

# **GUIDELINES FOR SUBMISSION**

**AT THE SYDNEY CHILDREN'S HOSPITALS  
NETWORK**

**Research and Development Office  
Kids Research Institute at The Children's Hospital at Westmead  
Level 2 of the Kerry Packer Building  
Cnr Hawkesbury Road and Hainsworth St  
WESTMEAD NSW 2145**

Mailing Address:  
Locked Bag 4001  
Westmead NSW 2145

**Phone: (02) 9845 3017  
Fax: (02) 9845 1317**

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## DEFINITIONS

<b>SCHN:</b>	The Sydney Children's Hospitals Network
<b>CHW:</b>	Royal Alexandra Hospital for Children, trading as The Children's Hospital at Westmead
<b>SCH:</b>	Sydney Children's Hospital (Randwick)
<b>HREC:</b>	Human Research Ethics Committee
<b>SAC:</b>	Scientific Advisory Committee, the scientific sub-committee of the CHW HREC
<b>NEAF:</b>	National Ethics Application Form, accessible in NSW through: <a href="http://www.ethicsform.org/au">www.ethicsform.org/au</a>
<b>LNR:</b>	Low & Negligible Risk application form, also accessible from the above website.
<b>SSA:</b>	Site Specific Assessment, allows NSW Area Health Services to determine whether the research study can commence at sites under their control. <b>This is an additional requirement to seeking ethics approval.</b> The form is created when completing your NEAF online through the above website. When referred to throughout document it includes Low and Negligible Risk SSAs and Access Request Forms.
<b>Lead HREC:</b>	A Human Research Ethics Committee accredited by NSW Health to conduct a single ethical and scientific review of multi-centre research projects. Lead Committees provide ethical approval that is valid for any site in NSW Health.
<b>NHMRC:</b>	National Health and Medical Research Council
<b>National Statement:</b>	<i>National Statement on Ethical Conduct in Research Involving Humans (2007)</i>
<b>PI:</b>	Principal Investigator of a research project at each site
<b>CI:</b>	Chief Investigator responsible for the co-ordination of multi-site projects at all sites

## PART 1: MULTI-CENTRE VERSUS SINGLE-SITE RESEARCH PROJECTS IN NSW

**1.1** The Single Ethical and Scientific Review system, which commenced in mid-2007, has the aim that every research project conducted within NSW Health will be scientifically and ethically reviewed once only, whether it is conducted at one site only or across many. Lead HRECs (such as the SCHN HREC) have been accredited to perform a single ethical and scientific review of multi-centre research on behalf of all sites within the NSW public health system at which a research project is to be conducted.

For more information about the Single Ethical Review system, see: [www.health.nsw.gov.au/ethics/research/governance.asp](http://www.health.nsw.gov.au/ethics/research/governance.asp)

**1.2** If your research project is multi-centred, i.e. will occur across multiple NSW Health jurisdictions (Local Health Networks), you need to ask yourself the following questions before proceeding with your application:

### **1. Have you already received ethics approval from another NSW Lead Ethics Committee?**

**YES:** You do not need to seek ethics approval from the SCHN HREC. You DO need to complete a Site Specific Assessment (SSA) Form. Continue to [Part 10](#) of these guidelines.

**NO:** Go to question 2.

### **2. Is your research being conducted ONLY at SCH and/or CHW sites?**

**YES:** Apply at the SCHN HREC for your ethics approval. (NB: you can also apply to other NSW Lead HRECs if their dates are more suitable and then submit an SSA to CHW.) Continue to [Part 2](#) of these guidelines.

**NO (i.e. your research will be conducted at other sites also):** You only need to seek ethics approval from ONE of the NSW Lead HRECs. This approval will cover you for all public health sites in NSW. The SCHN HREC are a Lead HREC for all types of research.

- 1.3** When the Single Ethical and Scientific Review system was introduced, a new process of Site Specific Assessment or Research Governance authorisation was introduced so that all of the sites involved in the research could sign off on the appropriateness of the proposed implementation of the research at their site. **Research Governance authorisation is an additional requirement to Research Ethics approval and must be obtained before research can commence at a site within NSW Health.**
- 1.4** If your project involves investigators or participants from outside the public health system it may be necessary to seek additional approval, for example:
- Investigators from other states will require ethics approval according to their own state / institution requirements
  - Investigators from universities also require approval from their university HREC – please note that universities will usually ratify the decision of a public hospital’s HREC and therefore it is best to seek approval through the NSW Health system first.
  - Projects involving participants from schools will require approval from the Department of Education / Catholic Education Office etc.
  - Investigators whose organization does not have access to a HREC can be granted approval by a NSW HREC after entering into an ‘External Entity agreement’. Fees may be applicable – see the NSW Health policy for further information.

## PART 2: RESEARCH APPROVALS AT SCHN

- 2.1 All research conducted within The Sydney Children's Hospitals Network must have Ethics Approval from either the SCHN Human Research Ethics Committee (SCHN HREC) or from one of the other Lead Committees in NSW.
- 2.2 To start a research project at either CHW or SCH you must also have received authorisation from the Chief Executive or their delegate. This authorisation is issued via the Site Specific Assessment (SSA) form. There are 3 different types of SSAs and these are described in [Part 10](#) below.
- 2.3 The SCHN HREC operates and subscribes to the ethical standards outlined in the *Declaration of Helsinki*, the Royal Australasian College of Physicians (Paediatrics and Child Health Division) *Paediatric Policy in regard to the Ethics of Research in Children* and the 2007 NHMRC *National Statement on Ethical Conduct in Human Research*:  
[www.nhmrc.gov.au/publications/synopses/e72syn.htm](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)
- 2.4 All "research conducted within the SCHN" includes any research (involving humans or human products such blood, tissue etc) conducted by SCHN staff within the Hospital or outside of the Hospital including but not limited to:

- As part of a staff's member's role within SCHN or in which CHW or SCH contact details will be used
- Research involving hospital patients, their friends and/or family
- Any research involving staff, volunteers or staff families (this includes staff surveys and questionnaires)

- 2.5 Project approvals within SCHN are currently separated into four categories. Each category has its own unique forms and approval process.

(a) **Quality Improvement Projects**

**At CHW:** Quality Improvement (QI) projects are submitted to and reviewed by the Service Improvement Unit (SIU). All QI projects are submitted and managed via [CHARLI](#), CHW's local database for research and improvement activities.

For more information about these projects or about CHARLI, contact the SIU and review the current CHW policy:  
<http://intranet.kids/o/documents/policies/policies/2007-8111.pdf>

*Please note: these projects are not considered research and do not go through a research governance authorisation step, however CHARLI does require department head sign-off in addition to QI ethics approval.*

**At SCH:** QI projects are submitted to and reviewed by the Clinical Practice Improvement Unit. A Quality Project Development Form is used. For more information about how to submit, contact the CPIU.

*Please note: these projects are not considered research and do not go through a research governance authorisation step.*

**(b) Clinical Case Report projects**

These projects require the in-depth study of one or a small number of patient records with the intent to publish the case details. Patient consent is to be obtained for the publication of their case and therefore can also be gained for the viewing of their records.

NSW Health has advised that this is not a type of project that requires HREC approval, but journals often require this. Therefore we have created a Clinical Case Report application form and consent form template which may be found on the Research Ethics internet site. Clinical Case Report applications can be submitted at any time and are usually reviewed out of session within 7-10 working days of receipt.

*Please note: these projects also do not go through a research governance authorisation step.*

**(c) Low & Negligible Risk Research Projects**

In late 2010 NSW Health launched a new process to deal with projects that are classified as 'low risk' or 'negligible risk'. They have produced a guidance document, which is based upon the National Statement, to explain what can be classified as these types of research: [www.health.nsw.gov.au/resources/ethics/research/pdf/nsw\\_lnr\\_guidance\\_version\\_1\\_0\\_2010.pdf](http://www.health.nsw.gov.au/resources/ethics/research/pdf/nsw_lnr_guidance_version_1_0_2010.pdf). **If you are unsure about whether your project meets this classification, please contact the Research Ethics Manager to discuss it.**

A full ethics (NEAF) application is **not** required for these projects. Instead, an 'LNR' application form should be completed. See [Part 3](#) for details about these online forms.

LNR research applications need to comply with the Single Ethical and Scientific Review process, i.e. if the project is multi-centred the application is to be reviewed once only by a Lead HREC. There is also an SSA for LNR projects, so they cannot be commenced until ethics approval and site authorisation are issued.

The LNR process replaces the previous Medical Record Review application processes. Therefore Medical Record / Chart Review applications must now be submitted using the LNR forms. In order to assist the Medical Records Department to retrieve your records, you will also need to fill out an additional form.

- At CHW: This is the [Record Information form](#) which can be found on the Research Ethics internet site. Please attach this form as an appendix to your LNR application form.
- At SCH: This is the Application for Access to Medical Records for Review. Contact the Medical Records Department on (02) 9382 7339 for more information. Please submit this form to the Operations Manager.

LNR applications are reviewed out of session at an HREC Executive meeting, which occurs weekly on a Friday afternoon. If approved, advice of approval should be received within approximately 10 working days. If there are any scientific issues, major ethical or privacy concerns raised during the review, the project will require the review of the Scientific Advisory Committee and the whole Ethics Committee at its next meeting. If the project is deemed to be of a higher level of risk, a full ethics (NEAF) application will be requested. **LNR applications may be submitted at any time.** For further information, see [Part 7](#): submission rules.

- (d) **All higher risk research projects** must be submitted to the HREC on a NEAF form (see [Part 3](#) for further details). These applications must comply with the Single Ethical and Scientific Review process, i.e. if the project is multi-centred the application is to be reviewed by a Lead HREC and there is to be an SSA submitted for each site.

Applications must be submitted by an advertised closing date and go to the full SAC and HREC meetings for review.

- 2.6 If you are planning to submit a research project you should attend the question and answer session on the advertised date (which is one week prior to the closing date).

## PART 3: ONLINE FORMS

- 3.1** All applications submitted to the SCHN HREC for Ethics approval must use the appropriate NSW form; either the National Ethics Application Form (NEAF) or Low and Negligible Risk (LNR) form. These are both online electronic forms that can be found on the 'Online Forms' website: [www.ethicsform.org/au](http://www.ethicsform.org/au)

Please note that although a different version of the NEAF form is also available on the NHMRC's website, the website detailed above must be used for projects submitted within NSW. Forms can be prepared using the NHMRC's NEAF website for multi-site Australia-wide projects and then exported as an 'XML' file to import into the NSW Online Forms format.

- 3.2** For first time users of the Online Forms website, you must create a user name and password before you can create an application.
- 3.3** It is recommended that the 'My Contacts' facility is used when entering investigator details into the NEAF / LNR form so that these can be re-used on the SSA form and in future applications.
- 3.4** Behind the 'Navigate' tab of the NEAF / LNR form there are a number of other tabs that allow you to do the following:
- On the Documents tab you can upload other documentation related to your application, such as parent / participant information sheets and consent forms.
  - The Submission tab is used to generate a 'submission code' when you are ready to finalise and print the form to then get investigator signatures and submit in hard copy as per [Part 7](#).
  - The SSA tab is used to generate the required SSA forms for submission to each site's Research Governance Manager. These forms work in a similar manner.
- 3.5** For any technical difficulties you are experiencing with your application, you should contact the Helpdesk between the hours 10am to 4pm on (02) 9037 8404 or email [helpdesk@infonetica.net](mailto:helpdesk@infonetica.net); please ensure that you request a job number if the Helpdesk staff cannot resolve the issue immediately, in order that you can follow up the issue.
- 3.6** For assistance regarding the interpretation of questions within the form or on how to navigate through the form you may also contact the Research Ethics Manager on (02) 9845 3017 or email [righas10@chw.edu.au](mailto:righas10@chw.edu.au).

## PART 4: PREPARING AN ETHICS APPLICATION USING LNR

If, after the review of an LNR application, the HREC decide that the project is of a higher level of risk then investigators will be requested to submit a NEAF by an advertised closing date. If in doubt about the level of risk associated with your project, please contact the Research Ethics Manager to discuss your project before you commence with either form.

- 4.1 You must ensure you select the correct Ethics Committee as your lead ethics committee for review: The **Sydney Children's Hospitals Network Human Research Ethics Committee (EC00130)**.
- 4.2 At question 3.1, list the sites involved with the project and indicate 'Yes' if the HREC is being asked to provide approval for the site (Yes should be selected for all sites within the NSW Health system).
- 4.3 The response provided to Question 5.1 should be a plain language summary of the project and then Question 5.3 should be where details of the methodology and analysis are provided.
- 4.4 If consent is not to be obtained, a reason / justification must be provided at Question 6.1. The fact that a project is a medical record review project or that the information will be de-identified upon collection is not a reason for the HREC to grant a waiver of consent. Please consider the *National Statement* and the Privacy Legislation when answering this question.
- 4.5 Please note that if data is collected from a Public Health Organisation question 7.1 should be 'yes' for State/Territory departments/agencies. 7.1a should specify the source of data eg. hospital medical records.
- 4.6 If you will not be gaining consent and you will be using patient data from medical records or a hospital database then you will be asking the Hospital to disclose individually identifiable information to you, therefore you should answer 'Yes' to question 7.2 and address each of the sub-questions. **Please note** that Part a asks why gaining consent is **impracticable**, not why it is inconvenient and the answer(s) must be appropriate to the individual project.

If your project is a Medical Record / Chart Review project, please complete and submit the additional local form (specified in section 2.5c) required by the Medical Records Department to your LNR application.

- 4.7** Please provide 3 single sided copies with no staples in hard copy together with the original LNR form with original signatures.

## PART 5: PREPARING AN ETHICS APPLICATION USING NEAF

The ethical approval process is complex, and should not be rushed. This is appropriate in a children's hospital, where the human rights of the child subjects are of paramount concern. Investigators should inform themselves of submission deadlines and plan ahead, particularly for research projects to be undertaken within time constraints (for example, for a higher degree or as part of a time-limited appointment such as a clinical fellowship or medical student elective term). Urgent or late applications are rarely accepted, and then only if there is some clinical imperative. Researchers should familiarise themselves with the 2007 NHMRC *National Statement on Ethical Conduct in Human Research*. Copies are available at the research office or you may go online to [www.nhmrc.gov.au/publications/synopses/e72syn.htm](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)

- 5.1 You must ensure you select the correct Ethics Committee as your lead ethics committee for review. We are The **Sydney Children's Hospitals Network Human Research Ethics Committee (EC00130)**.
- 5.2 The 'HREC Application Reference Number' should be left blank as this will be allocated by the Research Office after receipt of your application.
- 5.3 Part 3 of the NEAF asks questions in relation to **Conflicts and/or Declarations of Interest**. Please ensure you disclose all potential interests a sponsor/researcher has in the outcome of the project or any affiliations the researchers may have with the sponsor (this is **not** limited to financial interest). You should refer to Chapter 5.4 of the National Statement. **NB: you should also refer to the hospital's policies on [Conflicts of Interest](#) and [Code of Conduct](#) to ensure you declare necessary interests with the hospital's Audit Office. This is an individual's responsibility.**
- 5.4 The NEAF form is very reliant on you marking the appropriate boxes correctly in **Part 5/Q1** and **Part 6/Q1**. If, for example, in Part 5/Q1 of the NEAF you do not tick certain boxes relevant for your study such as "genetic testing/research", or in Part 6/Q1 "research intended to target children" – Questions won't be further opened later on in the form and therefore the HREC will be missing vital information to review your application and may reject your application if this is so. Please take care to ensure all relevant boxes are marked.
- 5.5 The following information must be included in a separate attached protocol (or contained in the NEAF) in order for an appropriate scientific review to be undertaken by the Scientific Advisory Committee:

## SCIENTIFIC PROTOCOL

**Aim of Project:** Set out clearly why you are undertaking the research and what question(s) you are seeking to answer.

**Hypothesis to be tested:** Not all research is hypothesis-testing, but if yours is you should formally state your hypothesis here. Each aim and hypothesis should be numbered for later reference in the statistical analyses section.

**Simple Description:** Describe the project in a style which can be readily understood by an educated person who does not have specific training in the field. You should also describe how your project will improve clinical care.

**Background/Literature review:** This should not be exhaustive. However you do need to outline the nature of the problem which you are addressing, demonstrate that you are aware of current publications in the area, and explain how your project will help to extend, confirm or refute existing information and opinion.

**Methods:** What study design are you using? A cohort study, a case-control study, a randomised trial, a non-randomised trial, a cross-sectional study, an ecological study, a qualitative study, a case study, a pilot study? Is it prospective or retrospective?

**Subjects:** How is the study group defined? Who will be excluded and why? How many subjects do you plan to study? What will you do about non-compliers or those who become lost to follow-up or drop out for other reasons? If randomisation is required, how is it to be achieved?

**Controls:** How many? How are they defined? Are they "normal" controls or "other disease group" controls? If they are historical controls, what evidence do you have that they will provide valid control data? Will they be matched to the subjects?

**Power Analysis:** How have you chosen the number of patients to be studied? Can you demonstrate the likelihood that you will be able to answer the question you are asking with the proposed number of subjects and controls? What is the likelihood of a type I or a type II statistical error? Have you consulted a biostatistician?

**Intervention:** What intervention is planned? If it is a drug, who will supply it? If a placebo is to be used, where will you obtain it?

**Measuring Instruments:** How will you be making your measurements of subjects and controls? Have the measuring instruments (be they questionnaires, laboratory assays or other tools) been shown to measure the parameter you are interested in reliably? Are age-appropriate normal values available? If you are designing your own questionnaire, how do you propose to test it for validity? Is a pilot study proposed? If you are setting up new laboratory assays, in what stages of development are they? What is the sensitivity, specificity and reproducibility of the test?

**Analysis of Data/Statistics:** For quantitative analyses, outline the statistical test(s) that will be used and give details of the outcome (dependent) variables, the explanatory (independent) variables and any confounding variables and how they will be used in each analysis. Number each section to match each numbered aim or hypothesis. If data is being collected but not used in any analyses, state why they are being collected and how they will be used.

For qualitative analyses, give a full description of the data analysis process and all steps that will be taken to ensure the rigour of these processes.

**Interpretation and Application of Results:** How will statistically significant or non significant results be interpreted? What (if any) clinical consequences are likely to flow from your research?

Once you have outlined the above, it would be useful to include a flow diagram of your project.

**Questionnaires to be used:** It is only necessary to include these if you have invented your own questionnaire. The use of standard questionnaires which have been well validated can be indicated in the methods section with an appropriate reference.

**References:** Any articles in the biomedical literature to which you refer in your background or methods sections should be listed according to the reference format which you find most convenient. The title of the article should be included.

Currently the NEAF does not clearly include a section to detail the above information (your scientific protocol). Please attach a separate document detailing this information or see the below suggestions for locations in the NEAF in which you can include this data. **Please note that for clinical trials it is mandatory that a separate protocol document be submitted.** For investigator driven trials, you may use the template produced by the Australian Children’s Clinical Trials Centre. Contact the Centre Manager on (02) 9845 2358 for a copy or access through: [http://intranet.kids/ou/acct/resources/templates\\_and\\_guidelines/protocol\\_template\\_for\\_rct.doc](http://intranet.kids/ou/acct/resources/templates_and_guidelines/protocol_template_for_rct.doc)

Scientific data required	NEAF question in which to include this data
<ul style="list-style-type: none"> <li>▪ Simple description</li> </ul>	<ul style="list-style-type: none"> <li>▪ Section 1, q.2: “Description of the project in plain language”</li> </ul>
<ul style="list-style-type: none"> <li>▪ Background/Literature review</li> </ul>	<ul style="list-style-type: none"> <li>▪ Section 5, q.2: “Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal”</li> </ul>
<ul style="list-style-type: none"> <li>▪ Aim of project AND hypothesis to be tested</li> </ul>	<ul style="list-style-type: none"> <li>▪ Section 5, q.3: “State the aims of the research and the research question and/or hypotheses”</li> </ul>
<ul style="list-style-type: none"> <li>▪ Subjects and controls - inclusion/exclusion criteria</li> </ul>	<ul style="list-style-type: none"> <li>▪ Section 6: “Participants”, q.1, 2, 3, 4 - Section 6: “Participants”, q.13 or 14</li> </ul>
<ul style="list-style-type: none"> <li>▪ Details of methods</li> <li>▪ Power analysis</li> <li>▪ Intervention</li> <li>▪ Measuring Instruments</li> <li>▪ Analysis of data/statistics</li> </ul>	<ul style="list-style-type: none"> <li>▪ Section 8, q.2: “Describe how information collected about participants will be used in this project”</li> <li>▪ <b>OR</b> Section 9.2, q.3 “Provide a statement addressing the following as may be applicable to the project” <b>IF</b> you have selected “Clinical Research” in Section 5, q.1.</li> <li>▪ <b>OR</b> attach information as a separate document</li> </ul>

**5.6 Part 6 Q13, 14 & 15-** Ensure you provide a step by step guide to how you will identify participants as potential participants, (i.e.

how they will be recruited). The Ethics Committee reviews recruitment procedures in great detail. **It is important to note that telephone contact as the first point of contact with a potential participant will not be approved.**

**5.7 Part 8 “Confidentiality/Privacy”, questions 10 and 15, require information about data storage.**

According to the NSW Government State Records department’s General Retention and Disposal Authority 17, data storage periods for records relating to the conduct of research are as follows:

- Clinical research: Retain for a minimum of 15 years after date of publication or termination of the study, then destroy.
- Non-clinical research: Retain minimum of 5 years after date of publication or completion of the research or termination of the study, then destroy.

For other storage periods (for example, for projects which do not proceed or requests for record access) and for more detail, please access the appropriate Research Management section of the General Retention and Disposal Authority document through the following link:

[www.records.nsw.gov.au/recordkeeping/government-recordkeeping-manual/rules/general-retention-and-disposal-authorities/public-health-services-patient-client-records-gda/part-1-the-general-retention-and-disposal/8.0.0-research-management](http://www.records.nsw.gov.au/recordkeeping/government-recordkeeping-manual/rules/general-retention-and-disposal-authorities/public-health-services-patient-client-records-gda/part-1-the-general-retention-and-disposal/8.0.0-research-management)

**5.8 Part 5 “Project”, question 18 requires information about your DSMB.**

DSMB stands for Data Safety Monitoring Board. A DSMB is an independent committee whose function is to provide data and safety monitoring of a research study. According to the National Statement (Paragraph 3.3.20 C and D), a DSMB is required to be used for large multi-centre trials. For local trials, there must be an identified person/s or committee with suitable expertise to assist and advise the HREC about reports of serious adverse events.

## **PART 5b: PROJECTS INVOLVING IONIZING RADIATION (IR)**

SCHN research applications utilising a NEAF &/or SSA, must declare all applications of IR – both standard clinical care and research based investigations.

Radiation Safety intranet pages are available for related information at Intranet CHW:

[http://intranet.kids/ou/radiation\\_safety/](http://intranet.kids/ou/radiation_safety/)

Internet SCH:

[www.sesiahs.health.nsw.gov.au/research\\_support/NHN/Human\\_Research\\_Governance.asp](http://www.sesiahs.health.nsw.gov.au/research_support/NHN/Human_Research_Governance.asp)

Please contact the site Radiation Safety Officer (RSO) if you are unsure about the IR within your submission before the SAC closing dates. See Part 11 for contact details.

As a Guide:

Ionising Radiation is used in the following test and treatment regimens:

- CT, X-ray, DEXA scans, pQCT and fluoroscopic imaging (eg MBS – modified barium swallow).
- All Nuclear Medicine scans: Bone scans, PET, PET/CT and SPECT.
- Radiation Therapy – external beam and isotope doses (eg I-131 therapy).

There is NO IR used in the following:

- MRI imaging.
- Ultrasound or Doppler type imaging

Form Submission:

NEAF submissions: If you are recruiting from BOTH campuses, you must submit BOTH of the following forms.

SSA's for projects with other HREC approval: Each SCHN site must receive their relevant form prior to submission.

CHW – [Ionising Radiation Declaration Form](#) (resources menu). A guidance document is also available for completing the CHW IRD.

SCH – [Area Form F032 – Radiation Research Study Request Form](#) (resources menu). Guidance notes are attached. Submit to Prince of Wales Hospital RSO – see Part 11 for contact details.

Note: Please DO NOT make dose statements in these forms. The dose assessment performed by the relevant RSO will provide effective doses for use in the information sheets. An estimate can be given verbally or by email in order to cover the risk assessment statements in Annex 1, p13 of RPS8.

RPS8: MANDATORY COMPLIANCE Code of Practice in NSW.

ARPANSA (Australian Radiation Protection and Nuclear Safety Agency) 2005 Code of Practice: Exposure of Humans to Ionising Radiation for Research Purposes.

<http://www.arpansa.gov.au/pubs/rps/rps8.pdf> . (Also known as the Radiation Protection Series no8.)

RPS8 contains information on researcher responsibilities for studies involving ionising radiation.

Please note:

2.1.3 (p3). The researcher must provide the research participant with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant to give informed consent. (The dose & risk statement paragraphs are available directly from RPS8 in Annex 2, p16)

2.4 (p6). The Responsible Person as defined in the glossary of this Code is responsible for establishing systems that ensure the overall observance of this Code and its implementation. (The SCHN nominated Responsible Person is the SCHN (CHW) RSO.)

Parent & Child Information Sheets

Annex 2 (p16) of RPS8 contains paragraphs addressing study dose estimates and the associated risk for inclusion into study information sheets. Simply copy and paste into your information sheets under the risks section and insert the dose returned on the applicable IR application form. Where the parent sheets comply, the wording may be simplified and minimised for the child information sheets.

#### Risk Assessment Statements

Annex 1 (p13) of RPS8 determines the level of justification required within the NEAF once the effective dose has been determined.

How is the radiation information for my study reviewed?  
All NEAF submissions are sent to the Radiation Safety Officer to be reviewed on behalf of the Radiation Safety Committee (RSC), in parallel with the review by the Scientific Advisory Committee.

During the review, should IR be detected throughout the study & the appropriate check box on the NEAF has not been selected, the information will be requested as a part of ethical and scientific review and the submission will then have the possibility of approval being delayed.

If the above is not complied with your project submission will incur delays in being approved by the RSC & subsequently SAC & HREC.

(24<sup>th</sup> June 2011)

## **PART 6: INFORMATION SHEETS AND CONSENT FORMS**

**6.1** The SCHN HREC is primarily concerned with research involving children, and as such, the information sheets and consent forms are usually written addressing the parents/guardians of the child. These information sheets should address the parent directly. It may also be relevant to have a Participant Information Sheet and Consent Form requesting the child's consent.

**6.2** In NSW, a child is able to consent to medical treatment from the age of 14 if they have the requisite understanding, knowledge and comprehension. **However, in research, children cannot consent until the age of 18.** Therefore for research involving our patients, consent must be obtained from a parent or a guardian.

Despite the legal age of consent, the *National Statement* and the HREC require that where possible, minors and legally incompetent people be given the opportunity to decide whether or not they are willing to participate. In the case of children, where possible, the child must be free also to consent or assent on their own behalf. In general, children should also be free to withdraw their participation regardless of their parents'/guardians' continued consent, unless there is good evidence that the research will have a demonstrable beneficial effect on that child. Freedom to withdraw from a classroom situation may not be possible and parents and guardians must be advised of these situations.

**6.3** The templates for parents and children must be followed. These are available on the CHW Research Ethics internet and intranet sites or from the Ethics Administration Assistant.

**6.4 IMPORTANT - FOR MULTI-SITE PROJECTS:** If your project is undergoing single ethical review by the SCHN HREC for use at multiple sites, please submit master 'templates' of your information sheets and consent forms (i.e. with no letterhead or local investigator details) to the HREC. The HREC will review and provide approval for these 'templates', which you may then attach appropriate local details when used at each individual site.

Please note that you will generally need to submit the 'localised' version of the approved templates with each of your Site Specific Assessment forms. We will go through this in more detail at the training session held before each closing date.

**6.5** For ease of reading, the following advice is written concerning 'participants', however you should keep in mind that 'a participant' can be read as 'participating child' or 'the parent/guardian of a participating child'.

In preparing your information sheets and consent forms you should keep in mind that these perform two functions:

- The information sheets should provide sufficient and clear information for potential participants to be able to make an informed decision about whether to participate in the research and;
- The consent form should provide the researcher with clear evidence that the participant has consented to their participation to the research.

The researcher has a responsibility to ensure that parents and participants understand the nature, aims, risks or burdens and possible outcomes of the research before consent is obtained. Further, the researcher has the responsibility to check whether the participant or parent of participant has withdrawn consent or continues to consent throughout the study. Unless there are good reasons to the contrary, all research participants must give their consent in writing. Consent must be given freely with no coercion or inducement to participate.

The information provided to participants should be written in a language that is understandable to potential participants so that it will allow them to make reasonable, intelligent and informed decisions concerning participation in the research. Information intended for literate adults should be presented using lay terms and short sentences as far as possible, so that it can be understood at a reading age of 12. It is important to avoid using overly technical language.

Where children are to be included in this process of negotiating consent, information should be presented and elicited in a manner appropriate to their age and abilities, with their parents receiving more detailed or sophisticated information. (This is the case for most research projects considered by the Ethics Committee).

If you anticipate that a significant number of potential participants and their parents will not be able to make an informed decision based on information written in English, you should arrange for translation of the Information Sheet and Consent Form into the relevant language(s). A copy of the translations should be submitted with your application.

The following list has been developed to assist you in constructing an appropriate information sheet and consent form. You are reminded that the Committee reviews all information sheets in great detail to ensure that all the criteria are met. Information sheets which do not appear to follow these

guidelines or require major changes, will not be accepted and must be rewritten and resubmitted for approval before the project can commence.

## **6.6 PARTICIPANT AND PARENT INFORMATION SHEET - GUIDE TO WRITING**

Please read in conjunction with the Information Sheet Template.

- If single site, should be on Hospital letterhead and should include the title of the research project (simplified or short title, if necessary), name of the investigator(s), supervisor's name (for student research), direct contact numbers, and the department(s) involved. If the sheet is for a multi-site project: see item [6.4](#) above.
- A description of the purpose and nature of the study in clear, non-technical language (where technical language is used it must also be explained in lay terms).
- Procedures to be used, tasks required of the participants, the number of times the task/procedure will be repeated, the amount of time required, and the purposes of the procedures should be clearly explained in lay terms. If any blood is to be taken, explain how much blood and how often. If a questionnaire is to be supplemented with 'non-invasive' body measurements (weight, height, and skinfold tests) state this clearly. Indicate any procedures that are experimental.
- Any risks, inconveniences and discomforts that could be reasonably anticipated should be explained in lay terms.
- Any benefits expected should be clearly described in a way that does not raise unrealistic expectations on the part of potential participants or their communities.
- The 'Standard Release' statement and 'Further Information' statement must be included. The 'MRI/MRS', 'Blood Collection' and 'Reproductive Risks' statements should also be included, if relevant. All these statements are provided below.
- Explain how data will be collected and stored. You must also explain how long the data will be kept and when and how it will be destroyed. If possible, provide a maximum time limit for storage of data. If appropriate, include a statement that the participant's anonymity and/or confidentiality will be maintained. If confidentiality is to be preserved, explain how

that is to occur (eg. assigning numbers to participants rather than using names; changing names; reporting only grouped data). Also include here how the results of the project will be fed back to participants or the wider community.

**STATEMENTS REQUIRED TO BE INCLUDED IN ALL INFORMATION SHEETS**

Welcome

Paragraph: 'We would like you to consider/consider your child participating in a research study that will be conducted.....'

Other Information: 'If you have any concerns about the conduct of this study please do not hesitate to discuss them with (name of investigators and contact numbers) or with the Research Ethics Manager (9845 3017), Secretary of the Ethics Committee that has approved this project.'

Standard Release: 'Participation in this project is voluntary and if you decide not to take part or decide to withdraw at any time this will not otherwise affect your child's care at the Hospital.

This information sheet is for you to keep. We will also give you a copy of the signed consent form.'

**STANDARD RISK STATEMENTS - if applicable to your study**

Blood Collection

(by venipuncture): *NB: 5ml = approx 1 teaspoon:*

'We will need to collect x mls of blood (approximately y teaspoons) from a vein in the arm. This can be painful and bruising can occur.'

MRI/MRS:

'Magnetic Resonance Imaging (MRI)/Spectroscopy (MRS) produces microscopic images of ....., so that its structure/content can be analysed by computer. It involves your child lying quietly on a table that moves in and out of a tunnel shaped scanning device for 20/40 minutes while the body is scanned. The machine at our hospital is larger and roomier than the usual models but is still quite noisy. Your child may

bring a CD to listen to while the test is performed (the machine is equipped with a CD player). If your child feels claustrophobic or becomes distressed at any time, we will stop the test.

MRI /MRS does not involve ionizing radiation, but uses radio frequency waves and a magnetic field to create the images.

If your child is not excluded from the MRI/MRS procedure by the pre-examination questionnaire – it has been found that there are no known adverse health effects in using MRI/MRS.'

Reproductive Risks: 'Because the drugs in this study can affect an unborn baby, your child should not become pregnant or father a baby while on this study. Your child should also not breastfeed their baby while on this study. If you request, we can provide counselling and more information about preventing pregnancy.'

Genetic Testing: 'Since there are many changes in DNA that have no implications for disease, the true significance of a positive finding may take some time to establish and may simply represent normal genetic variation. Likewise, a negative finding does not exclude the possibility that there is a genetic contribution to your child's condition. If a true genetic alteration is found, we will inform you unless you choose not to be notified. If you choose to be informed, you will have the opportunity to discuss the significance of the finding for your child with a genetic counsellor or a clinical geneticist.

We will attempt to maintain confidentiality at all times and information about future genetic analyses will not be available to other participants or others outside the study. Any information obtained from research involving the use of your child's DNA sample will be used solely for scientific purposes. Information about your participation in this study may

influence insurance and/or employers regarding your health status. Any results which may impact on your ongoing health will not be released to these institutions without your request to do so and prior written approval. Although every effort will be made to keep your participation confidential, we cannot guarantee absolute confidentiality.'

Compensation  
Paragraph for  
Clinical Drug/Surgical  
and/or Device Trials:

**'What happens if I suffer an injury or complications as a result of the study?**

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

*[if applicable]* The parties to this study agree to follow the Medicines Australia *Guidelines for Compensation for Injury Resulting From Participation in an Industry-Sponsored Clinical Trial*. These Guidelines allow for some claims for

compensation to be settled without the need for legal action to be taken. You can obtain a copy of these Guidelines from the Secretary of the Human Research Ethics Committee.'

- 6.7** Useful wording for information sheets for drug trials, genetic testing and DNA banks is also available in the NSW Health guidelines on Standardised Patient Information Sheets. Contact the Research Office for a copy or follow the link below: [www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007\\_016.pdf](http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_016.pdf)
- 6.8** If you use the templates provided, formulating your information sheets should be relatively simple and they should be returned to you with few changes.

## **PART 7: SUBMISSION RULES FOR ETHICS**

- 7.1 SIGN OFF:** Consultation and sign off by other departments is required if individuals outside the study team are needed to facilitate the study or provide access to patients, resources or data. This includes consulting with other clinicians outside the study team who are involved in the care of the participants- for example the Nursing team and Pharmacy if the study involves a variation to routine medical care; Pathology, Medical Imaging and/or Nuclear Medicine if there are testing implications; or the other Allied Health / Diagnostic Departments if access to discipline specific clinical test results/data sets is sought.

Please ensure that your NEAF or LNR form and your SSA form detail all departments that may be affected or involved in your research. Please ensure sign off from all relevant and supporting departments appears in both the NEAF, LNR and SSA forms. **All signatures should be obtained at the time of submission – one of the copies you submit should contain original signatures.** Your application will not be accepted if there are signatures missing and prior arrangements have not been made with the Research Ethics Manager or Ethics Administration Assistant.

**NB:** The NEAF / LNR form and SSA undergo two different review processes and therefore original signatures must be contained on the NEAF / LNR form and SSA.

- 7.2 PRIOR TO PRINTING YOUR NEAF OR LNR FORM AND YOUR SITE SPECIFIC ASSESSMENT FORM, MAKE SURE YOUR FORMS ARE “SUBMITTED”. ONCE PRINTED, A SUBMISSION CODE WILL APPEAR IN THE BOTTOM RIGHT-HAND CORNER. FORMS WHICH HAVE NOT BEEN SUBMITTED WILL PRINT WITH A ‘DRAFT’ WATERMARK AND WILL NOT BE ACCEPTED.**

Submitting is done in the Online form by selecting the **Submission Tab** then selecting the “**Generate Submission Code**” button.

- 7.3** You must submit **3 paper copies (4 for Drug trials)** of your **NEAF** applications with annexes by 5pm on the day of the advertised deadline. **You must ensure the copies are collated correctly. The Research Office will not accept your submission if they are collated incorrectly or not collated at all. This rule also applies for the LNR application form.**

Each copy should be collated as follows:

- **NEAF/LNR**
- **DECLARATIONS**
- **INFORMATION SHEETS**
- **CONSENT FORMS**

- **STUDY PROTOCOL** (mandatory for clinical trials)
- **ANY OTHER ANNEXES** i.e. IB Brochures, Questionnaires, advertising material etc.

For projects with a Study Protocol, please submit **2 additional copies of the protocol** to facilitate the SAC review.

2 boxes will be placed at the Research Office reception from the Monday before the closing date for submissions; 1 for the Ethics submission and one for the SSA.

LNR forms can be submitted at **any time**. Please note that if you want your application to be reviewed quickly, HREC Executive meetings are held weekly on a Friday, therefore, you should submit your application by midday on a Thursday.

**7.4** All copies must be single sided and not stapled – a bulldog clip or similar should be used to secure the paperwork (**exceptions: the original and ANY OTHER LARGE ANNEXES may be double sided, i.e. protocols, IB Brochures, Standardised Questionnaires**)

**7.5** Information Sheets, consent forms, advertisements and flyers should also be emailed to the Ethics Administration Assistant ([margard4@chw.edu.au](mailto:margard4@chw.edu.au)) for electronic review. Alternatively, electronic copies may be uploaded through the [Online Forms](#) website.

**7.6** 2011 information/Q &A sessions and closing dates:

If possible you should attend the information session prior to submitting your application. Information/Q&A sessions are held in the *Large Conference Room* in the Research Building.

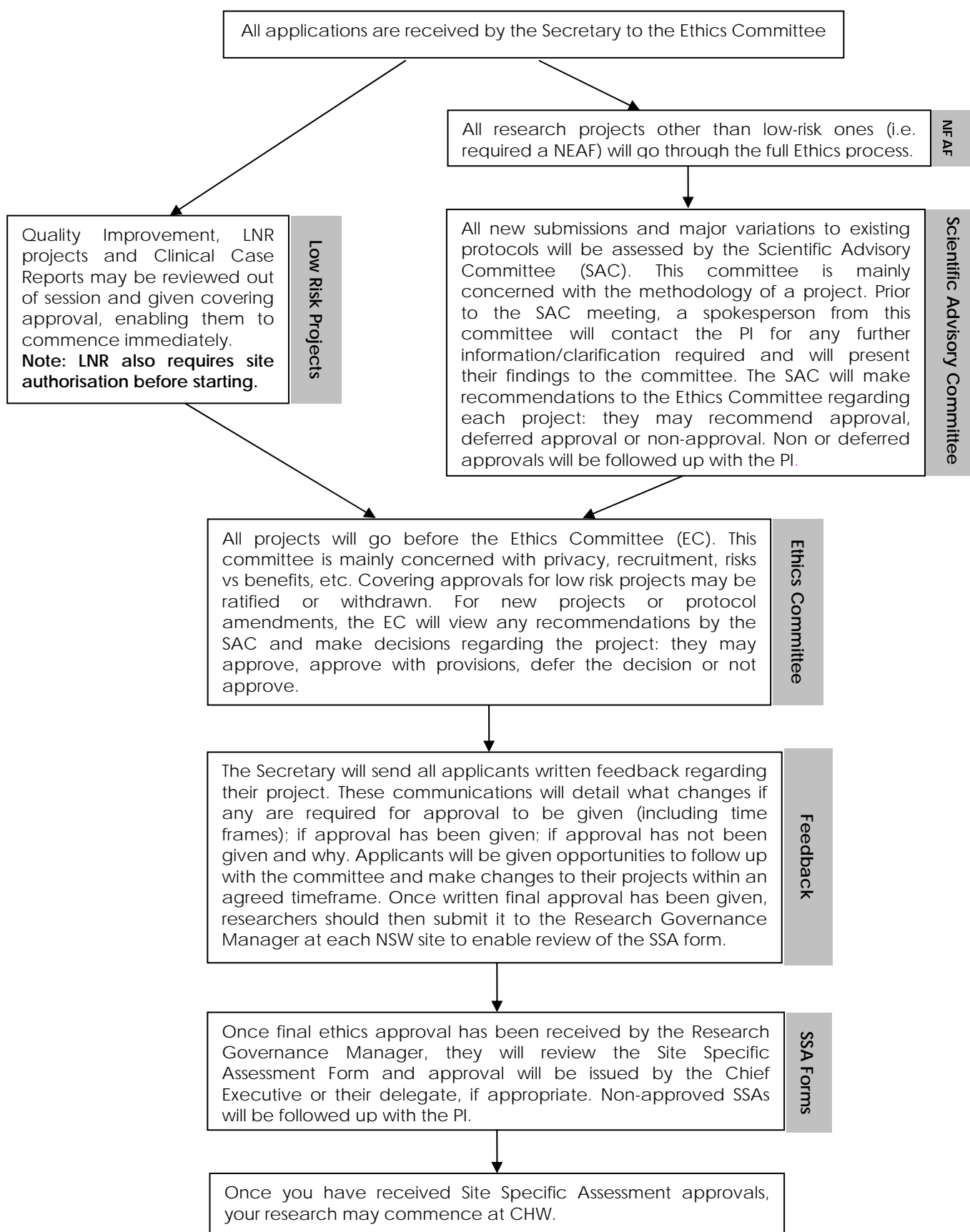
Q & A SESSION FOR APPLICANTS Wed 1- 2pm	CLOSING DATE Wed 5pm
12 January	19 January
23 February	2 March
6 April	13 April
18 May	25 May

29 June	6 July
10 August	17 August
21 September	28 September
2 November	9 November

**7.7 FEES** apply to the review of some ethics applications; this will be invoiced upon receipt of your ethics application. Please see the policy for further details (email the Ethics Administration Assistant for a copy if required): <http://intranet.kids/o/documents/policies/policies/2006-8242.pdf>

<b>Sponsor/Financial Support</b>	<b>Fee (GST included)</b>
Full Industry Sponsorship	\$3300.00
Investigator Driven or Collaborative Groups Sponsorship with partial industry funding	\$3300.00
Collaborative Groups Sponsorship or grant funded	\$150
Investigator initiated with no external funding source, Student	No charge

## PART 8: APPROVAL PROCESS



## PART 9: POST ETHICS APPROVAL

After your project has received final ethics **and** site specific approval you may commence your research. There are some ongoing, post-approval obligations and information you need to be aware of:

- **Study Start Date:** Upon commencing your research, please advise the Ethics Committee (and every NSW site) of your actual start date so that we may update the NSW Health ethics database.
- **Clinical Trials Registration:** All clinical trials (not just drug trials) should be registered on the Australian Clinical Trials Registry or another internationally recognised registry. For further information please go to [www.actr.org.au](http://www.actr.org.au). Please provide the Research Office with a copy of your registration number for our records.

**Amendments:** Any proposed amendments to your project (for example a change in protocol, of investigators, of recruitment methods) must be submitted to the HREC which provided your original ethics approval. The amendment must receive both Ethics and Governance approval before implementation. If the CHW HREC provided your ethics approval, please submit the details of your amendment on the CHW HREC's Amendment Form, which can be found on the CHW internet at: [www.chw.edu.au/research/ethics/human\\_ethics/](http://www.chw.edu.au/research/ethics/human_ethics/) Any updated documents (for example, information sheets) should be

- e attached and submitted with the amendment form.

**NB:** For all sponsored trials, please refer to the HREC fees policy to determine if fees will be charged for the processing of your amendments. Request a copy from the Ethics Administration Assistant or access through: <http://intranet.kids/o/documents/policies/policies/2006-8242.pdf>

- **Adverse Events:** You need to advise the Ethics Committee about adverse events related to your research. The timing for notification depends upon the site at which the incident occurred and the severity of the event. For details of adverse event reporting, including a flow chart and reporting forms, please refer to the Adverse Event Reporting in Clinical Trials policy, available from the Ethics Administration Assistant or access through: <http://intranet.kids/o/documents/policies/policies/2008-8063.pdf>

For all other types of research, a letter to the Ethics Committee will suffice.

- **Published Items/Media:** Please advise/submit to the Ethics Committee any articles, publications or interviews resulting from or with any reference to your research project. If articles/interviews/publications involve recruitment in any format, you need ethics approval **prior** to publication.
- **Annual Report:** every 12 months following approval for your project you need to submit an annual report to the Ethics Committee for your approval to remain valid. The template is available on the internet: [www.chw.edu.au/research/ethics/human\\_ethics/](http://www.chw.edu.au/research/ethics/human_ethics/) or intranet:

[http://intranet.kids/ou/ethics/resources/human\\_ethics/annual\\_report\\_-\\_final\\_update\\_form.pdf](http://intranet.kids/ou/ethics/resources/human_ethics/annual_report_-_final_update_form.pdf)

- **5 year resubmission:** Ethics approval expires after 5 years. If your project is still active after 5 years, you will need to submit a new ethics application for review. This application will need to use the current process and forms.
- **Final Report:** At the completion of your project, please submit a final report (same template as the Annual Report) along with copies of any publications resulting from your research.
- **(CHW ONLY) CHARLI** (Children's Hospital Achievements, Research, Links and Improvements) Database: Since May 2009, all approved research projects are being added into CHARLI so that the database may accurately reflect all research activity at the Hospital. You will receive an email alert from CHARLI when your project has been entered, and you may wish to use CHARLI to manage your project. At this stage there are no research ethics or governance requirements for you to use CHARLI.

## PART 10

### SITE SPECIFIC ASSESSMENT/RESEARCH GOVERNANCE

“Research projects to be conducted at sites under the control of NSW Public Health Organisations, whether they have undergone full or expedited HREC review, must undergo site specific assessment before authorisation can be granted by the Chief Executive or their delegate.”

[NSW Health Policy Directive Research - Authorisation to Commence Human Research in NSW Public Health Organisations](#) at 3.2

#### 10.1 SITE SPECIFIC ASSESSMENT

All site specific assessments (SSAs) relating to The Children’s Hospital at Westmead as a site and Sydney Children’s Hospital as a site are submitted to the research governance managers based at Westmead.

**CHW and SCH are considered separate sites for the purpose of site specific assessments.**

To complete an SSA you must have first completed:

- A National Ethics Application Form (NEAF); or
- An Application Form for Ethical and Scientific Review of Low and Negligible Risk Research (LNR Application Form)

Access to forms at: <https://www.ethicsform.org/au/SignIn.aspx>

#### 10.2 TYPES OF SSA FORM

There are 3 types of SSA form:

- (i) Site Specific Assessment (SSA)
  - Required if you have completed a NEAF and you will be conducting your project at CHW or SCH.
- (ii) Site Specific Assessment Form for Low and Negligible Risk Research (LNR SSA)
  - Required if you have completed an LNR Application Form and you will be conducting your project at CHW or SCH.
- (iii) Access Request Form
  - Required if you have completed a NEAF or LNR Application Form and only wish to access records, samples or advertise your project at CHW or SCH.
  - Please contact the research governance manager prior to completing an Access Request Form to make sure it is the most appropriate form.

### 10.3 COMPLETING THE SSA FORM

(i) Before you start

Check you have listed on the NEAF or LNR Application Form:

- All the investigators involved at your site – CHW or SCH; and
- The site - CHW or SCH.

(ii) Human Research Ethics Committee (HREC)

- Select the HREC which reviewed your project.
- Sydney Children's Hospitals Network (SCHN) HREC is currently coded as: The Royal Alexandra Hospital for Children Human Research Ethics Committee (EC00130)

(iii) Investigators/project personnel

- For each SSA list only investigators who will be involved at the particular site.
- Students who are involved on site or have access to identified data must be listed. See (viii) below regarding insurance for students.
- Non- investigators with patient contact must be listed on the SSA under either question 7 or 9 on the form. For example project nurses should be listed here.
- CVs must be provided for all investigators listed on an SSA form. The research governance office keeps CVs on file. Please check with the research governance office before you provide CVs.

(iv) Departments

- List all departments involved in your project, including the department of each investigator.
- For each department listed you must have sign-off by the department head.
- If a department head is also an investigator, their superior must sign off on behalf of their department.
- Consider supporting departments which may be required for your project e.g. pathology, radiology, pharmacy. The department head of each supporting department must also provide sign-off.

(v) Radiation sign-off

- Projects using ionising radiation that is standard care should provide a statement to that effect from the department head.
- If use of ionising radiation is not standard care, obtain approval from the local radiation safety officer:
  - CHW Radiation Safety Officer  
Yvette Wilson [YvetteW@chw.edu.au](mailto:YvetteW@chw.edu.au) (02) 9845 0998
  - SCH Radiation Safety Officer  
Brent Rogers  
[Brent.Rogers@sesiahs.health.nsw.gov.au](mailto:Brent.Rogers@sesiahs.health.nsw.gov.au)  
(02) 9382 8067

(vi) Budget

- Provide details of the funding provided and who may pay for tests, drugs etc. required for the project.

(vii) Contracts

- Attach to your SSA form any contracts or agreements associated with your project such as an agreement for payment of support or supply of the study drug.

(viii) Insurance

- All non-CHW/SCH employees such as students who will be on site for the project or have participant contact must provide evidence of insurance from their employer/university. This should be attached to the SSA form.
- Honorary positions relate only to medical staff.
- For further information [NSW Health Policy Directive: Clinical Trials - Insurance and Indemnity](#).

(ix) Documents e.g. participant information and consent forms

For multi-centre projects, please provide:

- i. The versions approved by the ethics committee; and
- ii. The versions you have adapted for the site – CHW or SCH – with the appropriate logo and investigator contact information.

For single site projects, please provide the versions approved by the ethics committee.

## 10.4 DRUG TRIALS

- (i) Two (2) copies of the SSA form are required for drug trials.
- (ii) Attach a copy of the investigator brochure and protocol.
- (iii) Where applicable, all contracts and indemnities must be signed by the sponsor prior to execution by the investigator and Chief Executive (or their delegate).

### Indemnity and Clinical Trial Agreements

The legal name and ABN for use in Indemnity and Clinical Trial Agreements:

**The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating the Royal Alexandra Hospital for Children)" - *address according to site***

ABN: 53 188 579 090

Signatory on behalf of the organisation:

Elizabeth Koff, Chief Executive

### Certificate of Currency

- o This must be in Australian dollars at \$20 million per occurrence.
- o The excess must be less than \$25 000 AUD.
- o The clinical trial must be listed on certificate and must be current.

### Clinical Trial Research Agreement (CTRA)

- o This must be the Medicines Australia Standard Agreement:  
<http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/>
- o For further information [NSW Health Policy Directive: Clinical Trial Research Agreement for Public Health Organisations \(Commercial Entities\)](#)

### Clinical Trial Notification (CTN)

- o This form must be completed to the extent possible.

## 10.5 SUBMITTING THE SSA FORM

**Ensure that you have attached all necessary documentation and have appropriate sign-off prior to submitting your form.**

- (i) If you are seeking ethics approval from SCHN HREC:
  - Submit your SSA form at the time you lodge your ethics application (i.e. by 5pm on the day of the advertised closing date).
  
- (ii) If you have received ethics approval from another lead ethics committee (i.e. not from SCHN):
  - You can submit your SSA form to the research governance manager at any time – you do not have to wait for an ethics closing date or receipt of ethics approval.
  - Provide a copy of your lead ethics approval letter and approved documents (e.g. information sheet templates) when you receive them.
  - Ensure you provide a copy of your NEAF application with your SSA form.

Address SSA forms to:

Ms Margaret Dennis  
Kids Research Institute  
The Children's Hospital at Westmead  
Locked Bag 4001  
Westmead NSW 2145

SSA forms can be sent:

- Via internal mail
- Deposited in the Ethics and Governance submission box placed in Professor Anne Cunningham's office:  
Level 3, Emergency Wing, School of Women's and Children's Health, Sydney Children's Hospital  
  
The box is transported to Westmead weekly and more frequently if required.
- Deposited in the submission box at the Kids Research Institute reception in the week of submission closing.

## 10.6 FEES

The review of some SSA forms will attract a fee; this will be invoiced upon receipt of your SSA form.

<b>Sponsor/Financial Support</b>	<b>Fee (GST included)</b>
Full Industry Sponsorship	\$3740.00
Investigator Driven or Collaborative Groups Sponsorship with partial industry funding	\$3740.00
Collaborative Groups Sponsorship or grant funded	\$150
Investigator initiated with no external funding source, student	No charge

## 10.7 POST APPROVAL

(i) Amendments

Amendments to your project (e.g. a change in protocol, investigators, procedures) must be submitted first to the lead HREC and then to the research governance office using the governance amendment form.

(ii) Annual site reports

A site report must be submitted annually using the approving HREC annual report form.

(iii) Adverse events

Adverse events that occur at CHW and SCH should be reported to the research governance manager.

## 10.8 FURTHER INFORMATION

Information sessions are held prior to each SCHN HREC submission closing date; these sessions will be advertised widely. Please contact the research governance managers to discuss your application at any other time.

## **PART 11: CONTACTS**

### **Research Ethics Managers and Secretaries of the CHW HREC:**

Righa Saroo

[Righas@chw.edu.au](mailto:Righas@chw.edu.au)

(02) 9845 3017

### **Ethics Administration Assistant**

(02) 9845 1253

### **Research Governance Managers:**

Carolyn Casey

[CarolyB3@chw.edu.au](mailto:CarolyB3@chw.edu.au)

(02) 9845 3029

James Cokayne

[Jamesc5@chw.edu.au](mailto:Jamesc5@chw.edu.au)

(02) 9845 1272

### **CHW Clinical Trials Pharmacist**

Pathma Joseph

[PathmaM@chw.edu.au](mailto:PathmaM@chw.edu.au)

(02) 9845 1329

### **SCH Pharmacist- for Paediatric Oncology Trials**

Genevieve Daly

[Genevieve.Daly@sesiahs.health.nsw.gov.au](mailto:Genevieve.Daly@sesiahs.health.nsw.gov.au)

(02) 9832 2334

### **SCH Pharmacist- for all other studies**

Joanne O'Brien

[Joanne.O'Brien@SESIASHS.HEALTH.NSW.GOV.AU](mailto:Joanne.O'Brien@SESIASHS.HEALTH.NSW.GOV.AU)

(02) 9382 2333

### **CHW Radiation Safety Officer**

Yvette Wilson

[YvetteW@chw.edu.au](mailto:YvetteW@chw.edu.au)

(02) 9845 0998

### **SCH Radiation Safety Officer**

Brent Rogers

[brent.rogers@sesiahs.health.nsw.gov.au](mailto:brent.rogers@sesiahs.health.nsw.gov.au)

(02) 9382 8067

### **CHW Biostatistician**

Janelle Bowden  
[janelleb@chw.edu.au](mailto:janelleb@chw.edu.au)  
(02) 9845 3068

**CHW Service Improvement Unit**  
(Quality Improvement projects)  
(02) 9845 3442

**SCH Clinical Practice Improvement Unit**  
(Quality Improvement projects)  
(02) 9382 6599