provide annual reports and are only required to notify the committee if there are any changes to the nature of the study or study documentation.

Actions taken in response to monitoring

Documentation provided may be reviewed by one or more of the following persons:
the Chairperson of HREC, the Chairperson of IDSC, the Chairperson of Cancer Subcommittee or by the original IDSC reviewer of research. The Chairperson of the HREC reserves the right to refer the ongoing approval to a full meeting of HREC or IDSC. In response to monitoring reports the HREC may take one or more of the following actions:

- Acknowledge the documentation provided.
- Approve the documentation provided.
- Refuse to approve changes to the research protocol according to the documentation provided.
- Allow continuation of the research without modification.
- Require modification of the proposed research.
- Suspend participant recruitment to a research project.
- Require participants to be informed of new information provided to the committee.
- Withdraw the HREC approval for the research.

Withdrawal of approval and refusal to approve changes to research will require dialogue with researchers and will not be undertaken without adequate opportunity for the researcher to respond to the HREC concerns.

Following withdrawal of approval the researcher must:

- Suspend all further recruitment to the research study;
- Inform existing participants in the research protocol
- Not recommence the research without a subsequent approval from the HREC.

Withdrawal of an ethical approval for research will be tabled at a full meeting of HREC.
Where the HREC considers that the withdrawal of approval is taken because of a significant and uncontrolled risk to all participants in the study it will notify the Therapeutic Goods Administration (TGA) of its decision.

References

[1] National Statement on Ethical Conduct in Human Research. NHMRC 2007
[2] Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research
[3] Procedure - HREC Committee Reporting Guidelines.
[4] Policy – Record Keeping.
[5] Request to Review Updated Documentation.

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 23 July 2010
Version 1.2 A Thornton 13 January 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: GUIDELINES FOR PAYMENT OF VOLUNTEERS

Guidelines for payment to volunteers

The NHMRC National Statement on Ethical Conduct in Human Research [Ref 1] (sections 2.2.10 and 2.2.11) sets out general principles for the payment of volunteers in clinical trials.

> *"2.2.10 It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.*
>
> *"2.2.11 Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted."*

The Royal Adelaide Hospital Research Ethics Committee interprets these principles to mean that in the ordinary course of clinical research no monetary payments (other than for *bona fide* expenses) should be made to the subjects participating in the trial. However, there are circumstances in which the participants are acting as normal volunteers in a project which is of no possible advantage to themselves and may involve inconvenience, loss of time and possible discomfort. In these circumstances, the payment of an honorarium may be justified subject to the following restrictions:

1. No financial inducements of this kind should be made to individuals who at the relevant time are patients under the care of the Royal Adelaide Hospital and where the research is directly related to their medical condition.

2. The payment must in no circumstance be offset against the possible risk of the procedure involved. It is only to be regarded as compensation for loss of time, inconvenience and possible discomfort.

3. Great care must be exercised to ensure that the volunteers to whom payment is made are of an age and maturity to be able to make an independent decision.

4. Payment for services of this kind in no way absolves medical staff concerned of their responsibility should the procedure have any untoward consequence.

The actual amount of reimbursement should not exceed the total of costs incurred and income forgone. In general this means that a subject may be reimbursed for the cost of travel to and from the research site and a sum of less than $25 per hour for time spent in the research facility.

Incentives for continued participation

The integrity of a clinical trial relies upon retaining a high proportion of enrolled subjects in the study. The principles about payment for participation apply equally to any payment or gift that may be made to a subject with the intent of encouraging them to maintain their enrolment in the trial. Notwithstanding this, simple study related materials such as newsletters and badged goods of no commercial value may be provided to participants with the idea of maintaining their interest in the trial process.

Payments at the end of a trial

No direct financial payments may be made to subjects who complete a clinical trial. As a gesture of appreciation a memento of participation may be provided to the subject. This may comprise a gift of no commercial value or, if appropriate, a device provided for use by the subject in the trial. An example of this type of gift may be a blood glucose meter used by the subject during the trial. It is very important that if such a gift is entertained that it not be used as an incentive for the participant to either enrol or to remain in the trial.

Guidelines for compensation for injury resulting from participation in a company sponsored clinical trial

If a subject is injured as part of their participation in a clinical trial which has been conducted at the Royal Adelaide Hospital they are provided with the best available care for their condition by the hospital at no charge to themselves. Further to this, under certain circumstances, the sponsor of the trial is expected to pay compensation to the injured participant. These guidelines have been established by the industry organisation Medicines Australia and have been agreed for the conduct of all company sponsored clinical trials in Australia [Ref 2]. A statement to this effect is included in the patient information sheet.

Revision details

Version 1.0 M. James 18 February 2007
Version 1.1 A. Thornton 22 February 2010
Version 1.2 A Thornton 23 July 2010

References

[1] National Statement on Ethical Conduct in Human Research. NHMRC 2007.

[2] Guidelines for compensation for injury resulting from participation in a company sponsored clinical trial. Medicines Australia Compensation Guidelines 2004.

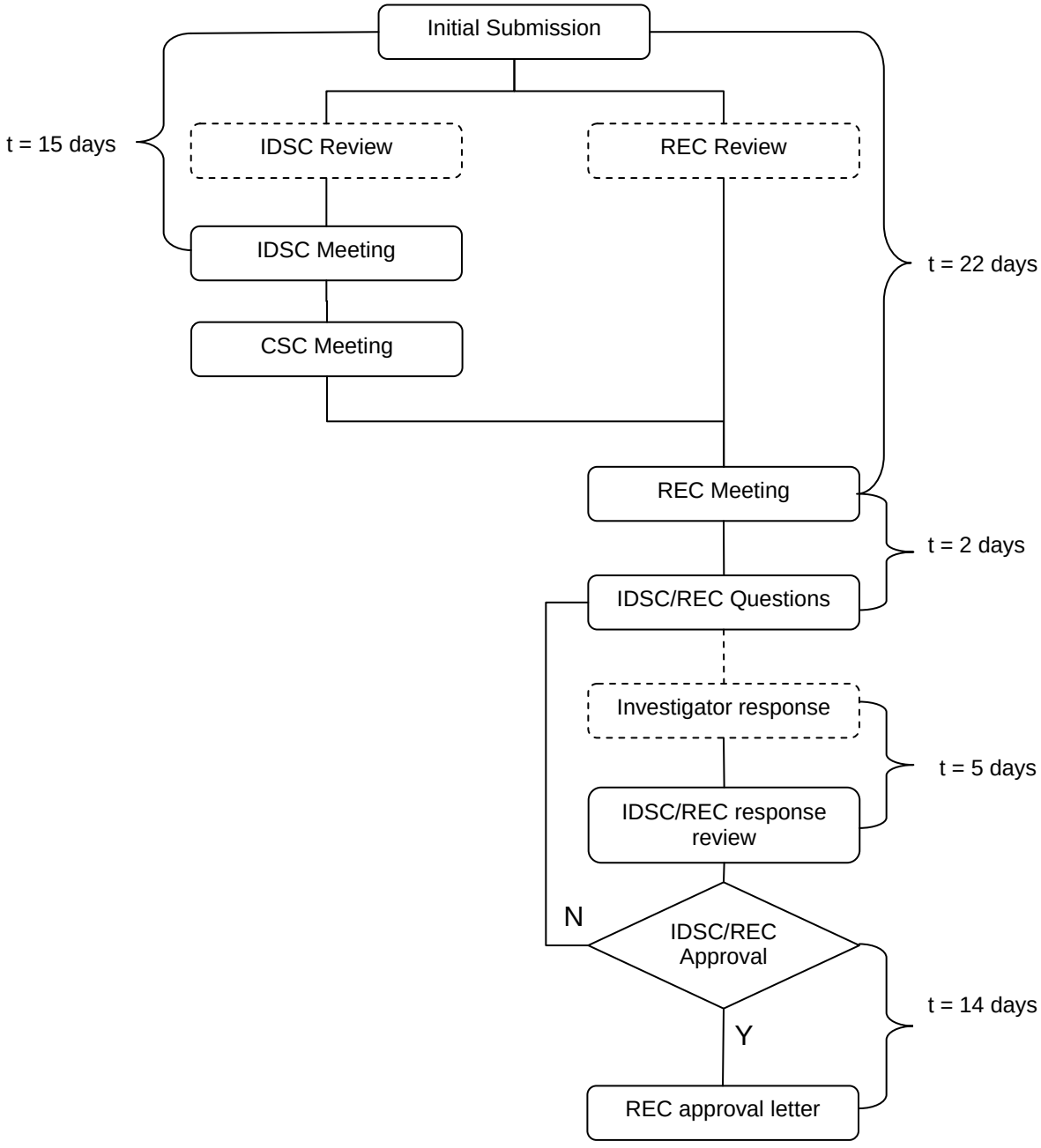
Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

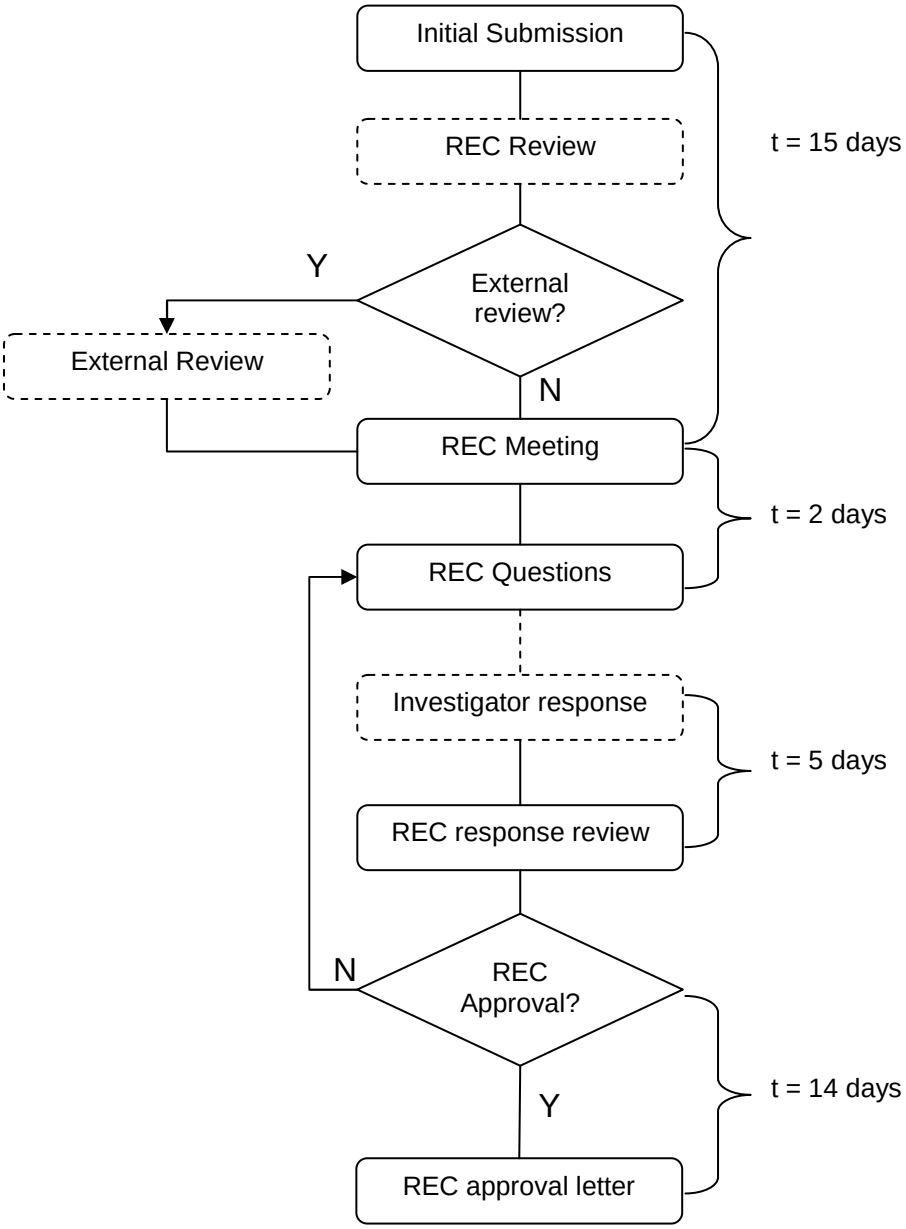
POLICY: RESEARCH ETHICS APPROVAL TIMELINES

The following diagrams are expected timeframes for review of initial submissions and amendments. Time frames may vary due to unexpected work pressures. The maximum total time for a review (excluding investigator/sponsor time) is 60 days.

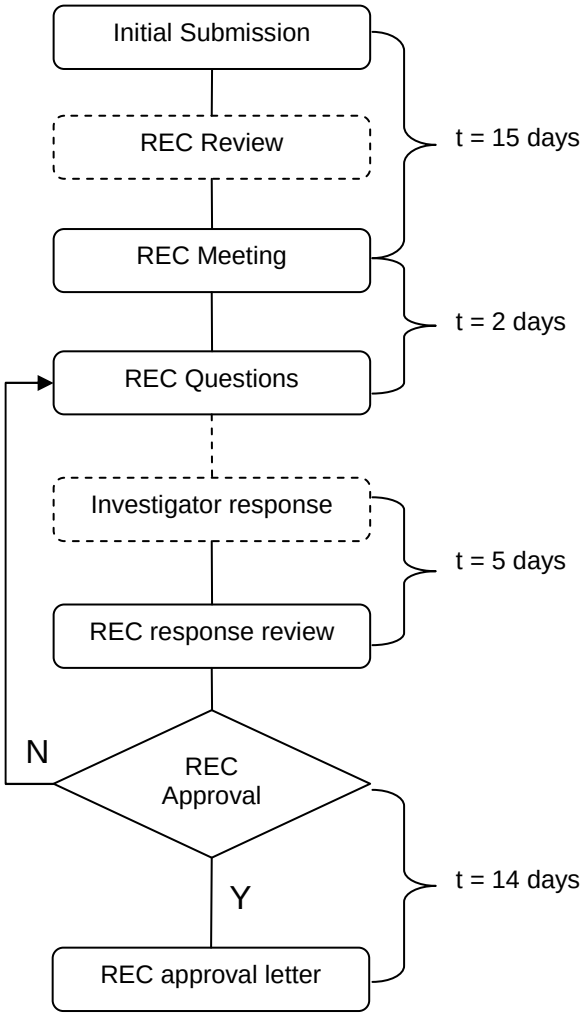
1. Drug studies requiring IDSC/CSC review



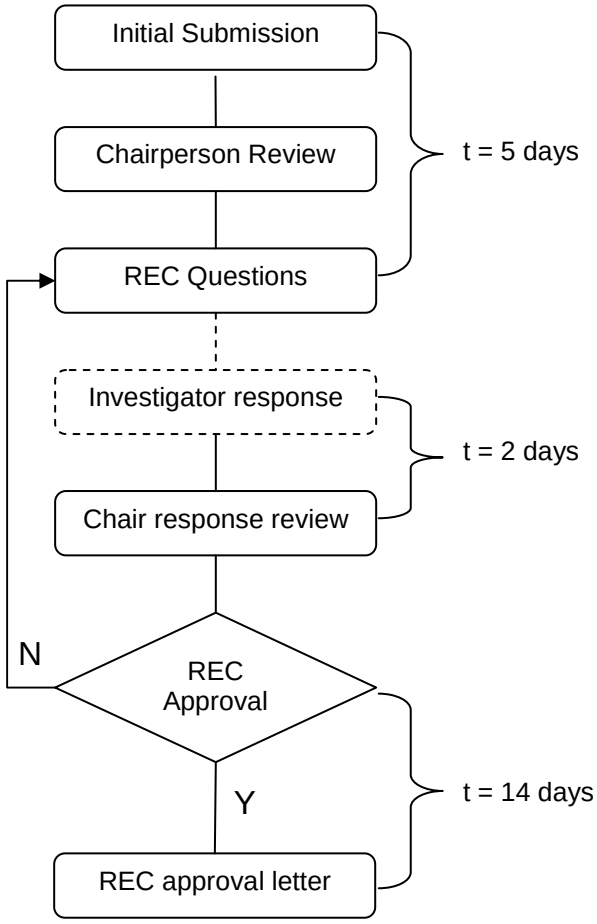
2. Device studies



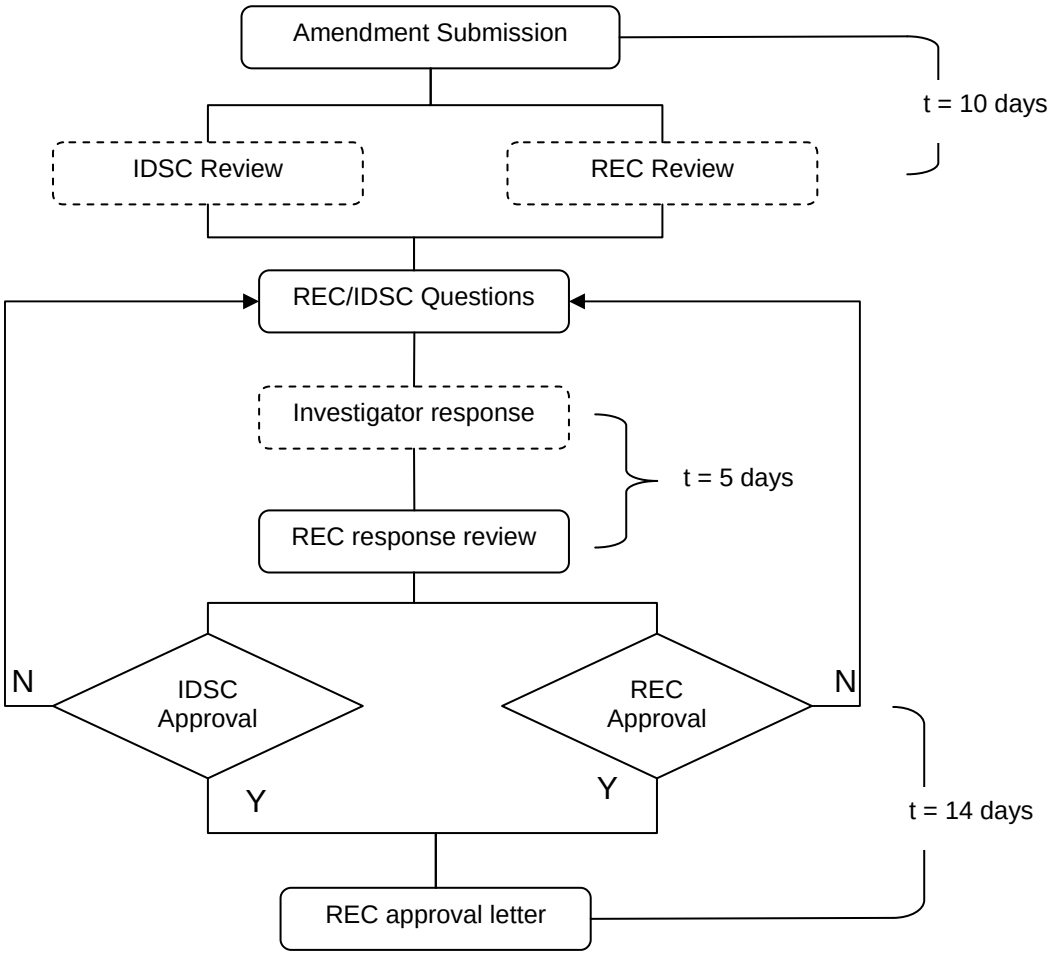
3. Non-device studies (REC only)



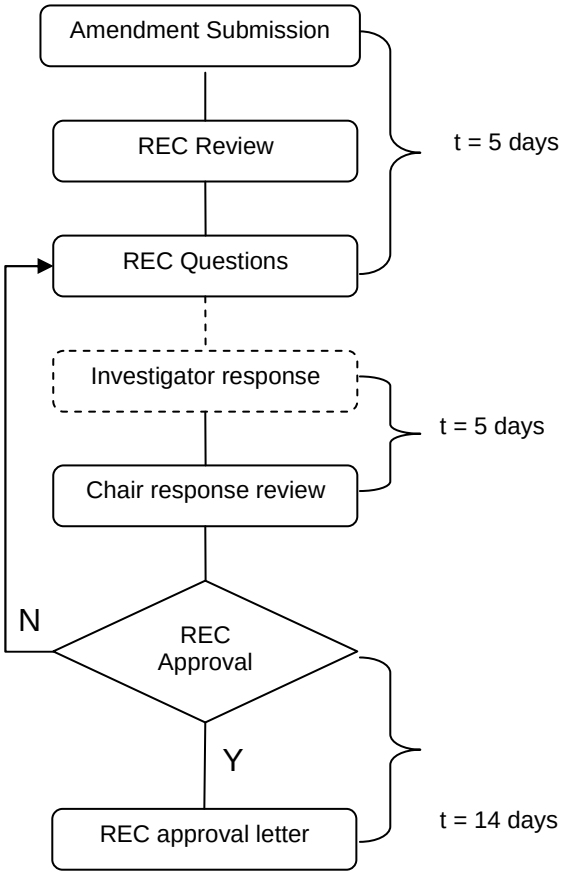
3. Expedited Review



4. Amendments with Drug Safety Issues



5. Amendments REC Issues Only



Revision history

Version 1.0 A Thornton 8 February 2010
Version 1.1 A Thornton 1 July 2012
Version 1.2 A Thornton 13 January 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: RECORD KEEPING

Background

Record keeping concerning a research protocol is a fundamental component of ICH-GCP. The Human Research Ethics Committee and its subcommittees at the Royal Adelaide Hospital continually review policies and procedures to ensure that they comply with these requirements and those of the NHMRC "National Statement on Ethical Conduct in Human Research" (Reference). Sections 5.2.24 to 5.2.27 are relevant.

> *"5.2.24 A review body should maintain a record of all research proposals received and reviewed, including at least the:*
>
> *(a) name/s of the institution/s to which the research approval is provided;*
>
> *(b) project identification number/s;*
>
> *(c) name/s of principal researcher/s;*
>
> *(d) title of the project;*
>
> *(e) correspondence between the review body and the researcher about the review;*
>
> *(f) acceptance or rejection of any changes to the proposal;*
>
> *(g) proposed date of completion of the proposal;*
>
> *(h) formal advice of final ethical approval or non-approval, with date;*
>
> *(i) terms and conditions, if any, of approval of any proposal;*
>
> *(j) duration of the approval;*
>
> *(k) name of any other review body whose opinion was considered;*
>
> *(l) mechanisms to be used to monitor the conduct of the research; and*
>
> *(m) relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.*
>
> *5.2.25 In addition, a review body should retain on file a copy of each research proposal and application for ethical approval, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved.*
>
> *5.2.26 A review body should record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to this National Statement."*

Documentation retained by HREC

The application documentation required by HREC is described in the document "Form – Application Guidelines". The reporting requirements are described in the document "Form – Reporting Guidelines". All documentation forming part of these communications is retained in a study specific file by the Executive Officer of the HREC. The details of any other *ad hoc* communication with researchers by the HREC office, the Chairperson of HREC or by any of the HREC subcommittees is also recorded and stored with the study file.

Where a research protocol is reviewed by another HREC (other than the RAH) and this review forms part of the application made to the RAH for review, this information is retained in the protocol specific file in compliance with section 5.2.27 of the National Statement.

> *"5.2.27 Where more than one review body has reviewed a research proposal, each such review body should record, as far as possible (see paragraph 5.3.3, page 87):*
>
> *(a) details of other review body/ies involved;*
>
> *(b) the decision/s of each other review body; and*
>
> *(c) details of any amendments required by each other review body."*

Electronic and Hard Copy Documentation

The RAH HREC supports the use of electronic documentation wherever possible. A single hard copy of the core documentation is retained within a study file.

For studies which are to be reviewed by IDSC and/or HREC the following documentation is required:

- NEAF (through on-line forms only)
- Cover letter (1 electronic copy and 1 hard copy)
- Protocol (1 electronic copy and 1 hard copy)
- Informed Consent (1 electronic copy and 1 hard copy)
- Advertising material (1 electronic copy and 1 hard copy)
- Questionnaires (1 electronic copy)
- Any other material (1 electronic copy)
- Radiation Safety Report (1 electronic copy and 1 hard copy)
- EPA Notification Form (1 electronic copy and 1 hard copy)
- Invoicing Form (1 electronic copy and 1 hard copy)
- Any other material (1 electronic copy)
- The submission must be complete with ALL documentation.

For studies which are suitable for expedited review the following documentation is required although exceptions may be made for simple studies such as audits:

- LNR on-line application form (through on-line forms only)
- Cover letter (1 electronic copy and 1 hard copy)
- Protocol (1 electronic copy and 1 hard copy)
- Informed Consent (1 electronic copy and 1 hard copy)
- Questionnaires (1 electronic copy)
- Advertising material (1 electronic copy)
- Any other material (1 electronic copy)

Record retention

The RAH HREC operates under the South Australian Government Guidelines for the retention of records which requires records to be maintained for 15 years from the date of completion of the trial. This exceeds the requirements of the National Statement. Documentation related the ethical review for all studies which remain active at the RAH is retained on-site until completion of the study. At this time, documentation on completed studies is archived to an external location when the study is closed but is not destroyed. Information specific to the function of IDSC is stored separately to the documentation for HREC but is subject to the same retention guidelines.

~~Records are kept in hard copy with the exception that large documents, for example line listings of serious adverse events, may be submitted on CD-ROM or DVD. Email correspondence related to a study is printed as hard copy and filed. (See Form – Reporting Guidelines).~~

Electronic documentation is not archived.

Record filing and access

The current hard copy information is stored in locked filing cabinets or in the office of the Executive Officer of HREC. It may be accessed by the Executive Officer or assistant or by the Chairperson of HREC. All filing of documentation is the responsibility of the Executive Officer or assistant. Archived documents are only accessible by request of the Executive Officer. Information specific to the function of IDSC is stored separately to the documentation for HREC but is subject to the same access guidelines.

Electronic documents are stored on SA Health managed servers protected through passwords and subject to regular backup procedures. Access is available to the Executive Officer of HREC and IDSC and assistants and the Chairman of HREC.

Reference

National Statement on Ethical Conduct in Human Research. NHMRC 2007

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 13 January 2014

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: REPORTING ON THE CONDUCT OF A TRIAL

Background

This document establishes the policy for information to be provided to the committee in respect of the conduct of Clinical Trials and other Clinical Research which has been approved by the RAH HREC.

The document aligns the requirements of the RAH HREC with the:

- NHRMC National Statement on Ethical Conduct in Human Research issued in March 2007 [Ref 1],
- NHMRC Australian Health Ethics Committee (AHEC) position statement issued in May 2009 [Ref 2],
- Principles of the International Conference on the Harmonisation of Technical Requirements For Registration of Pharmaceuticals For Human Use - Good Clinical Practice [Ref 3] and
- Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (TGA, 2004) [Ref 4]

In the event of a disparity between these guidelines and those required by regulation, the regulatory guidelines take precedence.

Changes to Trial Documentation

The Research Ethics Committee requires all changes to trial documentation to be communicated to it as soon as possible. Examples of the trial documentation that must be provided include:

- Protocol Amendments
- Changes to the Participant Information Sheet/Consent
- Changes to other trial documentation which impacts on patient safety or the ethical conduct of the trial.
- Patient recruitment documents

Failure to provide this information promptly is in breach of the provisions of ICH-GCP

> *"4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects." [Ref 1]*

Amendments to protocols or Particpant/Patient Information Sheets are reviewed by the Chairperson of HREC who may refer them to the Chairperson of the IDSC if they impact on issues relating to drug safety. An amended protocol must not be implemented until it has received HREC approval, subject to clause 3.3.7 of the ICH-GCP Guidelines.

> *"3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s))." [Ref 1]*

Examples of the trial documentation that need not be provided include:

- Change to Case Report Forms (CRF)

Administrative changes related to the conduct of the trial

The Committee requires administrative changes that impact on the conduct of a trial to be communicated to it as soon as practical. Examples of the trial documentation that must be provided include:

- Change of Principal Investigator
- Increase of enrolment number at Royal Adelaide Hospital from the originally approved number

Adverse events occurring at the local site

The Research Ethics Committee requires **does not** require notification of an Adverse Event (AE) **unless** it is judged by the researcher to materially impact the continued ethical acceptability of the trial or indicates the need for a change to the trial protocol, including changed safety monitoring. This is in line with the requirements of ICH GCP.

> *"4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects." [Ref 1]*

Serious adverse events and serious adverse device events occurring at the local site

The Research Ethics Committee requires notification of serious adverse events (SAEs) occurring at the local site within 72 hours. The events must be notified irrespective of whether they are judged to be drug related or not. Initial notification by email satisfies the time line but full details must be provided in due course. The details include:

- Patient or ID details - including Date of Birth, Age, Gender
- Initial or Follow-Up report
- Time of event
- Date of event
- Whether drug related, and name of drug
- Other contributing factor - ie, progressive disease, concurrent medication
- Type of event
- Category of event - ie, life-threatening, requiring prolonged hospitalisation, disability/incapacity, death, infection, etc.
- Description of event
- If SAE is treatment related, whether it is "expected"
- Drug details - names of all, dosings, time and dates of dosings, etc.
- Treatment
- Outcome

There is no prescribed form for reporting a SAE. SAE notifications are not acknowledged by the committee unless specifically requested.

Note that if the event is drug-related and unexpected the Therapeutic Goods Administration guidelines place obligations on sponsoring organisations to notify TGA.

The Committee also requires notification of serious adverse device events (SADEs) occurring at the local site within 72 hours. Initial notification by email satisfies the time line but full details must be provided in due course. Information provided should be as described for SAEs (see above).

Note that if the event is unexpected (an unexpected adverse device events - UADE) the Therapeutic Goods Administration guidelines place obligations on sponsoring organisations to notify TGA.

SAEs and SADEs are reviewed by the Chairperson of HREC who may refer them to the Chairperson of the IDSC if they impact on issues relating to drug safety. If the SAE or SADE warrants further action the Chairperson will communicate this to the researcher and provide a timeline for any remedial action that may be required. Remedial action may be a change in

procedures or information sheets, a requirement to notify subjects or suspension of recruitment to the trial. Any action will be reviewed following a response from the researcher.

Serious adverse events occurring at other sites

The Research Ethics Committee requires does not require notification of an SAE at a site for which it is not providing monitoring unless it is judged by the local investigator to materially impact the continued ethical acceptability of the trial or indicates the need for a change to the trial protocol, including changed safety monitoring.

Other events affecting the conduct of a trial

The Committee requires notification of any events occurring during the conduct of a trial which could reasonably be expected to reflect on the safety or ethical conduct of the trial at this site. Notification must occur with 72 hours. Examples of events that require notification include:

- Changes to the study status, such as suspension or hold, either in Australia or in an overseas country in which the same or closely related study is being conducted.
- Other communication from sponsors to researchers such as “Dear Investigator” letters.
- Deviations from informed consent process occurring
- Significant deviations from protocol
- Complaints related to study conduct

Events which have no immediate impact on the safety or ethical conduct of the trial may be reported in the annual report to the Committee. Examples of events that should be reported in the annual report include:

- Protocol deviations which do not impact safety or ethical conduct.
- Patient withdrawal of consent except where it is the result of a safety related concern or complaint (see above).
- Study recruitment closure

Changes to the Investigator Brochure

For sponsored trials, the committee requires an updated Investigator’s Brochure on an annual basis or more frequently where significant new findings related to the safety of the trial are discovered. The submission of the investigator’s brochure from the sponsor should contain a listing of changes and an indication whether the sponsor considers that the new information has impacted on the safety or ethical nature of the trial.

The researcher must review the investigator’s brochure and form his/her own view of whether the new information has impacted on the safety or ethical nature of the trial. The researcher must provide this information to the committee in the form of a covering letter.

The submission of the investigator’s brochure is reviewed by the Chairperson of HREC who may refer it to the Chairperson of the IDSC if changes impact on issues relating to drug safety. If it is judged that the new information warrants further action the Chairperson will communicate this to the researcher and provide a timeline for any remedial action that may be required. Remedial action may be a change in procedures or information sheets, a requirement to notify subjects or suspension of recruitment to the trial. Any action will be reviewed following a response from the researcher.

Line listing of suspected unexpected serious adverse reactions (SUSARs) relating to the study drug(s) or devices.

It is a requirement of the NHMRC Australian Health Ethics Committee (AHEC) position statement [Ref 2] that periodic listings provided by the sponsor are submitted to the HREC. The submission of the line listing from the sponsor should contain an indication of whether the sponsor considers that the new information has impacted on the safety or ethical nature of the trial.

The researcher must review the line listing and form his/her own view of whether the new information has impacted on the safety or ethical nature of the trial. The researcher must provide this information to the committee in the form of a covering letter.

The submission of the line listing is reviewed by the Chairperson of HREC who may refer it to the Chairperson of the IDSC if changes impact on issues relating to drug safety. If it is judged that the new information warrants further action the Chairperson will communicate this to the researcher and provide a timeline for any remedial action that may be required. Remedial action may be a change in procedures or information sheets, a requirement to notify subjects or suspension of recruitment to the trial. Any action will be reviewed following a response from the researcher.

Annual safety information (non-sponsored trials)

For trials involving an intervention or the administration of a non-approved medicine, the researcher must provide to the committee a detailed listing of serious adverse events as for SUSARS provided for sponsored trials (see above). For non-interventional trials this information may be contained within the Annual Report (see below).

Annual report

The researcher shall provide to the committee an Annual Review or Report of the study occurring at this site. The report shall contain the following information:

- Study Identification
- Principal Investigator identification
- Current Status of the Project (Complete/In Progress/Ceased/Not commenced)
- The occurrence of serious adverse events at this site
- The number of subjects entered into the trial
- The number of subjects withdrawn from the trial
- A brief description of the progress of the trial
- Identification of the person completing the form.

Annual reports and reviewed by the Chairperson of HREC and filed with study documentation.

Final study closure

At the conclusion of a trial the researcher must notify the HREC of the site closure using the Annual Review form or similar.

Information that does not require submission

- Publications
- Sponsor newsletters or recruitment updates

References

[1] NHMRC National Statement on Ethical Conduct in Human Research, 2007 Available at: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf.

[2] NHMRC Australian Health Ethics Committee position statement: Monitoring and reporting of safety for clinical trials involving therapeutic products, May 2009. Available at: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf

[3] International Conference On Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use. Available at http://ichgcp.net/

[4] Therapeutic Goods Administration. Access to Unapproved Therapeutic Goods – Clinical Trials in Australia – October 2004 available at http://www.tga.gov.au/docs/pdf/unapproved/clintrials.pdf

Revision history

Version 1.0 M James May 2007
Version 1.1 A Thornton 19 February 2010

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: STANDARD OPERATING PROCEDURES

The Royal Adelaide Hospital Human Research Ethics Committee recognises the need for policies and procedures (Standard Operating Procedures) which describe the operation of the committee and its subcommittees. The SOPs are designed around the requirements of the National Certification Scheme [Ref 1] and are in line with the "National Statement on Ethical Conduct in Human Research" [Ref 2].

SA Health, Central Northern Adelaide Health Service and Royal Adelaide Hospital requirements are also considered in the preparation of the HREC SOPs.

A list of SOPs is included as Attachment 1.

Preparation of SOPs

It is the responsibility of the Chairperson of the HREC to ensure that SOPs (Policies, Procedures and Forms) for the HREC and its subcommittees are complete and current. SOPs may be prepared by any person with appropriate expertise but in general those most likely to contribute to SOPs are:

- Chairperson HREC
- Chairperson IDSC
- Chairperson Cancer Subcommittee
- Executive Officer HREC
- Executive Officer IDSC

New SOPs are circulated to the HREC or relevant subcommittee in draft form for comment. A minimum two week period is allowed for comment. The SOP may be revised to take into account the views of other members. The final SOP is presented to the relevant committee meeting for endorsement. When endorsed SOPs are published as secure documents on the RAH intranet.

Review or withdrawal of SOPs

SOPs are reviewed annually. It is the responsibility of the Chairperson of the HREC to ensure that SOPs for the HREC and its subcommittees are reviewed. Those most likely to contribute to review of SOPs are:

- Chairperson HREC
- Chairperson IDSC
- Chairperson Cancer Subcommittee
- Executive Officer HREC
- Executive Officer IDSC

Clarifications, minor amendments of an administrative nature or grammatical corrections may be made and endorsed by the Chairman of HREC without endorsement of the full committee.

Revised SOPs are circulated to the HREC or relevant subcommittee in draft form for comment. A minimum two week period is allowed for comment. The SOP may be further revised to take into account the views of other members. The revised SOP must shown the revision history, the date of the review and the name(s) of the reviewer(s). Revised SOPs must be indicated by the word DRAFT in the footer.

Superseded SOPs are to be withdrawn and stored in an archive directory.

Reviewed SOPs are published as secure documents on the RAH intranet.

History of SOPs

Sections added to a SOP are highlighted by underlining. Sections removed from a SOP are indicated by strikethrough text. Minor changes of an editorial nature are not highlighted to aid readability. The highlighted sections are retained for the life of the version of the SOP and removed or added as appropriate when the SOP is next revised.
Any change to a SOP will normally require the issuing of a new version number although grammatical corrections may be made without incrementing the version. Substantial amendments will require a new major number (eg 2.0), other amendments a minor number (eg 1.2).

All SOPs must shown the revision history, including authorship.
All implemented versions of SOPs are saved in electronic form on a RAH network drive.

References

[1] National Certification Scheme for Institutional Processes related to the Ethical Review of Multi-Centre Research.
[2] National Statement on Ethical Conduct in Human Research. NHMRC 2007

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 20 July 2010

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

POLICY: TGA REQUIREMENTS FOR CLINICAL TRIALS

Choice of CTN or CTX schemes

The Therapeutic Good Administration (TGA) provides two schemes under which a clinical trial can be conducted, the CTN and the CTX scheme. A trial involving an unapproved good or device must be conducted under one of these schemes. From the HREC perspective, the fundamental difference between the schemes is whether the TGA conducts an initial review prior to the HREC review of the study.

The TGA document provides guidance on the choice of which scheme a sponsoring company may use. The vast majority of trials are conducted under the CTN scheme which is an institution specific scheme requiring the sponsor to register a CTN application for each participating institution. Nevertheless if HREC feels that the submission should be made under the CTX scheme it may require that of the sponsor. This might be the case for trials of devices which are first use in humans and have not be used overseas. Wherever the HREC feels it does not have the expertise to assess an application it may require a CTX application.

> *"The choice of which scheme to follow (CTN or CTX) lies firstly with the sponsor and then with the ethics committee that reviews the protocol and provides advice to the "Approving Authority" which decides whether the trial is allowed to proceed. The determining factor for an HREC is whether the Committee has access to appropriate scientific and technical expertise in order to assess the safety of the product. As a general rule, phase III, IV and bioavailability/bioequivalence studies of medicines are most suited to the CTN scheme. However, the CTN Scheme can also be an option for earlier phase (I & II) studies if there is adequate preclinical review available, especially of safety. For medical device trials, the CTX scheme may be more appropriate where the experimental device introduces new technology, new material or a new treatment concept which has not been evaluated previously in clinical trials in any country. However, so long as adequate guidance is available to give an HREC confidence that it has the competence to make a decision based on scientific advice, there is no reason why the CTN route could not be considered for any study. An HREC may determine that it does not wish to review the proposed trial under the CTN Scheme and recommend its review under the CTX Scheme." [Ref 1]*

CTN/CTX application

It is the responsibility of the trial sponsor to provide the relevant documentation for submission to TGA. Following final approval of the trial, the CTN or CTX is signed by the Chairperson of HREC and by the CEO or delegate of the Royal Adelaide Hospital.

Withdrawal of approval for a trial

When the HREC rejects a trial or withdraws approval for a trial at the local site, it is expected that the HREC will notify the TGA of its decision. Reasons that might lead to discontinuation of a trial at the local site include:

- *"evidence of significant deviation from the trial protocol and that, as a result, the welfare and rights of participants are not or will not be protected;*
- *"evidence that allowing the trial to continue carries an unacceptable risk of death, serious illness or serious injury to trial participants;*
- *"evidence from progressive review of a comparative study shows that one treatment proves to be so much better or worse that to continue the trial would disadvantage one group of participants; and*
- *"evidence that the conduct of the trial is in breach of Commonwealth, State and/or Territory Laws." [Ref 1]*

The HREC may withdraw approval for a trial if it judges that there is a serious risk to patient safety. If this occurs, following consultation with the researcher, the HREC will notify the sponsor and the TGA of its decision.

Revision details

Version 1.0 A. Thornton, 22 February 2010

References

[1] Therapeutic Goods Administration. *Access to Unapproved Therapeutic Goods – Clinical Trials in Australia – October 2004 available at* *http://www.tga.gov.au/docs/pdf/unapproved/clintrials.pdf*

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

PROCEDURE: COMMITTEE MEMBERSHIP

Tenure of Members – Research Ethics Committee

In March of each year approximately one third of the positions on the Research Ethics Committee are declared vacant. In this way, each position of the committee will be declared vacant every three years.

Tenure of Members – Specialist Subcommittees

The subcommittees are comprised of experts whose function is to advise the REC. Tenure will continue while the member is able and willing to perform the duties effectively.

Appointment of New Members – Research Ethics Committee

On the occurrence of a vacancy or the recognition of a gap in committee expertise the Chairperson may commence the process of recruitment of a new committee member. As far as possible when a vacancy arises for a position with specific clinical expertise the position should be filled by a person with similar expertise. In the case of resignation of one of the compulsory members of National Statement on Ethical Conduct in Human Research - section 5.1.30, replacement with another person meeting these requirements is mandatory.

On the occurrence of a vacancy, nominations are called for appointment:

- Nominations for lay persons are advertised in the local press.
- Nominations for a legal professional or person involved in pastoral care are advertised through appropriate professional networks
- Nominations for positions of clinical expertise are advertised within the Royal Adelaide Hospital and North Terrace Campus of SA Pathology. Where a specific skill gap is identified the advertisement may specifically target clinicians with knowledge in the relevant clinical area.

Advertisements will allow approximately two weeks for response. Current members may renominate for vacant positions. Nominations will be reviewed by a subcommittee of the Research Ethics Committee. This sub-committee will consist of the Chair, one other member and the Executive Officer of the Committee. The recommendation of the subcommittee will be presented to the full committee at the next HREC meeting. When approved by the committee the nomination will be forwarded to the Chief Executive of the Central Adelaide Local Health Network for final approval and issuing of a letter of appointment. (See Attachment 1)

Appointment to the Investigational Drugs Subcommittee IDSC

The Investigational Drugs Subcommittee is a committee of technical experts appointed to provide specialist advice to HREC for research proposals involving the administration of drugs. Members of IDSC are recruited on the basis of their expertise in pharmacology and disciplines of clinical medicine. The Chairperson of IDSC will discuss potential recruitment of new members with the Chairperson of HREC and approach nominees as discussed above. A letter of appointment will be sent to the new member (See Attachment 2)

Appointment to the Cancer Subcommittee

The Cancer Subcommittee is a committee including technical experts in oncology who are

able to render an expert opinion on relevant research proposals. To minimise conflict of interest, the Cancer Subcommittee must have available to it cancer researchers with expertise in medical oncology or haematological oncology. Members of the Cancer Subcommittee are recruited on the basis of their expertise. The Chairperson of the Cancer Subcommittee will discuss potential recruitment of new members with the Chairperson of HREC and approach nominees as discussed above. A letter of appointment will be sent tothe new member (See Attachment 2)

Induction of New Members

New members will be oriented to the committee functions and their role and responsibility by interview with the HREC Chair and the HREC Executive Officer. They will also be invited to attend one meeting of HREC prior to final acceptance of the nomination.
On appointment the new member is provided with a copy of the following documents:

- HREC Terms of Reference (Intranet site)
- HREC Policies (Intranet site)
- NHMRC National Statement on Ethical Conduct in Human Research
- Minutes of previous HREC meeting.

On appointment to a subcommittee the new member is provided with a copy of the following documents:

- HREC Terms of Reference (Intranet site)
- HREC Subcommittee Terms of Reference (Intranet site)
- HREC Policies (Intranet site)
- NHMRC National Statement on Ethical Conduct in Human Research

Training of Members

SA Health and CALHN provide training opportunities for HREC members. HREC members are expected to attend these sessions wherever possible. In addition, within budgetary constraints, the RAH HREC will support members attendance at other relevant training or educational events.

Appointment of Chairperson

It is expected that the new Chairperson will be an existing member of the committee and likely that the appointed person will have served in an executive role on the committee, either as a Deputy Chairperson or as a senior member of the committee. Candidates for Chairperson are expected to have a minimum of three years experience as a member of an HREC.
Nominations for Chairperson will be sought within the Committee. If no such nomination is received, a recruitment process (as above) may be undertaken to seek nomination of a suitably qualified person who is external to the committee.
Following identification of a nominee for Chairperson, the current Chairperson will introduce the new Chairperson to a full meeting of HREC. In the absence of dissent the nomination will be taken to be confirmed.
A period of a minimum of one month, including one more full committee meeting will be taken by handover of processes and responsibility.

Appointment of Deputy-Chairperson

Processes for appointment shall be as for the appointment of Chairperson (see above)

Revision history

Version 1.0 A Thornton 6 February 2010
Version 1.1 A Thornton 23 July 2010
Version 2.0 A Thornton 21 November 2011
Version 2.1 A Thornton 18 May 2012
Version 2.2 A Thornton 16 June 2012
Version 2.3 A Thornton 14 January 2014

Attachment 1 – Letter of Appointment New Committee Member

CALHN CORPORATE LETTERHEAD

REC Committee Member
Dear Sir/Madam,
Re: Membership of the Royal Adelaide Hospital Human Research Ethics Committee

Thank you for accepting a nomination to the Research Ethics Committee. I am pleased to inform you that, following due process, you have been elected to serve on the committee. Tenure of the committee is for a period of three years, commencing <<INSERT DATE>> and concluding on <<INSERT DATE>>.

The conditions of membership are contained within the Research Ethics Committee Terms of Reference and associated policy documents. The Chairperson of the Committee will provide appropriate induction to the operation of the committee prior to you assuming your position of the committee. You should be aware that members of the Research Ethics Committee are indemnified under SA Health's indemnity and insurance program.

Yours sincerely

Chief Executive Officer
Central Adelaide Local Health Network

Attachment 2 – Letter of Appointment New Subcommittee Member

CALHN CORPORATE LETTERHEAD

REC Subcommittee Member
Dear Sir/Madam,
Re: Membership of the Investigational Drugs Subcommittee/Cancer Subcommittee of the Royal Adelaide Hospital Human Research Ethics Committee

Thank you for accepting a nomination to the subcommittee. I am pleased to inform you that, following due process, you have been elected to serve on the subcommittee. Your commencement date is <<INSERT DATE>>.

The conditions of membership are contained within the Subcommittee Terms of Reference and associated policy documents. The Chairperson of the Committee will provide appropriate induction to the operation of the committee prior to you assuming your position of the committee. You should be aware that members of the Research Ethics Committee and Subcommittees are indemnified under SA Health's indemnity and insurance program.

Yours sincerely

Chief Executive Officer
Central Adelaide Local Health Network

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545www.rah.sa.gov.au

Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

PROCEDURE: COMMITTEE REPORTING GUIDELINES

Summary:

This document replaces previous statements from the Royal Adelaide Hospital (RAH) Human Research Ethics Committee (HREC) relating to the information to be provided to the committee in respect of the conduct of Clinical Trials and other Clinical Research which has been approved by the RAH HREC.

The document aligns the requirements of the RAH HREC with those of the NHRMC National Statement on Ethical Conduct in Human Research issued in March 2007 [Ref 1] and NHMRC Australian Health Ethics Committee (AHEC) position statement issued in May 2009.[Ref 2]

The information which follows should be considered to be a minimum requirement and, depending on the complexity, design and risk perceived, the HREC may require that additional information be reported.

TRIAL DOCUMENTATION				
ETHICS COMMITTEE REQUIREMENTS FOR LOCAL REPORTING	**Is reporting required by EC?**	**Does EC acknowledge receipt?**	**Timeframe required by EC for reporting event**	**Additional explanatory information**
Protocol Amendments	Yes	Yes	As soon as possible	All amendments must be submitted. Except for amendments that involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone numbers), the submission documents must include: • A clean and tracked copy of the amended protocol • A summary of changes including the rationale for each amendment
Changes to the PIS/Consent	Yes	Yes	As soon as possible	All amendments must be submitted. The submission documents must include: • A clean and tracked copy of the amended PIS/Consent • An explanation of the need for change
Changes to other trial documentation	Yes	Yes	As soon as possible	Any changes to documents previously approved must be submitted. This may include questionnaires, advertisements, study specific information and instructional information for participants.
Change to Case Report Forms (CRF)	No	No		
Change of Principal Investigator	Yes	Yes	As soon as possible	
Increase of enrolment number at Royal Adelaide Hospital from the originally approved number	Yes	Yes	As soon as possible	

SAFETY RELATED INFORMATION				
ETHICS COMMITTEE REQUIREMENTS FOR LOCAL REPORTING	**Is reporting required by EC?**	**Does EC acknowledge receipt?**	**Timeframe required by EC for reporting event**	**Additional explanatory information**
Serious Adverse Events (SAE) at local site	Yes	Yes	Within 72 hours	Appropriate supporting information such as a copy of the incident documented in a patient's medical record must be provided [Ref 3]
Serious Adverse Device Events (SADE) at local site	Yes	Yes	Within 72 hours	Appropriate supporting information such as a copy of the incident documented in a patient's medical record must be provided.
Unexpected Adverse Device Events (UADE) at local site	Yes	Yes	Within 72 hours	Appropriate supporting information such as a copy of the incident documented in a patient's medical record must be provided.
Adverse Events (AEs)	No	No		Not required unless the occurrence of the AE indicates the need for a change to the trial protocol, including changed safety monitoring
Serious Adverse Events at other sites	Conditional - see comment	Conditional - see comment	Within 72hours	The researcher shall report to the HREC any SAE, irrespective of where it occurred, if it is judged by the researcher or sponsor to materially impact the continued ethical acceptability of the trial or indicates the need for a change to the trial protocol, including changed safety monitoring.
Deviations from informed consent process occurring	Yes	Yes	As soon as possible – within 14 days	
Significant deviations from protocol	Conditional - see comment	Conditional - see comment	Within 72hours	The researcher shall notify the REC of any protocol violation or deviation which is judged by the researcher to materially affect the ongoing safety of the subject in the trial. If protocol exemption granted by the sponsor falls into this category, the event needs to be reported
Other protocol deviations	No	No	With Annual Report	Other protocol deviations which do not meet the above criteria may be reported with the Annual Review.
Patient Withdrawal of Consent	No	No		
Complaints related to study conduct	Yes	Yes	Within 72hours	The researcher shall provide to REC a report on any complaint from participants received by any of the investigators. The report shall contain a description of what occurred and the steps taken to resolve/address the complaint.

PERIODIC REPORTING REQUIREMENTS				
ETHICS COMMITTEE REQUIREMENTS FOR LOCAL REPORTING	**Is reporting required by EC?**	**Does EC acknowledge receipt?**	**Timeframe required by EC for reporting event**	**Additional explanatory information**
Investigator Brochure Update (Sponsored Trials)	Yes	Yes	At least annually	The document must be reviewed and acknowledged by signature of the Investigator. The Investigator must draw to the attention of the committee any information which may impact on ongoing safety of participants in the trial.
Annual Safety Information (Non-Sponsored Trials)	Yes	Yes	At least annually	For trials that are initiated by investigator(s) or a collaborative group of clinicians and in which an IB or PI is unavailable, a trial update may be submitted that provides appropriate review of safety information in the previous 12 months. The document must be reviewed and acknowledged by signature of the Principal Investigator
Suspected unexpected serious adverse reactions (SUSARs) relating to the study drug(s) or devices.	Yes	Yes	At least 6 monthly.	The researcher shall review, interpret and acknowledge, by signature, listings of suspected unexpected serious adverse reactions (SUSARs) relating to the study drug(s). The submission must include the researcher's own opinion in regard to potential impact on ethical acceptability and need for action The listing is provided by the sponsor at least six monthly and should include a statement that indicates action to be taken by the sponsor in relation to the continuation or conduct of the trial.
Study Recruitment closure	No	No		Report in annual review
Changes to the study status.	Yes	Yes	Within 72 hours	If a study is placed on hold or suspended (for example), this must be notified to the committee as soon as possible. An explanation for the change of status must be provided.
Final Study Closure	Yes	Yes	Within 14 days	
Annual Review	Yes	Yes	Annually	From approval date until final study closure
Publications	Optional	No		Submission of publications is optional
Sponsor newsletters or recruitment updates	No	No		

Note;

1) If notification of receipt is needed, the following must be added to the bottom of the accompanying letter as well as a copy of the original letter.

Confirmation This Notification Received by Research Ethics Committee
Date _____ **Received by REC**_____

2) Where periodic information such as SUSARS is of a substantial size, for example 30 pages or more, submission on electronic media is recommended. Consult the Ethics Committee office if unsure.

Revision History:

Version 1	4 January 2008	M James
Version 2	25 November 2009	A Thornton
Version 2.1	1 February 2010	A Thornton

References:

[1] NHMRC National Statement on Ethical Conduct in Human Research, 2007 Available at: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf.

[2] NHMRC Australian Health Ethics Committee position statement: Monitoring and reporting of safety for clinical trials involving therapeutic products, May 2009. Available at: http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf

[3] Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - annotated with TGA comments. DSEB. July 2000. http://www.tga.gov.au/docs/html/ich13595.htm)

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

PROCEDURE: COMPLAINTS

NHMRC National Statement

The RAH HREC is committed to fulfilling Section 5.6 of The National Statement on Ethical Conduct in Human Research [Ref 1] and ensuring that research is conducted according to the Australian Code for the Responsible Conduct of Research by ensuring all complaints are handled appropriately. All complaints must be handled promptly with due sensitivity and in recognition of principles of natural justice.

Scope

This policy outlines how the RAH HREC will efficiently, effectively and ethically deal with complaints made to the HREC irrespective of source of the complaint or the nature of the complaint.

Complaints received by HREC may concern:

- The HREC processes.
- The HREC decision.
- The nature or content of a HREC approved research study.
- The conduct of a researcher undertaking an HREC approved study.
- Other issues unrelated to the HREC.

Complaints received by HREC may be initiated by:

- Researchers.
- Participants in research or their relatives or other concerned parties.
- Researchers involved in the approved or other studies.
- Institutions, organisations or other individuals with a direct or indirect interest in the approved research.

Receiving complaints

Research participants, their families and other concerned parties have the right to communicate their concerns about any aspect of the services provided and are encouraged to do so. To facilitate this process the HREC will ensure that all Information Sheets for research participants contain the contact information for the HREC Executive Officer.

The HREC may receive the complaint in any form: in person, by telephone, by email or in writing. If the complaint is not received in writing the complainant will be encouraged to document the complaint in a letter or email to the Chairman of the HREC but, although desirable, this is not essential for the complaint to be investigated. Notes are taken by the person receiving the complaint (usually the Executive Officer) and a confidential memorandum is written to the Chairman of HREC. The complainant may be identified or anonymous.

If the complainant is identified a letter acknowledging the receipt of the complaint will be sent to the complainant irrespective of the nature of the complaint. This letter will be sent within 5 working days of receiving the complaint.

Details of the complaint are recorded in the HREC Complaints Database by the Executive Officer in the first instance and then updated by the Chairman or other delegated person in due course.

Investigating complaints

The Chairman of the HREC will make the initial determination about the seriousness of the complaint and the action required to deal with the complaint. This course of action may not finally be determined until other persons have been consulted. In all cases the course of

action will be consistent with the Royal Adelaide Hospital Research Code of Conduct [Ref 3], the SA Health Research Ethics Operational Policy Directive [Ref 4], the SA Health Research Governance Policy Directive [Ref 5] and the Australian Code for the Responsible Conduct of Research [Ref 2].

Complaints about the HREC

Complaints about HREC processes or decisions are appropriately managed by a third party. The SA Health Research Governance Policy Directive [Ref 5] includes a hierarchical approach to dealing with complaints about the Site Specific Assessment process. This has been adapted to deal with complaints about the ethics process as follows:

1. The Principal Investigator (PI) (also taken to include the Coordinating Principal Investigator (CPI) in the case of a process under the National Mutual Acceptance model) may appeal the final decision of the HREC, where a decision has been made to not approve an application, if he/she considers the decision has been made improperly or without due consideration of all relevant information.
2. The PI may also lodge a formal complaint about the HREC review process, where the PI considers the process has been unsatisfactory.
3. In both instances, the PI should outline their concerns in writing to the institutional Research Governance Officer (RGO, or equivalent).
4. The institutional Research Governance Officer will consult with the Chairman of the HREC on the substance of the complaint.
5. The PI may resubmit or amend their ethics application to meet any requirements outlined by the RGO. This application will be assessed according to the usual processes of the HREC and within a reasonable timeframe.
6. Where a complaint has been lodged, the RGO will notify the responsible Chief Executive Officer (CEO, or delegate) of any such complaints in a timely manner.
7. Following consideration and further investigation by the RGO, the Chairman of HREC and CEO/delegate (as required), the PI will be notified in writing of the outcome of the investigation including any further action to be taken to resolve the complaint.
8. If the PI remains dissatisfied with the outcomes of any further action by the RGO, the Chairman of HREC and/or CEO/delegate, this should be communicated in writing to the CEO/delegate. In these instances, the following process will be followed:
    a) The CEO will determine if further investigation is necessary. If so, the CEO will establish a panel to consider the matter. The panel will include the following members:
        i. The CEO/delegate;
        ii. Two nominees of the CEO/delegate, including at least one independent nominee with expertise in research governance and ethics matters, including the requirements of the SA Health Research Governance Policy, the Australian Code for the Responsible Conduct of Research, and other applicable policy documents and guidelines.
    b) The panel will allow the RGO, the Chairman of HREC, the local PI and the coordinating PI the opportunity to make submissions.
    c) The CEO/delegate will notify the RGO, the Chairman of HREC, the PI and the CPI of the outcomes of the investigation.
9. Any recommendation or decision of the panel will be final.
10. The complaint and the outcome will be communicated to the Research Ethics Committee.
11. The complaint and the outcome will be recorded in the HREC Complaints database.

Complaints about the Research or Research Conduct

Complaints about the nature or conduct of a research study may take many forms and many different forms of resolution or response may be appropriate. In deciding upon the course of action the Chairman of HREC must take into account many factors including:

- Whether the alleged actions or processes have impacted or have the potential to impact on the health, safety or rights of research participants.
- Whether the researcher has deviated from the agreed research protocol.
- Whether the deviation has been deliberate or accidental.
- The confidentiality requested by the complainant and confidentiality due to researchers through the process of natural justice.

With due regard to the issues of the complaint the Chairman may decide that the complaint can be investigated by a number of methods including:

- An internal investigation conducted by the Chairman of HREC.
- An internal investigation conducted by the Chairman of HREC and designated committee members.
- An internal investigation conducted by a third party such as the Research Governance Officer and/or members of the RAH research community.
- An external investigation conducted by a third party such as another SA Health HREC or SA Health researchers external to the RAH.
- An external investigation conducted by a third party from another state.

In each case the Chairman will ensure that the method of investigation is consistent with the processes described in the Australian Code for the Responsible Conduct of Research [Ref 2].

Following Investigation of the complaint the HREC Chairman or other appropriate person, depending on the type of investigation, will communicate the result of the investigation to the complainant. This communication may be verbal or written depending upon the seriousness of the complaint and the method of investigation.

Where the content of the complaint is substantiated and the outcome may create risk for the institution, the HREC Chairman or other appropriate person, will communicate the outcome of the investigation to the Research Governance Officer and the Executive Director of Medical Services. This communication will be in writing.

Where the content of the complaint is substantiated the HREC Chairman will report on the complaint to the HREC Committee.

Complaint Resolution

Before any action is taken against a researcher as a result of a complaint the HREC Chairman will consult with the Research Governance Officer and the Executive Director of Medical Services. Consensus will be reached about the action required.

Actions to be taken in response to a substantiated complaint are varied but must be commensurate with the seriousness of the complaint and must take into account the wilfulness or otherwise of the actions which triggered the complaint. Actions may range from counselling through to termination of the research study and suspension of research privileges. Any discussion, counselling or sanction conducted as part of complaint resolution will be documented in a Memorandum and/or in the HREC Complaints Database.

In each case the Chairman will ensure that the resulting sanctions are consistent with the processes suggested in the Australian Code for the Responsible Conduct of Research [Ref 2]. Breaches of the Code will in general require less serious sanctions than research misconduct.

Where the researcher or research project is affiliated with a University or other institution the HREC Chairman, Research Governance Officer or the Executive Director of Medical Services will communicate the outcome of the investigation and the sanctions applied to the appropriate person, for example, the Deputy Vice Chancellor of Research. This communication will be in writing.

Appeals

Where a complainant considers that the process of dealing with the complaint has not been appropriate or that the outcome is unsatisfactory they may seek to review the outcome of the complaint through similar processes to those above:

1. If the complainant is dissatisfied with the outcomes of the complaint investigation this should be communicated in writing to the CEO/delegate. In these instances, the following process will be followed:
    a) The CEO will determine if further investigation is necessary. If so, the CEO will establish a panel to consider the matter. The panel will include the following members:
        iii. The CEO/delegate;
        iv. Two nominees of the CEO/delegate, including at least one independent nominee with expertise in research governance and ethics matters, including the requirements of the SA Health Research Governance Policy, the Australian Code for the Responsible Conduct of Research, and other applicable policy documents and guidelines.
    b) The panel will allow the complainant, the Chairman of HREC, the RGO and the person who is the subject of the complaint the opportunity to make submissions.
    c) The CEO/delegate will notify the complainant, the Chairman of HREC, the RGO and the person who is the subject of the complaint of the outcomes of the review.
2. Any recommendation or decision of the panel will be final.
3. The complaint and the outcome will be communicated to the Research Ethics Committee.
4. The complaint and the outcome will be recorded in the HREC Complaints database.

References

[1] National Statement on Ethical Conduct in Human Research. NHMRC 2007 as updated from time to time.

[2] Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. (2007) Available at http://www.nhmrc.gov.au/guidelines/publications/r39.

[3] Royal Adelaide Hospital Research Code of Conduct. Instruction Number OWI-02238. Available on the RAH website at eCentrRAHl.

[4] SA Health Research Ethics Operational Policy Directive. Available at: http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Health+and+medical+research/Research+ethics/Research+ethics

[5] SA Health Research Governance Policy Directive. Available at: http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Health+and+medical+research/Research+ethics/Research+governance

Revision history

Version 1.0 A Thornton 1 August 2014

Appendix 1 Definitions

Research is defined as that which:

"includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction."[1]

Complaint is defined as:

A verbal or written expression of dissatisfaction which requires a response.[2]

Research Misconduct is defined as

"Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest.

Misconduct includes avoidable failure to follow an approved research protocol, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

Research misconduct does not include honest differences in judgement in the management of the research project, and may not include honest errors that are minor or unintentional."[3]

The term misconduct is used for serious or deliberate deviations from the Code for the Responsible Conduct of Research.

Breach of the Code is defined as

The term breach is used for less serious deviations from this Code that are appropriately remedied within the institution.

[1] From Research Assessment Exercise for Universities in the United Kingdom as cited in Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. (2007)

[2] Adapted from the MacMillan Dictionary.

[3] Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. (2007) Available at http://www.nhmrc.gov.au/guidelines/publications/r39

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

PROCEDURE: ETHICAL REVIEW PROCEDURES

Research reviewed by other SA Health institutions

Research Ethics Committees within the SA Health public framework have agreed that ethical review conducted by one of the committees will be accepted by another committee without further ethical or scientific review. These processes may be applied to both research which is normally subject to review by the full committee and research which is of low and negligible risk and has previously been managed through expedited processes.

The RAH HREC requires:

- The Patient Information Sheet to include a heading that indicates that the research is being conducted at the RAH. RAH letterhead or dual badged letterhead is preferred.
- The Patient Information Sheet to include a providing contact details for the RAH HREC. The preferred statement is:

  "If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, Royal Adelaide Hospital on 8222 4139."

Research approved under these guidelines will be listed on the agenda of the next HREC meeting for information.

Research to be conducted at other SA Health institutions

The Royal Adelaide Hospital Research Ethics Committee will review studies to be conducted at the Royal Adelaide Hospital and other SA Health Institutions. It is expected that where research is conducted at multiple SA Health Sites, the Ethics Committee responsible for the primary review will be the committee that services the Institution of the main investigator – to be known as the Coordinating Principal Investigator (CPI).

Research reviewed by other institutions

The NHMRC have established a framework to facilitate the ethical review of research conducted at multiple sites throughout Australia. The National Approach (previously called HoMER – Harmonisation of Multicentre Ethical review) is not yet implemented within South Australia.

Application procedures for studies submitted to RAH

If a study is to be conducted at RAH or SA Pathology (IMVS campus) and not at other SA Health Institutions, it is considered as a single site submission. If a study is to be conducted at RAH and secondarily at other sites within SA Health, it is considered a multi-site submission. In respect to submission to the RAH ethics committee, the requirements for both types of studies are the same.

SA Health has mandated that all research conducted within SA Health Institutions be entered into a database called AU-RED. A portal for Investigators to submit to this database is provided through a website called "On-line forms" available at www.ethicsform.org/au. If a study will require committee review it must be submitted through on-line forms which requires completion of the National Ethics Application Form (NEAF). All applications undergoing full committee review will also require the completion of a site-specific assessment form (SSA) which is also available through on-line forms. Instructions for submission are on the on-line forms website. In brief the application requires:

- Establishing a user account
- Completing the NEAF (note that a NEAF provided by the sponsor or from another site may be imported and modified for local applicability).

- Completion and submission to on-line forms of the other required documents listed in the Form - RAH required submission documents ~~(see Appendix 1).~~
- When complete the application must be submitted and a submission code obtained.
- The submission code must be provided to the Executive Officer of the Ethics Committee – Note that until this is communicated to the Ethics Office, the office does not know that a submission has been made.
- Completion of the SSA process which links to the Ethics Application through the submission number and the HREC application number.

Application procedures for studies submitted elsewhere

If a study is to be conducted at multiple sites within SA Health the submission should be made to the site of the CPI and an SSA completed at all sites at which the study is being done. The local committee application guidelines should be followed for determination of additional documents required for each committee. The RAH does not require an ethics application but an SSA must be completed and the Executive Officer of HREC should be advised.

Application procedures Low and Negligible Risk Research

SA Health are developing a process for on-line submission of low and negligible risk research studies which will be based upon procedures in place in New South Wales. A checklist will be provided to assist the researcher to determine whether the research is suitable for this process. If in doubt, researchers should call the Executive Officer of the committee. At present low and negligible risk research should be submitted to the RAH committee using the existing processes. A site specific assessment process must be completed for all low and negligible research which has resource or indemnity implications. A list of required documents is provided in the Form - RAH required submission documents. ~~shown in Appendix 1.~~

Application procedures Audits

SA Health have agreed that audits do not need to be submitted through on-line forms or entered into AU-RED. Applications should be submitted to the Executive Officer of the committee. The Chairman will decide whether the application can be classified as an audit.

Revision history

Version 1.0 A Thornton 6 February 2010
Version 2.0 A Thornton 29 June 2012
Version 2.1 A Thornton 10 July 2014

PROCEDURE: GUIDELINES FOR AN ETHICS APPLICATION

Cover Letter – Investigator Statement

Each submission requires a cover letter from the investigator which provides a rationale for the proposed study. The cover letter should also contain a complete list of all documents which are submitted for approval. The documents should be decribed by exact title, version number and date. The cover letter should include a statement from the investigator which addresses the following issues:

- What is the current standard treatment or process for this patient population at the Royal Adelaide Hospital?
- What are the overall benefits to the study participant or to the field?
- Are there any risks to the study participant?
- Are there any other trials in the unit which recruit a similar participant population? If so, how will it be determined as to which study the participant will be recruited into?

Study Protocol

The protocol is the document used to describe the proposed study. It should accurately describe all the procedures and discuss any ethical issues associated with the study. Sample headings for a protocol are provided in Appendix 1. The protocol should have numbered pages and a version number and date in the footer.

Participant Information Sheet

The HREC requires an Information Sheet to be given to potential research subjects to assist them in their decision about involvement. The HREC requires certain clauses to be included in the PIS for use in all research conducted at the RAH. These are derived from the NHMRC National Statement on Ethical Conduct in Human Research. Deviations from these forms may be allowable provided that in the opinion of the Chairperson or HREC they do not compromise the informed consent process. The Royal Adelaide Hospital must be identified on the header of the first page of the documents.

The Information sheet is only one aspect of providing information so that people may come to informed decisions about their involvement in research. It must not replace personal communication between the investigator and the potential subject.

The investigator should ensure that the potential subject has the mental capacity and English comprehension necessary and is given sufficient time to consider the verbal and written information provided, and to discuss it with other people, before being asked to give consent to involvement. The Information Sheet should use simple language with minimal technical terminology or jargon. The sheet must be translated if non-English speaking subjects are to be recruited. The Information Sheet is to remain the property of the subject and a copy of the signed Consent Form should also be provided on request. A sample Information Sheet in shown in Appendix 2. The Information Sheet should have numbered pages and a version number and date in the footer and should be on appropriate departmental letterhead.

Consent Form

The Consent Form is the document to be signed by participants and researchers to record their agreement to participate in the study. The Consent Form must be signed before any study-related procdures are conducted. Where the participant is unable to provide informed consent, an appropriate third party (usually next of kin) may sign the consent. The form should be specifically configured for third party consent. The Consent Form should have numbered pages and a version number and date in the footer and should be on appropriate departmental letterhead. The preferred content for the Consent Form is shown in Appendix 3.

Appendix 1 Sample Protocol

1. TITLE (Full title of project)

2. INVESTIGATOR DETAILS AND QUALIFICATIONS

Contact details (location, phone numbers, email) and addresses for correspondence.

3. PURPOSE OF STUDY (general) and AIMS (specific)

4. BACKGROUND AND PRELIMINARY STUDIES (if any)

5. PARTICIPANTS

Selection, Inclusion, Exclusion and Withdrawal Criteria.
How will participants be recruited?
Note: For RAH patients, the initial contact should come from their treating clinician, or someone who was responsible for their care at the RAH.

6. STUDY PLAN AND DESIGN

A clear description of procedures to be performed on patients or volunteers and an indication of whether the procedure is part of normal diagnosis and treatment.

7. OUTCOMES

How will the outcomes of the study be evaluated?
Can the aims be realized?

8. ETHICAL CONSIDERATIONS

Issues which may need special consideration by the committee. This might include possible risks, pain or discomfort and issues of informed consent. Please refer to the NHMRC National Statement on Ethical Conduct in Human Research (available at www.nhmrc.gov.au).

9. SPECIFIC SAFETY CONSIDERATIONS (eg. Radiation, toxicity)

Radiation risks outlined in the **Code of Practice** from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) must be followed for all Exposure of Humans to Ionizing Radiation for Research Purposes. (Available at *www.arpansa.gov.au/Publications/codes/rps8.cfm*

The following should be detailed:-

- Why the participants are exposed to ionizing radiation.
- The number of participants to be exposed.
- The precautions to be taken to keep exposure to a minimum

The exposure to radiation needs to be addressed with a formal **Radiation Safety Report** from the RAH Radiation Safety Officer (Peter Collins – contact ext 25478).

You are also required to complete a '**Notification**' form for the REC to submit to the SA Government EPA Radiation Protection Division. An electronic copy is available on RAH Intranet or Internet.

It is the responsibility of the investigator to address the dose constraints for research participants (e.g. no more than 5mSv / year and no more than 10mSv in 5 years).

10. DRUGS/DEVICES

Including the approval status of and detailed information on investigational drugs or devices, if applicable. For studies with investigational drugs or devices or drugs or devices used outside their stated indication complete a CTN drug/device form, and an Invoice Details Form *(Appendix B)*, if applicable.

For all approved clinical trials, it is a HREC condition that it is registered in a publicly accessible trials registry prior to enrolment of the first participant. This is the responsibility of the investigator.

11. ANALYSIS AND REPORTING OF RESULTS

A copy of your datasheet, questionnaire or other relevant material must be provided.
Specify:

- How will data be collected and recorded?
- Who will have access to the research data and results?
- How will the recorded data be stored.
- Who will own the data and results of your research?

12. REFERENCES

13. OTHER RELEVANT INFORMATION

Advertising, Publishing.

14. OTHER ETHICS COMMITTEES TO WHICH THE PROTOCOL HAS BEEN SUBMITTED.

Please give current status, and date of approval.
If using another Institution's format for your protocol, please ensure all of the REC required details are included, and amend to be RAH specific with RAH contact details.

15. DATE OF PROPOSED COMMENCEMENT AND DURATION.

16. SIGNATURES OF INVESTIGATORS

The Principal Investigator to confirm that the protocol has been read and endorsed.
The signatures may be in a covering letter or at the end of the Protocol.

Appendix 2 - Sample Information Sheet

1. The following items will usually be included:-

(i) Purpose of the study.

(ii) If possible benefits from the study, to the subject and/or the Community are outlined, a statement indicating that these benefits are by no means assured.

(iii) All procedures that involve the subject, including the use of drugs or radioisotopes.

(iv) Alternative procedures or treatments for patients, if they elect not to enter the study.

2. The following statements must be included at an appropriate place:

(i) This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.
(include this at or near the beginning of the information sheet).

(ii) Compliance with NHMRC National Statement.
The research will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research, 2007.
(include this at or near the end of the information sheet).

(iii) Chairperson statement and phone number.
If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, Royal Adelaide Hospital on 8222 4139.
(include this at or near the end of the information sheet).

3. The following issues must be addressed at an appropriate place:

(i) Foreseeable risks, side effects, discomforts, inconveniences and restrictions, both immediate and late (especially after leaving hospital) that will be involved, eg. travel, absence from work.
(ii) A comparison of the likelihood and probability of adverse effects from other procedures (or drugs) used for the same purpose.
(iii) An explanation that random allocation and/or placebos may be used (where relevant).
(iv) Assurances of confidentiality.
(v) Measures that will be taken in case of an adverse event.
(vi) The name and telephone numbers (work and after hours) of all members of the research group who can be contacted if any problems arise.

4. Radiation risks

In protocols that involve the use of Radiation, there needs to be information about the extra radiation, using the examples of wording contained in the *Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes, 2005 – Annex 2*, according to the dose of radiation (*www.arpansa.gov.au/Publications/codes/rps8.cfm*)

5. Drugs

In protocols involving significant drug therapy or devices the following information should be included. (i-ix)

(i) name of medicine(s) / device - generic mandatory, trade name(s) if necessary to study design.
(ii) conditions in which the medicine/device should not be taken - e.g pregnancy.
(iii) whether the drug/device is meant to treat the disease or to relieve symptoms and therefore how important it is to take the medicine.
(iv) how to tell if the medicine/device is working and what to do if it appears not to be working.
(v) when, how and how long to take the medicine/device, before or after meals etc.
(vi) what to do if a dose is missed and the implications of ceasing the medicine/device use for any length of time.

(vii) important side-effects and what to do about them, including effects on driving, work etc.
(viii) interactions with alcohol and other drugs (generic and trade names).
(ix) storage and disposal of medicines/devices.

Appendix 3 Sample Consent Form

On Appropriate Departmental Letterhead

PROTOCOL NAME: _____

INVESTIGATORS: _____

1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part.

2. I understand that I may (or will) not benefit from taking part in the trial.

3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

4. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.

5. * I understand that I should not become pregnant during the course of this trial. In the event of a pregnancy occurring, I agree to notify the investigator as soon as is practically possible.

6. ** I understand the statement concerning payment to me for taking part in this study, which is contained in the Information Sheet.

7. *** I have not been a volunteer in any other research projects which have involved radiation exposure in the last twelve months.

8. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

Name of Subject:

Signed: _____

Dated: _____

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

Signed: _____

Dated: _____
(Investigator)

* The pregnancy clause should be adjusted to the requirements of the study, eg “I should not be pregnant…” or “I should not become pregnant…”. If a male should not father a child, please include this statement separately. If not applicable delete.

** Investigators are responsible for including an appropriate statement regarding payments to subjects on the information sheet. If not applicable delete.

*** For protocols involving radiation exposure to volunteers. If not applicable delete
For third party consent, customise all statements to refer to the participant and include a statement “I undertake to inform my relative/friend that they have been enrolled in this study as soon as they are able to understand”.

References

National Statement on Ethical Conduct in Human Research. NHMRC 2007
RAH HREC Policy – Payment to Volunteers
ARPANSA - Code of Practice for Exposure of Humans to Ionizing Radiation for Research Purposes, 2005

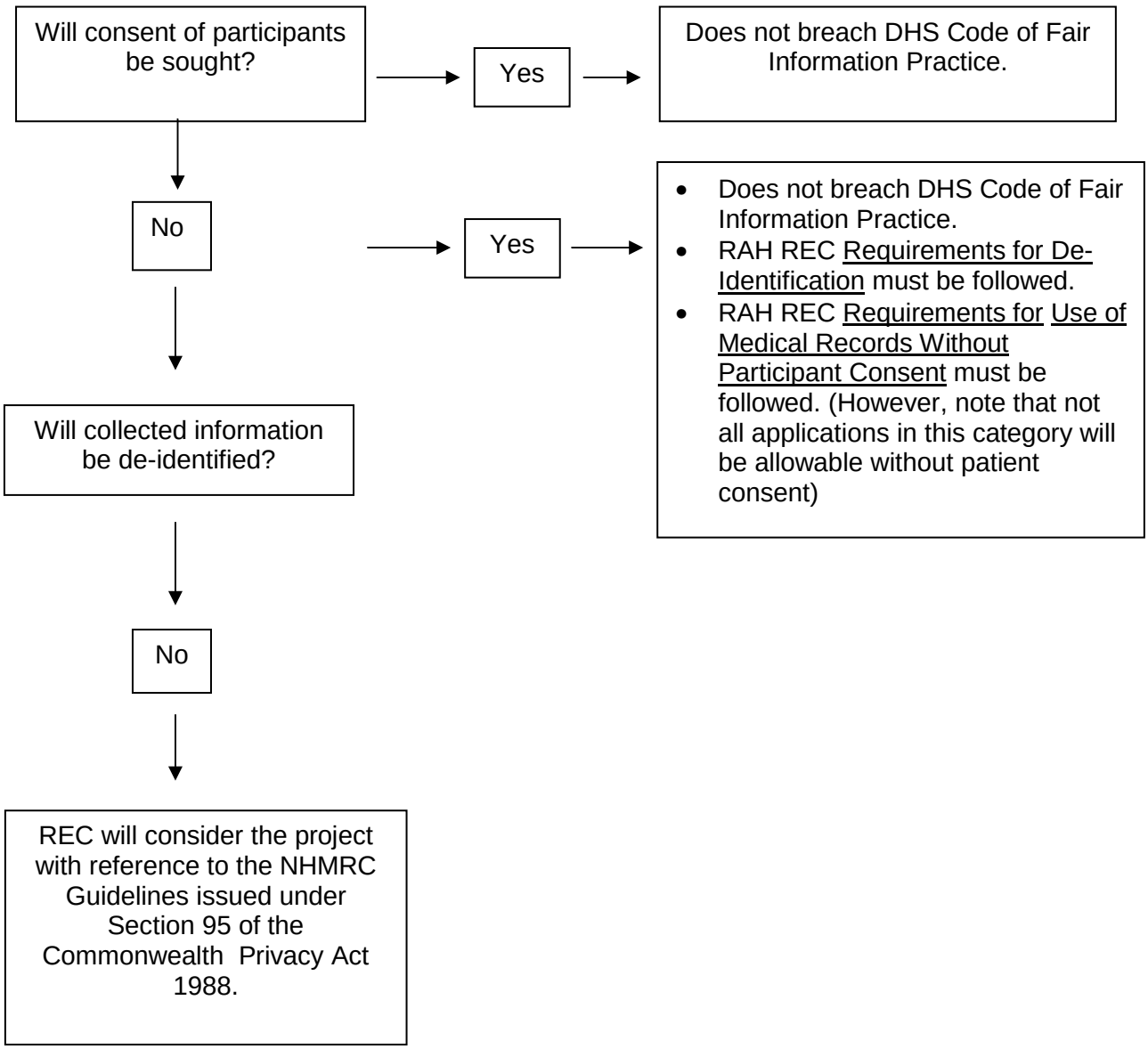
Revision history

Version 4	M James September 2008
Version 5	A Thornton September 2009
Version 5.1	A Thornton 20 July 2010
Version 6	A Thornton 1 July 2012

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

PROCEDURE: ACCESS TO MEDICAL RECORDS



REC REQUIREMENTS FOR DE-IDENTIFICATION

1. The data sheets or computer records must not contain patient/participant identifiers. This includes UR numbers. A code must be used. If the information may need to be re-identified in the future, the code must be stored securely and separately from the study data.

2. Where identifiers are needed initially for patient/participant linkages, the data must be de-identified as soon as possible while still allowing the aims of the project to be achieved.

REC REQUIREMENTS FOR USE OF MEDICAL RECORDS WITHOUT SUBJECT CONSENT

1. No more information than that needed to accomplish the study must be recorded. The data sheet which contains the information to be recorded must be submitted with the protocol for REC approval. It should contain a footer with the version number and the date. After initial REC approval, modifications to this sheet must be approved by the REC. Therefore, investigators should give careful consideration to the design of this form.

   Note that where it is planned to consider information that may be considered 'sensitive' it may be considered necessary to obtain prior consent of the participant.

2. It should not be intended to contact the participant in relation to this study. Nor should there be a foreseeable requirement to contact the participant, eg due to a 'duty of care' type of notification which might become necessary as a result of the study findings. In this latter regard, it must be considered carefully whether the study results could have any health implications for the patient. If so, the study cannot proceed without prior consent of the patients / participants.

3. It is preferable that the Medical Records are examined by the investigator(s). If this is not practical, the examination should be performed by an RAH employee under the supervision of the investigators.

4. The investigators and any persons involved in examining the Medical Records, are required to sign and date the following statement in their submission:

   "The investigators and any persons involved in examining the Medical Records undertake:
   (a) to keep confidential all information in the Medical Records which is viewed during the conduct of this study, and
   (b) to record only that information which is indicated in the REC approved data record."

REVISION DETAILS

Version 1.0 M. James 24 September 2004
Version 1.1 A Thornton 23 July 2010

Government of South Australia
SA Health

ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5939
ABN 80 230 154 545
www.rah.sa.gov.au
Research Ethics Committee
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email:
rah.ethics@health.sa.gov.au

PROCEDURE: HREC MEETING PROCEDURES

1. The composition of the Research Ethics Committee (REC) membership may vary from time to time, but the minimum composition will always comply with that indicated in the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans, 2007 (The NHMRC Statement). This requires that there shall be:
   - equal numbers of men and women
   - at least one third of the members from outside the institution for which the HREC is reviewing research.
   - a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
   - at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
   - at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
   - at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
   - at least one lawyer, where possible one who is not engaged to advise the institution;
   - at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

2. The REC will meet on the third Thursday of each month, excepting for January when no meeting will be held.

3. The meeting agenda, including copies of protocols, will be distributed to all members on the Friday preceding each meeting.

4. If notification is received that a member will not attend the following meeting, the agenda, including copies of the protocols, will be sent to a proxy member.

5. If a member is unable to attend but is able to provide written feedback about proposals before the meeting they are encouraged to do this and such information will be tabled in discussions of the relevant protocol.

6. Attendance of members, apologies and proxy members are recorded in the mi8nutes of the meeting.

7. When there is less than full attendance, the Chairperson must be satisfied, before a decision is reached, that the minimum membership listed in paragraph 1 have received all documents and have had the opportunity to comment. This procedure is in compliance with The NHMRC Statement.

8. At each REC meeting, the Minutes of each preceding meeting will be ratified.

9. Decisions will be reached by consensus. Only members who participate in the review and discussion process will be allowed to vote to approve or reject a protocol.

10. Decisions to approve a protocol will be recorded in the minutes and the investigator will be promptly notified in writing of the decision.

11. Decisions to reject a protocol will be recorded in the minutes and the investigator will be promptly supplied in writing with the reasons for the decision and actions that can be taken to discuss the situation further (where applicable).

12. When a decision is delayed:
    - the reasons will be recorded in the minutes and the investigator will be supplied in writing with the reasons / queries.
    - responses from the investigator to REC queries must be in writing (responses may take the form of clarifications, agreement to protocol modifications, appeal against protocol modifications)
    - the REC will decide whether the investigator's response should be considered at the following meeting or whether authority will be delegated to the Chairperson to consider the response. This decision will be recorded in the Minutes.
    - if authority is delegated to the Chairperson, the Chairperson may approve the protocol or may decide the response will be considered at the next REC meeting.
    - approval will be recorded and tabled in the Agenda at the following REC meeting.

13. When a decision is made to terminate or suspend a previously approved protocol, the reasons will be recorded in the minutes and the investigator will be supplied in writing with the reasons for the decision and actions that can be taken to discuss the situation further (where applicable).

14. Any REC member who is an investigator on a protocol under consideration, must leave the meeting room during Committee discussion and decision making on that protocol.

15. At all times, the Chairperson has the delegated authority to consider and to approve protocols in which there is little or no intervention and little or no risk to subjects. The written criteria for consideration for this accelerated review have been approved by the REC. The principal details of any protocol (Title, Investigators) which is approved by this process of accelerated review will be listed on the agenda for the following REC meeting. The REC may ask the Chairperson for details of aspects of the protocol and reasons for approval at the following meeting.

16. The Chairperson has the delegated authority to consider and approve all amendments to approved protocols. The written criteria for consideration for this accelerated review have been approved by the REC. The principal details of any protocol (Title, Investigator) which is approved by this process of accelerated approval will be listed on the agenda for the following REC meeting. The REC may ask the Chairperson for details of aspects of the protocol amendment at the following meeting.

17. The Chairperson may co-opt individuals for expert opinion at any time.

18. The Chairperson may invite a researcher to attend the committee meeting to support their proposal.

19. Complaints from researchers about REC decisions will be tabled at REC meetings. Complaints that cannot be resolved by discussions between the REC and the complainant will be referred to the Director, Medical Administration.

20. Relevant records, including written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings and correspondence, will be retained for at least 15 years.

21. Information submitted to the REC will be treated as confidential by all members of the REC and its subcommittee(s).

22. A Committee audit of Expedited Approvals will be conducted at the March and September meetings. Prior to these meetings, the REC Secretary will distribute to each Committee member 1 to 2 protocols which have received Chairperson's Approvals in the preceding six month period. During the meeting, Committee members will provide comments to the Deputy Chairperson, in the absence of the Chairperson from the meeting room. These will be discussed with the Chairperson at the same meeting.

23. The Radiation Protection Branch of the Department of Health, will be notified each month of protocols involving radiation for research which have been approved.

Revision history

Version 6.0 M James 19 July 2007
Version 7.0 A Thornton 6 February 2010