



NEPEAN BLUE MOUNTAINS LOCAL HEALTH DISTRICT (NBMLHD)

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

GUIDE TO HREC SUBMISSION

*A guide to assist in the submission of documents for
Human Research Ethics Approval*

***For enquiries and for forwarding research documentation within the
Nepean Blue Mountains Local Health District, please contact:***

*Executive Officer
NBMLHD Human Research Ethics Committee
Research Office
Ground Floor, Court Building
Nepean Hospital
Cnr Derby & Somerset Streets
KINGSWOOD NSW 2747*

All enquiries to:

*Paula Ewings, HREC Executive Officer
Telephone: 47 34 3441 Fax: 47 34 1365
Email: Paula.Ewings@health.nsw.gov.au*

BACKGROUND

On 1 July 2007, the NSW Department of Health (NSW Health) introduced a process for the single ethical review of all human research to be conducted in at public health organisations in NSW. Information for researchers has been made available by the NSW Ministry of Health Research and Ethics Branch's website: www.health.nsw.gov.au/healthethics

The NBMLHD HREC is accredited as a lead human research ethics committee under the NSW Health model for single ethical and scientific review of multicentre research to be undertaken within NSW. **Information re multicentre v single site commercially sponsored clinical trials** contained on Pages 19-21 of this Guide.

The **NBMLHD HREC** accepts HREC submissions for:

- **Single site** research proposals conducted in Nepean Hospital, Blue Mountains Hospital, Hawkesbury Hospital, Springwood, Lithgow and Portland hospitals, Pialla, Tresillian Wentworth Family Care Centre, Bungarribee House, Community Health facilities
- **Multicentre** research proposals for single ethical review. The term 'multicentre' refers to more than one NSW public health organisation.

Mutual Acceptance Initiative/Acceptance

In February 2012 NSW Health entered into a Memorandum of Understanding with Health Departments in Queensland and Victoria for the 'Mutual Acceptance initiative' for single ethical review of multicentre research in two or more of these states for clinical trials. Certain research projects are excluded from the initiative because of State specific requirements and researchers should check with the Research Office before embarking on this process.

As of November 2013 a Memorandum of Understanding (MOU) forming the Interstate Mutual Acceptance (IMA) initiative between NSW, QLD, and VIC has been re-negotiated in order to accommodate other Australian jurisdictions into a National Mutual Acceptance (NMA) scheme.

Scope

The NMA scheme will operate just as the IMA initiative did, but will now include South Australia. That is, from a NSW perspective:

- (1) studies that are reviewed and approved by a certified South Australian public health organisation's (PHO's) Human Research Ethics Committee (HREC) may be accepted by NSW PHOs for conduct at their site without requiring further ethical and scientific review by a NSW PHO HREC;
- (2) studies that are reviewed and approved by a certified NSW PHO HREC may be accepted by South Australian PHOs for conduct at their site without requiring further ethical and scientific review by a South Australian PHO HREC.

Therefore, participating HRECs in NSW, QLD, SA & VIC can approve studies in any combination of participating sites in NSW, QLD, SA, & VIC.

Roles and Responsibilities of the HREC

The HREC operates under the following documents which are available on the Research Office intranet and internet sites:

- HREC Terms of Reference
- HREC Standard Operating Procedures
- NHMRC Australian Health Ethics Committee (AHEC) Position Statement

Responsibilities of Researchers and Staff

Researchers undertaking approved research must follow a strict set of guidelines while conducting their research. Researchers should refer to the Abbreviated Standard Operating Procedures for Researchers on the intranet site. They must ensure that :

- No research is commenced before HREC and Research Governance approval is received.
- All relevant information has been provided to the HREC.
- All relevant guidelines and legal requirements are complied with.
- Monitoring requirements are complied with, eg submission of Annual Reports and a Final Report at the conclusion of the project. Annual / Final Report Form is available on the intranet site.
- Proposed protocol modifications / amendments (including amendments to the Participant Information and Consent Form) are submitted to the HREC Sub-Committee for approval . Request for Modification / Amendment Form and Information / Requirements are available on the intranet site.
- Adverse events are promptly reported - SUSAR/SAE Report Forms and relevant information are available on the intranet site.

GETTING STARTED

Researchers must ascertain whether their proposed research is:

- A full HREC submission on the National Ethics Application Form (NEAF)
- Low/Negligible Risk (LNR) research
- Quality Assurance (QA)/Audit

LOW / NEGLIGIBLE RISK (LNR) RESEARCH

Information regarding criteria for LNR research is available on the intranet site. Details are included of what paperwork is required for an LNR submission and you should obtain and read this information prior to accessing the LNR application form www.ethicsform.org/au

Either a Site Specific Assessment (SSA) application or an Access Request application is also required for LNR and those forms are available on the same site.

QUALITY ASSURANCE / QUALITY IMPROVEMENT / AUDIT

Quality Assurance/Quality Improvement/Audit Application Form is available on the intranet site. There is a Checklist on pages 3 & 4 of the application form which, when completed, will identify whether or not your project qualifies for QA.

NEAF APPLICATION

HREC applications are to be completed on the National Ethics Application Form (**NEAF**) which can be found at www.ethicsform.org/au If you have any difficulties completing the form contact the NSW Health help line on phone 9037 8404 (available from 10am to 4pm AEST Mon to Fri).

Research projects range from fully funded commercially sponsored clinical trials of drugs/devices, investigator initiated studies, biomedical (laboratory) studies, to student studies, eg –

- Clinical (all disciplines including Dentistry)
- Basic Biomedical / Laboratory research
- Nursing and Allied Health
- Mental Health
- Public Health and Epidemiological
- Health Services
- Psychological and Behavioural
- Social Science
- Qualitative (using questionnaires, surveys, focus groups)

The following documents should be submitted in support of the HREC application and templates for most of these documents are on the intranet site:

- National Ethics Application Form (NEAF) with Chief Investigator's original signature
- Scientific Protocol / Study Plan
- Participant Information and Consent Forms
- Study Surveys (if applicable)
- Recruitment advertisements (if applicable)
- Radiation Safety Committee Report (if applicable)
- CTN form (if applicable)

For commercially sponsored clinical trials the following are also required:

- Investigator's Brochure / Product Information (if applicable)
- Copy Medicines Australia Standard Form of Indemnity
- For multicentre, Medicines Australia HREC Review Only Form of Indemnity, naming each investigator / site in Paragraph 1
- Certificate of Currency for Clinical Trial insurance for a minimum of \$20million
- CTN Form/s (if applicable) for sign off by the HREC

Allow sufficient time for obtaining ethical approval. The review process takes approximately 8 weeks from submission of proposal to your receipt of approval letter and can take longer if there are major difficulties with the application. As part of the NSW Ministry of Health Lead HREC model, we will aim to comply with the 60 day clock.

Submit your proposal by the monthly deadline (Submission / Meeting Date Schedule is on the intranet site) and allow sufficient time in your research plan for this process to take its course. **Deadlines are strictly adhered to.** The HREC application documents must be **collated**, then stapled / clipped together. Uncollated submissions will be returned. Bulldog clips of varying sizes are available from the Research Office.

Once submitted, the application will undergo initial scrutiny by the administrative staff. Where there are minor problems with the paperwork, the applicant will be asked to rectify these, but the proposal may still proceed to review. Where major difficulties exist with the submitted paperwork, the proposal will not be accepted and will be returned to the researcher for amendment and subsequent resubmission.

RESEARCH GOVERNANCE / SSA (Site Specific Assessment) CLEARANCE

This is a separate process. Refer to the Research Governance (SSA) Submission Guide. The submission of the Site Specific Assessment (SSA) Form and accompanying documentation (see checklist at the end of the SSA Form) runs separately from, but in parallel with the ethics application process.

Please do not attach an SSA Form to the NEAF. The NEAF and SSA Form are two separate documents. They must be submitted separately and not as one document. For information regarding the SSA form and Research Governance Clearance please refer to the Guide to SSA / Governance Submission which is on the intranet site or can be obtained by contacting the Research Office.

The **Chief/Principal Investigator** on the SSA application should be an experienced NBMLHD researcher with a proven research record, to be responsible for the research being conducted within NBMLHD. Please see below for studies being submitted by Students, Research Fellows and Junior Medical Staff.

The following information is required for **all** HREC submissions:

- The NBMLHD status of each investigator on the study, ie whether they are a Staff Specialist (what level, ie Level 1 or Levels 2-5 as different rules apply re indemnity/insurance), VMO, research fellow, junior medical staff etc.
- Advice as to whether only public patients will be recruited, or public and private patients, and where the patients will be recruited ie from public clinics, private rooms or both.
- In the case of clinicians (Staff Specialist Levels 2-5) a copy of their medical indemnity insurance which should cover patients in research studies (to be submitted with SSA application)
- In the case of researchers who are academics or students, they must submit proof of indemnity from their University covering them for their research activities (to be submitted with SSA application)

Please note: You cannot commence a project at your site until you receive authorisation from the Chief Executive / designee. Governance clearance will be confirmed in writing by the Research Governance Officer (RGO) after approval of the Site Specific Assessment (SSA) application (see separate Guide to Site Specific Submission).

STUDENTS (PhD / Honours), RESEARCH FELLOWS, JUNIOR MEDICAL STAFF

Before commencing the submission process and completing the NEAF, **you must identify a NBMLHD Researcher to act as Principal / Chief Investigator** for your research study. *This is separate from your University requirements.*

For **students employed by NBMLHD**, your site supervisor may be named as Principal / Chief Investigator and research activities may be designated to you, with your supervisor overseeing those activities.

For **external students** wishing to undertake research within a NBMLHD department, you should contact the department head to discuss the research and request a senior researcher in that department to act as Principal / Chief Investigator on your project and oversee the research.

As a student, the LHD expects that you will be conducting the research project under the supervision of a responsible individual who can provide you with appropriate advice and supervision whilst conducting your research within NBMLHD, with respect to a number of areas including, how to access and communicate with your participant population, the provisions of the Privacy Act and access to health care records etc. The nominated NBMLHD Researcher is responsible for the overall conduct, compliance and reporting of the research study/project within NBMLHD.

A student, research fellow or junior medical staff cannot be named as **Principal / Chief Investigator** - you should be listed as the **Associate Researcher**.

INTELLECTUAL PROPERTY

Before being passed to the NBMLHD Human Research Ethics Committee (HREC) applications are assessed by the Nepean Scientific Advisory Committee (SAC) . During this assessment possible intellectual property issues may be identified and if this is the case, the SAC and HREC Committee will contact researchers to provide advice. This is to avoid any possible conflict with any other organisation to which the researcher may have a prior obligation.

It is important to note that the Commercialisation Unit is separate and independent of the University of Sydney and other administrative organisations. Researchers who either work for the University or are supported by University funds, will need to approach the University with intellectual property issues rather than the NBMLHD Commercialisation Unit. If this is not done, the value of intellectual property may evaporate due to 'prior disclosure'.

RECRUITMENT OF CULTURALLY AND LINGUISTICALLY DIVERSE (CALD) PARTICIPANTS

Please be aware that NSW Health Policy Directive PD2006_053 (Interpreters - Standard Procedures for Working with Health Care Interpreters) directs that culturally and linguistically diverse (CALD) patients should be given the opportunity to be included in clinical trials and research projects with the assistance of the Health Care Interpreters.

Further, the National Statement on Ethical Conduct in Human Research 2007 recognizes the cultural diversity of Australia's population and the importance and respect for that diversity in the recruitment and involvement of participants. (National Statement Chapters 2.2.3 and 5.2.16)

ASSEMBLE AND SUBMIT THE REQUIRED DOCUMENTATION ***For number of required copies see Checklist at the end of this Guide***

SUBMISSION PACKAGE FOR ALL RESEARCH (except clinical drug / device studies)

All the documents should be photocopied (double-sided where possible) and **collated** in the following order where applicable for your research project:

- **One (only) copy** of the completed NBMLHD HREC Questionnaire / Checklist / Submission Cover Sheet;
- **One (only) copy** of the Internal Fee Form or a cheque or receipt for application fee
- National Ethics Application Form (NEAF) from www.ethicsform.org/au website
- Separate Scientific Study Protocol / Research proposal
- Master Participant Information and Consent Forms (multicentre only)
- Local Participant Information and Consent Forms (single site only)
- Study Surveys / Patient Questionnaires (if applicable)
- Recruitment advertisement (if applicable)
- Letters from other HRECs (if applicable) outside of NSW
- Radiation Safety Committee Report (if applicable)
- Original Form of HREC Review Only Indemnity (multicentre only) and if applicable (ie for a collaborative group).

SUBMISSION PACKAGE FOR CLINICAL DRUG / DEVICE TRIALS

All the documents should be photocopied (double-sided where possible) and **collated** in the following order where applicable for your research project:

- **One (only) copy** of the completed NBMLHD HREC Questionnaire / Checklist / Submission Cover Sheet;
- **One (only) copy** of the Internal Fee Form or cheque / receipt for application fee
- National Ethics Application Form (NEAF) from www.ethicsform.org/au website
- Separate Scientific Protocol / Research proposal
- Investigator 's Brochure or product information(as applicable)
- Master Participant Information and Consent Forms (multicentre only)
- Local Participant Information and Consent Forms (single site only)
- CTN form (if applicable)
- Original Indemnity for HREC Review Only for NBMLHD naming each investigator and site (multicentre research only)
- Copy Standard Form of Indemnity
- Copy Certificate of Currency of Clinical Trial Insurance
- Study Surveys / Patient Questionnaires (if applicable)
- Recruitment advertisement (if applicable)
- Letters from other HRECs (if applicable) outside of NSW
- Copy of Radiation Safety Committee applicable Form (if applicable)

REQUIRED DOCUMENTATION

1. (One copy only) completed NBMLHD HREC Questionnaire / Checklist / Submission Cover Sheet;

The Questionnaire / Checklist must be completed and attached to the original copy of your submission. The checklist is a prompt for you to ensure all the documents required are attached to your submission. This information will assist the ethics officer with the allocation and review of submission.



2. (One copy only) Internal Fee Form or cheque for application fee

Two mechanisms of fee payment are provided for attachment to your submission. Please refer to the document entitled 'Ethics Application Submission fees, Site Specific Submission fee and Clinical Trials Levy'.

Application fees

Application for commercially sponsored clinical trial (GST inc)	\$3,300
Application with sponsorship / support from collaborative group (GST inc)	\$150
Investigator initiated and company (financially) supported study (GST inc)	\$550
Investigator initiated studies, no external funding / research grant funded (internal NBMLHD application)	\$50
Investigator initiated studies, no external funding / research grant funded (external application, GST inc)	\$55
Fee for SSA for commercially sponsored clinical trial (GST inc)	\$3,740
Fee for SSA for any other research study	Nil

3. National Ethics Application Form (NEAF)

The NEAF must be completed on the following website www.ethicsform.org/au for all research submitted to NBMLHD and other public health organisations in NSW. The **applicant** is the Coordinating Principal Investigator for multicentre research and the Chief Investigator / Principal Investigator for single site research.

- For **multicentre research submitted for single ethical review**, when completing **Section 2** of the NEAF, your own site should be listed as Site 1 followed by **all of the other NSW (and if an application under the Mutual Acceptance initiative, Qld. & Vic. and S.A. sites) for which the ethical approval will apply and is being sought under this application**. Section 3 of the NEAF should list all the other sites in Australia and globally.
- There should be an Investigator listed for each site **for which approval is sought under this application**.
- For **single site research**, complete Section 2 with the site details and Section 3 with any other sites outside of NSW if applicable.
- When completing the NEAF there will be a watermark 'Draft' on it. Once you have completed the form, press the 'Generate submission code' button and two things will happen –
 - The 'Draft' watermark will disappear
 - A submission code 'AU/' will appear in the bottom right hand corner of each page.
- Only submit NEAF forms with a submission code for HREC review. If you have not successfully generated a submission code, the forms cannot be accepted as they cannot be logged onto the AU RED database by Research Office staff and processed.
- The only signature required on the NEAF is that of the Principal / Chief Investigator and it must be an original (hand written) signature.

4. Investigator Brochure or Product Information (Clinical Drug / Device Trials Only)

The above mentioned documents are required for research proposals involving the use of a drug. If your proposal or study involves the use of a device, please include information about the device and its registration status with the Therapeutic Goods Administration (TGA).

5. CTN / CTX form (Clinical Drug / Device Trials Only)

1 copy of a TGA Clinical Trial Notification form (if applicable) is required for each site. Please insert the following details in the appropriate section:

- **Section 1** should be completed by the sponsor.
- **Section 1.5 Trials site details** eg Nepean Hospital, Cnr. Derby & Somerset Streets, **KINGSWOOD NSW 2747**
- **Section 2 Principal Investigator** eg for the study in NBMLHD
- **Section 3 HREC Member** NBMLHD Human Research Ethics Committee
- **Section 4 Approving Authority** Nepean Blue Mountains Local Health District, **ABN 31 910 677 424**, Cnr. Derby & Somerset Streets, **KINGSWOOD NSW 2747**

6. Original Medicines Australia HREC Review Only Form of Indemnity (Multicentre Drug Trials Only)

A **Medicines Australia HREC Review Only Form of Indemnity** must be provided for multicentre review. A list of the investigators / sites covered by the HREC review must be included in the Indemnity.

3 copies of the Indemnity should be provided. **Signature** by Sponsor is required prior to submission to the HREC.

No alterations to this template will be accepted. The template is on the following website:
<http://www.medicinesaustralia.com.au/pages/index.asp>

Parties to the indemnity agreement:

From: Pharmaceutical company or Clinical Research Organisation (with full name, ABN and address). This must be an Australian company operating under Australian / NSW laws.

- **To:** Nepean Blue Mountains Local Health District, **ABN 31 910 677 424**, Cnr. Derby & Somerset Streets, **KINGSWOOD NSW 2747**

The names of the Chief Investigators and all participating Sites should be included in Paragraph 1 of Page 1 (where indicated).

7. Copy Medicines Australia Standard Form of Indemnity for NBMLHD (Clinical Drug Trials Only)

As required by the NHMRC National Statement on Ethical Conduct in Human Research (2007) Chapter 3.3, proof of indemnity must be supplied to the HREC at the time of review. A **copy** of the Medicines Australia Standard Form of Indemnity that will be supplied to the sites as part of SSA / Governance must be supplied with the HREC submission.

8. Copy Certificate of Currency for Clinical Trials Insurance (Clinical Drug Trials Only)

As required by the NHMRC National Statement on Ethical Conduct in Human Research (2007) Chapter 3.3, proof of adequate insurance must be supplied to the HREC at the time of review. The minimum amount of insurance required for clinical trials is \$20,000,000. A **copy** not originals, of the insurance certificate that will be supplied to the sites as part of SSA / Governance must be supplied with the HREC submission.

9. Separate Scientific Protocol / Research proposal (all projects)

A detailed and descriptive research proposal or scientific protocol must be supplied with all submissions. Detailed **completion of the NEAF is not sufficient** and all **applications will be returned** if a separate study / scientific protocol is not submitted with HREC paperwork.

Please ensure the study title is on each page and there is a version number, date and page numbering (Page 1 of ...) in the footer of the document..

10. Master Participant Information and Consent Forms (PICF) (multicentre only)

'**Multicentre**' for the purposes of NEAF submission, means more than one NSW public health organisation. This includes studies where there are two or more sites within NBMLHD. A master PICF must be provided for review. The master PICF must be on blank paper, with the fields left blank for the site investigator, site contact and complaints details.

Each site then adapts the approved master for their own site, and puts it on their own site letterhead. The site investigator, site, contact and complaints details are then inserted. This can only be done after HREC final approval of the master is obtained.

Please refer to NSW Health Policy Directive PD2010_055 '*Ethical and Scientific Review of Human Research in NSW Public Health Organisations*'. . The policy directive can be found at the following website: http://www0.health.nsw.gov.au/policies/pd/2010/PD2010_055.html

Note: Site specific PICF is submitted on institution letterhead along with a copy of the approved **master** version with the SSA / Governance application. Please ensure there is a version number, date and page numbering ('Page 1 of ...') in the footer of this document stating it is 'based on Master PI&CF version ... dated

For standard wording and formatting the NBMLHD HREC has adopted the wording and formatting as per the NSW Health Guideline *GL2007_016 'Human Research Ethics Committees - Standard Patient Information Sheets (PIS)'* Compliance with the standard templates will assist with the review and approval process. Non-compliance with the suggested wording may result in delays in approving your research project. The policy directive can be found at the following website:

http://www0.health.nsw.gov.au/policies/gl/2007/GL2007_016.html

11. Local Participant Information and Consent Forms (single site only)

Where research is only being conducted at one NBMLHD site a local PICF on NBMLHD letterhead, with all site details inserted is required.

The study title must be on each page in a header, and there must be a version number, date and page numbering ('Page 1 of ...') in the footer.

12. Study Surveys / Patient Questionnaires (if applicable)

Please provide a copy of any questionnaires, surveys or tools to be completed by participants in your research proposal.

The study title should be on each page, it should be on NBMLHD letterhead and please ensure there is a version number, date and page numbering (Page 1 of ...') in the header or footer of the documents.

13. Recruitment advertisement (if applicable)

Ethical approval must be sought prior to any advertising material being used, including voice (script), print media, posters or flyers. Please supply a copy of the material in the format that will be used, for review by the HREC.

Any advertising should include:

- the study title
- a statement 'This research project has been approved by the Nepean Blue Mountains Local Health District Human Research Ethics Committee'
- a version number and date in a footer.

14. Letters from other HRECs (if applicable)

If applicable please provide.

15. Radiation Safety Committee Report (if applicable)

Where ionising radiation is used, a radiation safety committee report or copy of application to the Radiation Safety Officer must be provided at the time of submission. The Radiation Safety Committee application form, which is available on the intranet site, together with a copy of your complete proposal should be submitted to Sean White (Medical Physicist), NBMLHD Radiation Safety Officer, email Sean.White@health.nsw.gov.au.

16. Certificate from Biomedical Engineer (if applicable)

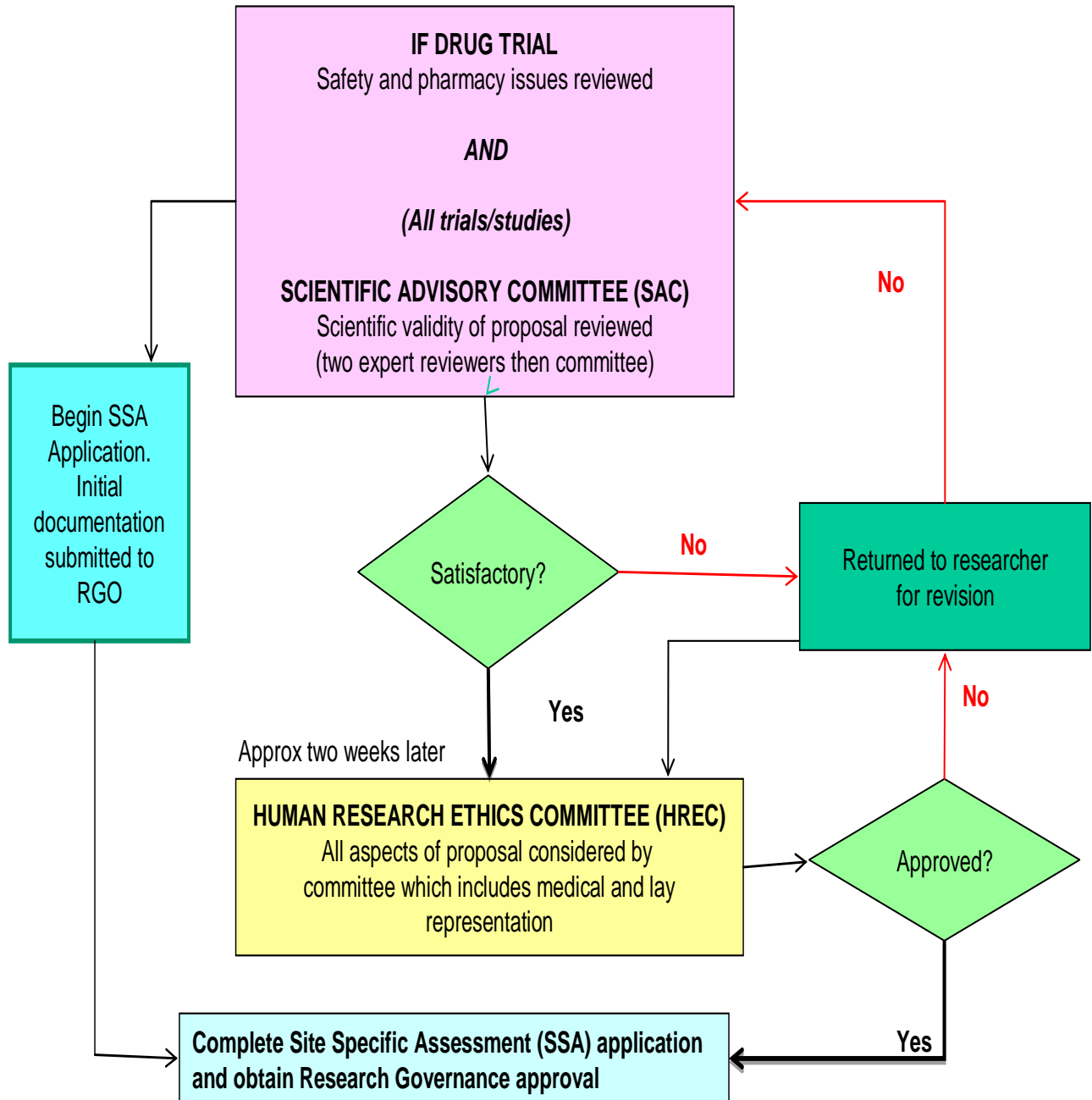
If the trial is investigating a new (unregistered) device, a certificate from the NBMLHD Biomedical Engineer may be requested to assess the safety and construction of the device and its components, and whether it complies with Australian safety standards. There may be a fee for such a certificate and researchers should enquire at the time of submission. If the device is registered, a copy of the registration certificate should be included with your application

FURTHER INFORMATION WORTH NOTING AND WHICH YOU MAY FIND HELPFUL

- **Ensure you have the current documentation** which is available on the intranet site or from the Research Office by emailing NBMLHD-Researchoffice@health.nsw.gov.au. Never use documentation you have received from a colleague or which you have sourced previously, as you may not have the latest version of the documents.
- **The first person to liaise with about your research is your supervisor / senior researcher.** The Research Office staff can assist with making the documentation templates available, but cannot write your protocol or other documentation for you. This is for you and your supervisor / co-investigator/s to do.
- **Construct your study protocol and finalise it before starting your NEAF** (a template is available on the intranet site which may assist you in what information / headings you need to include in your protocol) . The scientific validity of your project is assessed by the reviewers on the Scientific Advisory Committee (SAC).

- ***Don't rush the preparation of your paperwork.*** Plan your research properly and give yourself enough time to submit correct and complete paperwork. Keep in mind the minimum time between submission and HREC approval is 8 weeks, and then you need to obtain governance (site specific assessment) approval of your study. Don't rush your submission to meet a submission deadline - rushed submissions which have not been properly planned may be rejected by the SAC and will need to be amended and resubmitted for re-review the following month. Take your time with your submission to get it right, so that it has more chance of being approved at SAC and recommended to the HREC without unnecessary delay. It is better and much less frustrating for you to submit a complete, well thought-out project which progresses smoothly through the committees, than having it rejected and having to rewrite it.
- ***The SAC members are there to offer constructive criticism, not to throw up road blocks.*** If your project is not approved at the SAC, which comprises experienced and senior researchers, it is because in the expert opinion of the reviewer/s what you hope to achieve will not be achieved by your stated methods. Suggestions will be offered to assist you to improve the quality of your research. Only projects which have scientific merit and are approved by SAC will be recommended to the HREC.
- ***Create a study file*** and always keep copies of all documentation in it. Never submit anything without first taking a copy for your study file. If an audit is carried out on your research and you do not have a complete study file, your study will be stopped.
- ***Quote your reference number*** in any correspondence. It will look like 'Study 14/ - HREC/2014/NEPEAN/xx' and will be on any correspondence you receive from the Research Office. These reference numbers are assigned when you submit your research and enable the Research Office staff to locate your file quickly. The AU RED portion of the study number corresponds to the database where your research is registered. This is a NSW Ministry of Health requirement.
- ***Make a diary note to submit an Annual Report*** as your HREC approval will be for 12 months and continuation of the study after that point is contingent upon the HREC receiving an annual report at the end of that period. If annual reports are not received each year, your ethics approval condition is breached and you may be made to stop your study.
- ***Protocol Amendments / updated Participant Information and Consent Forms / Updated Investigator's Brochure*** – You may find sometime in the future you need to amend the original HREC approved protocol, update a Participant Information and Consent Form, add a site/s or investigator/s, remove a site/s or investigator/s. All of these situations require a Request for Amendment / Modification and these are considered by the SAC and HREC Committees which meets monthly. The required Request for Amendment / Modification Form is available on the intranet site.

HREC SUBMISSION - ASSESSMENT PROCEDURE



Submission documentation – number of copies required

Required documents and completion guidelines (where applicable)	Number of copies required for proposals <u>involving</u> drugs	Number of copies required for proposals <u>not involving</u> drugs / devices
National Ethics Application Form (NEAF) signed by the Coordinating Chief / Principal Investigator	<u>Original</u> + 20 Total 21	<u>Original</u> + 20 Total 21
Participant Information and Consent Form (Master for multicentre, Local for single site)	21	21
Separate Scientific / Study Protocol including aims, hypotheses, research plan, methods, analysis, potential significance, reference list etc – <i>should have version number & date in footer. Draft template available on intranet site</i>	21	21
CTN Form (if required) signed by the Coordinating Principal Investigator. All boxes / details must be completed prior to submission. Please do <u>not</u> submit double sided.	1	N/a
Multi-centre submission - Medicines Australia HREC Review Only Form of Indemnity from trial sponsor addressed to <i>Nepean Blue Mountains Local Health District</i> Nepean Blue Mountains Local Health District, ABN 31 910 677 424 , Cnr. Derby & Somerset Streets, KINGSWOOD NSW 2747 'the Authority' indemnifying the HREC and including the name of each investigator and site in paragraph 1. This must be signed by the sponsoring pharmaceutical company prior to submission. <u>Not required for single site submission</u>	3 x Originals for signature	N/a
Medicines Australia Standard Form of Indemnity from trial sponsor to NBMLHD (<i>addressed as above</i>). This must be signed by the sponsoring pharmaceutical company prior to submission with Site Specific Assessment (SSA) application	2 x Originals for submission with SSA + 1 copy attached to each HREC application	N/a

Required documents and completion guidelines (where applicable)	Number required (proposals involving drugs / devices)	Number required (proposals <u>not</u> involving drugs / devices)
Certificate of Currency (Clinical Trials / Public Liability Insurance) for a minimum of AUD \$20,000,000	21	N/a
Investigator Brochure (if applicable) or Product Information (if study drug is registered)	5	N/a
Copy of study questionnaire/s, survey questions, interview topics to be covered, recruitment advertisement / flyer, patient diary etc ie any document which will be given to study participants. These must have the study title on each page together with version number / date and page numbering ie 'Page 1 of ...' etc in the footer. NB Recruitment advertisement/flyer must contain the study title, a version number and date, and a statement 'This study has been approved by the NBMLHD Human Research Ethics Committee'	21	21
Evidence of approval / rejection by other HRECs outside NSW including comments and requested alterations to the protocol	21	21
NBMLHD Radiation Safety Committee Report (if applicable)	21	21
One completed copy of the Submission Questionnaire / Checklist / Cover sheet	1	1
Application fee – Cheque, Receipt or Submission Fee Transfer Form (one only). Application will not be accepted without fee.	1	1

Information re multicentre v single site commercially sponsored clinical trials

There appears to still be a lot of confusion about several aspects of this and what is required for HREC approval and what is required for governance approval.

Single site, for the purposes of the NSW Health (NEAF) system, means the application for HREC approval covers only one public health organisation (PHO) in NSW. The application may state the trial is being conducted at interstate and overseas sites and/or NSW private hospital/s or a clinician’s private practice, but if there is only one NSW PHO it is classed as ‘single site’.

Multicentre is when there are more than one NSW PHO in the HREC application.

Single site	Multicentre
<p>Standard Participant Information and Consent Form on the site’s letterhead should be submitted with HREC application</p>	<p>Master version of the Participant Information and Consent Form on blank paper with all identifying information left blank ie</p> <ul style="list-style-type: none"> • the name of the chief investigator • the site • the complaints person’s name (patient representative) and contact details • the contact person for information (the site clinician / clinical trials coordinator) phone numbers • The footer should state ‘Master version for multicentre, Version No xxx dated xxx <p>The Master version should be submitted with HREC application and when approved by the HREC, a copy of the approved document should be submitted with SSA paperwork.</p>
	<p>Local version of the Participant Information and Consent Form should be submitted with SSA paperwork with local identifying details inserted and the footer should state ‘Local Version No xxx dated xxx based on Master Version No xxx dated xxx’</p>
<p>Medicines Australia Standard Form of Indemnity x 3 from the sponsoring pharmaceutical company to WSLHD and signed by the pharma company. Paragraph 1 should name the Investigator and the Site, ie Dr Joe Smith, Westmead Hospital</p> <ul style="list-style-type: none"> • A photocopy of this form should be attached to each bundle of papers when submitting the HREC application <p>Do not submit the 3 originals with the HREC application - they should be submitted with SSA paperwork and will be signed on behalf of WSLHD when the study receives governance clearance.</p>	<p>Medicines Australia Standard Form of Indemnity x 3 from the sponsoring pharmaceutical company to NBM LHD and signed by the pharma company. Paragraph 1 should name the Investigator and the Site, ie Dr Joe Smith, Nepean Hospital</p> <ul style="list-style-type: none"> • A photocopy of this form should be attached to each bundle of papers when submitting the HREC application • Do not submit the 3 originals with the HREC application - they should be submitted with SSA paperwork and will be signed on behalf of NBMLHD when the study receives governance clearance.

Medicines Australia HREC Review Only Form of Indemnity is not required for single site applications as the HREC is indemnified under the standard form.	Medicines Australia HREC Review Only Form of Indemnity x 3 from the sponsoring pharmaceutical company to NBMLHD naming all (NSW PHO) Investigators and the sites, ie Dr Joe Smith, Nepean Hospital, Dr Tom Jones, RPAH, Dr Harry Brown, RNSH etc These forms should be submitted with the HREC submission and will be signed off when the study is approved by the HREC.
CTN form signed by the investigator should be submitted with HREC application and will be signed off by the HREC after approval and returned to the investigator with the letter of approval. This should then be submitted with SSA paperwork for sign off by WSLHD.	CTN form signed by the investigator should be submitted with HREC application and will be signed off by the HREC after approval and returned to the investigator with the letter of approval. This should then be submitted with SSA paperwork for sign off by the research governance officer of the site.
Copy of the Certificate of Currency should be attached to each bundle when submitting HREC application and should also be attached to SSA application.	Copy of the Certificate of Currency should be attached to each bundle when submitting HREC application and should also be attached to SSA application.

Adding an additional site (PHO) to a single site study for a sponsored clinical trial -

If a study is approved as a single site study and at a later date the investigator wishes to add an additional site so that it becomes a multicentre study, the process is:

1. Write a letter to the HREC requesting approval to add a site –
2. Complete and submit
 - Request for Modification / Amendment form with the details of the investigator at the new site on Page 1 (with their original signature) and signed where indicated by the Principal Investigator on Page 5.
 - CTN form for the new site for signature on behalf of the HREC.
 - 3 x Medicines Australia Form of Indemnity (HREC Review Only) naming the investigator and new site in paragraph 1 and signed by the sponsor, for signature on behalf of WSLHD.
 - Master Participant Information and Consent Form
 - If the study was approved prior to the NEAF system (mid 2007), then a NEAF must be prepared and submitted.

The HREC will consider the request then, if approved, will:

- issue an approval letter
- stamp the Master Participant Information and Consent form 'Approved',
- sign the CTN form on Page 8
- Have the Forms of Indemnity signed on behalf of the Local Health District and return two copies to the investigator and retain one in the HREC file.

From that point on, the study should be treated as a multicentre study and all requirements of a multicentre study must be adhered to.

Adding an additional site (PHO) to a multicentre sponsored clinical trial -

If a study is already approved as a multicentre study and at a later date the investigator wishes to add an additional site, the process is the same as above however a new Master Participant Information and Consent Form is not required as one would already have been approved.

Adding an additional site (PHO) to a single site study for an investigator initiated (non sponsored) study –

1. Write a letter to the HREC requesting approval to add a site
2. Complete and submit
 - Request for Modification / Amendment form with the details of the investigator at the new site on Page 1 (with their original signature) and signed where indicated by the Principal Investigator on Page 5.
 - Master Participant Information and Consent Form.
 - CTN form for the new site for signature on behalf of the HREC (if a drug / device is involved)
 - If the study was approved prior to the NEAF system (mid 2007), then a NEAF must be prepared and submitted.

The HREC will consider the request then, if approved, will:

- issue an approval letter
- stamp the Master Participant Information and Consent form 'Approved',
- sign the CTN form on Page 8

From that point on, the study should be treated as a multicentre study and all requirements of a multicentre study must be adhered to.

Adding an additional site (PHO) to a multicentre study for an investigator initiated (non sponsored) study

If a study is already approved as a multicentre study and at a later date the investigator wishes to add an additional site, the process is the same as above however a new Master Participant Information and Consent Form is not required as one would already have been approved.

Thank you for taking the time to read this document