

Austin Health REU HREC working procedures:

Abbreviations

DTSC – Drug Trial Sub Committee

HREC – Human Research Ethics Committee

NDSRC – Non-drug Study Review Committee

NEAF – National Ethics Application Form

NHMRC – National Health & Medical Research Council

PI – Principal Investigator

PICF – Participant Information and Consent Form

REU – Research Ethics Unit

REU website - <http://www.austin.org.au/Page.aspx?ID=416>

SAE – Serious Adverse Event

- Frequency of HREC meetings – monthly [third Thursday of the month unless constrained by a Public Holiday (when a date in lieu will be chosen) or December (when the third Friday will be chosen)]. Meetings will commence at 3pm (except the December meeting which will commence at 1pm).
- Attendance at HREC meetings – up to two members from each category may attend a meeting. Where there are more than two members in a category, the members will be rostered to attend according to the REU. All seven core members must be represented at every meeting, either in person or having read the Agenda papers and submitted comments.
- Conduct and structure of HREC meetings and deliberations – General items for discussion will be raised first. Any researchers invited to attend a meeting to discuss their submissions will be invited to attend a specific time prior to 6pm at a time mutually convenient. Following this, all the new protocol submissions, in turn, will be reviewed. For each new submission, 4 HREC members will be specifically allocated to the submission (although all members are encouraged to review all submissions). After a brief introduction from the Research Ethics Unit Manager or nominee, all members who wish to comment on the submission are invited to do so in turn. All members are offered equal time for discussion. Any required administrative changes (e.g. grammar and spelling changes to the PICF) should be simply handed in to the Minutes Secretary, in writing. Any substantive issues will be discussed and a consensus arrived at. This does not require unanimity. The Chairperson will state whether the submission is approved or not. Approval may be outright or subject to response to HREC queries. Non approval may be outright, a request for the researchers to attend an HREC meeting to discuss the submission, a request for further expert advice, a request for a 'small group meeting' between the researchers and some HREC members out-of-session, or a request for resubmission to HREC or one of the sub-committees. In addition, if a researcher does not reply to HREC queries within three months of the meeting (without requesting further time to submit), the submission is removed from the

Agenda and if a decision is made later to go ahead with the trial, it must be re-submitted. Finally, failure to submit an annual report is cause for rescinding of approval. Apart from the new submissions, the remainder of the Agenda items will be discussed by exception. Each section of this part of the Agenda will have been assigned to one HREC member to read (in addition the Chairperson, the REU Manager and the representatives of the sub-committees will have read these items). At about 5pm, the meeting will break for about 15 minutes for dinner.

- **Preparation of HREC agendas and minutes** – the REU is responsible for the preparation of the Agenda papers. For assistance with preparation of the minutes the meeting will be recorded. The REU will write up the minutes and will send them to the Chairperson for approval then prepare letters for researchers. Normally the letters will be posted prior to the close of business on the Friday of the week following the meeting (this may be delayed should public holidays intervene). The minutes are confirmed by the full HREC at the next meeting.
- **Timely distribution of papers prior to meetings** – Agenda Papers will be sent, by courier for same day delivery, to members on the Thursday or Friday prior to the meeting week. The required ‘reading split’ will be emailed to members on the Thursday or Friday prior to the meeting week.
- **Presentation of applications for ethical review** – Researchers are required to submit their applications using the NEAF and all required associate documents. All submissions are first reviewed by a sub-committee: the DTSC or the NDSRC. Submission dates are advertised on the REU website. The NDSRC submission date is approx. 7 weeks prior to the HREC meeting while the DTSC submission date is approx. 4 weeks prior. *The reasons for the different submission dates include i) NDSRC requires more time between their meeting and the HREC meeting to approve minutes and receive replies; ii) Having different submission dates spreads out the workload of the REU.* The DTSC currently remains paper based while the NDSRC has converted to an electronic process. For submissions from DTSC, the submission together with the letter from DTSC and the reply from the researchers along with any changed documents (in tracked format) will form the Agenda item for that study. The letter from the sub-committee and the reply from the researchers along with any changed documents are placed in front of the original submission and separated from it by a page of coloured paper. When reviewing the submission, the latest version of documents (ie those in front of the coloured paper) should be reviewed noting that not all documents may have required review and may thus be behind the coloured paper. For submissions from NDSRC, because the NDSRC is electronic and no paper copies are initially supplied, the complete hard copy submission incorporating any NDSRC requested changes will make up the agenda item for that study. The letter from NDSRC and the reply from the investigators will be

placed in front of the complete application showing tracked changes. Because of this there should be no duplication of documents and only the latest version of each document is supplied.

- **Timely consideration and review of applications** –a final submission date is advertised for each of the sub-committees via the REU website. The sub-committee review occurs within 8 days of the submission date (allowing time for meeting Agenda collation and distribution and time for members to read the applications).

DTSC: Meeting minutes are approved and letters are sent, within three working days of the meeting, to researchers (with a copy by email for letters requiring a reply). A reply is required within 4 working days to ensure addition to the next HREC Agenda. Following the HREC meeting, minutes are approved and letters sent out within 5 working days. If there are no delays and the HREC approves the study outright, approval can be obtained between 27 and 32 working days (depending on the month).

NDSRC: Meeting minutes are approved and letters are sent, within eight working days of the meeting, to researchers (with a copy by email for letters requiring a reply). A reply is required within ten working days to ensure addition to the next HREC Agenda. Following the HREC meeting, minutes are approved and letters sent out within 5 working days. If there are no delays and the HREC approves the study outright, approval can be obtained between 40 and 45 working days (depending on the month). *The approval times lines for non-drug studies are extended in order to i) allow extra time for single researchers or students to prepare their response (within their busy working lives) and ii) to spread out the workload of the REU.*

Should HREC approval be subject to changes, replies are reviewed on three days per week ie Mondays, Wednesdays and Fridays.

- **Managing conflicts/dualities of interest** – At the start of each meeting, it is the responsibility of the HREC Chairperson (or the sub-committee chairperson) to ask members if they have a conflict of interest to declare. Where a member of the HREC is also an investigator or related to an investigator, he/she must leave the room while discussion and final decision-making, on any of their studies, are held. Where an investigator is a member of a sub-committees, although the investigator may remain in the room for preliminary discussion of his/her study, he/she must leave the room while discussion and final decision-making are held.
- **Communicating with researchers, including face to face, by telephone and in writing (including email)** – The majority of communication between researchers and the committees is via mail. When replies are needed to sub-committee letters, this mail is both posted and emailed. If specifically requested, HREC letters can be emailed as well as posted. There are times when written communication is unsatisfactory and researchers may be invited to attend an HREC meeting, in person or via a telephone link-up. In addition, out-of-session ‘small group meetings’

may be arranged between HREC members and researchers. Researchers may request an interview with the HREC. From time to time, HREC may invite researchers to give an 'overview' of their research in order to educate the HREC and clarify general matters or concerns. Researchers are also encouraged to contact the Research Ethics Unit for assistance with submissions or replies.

- **Reporting on its activities to the institution** – The Chief Medical Officer (CMO) attends the HREC meetings as a representative of the Institution. The Manager of the Office of Research attends on behalf of Austin Life Sciences. The Chairperson will submit an annual report to the Austin Health Board.
- **Methods of decision-making** – Final decision-making is by consensus. When approval is subject to response to HREC queries, this response is received and reviewed by the REU. When the queries are definitive, the REU can decide if the reply is suitable for approval to be given. If the queries are subjective, the REU will circulate the response (usually via email) to i) the Chairperson; ii) nominated HREC members as decided by the chairperson at the HREC meeting; or iii) the whole committee; for a decision.
- **Prompt notification of decisions** – HREC meeting decisions are notified to investigators within 5 working days of meeting. Should HREC approval be subject to changes, replies are reviewed on three days per week ie Mondays, Wednesdays and Fridays. Approval letters are posted to the PI.
- **Record keeping** – All submissions to HREC are noted in the Austin Health ethics database. When a submission is received, it is entered into the database under – new protocol; protocol amendment; correspondence; internal SAE; external SAE and annual report. All new studies are identified by a unique project number. After the submission is processed through the appropriate sub-committee, if no outstanding issues are noted, it is tagged to go to the next HREC meeting. Thus it is possible to electronically track the submission through the meetings. Since mid-2005, all agendas, minutes and letters from all meetings are kept electronically. In addition, hard copies of all submissions are kept in project files. Prior to 2006, hard copies were kept in meeting order and they remain thus as there have been no resources provided to back-file.
- **Monitoring of approved research** – Minimal monitoring requires the submission of an annual report on an Austin Health template. A final report is also required at study completion.
- **Reporting and handling of adverse occurrences** – Internal SAEs are expected to be reported in a timely fashion and certainly to the next sub-committee meeting. Internal SAEs where unexpected patient harm has occurred that is deemed to be related to the study drug/ activity are expected to be reported, directly to the Manager REU, within five working days. External SAE's: Austin Health HREC follows the requirements of the NHMRC Australian Health Ethics Committee

(AHEC) Position Statement 'Monitoring and reporting of safety for clinical trials involving therapeutic products' May 2009.

- **Appropriate monitoring** – the HREC will determine monitoring requirements, over and above, the minimal requirement of an annual report and final report. The REU has provided a 'Self-Audit' tool for researchers (available on the REU website). It is recommended that non-commercially sponsored studies are annually self-audited and that the signed audit tool is filed in the study file. This 'self-audit' tool will be the basis for more in-depth monitoring when the HREC commences auditing individual studies.
- **Receiving and handling of complaints** – complaints are generally received by the Chairperson HREC or the REU. Details of the complaint, the trial involved and the contact details of the complainant are recorded. Where it is deemed useful, Austin Health's Patient Representative is contacted. The trial PI is notified as soon as possible. The Chief Medical Officer is notified of the complaint and the proposed course of action. This may require a meeting between the complainant, the PI, the HREC Chairperson, an Institution Representative and the REU Manager. If so, this meeting will be held as soon as possible. All through this process the complainant is kept up to date with regular follow-up of the issue until the complaint is resolved or appropriately dealt with.
- **Advising institution(s) or organisation(s) of decisions to withdraw ethical approval of a research project** – should ethical approval of a project be withdrawn, the PI will be immediately notified. The PI will be requested to immediately notify all other institutions participating in the research of this decision.
- **Attendance, as observers, of people other than members or researchers** – As a general rule, apart from HREC members from other health institutions, observers are not permitted at HREC meetings. Observers are invited to attend DTSC or NDSRC meetings (e.g. new researchers, trial coordinators). Requests to attend meetings should be directed to the REU. Observers are required to sign a confidentiality agreement.
- **Fees, if any, to be charged** – As the running of the HREC and its sub-committees and the REU are self-funded, all new protocol submissions and some protocol amendment submissions attract a fee. This fee is posted on the Austin Health Research Ethics website and in the HREC Review Fee Policy.
- **Confidentiality of the content of protocols and of committee proceedings** – HREC meetings are held *in camera*. All Agenda papers are shredded post meeting. All committee members are required to sign confidentiality agreements upon appointment. HREC and sub-committee electronic recordings are destroyed after minutes are confirmed. Observers attending DTSC or NDSRC meetings are required to sign confidentiality agreements.