

## **1. REVIEW OF NEW RESEARCH PROPOSALS**

Under the Single Ethical and Scientific Review model for multi-centre research, any research, whether it is carried out at a single-site or at several, needs to be scientifically and ethically reviewed once only.

As a Lead Human Research Ethics Committees (HREC), Sydney Local Health District HREC is therefore accredited to review the following:

**SINGLE SITE RESEARCH:** proposals for research involving humans which will be carried out at Concord Hospital only.

**MULTI-CENTRE RESEARCH:** research to be performed at sites under the jurisdiction of more than one local HREC.

**For organisations outside the NSW Public Health System which seek access to the services of the SLHD HREC, an External Entity Agreement (Memorandum of Understanding) will need to be drawn up. Please contact the Research Officer for more information.**

**SITE SPECIFIC APPROVAL:** Although a Lead HREC can provide overall approval for a particular project, each individual public-health site must submit a Site Specific Application (SSA) in order for a Research Governance assessment to be carried out.

**Research cannot commence at a site until the SSA is approved.**

**ACCESS REQUEST REVIEW:** if a research project only requires access to participants, their tissue or their data but does not involve the conduct of research at a public-health site then an SSA may not be required and an Access Request Review may be submitted instead – please check with the Research Governance Officer. Access Request Review should be used for:

- Recruitment through posters, leaflets, handouts and letters of invitation (but not direct enrolment)
- Distribution of surveys and questionnaires
- Access to data or tissue held at a public-health organisation.

**LOW AND NEGLIGIBLE RISK RESEARCH (LNR):** An expedited review process is available for research where the only foreseeable risks are discomfort or inconvenience. Further advice on what constitutes Low and Negligible Risk Research is available on the Online Forms website (see below) but please note that the following are not eligible for LNR review:

- Interventions and therapies including clinical and non-clinical trials and innovations or new treatment modalities
- Active concealment or planned deception of participants

- Exposure of illegal activities
- Research specifically targeting Aboriginal or Torres Strait Islander people

Research involving the following are only eligible for LNR review where the research involves the collection of non-identifiable data and carries only a negligible risk:

- Human genetics
- Human stem cells
- Women who are pregnant and the human foetus
- People who are highly dependent on medical care who may be unable to give consent
- People with cognitive impairment
- People with an intellectual disability or a mental illness
- People who may be involved in illegal activities

**SCIENTIFIC REVIEW:** Research proposals involving a clinical drug or device trial or which would otherwise benefit from a scientific oversight are reviewed by the Scientific Sub-committee prior to ethical review by the HREC.

## **2. SUBMITTING A PROPOSAL**

The following application forms are available at the “Online Forms” website at: [www.ethicsform.org/au](http://www.ethicsform.org/au)

First time users of the site must create an account before proceeding.

- National Ethics Application Form (NEAF) for both multi-centre and single-site research\*
- Low and Negligible Risk Research\*
- Site Specific Applications (NEAF and LNR)
- Access Request Review

\*There is no need to complete both a NEAF and an LNR.

**PLEASE NOTE THE FOLLOWING WITH REGARD TO NEAF SUBMISSIONS:**

### **SECTION 1.2 – Description of the project in plain language**

Please keep in mind that this description will be used by lay members of the Ethics Committee to get an overall picture of the project. More technical information regarding the study can be given in Section 5 or in the Research Protocol.

## ELECTRONIC SUBMISSION

When the NEAF or LNR has been completed you need to submit it using the “Submission Tab”. This will generate a “submission code” and also remove the “draft” watermark. The form can then be printed out and signatures obtained before submitting the “hard copy” to the Research Office.

### **3. DOCUMENTS TO BE SUBMITTED**

For both single and multi-site research the following documents are required.

- NEAF/LNR – one hard copy with submission code and signatures.
- Study Protocol – 1 copy
- Participant Information Sheet – 1 original. (See 7 below) (A pro-forma is available under FORMS.) For multi-site research this should be a Master Version from which all sites can prepare their own local version. It should contain a version number and date.
- Participant Consent Form – 1 original. (See 8 below)
- Separate Participant Information Sheets and Consent Forms for genetic sub-studies. (See 12 below)
- Site Specific Assessment (SSA) Form – one hard copy with submission code and signatures. Only the SSA for Concord Hospital needs to be submitted to this office and can be done at any point during the ethics approval process.

#### **Additional documentation for clinical drug or device trials:**

- Study protocol – 9 copies
- Investigators brochures/product information – 4 copies
- Therapeutic Goods Administration form (CTN or CTX) – 1 original
- Medicines Australia Standard Form of Indemnity for Clinical Trials (commercially sponsored trials only) – 3 originals\*
- Medicines Australia Standard Clinical Trial Agreement (commercially sponsored trials only) – 2 or more originals\*\*
- Insurance Certificate (commercially sponsored trials only) – 1 copy

#### **\*Form of Indemnity**

Three originals (standard *Medicines Australia* form – January 2004. The indemnity documents must name Sydney Local Health District ABN 17 520 269 052) as the indemnified party.

#### **\*\*Insurance**

The sponsor should provide evidence that it has appropriate and sufficient insurance to meet its responsibilities under the Medicines Australia Standard Indemnity. Sufficient evidence is a current certificate of insurance which covers the conduct of the relevant clinical trial in Australia and contains insurance cover for a minimum amount of AUD \$20 million for any one occurrence and in the annual aggregate. The Insurance Policy must not contain an excess/deductible greater than AUD \$25,000 per claim.

**ALL SUBMITTED FORMS SHOULD BE SINGLE-SIDED AND UNSTAPLED.**

**4. FEES RELATING TO CLINICAL TRIALS (Commercially Sponsored Trials Only)**

The Principal Investigator is responsible for negotiating with the sponsoring company (or collaborative group) in requesting payment of all applicable fees.

**ETHICS COMMITTEE FILING FEES**

Application for clinical trial with full industry sponsorship	\$3,300 (inc GST)
Application for clinical trial with sponsorship from collaborative groups	\$150 (inc GST)
Amendments to trials with full industry sponsorship*	\$500 (inc GST)
Addition of sub-studies to trials with full industry sponsorship^	\$1,665 (inc GST)

\*Amendments include any changes to the protocol excluding minor administrative changes.

^Sub-studies will be reviewed and the fee determined on a case by case basis. The Human Research Ethics Committee may request that the sub-study be submitted as a new application and the full fee be charged.

**SITE SPECIFIC ASSESSMENT FEES**

Fees for governance review of commercially sponsored research by public health organisations:

For research projects with full industry sponsorship	\$3,740 (inc GST)
For research projects with sponsorship from collaborative groups	Nil
For amendments and additions of sub-studies	Nil

**PHARMACY FEES**

The CRGH Pharmacy Department levies fees for the conduct of clinical trials in line with the “Schedule of Fees for Clinical Drug Trials NSW Teaching Hospitals Pharmacy Departments.

PLEASE SEE “PHARMACY FEES FOR CLINICAL DRUGS TRIALS” on the Concord Research Office website or contact the Clinical Trials Pharmacist on (02) 9767 7035.

**CLINICAL TRIALS SERVICE FEE (CTSF)**

All clinical trials that are fully sponsored by an industry sponsor will be subject to a clinical trials service fee of 7.5% (plus GST) of the total funding.

This fee will be levied on the amount of funding after payment of the Ethics Filing Fee (and pharmacy fee if paid separately). If the pharmacy fees are not separated but included in the total trial budget the service fee will apply to the total budget.

The CTSF will be administered by the Concord Hospital Finance Department and will be automatically deducted from each payment made by the sponsoring company to the investigator's nominated cost centre for that particular trial. If exemption from payment is granted (e.g. in the case of a partially funded trial) this transfer will be reversed.

For more information (including requests for a waiver or reduction) please contact the Research Office on (02) 9767 5622.

## **5. SUBMISSION DATES**

Cut-off dates for the submission of research proposals to the HREC can be found on the Concord Research Office website: <http://www.slhd.nsw.gov.au/concord/ethics/>

## **6. GUIDE TO WRITING A RESEARCH PROTOCOL**

If submitting a NEAF application, a Research Protocol is mandatory. Guidance on writing a Research Protocol is available on the Concord Research Office website at: <http://www.slhd.nsw.gov.au/concord/ethics/>

## **7. PARTICIPANT INFORMATION SHEET (PIS)**

A template for a Participant Information Sheet is available on the Concord Research Office website at: <http://www.slhd.nsw.gov.au/concord/ethics/>

- All participants in research studies are required to give their informed consent. The Participant Information Sheet (PIS) is a vital part of the process of giving potential participants sufficient information to enable them to make a decision on whether or not to take part in the research.
- When compiling a PIS, please bear in mind The National Statement on Ethical Conduct in Human Research (Section 3.3.13) advice that: "Written information should not be unduly long or complex."
- Avoid technical terms where possible or explain them in lay terms.
- A good rule of thumb is that the information should be readily understood by a 13 year old or Grade 8 student).
- Australian spelling and terminology should be used throughout.
- In line with the National Statement please refer to research "participants" rather than "subjects".
- Write in a conversational style as if you were verbally explaining the study to someone.
- Use reader-friendly formatting.
- Use short words and short sentences.
- Use flow charts or diagrams where possible
- Avoid repeating information.
- Use at least a size 12 font.
- If you are submitting a multi-site application, you should make your PIS a Master Version. All participating sites can then use this to produce local versions.

- Number each page (i.e. 1 of 3, 2 of 3 etc) and include a version number and date (i.e. Version 1 dated 15/07/XXXX)
- Local versions should use the institution's headed notepaper.

## **8. CONSENT FORM**

A template for a Consent Form is available on the Concord Research Office website at: <http://www.slhd.nsw.gov.au/concord/ethics/>

The above advice relating to the clarity of the PIS (plus page numbering, dating and including a version number) also applies to the Consent Form.

## **9. PARTICIPANTS WHO ARE UNABLE TO PROVIDE CONSENT**

A person who is over the age of 16 and who is unable to provide informed consent, cannot participate in a clinical trial\* unless the trial has been approved by the NSW Guardianship Tribunal. In reviewing such a trial, the Guardianship Tribunal will decide whether consent can be granted by the person responsible or should be granted by the Tribunal itself. This approval is additional to the review of the clinical trial by the HREC.

\*The definition of a clinical trial under the Guardianship Act 1987 (NSW) is narrower than the usual definition. Under the Act, a clinical trial is defined as a trial of drugs or techniques that necessarily involves the carrying out of medical or dental treatment.

## **10. CLINICAL TRIALS OF DRUGS OR DEVICES**

**CLINICAL TRIALS NOTIFICATION (CTN) SCHEME:** A trial of any medicine or device (or its software) not entered on the Australian Register of Therapeutic Goods (ARTG) including any new formulation of an existing product or any new route of administration must be conducted under the CTN Scheme.

**An application under the CTN Scheme must include the following:**

- a) “Notification of Intent to Supply Unapproved Therapeutic Goods Under the Clinical Trials Notification (CTN) Scheme” – TGA Application Form, Version May 2011
- b) The phase of the trial ie. Phase I, II, III or IV
- c) An Investigator’s Brochure or product information.

## **11. RESEARCH PROTOCOLS INVOLVING IONISING RADIATION**

Research protocols should follow the guidelines set out by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) in its “Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes 2005” – Radiation Protection Series No. 8 (<http://www.arpansa.gov.au/Publications/codes/rps8.cfm>)

Section 2.1 of the Code outlines the responsibilities of researchers.

The **CRGH Radiation Safety Officer** should be consulted about the protocol during its preparatory stages in order to ensure that the appropriate radiation safety clearances are obtained.

All procedures involving ionising radiation should be listed in the protocol. The effective dose from radiation exposure for each procedure must be stated along with the basis for this estimate.

## **12. PROPOSALS FOR GENETIC RESEARCH**

A checklist for proposals involving genetic sampling can be found under FORMS on the Concord Research Office website - <http://www.slhd.nsw.gov.au/concord/ethics/>

## **13. APPROVAL**

When the HREC is satisfied with the ethical aspects of a research proposal it will issue a written approval to the Chief Investigator or Co-ordinating Investigator.

## **14. ANNUAL REPORTS**

Ethics approval is for a period of five years subject to the receipt of satisfactory annual reports. The Research Office will send a reminder.

If the study continues beyond five years then a resubmission request will need to be made and you may need to submit a fresh NEAF.

## **15. RESPONSIBILITIES OF INVESTIGATORS**

The HREC requires, as a condition of approval, that Investigators immediately report anything which might warrant a review of the ethical approval of a study. For example:

- Proposed changes in the research protocol or conduct;
- Unforeseen events that might affect the continued ethical acceptability of the project;
- Serious or unexpected adverse events;
- The study is abandoned for any reason.

## **16. AMENDMENTS**

Any proposed amendment to the study protocol must be notified to the HREC prior to the change being implemented.

## 17. ADVERSE EVENTS IN CLINICAL TRIALS

**SERIOUS ADVERSE EVENT (SAE):** An event (i) resulting in hospitalization (or prolongation of hospitalization); OR (ii) resulting in death or congenital abnormality; OR (iii) which is life threatening or medically important OR (iv) which results in a persistent disability.

**SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR):** a serious adverse event for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

IT IS A CONDITION OF THE HREC'S APPROVAL THAT THE PRINCIPAL INVESTIGATOR MEETS THE FOLLOWING REPORTING REQUIREMENTS FOR ADVERSE EVENTS:

For SAEs or SUSARs occurring at a site under the CRGH HREC's approval, the adverse event must be reported to the HREC within 72 hours. The report must be accompanied by a comment from the Principal Investigator on whether the event impacts on the continued ethical acceptability of the trial, or warrants changes to the protocol or informed consent documents.

[Such an event should be reported to the Sponsor of the trial within 24 hours for expedited reporting to the TGA. In the case of an investigator-initiated study, the investigator is responsible for reporting to the TGA].

The adverse event reporting form is available under "Forms & Proformae to Download":  
<http://www.slhd.nsw.gov.au/concord/Ethics/>

For SAEs or SUSARs occurring at sites other than those under the CRGH HREC's approval, the event should be reported within 72 hours only if it affects the ethical acceptability of the research and action is planned to change the protocol or informed consent documents.

Quarterly or 6 monthly summary SUSAR reports (Australian and international) should be submitted to the Lead HREC as they become available. These should be accompanied by a comment from the investigator as to whether action is planned for the trial on the basis of these reports.

Annual Safety Reports or updated Investigator Brochures should be submitted at least annually to the HREC (preferably with the annual project report).