ABSTRACT

Seeking and gaining ethics approval for student research is not necessarily a straightforward affair. Many struggle for months against what may seem a behemoth task whilst others simply run out of time. This guide is written by a student for other students in an attempt to demystify the process somewhat – or at the very least prevent stress induced premature baldness.
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Why bother?

With this guide, that is, not life in general.

There are few reasons; firstly medical students are busy. Much busier than clinicians realise. Between lectures, clinical rotations, OSCEs, long cases, barrier exams and the season premier of Game of Thrones there is very little time for a home life let alone extra research. Trying to squeeze in a never-ending ethics application would require the existence of negative-time for many people. By having the necessary information laid out clearly and succinctly in one place you may be able to claw back a few precious hours to study more or perhaps even shower occasionally.

The second reason is that many students really struggle with the process of ethics approval. Although supporting a student through the throes of an application is largely the purview of the student supervisor there are so many potential pitfalls and delays it seems inevitable that something at some point will be overlooked. There have also been several recent changes at a state level affecting the application process and not everyone may be up to speed on the specific requirements for your particular project. As you will see there is also considerable variation at the local level. Just because a particular project was approved at one hospital last year does not mean that it will be approved at your hospital this year.

Another important reason is that you must be able to talk the talk. Ethics committee members and Research Governance Officers are generally lovely people but they speak a language unknown to common man. Everyday words are given entirely new definitions and it can seriously derail your application if you assume you know what “inconvenience” means to an ethics committee without checking first.

When using this guide you will see that certain sections have been labeled as an “important bit” – it’s probably a good idea to read those. Not all sections will be relevant for every project but generally if a section has been highlighted as important it typically relates to a fundamental aspect or frequent pitfall. If you really can’t be bothered reading a whole section the key points are generally highlighted at the end but don’t solely rely on these as they are there more as a landmark to help you identify relevant bits. TLAs (three letter acronyms) have been limited where possible but it gets really boring typing out long department names or job titles so there’s a glossary at the end if you get stuck.

Finally, this document is intended to be an aid, not gospel, when it comes to approaching an application. Consider it a snorkel as you wade to the murky waters ethics review and with a little luck your application might just go through without a hitch!

Research Governance, say what now?

Research governance is the framework by which institutions, investigators and their managers share responsibility and accountability for research conducted according to ethical principles, scientific, regulatory and professional standards and the principles of risk management.

In plain English, research governance is essentially the way organisations cover themselves and the public to ensure nobody does a Doctor Frankenstein. To keep everyone in line the National Health and Medical Research Council (NHMRC) has issued a National Statement on Ethical Conduct in Human Research. This is a long and tedious document which sets out a series of guidelines regarding research governance. The good news is the really important bits are in this guide. Within these guidelines the NHMRC has stated that institutions may establish their own process for ethical review of research or use those of another institution provided it meets the criteria. As you’ll discover, the variability between institutions can be a bit of a headache when it comes to figuring out just what exactly it is that they want.
The most important bit...Read this!

Research governance encompasses two distinct processes:

1. Ethical Review

2. Site Specific Assessment

You must have BOTH of these BEFORE you begin your project!

1. Ethical review of human research is undertaken by a Human Research Ethics Committee (HREC). A HREC assesses proposed research in the context of participant rights, welfare, and dignity. Basically, had Dr Frankenstein applied, the Executive Ethics Officer would have told him that body snatching was a bit of an ethical no-no and that his application needed review and resubmission.

2) A site specific assessment (SSA), also known as a research governance review, assesses whether a particular research project is appropriate for the institution in terms of resources, risk management and regulatory requirements. The important distinction to make here is that the HREC doesn’t see the SSA application. The Research Governance Officer reviews and approves SSA applications and the outcome is an institutional authorisation of a research project. The implication is even if a research project gains ethical approval, the institution may still decide not to authorise it due to other factors. So even if Dr Frankenstein successfully got ethics approval the Research Governance Officer would have rejected his SSA application - probably on the grounds that they lacked the budget to artificially create life this financial year and that the OH&S guys weren’t thrilled about the whole lightning ball in the lab thing.

As a result of this dual system there is considerable duplication when completing the two applications which is incredibly frustrating but unavoidable. You do not need to wait for the outcome of your HREC application before submitting your SSA application. Most people tend to submit them simultaneously to speed up the process.

Key Point: you must have HREC ethics approval as well as a Site Specific Assessment from the Research Governance Officer BEFORE you may begin your research.
Do I even need ethics approval?

Yup. You may think you don’t, but you do. The official party line is: *all research involving humans conducted within the NSW public health system must be ethically and scientifically reviewed and approved by a Human Research Ethics Committee (HREC) in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007)*.

But I’m just doing a survey...

The National Statement is very explicit in what constitutes human research and thus requires ethical review. The NHMRC definition of human participation in research includes;

- taking part in surveys, interviews or focus groups
- undergoing psychological, physiological or medical testing or treatment
- being observed by researchers
- researchers having access to their personal documents or other materials
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath
access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database

Just about every student research project will fall under one of the above so contact your local HREC even if your supervisor suggests that a particular project does not need ethics approval. There have been a few unfortunate cases in the past where students have been told erroneously that their project did not require ethics approval and failed to have their work recognised as a result. If you are utterly and irrefutably sure (or outright delusional) that you do not need ethics approval you need to contact your local Human Research Ethics Committee anyway to get written confirmation.

Key point: just about all medical student research will require ethics approval and SSA approval – even surveys and database reviews.

Do medical students count?

Not only do Sydney medical students count – they get special treatment! If you are planning on surveying medical students you do not necessarily have to get local HREC approval but you will need to get the okay from the SMP Evaluations Unit. This is what they have to say:

“The Head of Assessment and Evaluation... is responsible for the oversight of all research projects within the Medical Program. Consideration of research applications by the Faculty is largely to ensure that the medical students are not over-surveyed. As such, applicants are advised to plan their research schedule around the assessment schedule of the students and other research projects already reserved. “

Only two research projects per month are accepted by the Evaluations unit so the website suggests getting in your application well ahead of time. Apparently, March and April are the best months to survey students to avoid clashing with other in-house surveys. You can find more information here:


The steps listed on the SMP website instruct students to complete an “Approval to Conduct Research Involving Students in the Sydney Medical Program” registration form and submit it with copies of your Participant Information Statement and Participant Consent Form. The small print says that faculty approval of research projects are subject to prior approval from the Human Research Ethics Committee. Here it becomes a bit murky about which projects may need approval from the University HREC or another HREC - if at all, so if in doubt, ask. In general terms, if you are surveying students for the purpose of collecting educational information that will be used to improve education in the faculty and will only be published in house then you may not need ethics approval. If you want to publish your work, or if sensitive or personal details are being gathered (such as income level or family details) then you likely will need University HREC approval. You can find the contact details for the Sydney University HREC funnily enough in the section titled University of Sydney Ethics Approval.

My local HREC isn’t on Facebook, how do I contact them?

Figuring out which HREC to contact is fairly straightforward if your research is based in a NSW Public Health facility as a complete list of Human Research Ethics Committees (HRECs) registered with NHMRC by state/territory can be found here:


As with most government websites it is not regularly updated and there are a few broken links. You will find links current as of January 2014 in Table 1 Contact Details (page 19).
Most HRECs are happy to, and in fact, insist upon giving advice throughout the application process. Turnaround on correspondence via email, however, can take some time (to put it very mildly). It is often more effective to contact your local HREC by telephone and get a contact name. Most will still insist that you put all the relevant information into an email anyway but by directing your email to an individual you may find you receive a more timely reply.

Information you should include when enquiring about whether a project requires ethics approval:

- your contact details, including clinical school contact details
- your supervisor’s contact details
- clearly state that it is student project (HRECs understand that students are restricted by university session dates and do try to respond speedily)
- a project protocol outline—this does not have to be a comprehensive protocol but should clearly indicate your proposed methods, data type and analysis
University of Sydney Ethics Approval

Do I need to jump through Sydney Uni HREC hoops as well?

Good news! In order to minimize duplication of ethical review, research approved by an ethics committee registered with the National Health and Medical Research Council (NHMRC) does not require approval from the Sydney University Ethics Committee. Again, this covers most medical student projects. Huzzah!

The Sydney Uni HREC website has more details but upshot of it is that once you have gained ethics approval from a NHMRC registered external HREC (and the approving committee has stated it is willing to be responsible for all the sites at which the research is being conducted) you do not have to even notify the Sydney Uni HREC. This is a fairly recent change and one not everyone might be aware of so you can refer naysayers here:


Note that research approved by an overseas ethics committee (with a few exceptions) or an Australian ethics committee which is NOT registered with the NHMRC will require an application to the Sydney University HREC.

Key Point: the USYD ethics committee does NOT need to approve research already approved by a NHMRC registered HREC.

What if my HREC is not registered with the NHMRC?

In this instance you should really confirm first that you have the appropriate HREC - a complete list of Human Research Ethics Committees (HRECs) registered with NHMRC by state/territory can be found here:


A few registered HRECs relevant to SMP students are also listed in Table 1 Contact Details.

If your project is based overseas or has been approved by an unregistered HREC then get hold of someone at the University HREC for some guidance as soon as possible at;

ro.humanethics@sydney.edu.au

The University of Sydney has two Human Research Ethics Committees to deal with the volume of applications and currently meets every 2 weeks, the dates of which may be found here:

Before you begin

There are a few more boxes to check off before you can really get going and like most bureaucratic processes they are not necessarily intuitive so be sure to read the definitions carefully to see if they apply to your project.

Is my research of low or negligible risk? ...Read This

Once you have identified the need to gain ethics approval, a site specific assessment (SSA) and the appropriate HREC you are best to contact the research office as soon as possible as there is considerable variation of requirements between HRECs. Some HRECs will allow expedited applications for projects deemed “low or negligible risk (LNR) research”. Although a LNR application is comparatively more streamlined it is typically still quite involved and takes considerable time to navigate through.

The National Statement has clear definitions of low or negligible risk research;

**Low risk**: research in which the only the only foreseeable risk is one of discomfort.

**Negligible risk**: research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

**Discomfort**: examples include minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

**Inconvenience**: examples include filling in a form, participating in a street survey, or giving up time to participate in research.

Many student initiated projects will fall into these categories and it is important to confirm with the appropriate research office/HREC that you can submit a LNR application and what their requirements are.

Key Point: some HRECs will allow expedited applications for Low or Negligible Risk (LNR) research where the only foreseeable risk to participants is that of discomfort or inconvenience.

Multi-centre research

Multi-centre research is conducted at more than one site within the NSW public health system, where those sites are within the jurisdiction of more than one NSW Health HREC. There has been a recent push nation-wide to reform and streamline the way multi-centre projects are authorised. Under the “National Approach to Single Ethical Review,” site assessment and project authorisation (SSA) are the responsibility of each institution participating in a multi-centre human research project while ethical review is provided by only one HREC using certified ethical review processes.

Not all HRECs were created equal when it comes to multi-centre research. A **Local HREC** is the HREC associated with the research site and can grant ethics approval for research at that site only. A **Lead HREC** on the other hand is accredited to conduct the ethical and scientific review of multi-centre research. This means you only have to get ethics approval once from a Lead HREC (note you will need to get SSA approval for each site but its not as hard as it sounds).

**Table 1. Contact Details** has a few of the lead HRECs listed but NSW Health has a more comprehensive list of HRECS and their multi-centre approval status;


Obviously a project spanning more than one research site will require a bit of man power and they all get spiffing titles like Co-ordinating Investigator and Local Principle Investigator. There are prescribed tasks associated with each of these, however, so it is important that you are very clear on your role in
the project so you aren’t the one holding everything up because you forgot to put the SSA form in! A quick overview of multi-centre research from NSW Health can be found here;


**Key point: A single Lead HREC can give ethics approval for research spanning multiple sites but a SSA application must be made for each site.**

### Research involving vulnerable groups

There are a few groups of participants which require special consideration when applying for ethics approval. These are;

- **persons in custody in NSW**
- **access to data collections owned or maintained by NSW Health**
- **projects specified within section 6.4 of the NSW Aboriginal Health Information Guidelines**
  - including
    - participants for whom Aboriginality is the key determinant
    - data collection explicitly directed at aboriginal people
    - Aboriginal peoples, as a group, are to be examined in the results
    - the information has an impact on one or more Aboriginal community
    - Aboriginal health funds are a source of funding

### Research involving people in custody in NSW

All health research undertaken with people in the “correctional environment” must be reviewed by the Justice Health Human Research and Ethics Committee (HREC). The Justice Health HREC uses the same online forms system that most local hospital HRECs do (see How do I start an application?). They are no friend of the forests though as they also require 12 hardcopies of your application. It pays to get your application right first time round as they only meet 5 times a year and only assess 15 new research protocols in total for a whole year!

The Justice and Forensic Mental Health Network also requires a SSA signed by the relevant Justice & Forensic Mental Health Network Executive Director for operational approval. They seem to be quite cagey about the whole process and haven’t published a copy of the application guidelines electronically. Instead you have to contact them personally and request a copy of the guidelines. Don’t forget to say please.

Your first point of contact if you are considering a project which involves either people in custody or Justice & Forensic Mental Health Network staff is:

Head of Research  
PO Box 150  
Matraville NSW 2036  
P: (02) 8372 3010  
F: (02) 9344 4151  
E: devon.indig@justicehealth.nsw.gov.au

The website is not very forthcoming but you can find it here:


Don’t forget - if your research involves other participants (not in a “correctional environment”) then you must also submit an application to the relevant local HREC as well.
Access to NSW Health Data Collections

For the theorists undertaking projects requiring access or linkage to state-wide data collections owned or managed by NSW Health or the Cancer Institute NSW they must be reviewed by the NSW Population and Health Services Research HREC (NSW PHSREC). This group covers data collections owned or managed by the NSW Ministry of Health as well as Cancer Institute NSW.

Examples of data collections owned by the NSW Ministry of Health include:

- NSW Admitted Patient Data Collection
- Perinatal Data Collection
- NSW Emergency Department Data

Examples of data collections owned by the Cancer Institute NSW include:

- NSW Central Cancer Registry
- NSW Pap Test Registry
- Breast Screen Registry

This group meet more regularly (monthly) and submission closes 9 working days prior to the next meeting which is more reasonable than many HRECs. They review submissions for both cancer and non-cancer research and are accredited as a lead HREC for single ethical review of multi-site research. These guys are so nice they will even review a mixed methods research project where only a component of the research involves utilising and/or linking routinely collected health data. Unfortunately, the NSW PHSREC is not accredited to review clinical trials so you will still need to submit an application to the relevant local HREC as well if your research involves more than simply using existing data.

You will of course have to submit a SSA to the local Research Governance Officer (RGO) for any research carried out in a Public Health Organisation. Contact the RGO as soon as possible to get explicit advice as it would be extremely frustrating if that was a cause for delay.

Don’t Skip this step!
You will need to have your research proposal reviewed by the relevant Data Custodian BEFORE applying to the NSW PHSREC. This is a simple one-page form, which should in theory be fairly straightforward. A list of NSW data custodians is available here:


All the details and requirements of the NSW PHSREC can be found on the Cancer Institute website which is uncommonly easy to navigate and up-to-date. Submission guidelines, checklists, required forms (including the Data Custodian Sign Off form) and contacts can all be found on one marvelous page - its almost as if they want people to do research. You can find more information here:


Key Point: research involving access to NSW data collections will require sign-off by the relevant Data Custodian and submission to the NSW Population and Health Services Research HREC

Research involving Aboriginal people

If your research is related to the health and well-being of Aboriginal people and communities you will need to seek ethics approval from the Aboriginal Health and Medical Research Council (AH&MRC) HREC in addition to your local HREC. Here’s where the timing can get a bit tricky - the AH&MRC will
accept applications before you have applied to your local HREC but some local HRECs require a copy of the AH&MRC ethics approval before they will consider an application for research involving Indigenous participants. Again, it is best to ask what your local HREC requires before spending hours deciphering the application forms. Don’t get caught out by the infrequent meeting dates though – the AH&MRC HREC meets only every 2 months!

The AH&MRC Ethics Committee Secretariat can be contacted for advice on Phone: (02)9212 4777

Guidelines and requirements for submission to the AH&MRC Ethics Committee are essential reading and can be found here:


And a step-by-step breakdown of the application process can be found here:


Key Point: research involving Aboriginal people will require an application to the Aboriginal Health and Medical Research Council (AH&MRC) HREC in addition to your local HREC.
Applying for approval in NSW

So can I start my application now?

Firstly, congratulations on making it this far! Just to make sure you haven’t skipped anything here are the steps you must complete prior to starting your application summerised in the box below.

Pre-Submission

- Develop proposal
- Obtain support for the project from Supervisor/Dept Head
- Determine level of risk to participants
- Discuss the project with HREC Executive Officer and Research Governance Officer(s)
- Determine whether the project has specific review requirements in addition to review by local HREC (eg research involving Aboriginal people or communities, those unable to give consent, accessing state-wide data collections)

Once you have completed the steps above and have sobered up from your pre-submission celebratory bender you would do well to start familiarising yourself with the application website. All applications for ethical and scientific review and site authorisation of research taking place within the NSW public health system must be submitted through the Online Forms Website.

www.ethicsforms.org/au

The Online Forms Website

When registering to use the Online Forms website (www.ethicsforms.org/au) you will be asked to supply your email which will become your user login. This email address will be sent to the HREC and any supervisor or head of department required to sign off on your application so its probably best to use your Unimail address as opposed to your thinly-veiled-innuendo novelty email account. There is also a rather cumbersome system of electronic signatures. Anyone who must sign off of the submission must also create an account in order view and authorise your application. Any changes made to the application including attached supporting documentation nullifies previous authorisation and you must complete the process again. This can be extremely time consuming so make sure your application is completed in full and all supporting documentation uploaded before submitting an electronic signature request.

In addition to applications being submitted electronically applications must also be submitted in hard copy (with signatures and supporting documents) to:

- the HREC Executive Officer (for HREC review)
- the Research Governance Officer (for site authorization (SSA))

Navigating and using the Online Forms website is considerably easier if you know what you’re doing ahead of time. The “Getting Started” section, whilst helpful, assumes you are already familiar with the application forms and focuses more on navigating around the site.

There are several different form options on the website so it is important to be clear before you begin the application process if your research is multi or single centre, low or negligible risk, or only requires access to participants, their tissue or data via a NSW Public Health Organisation. Below is a brief description of the relevant forms10:
NEAF: National Ethics Application Form (applications for ethical and scientific review in which the risk to participants is more serious than discomfort).

LNR Application Form: Application Form for Ethical and Scientific Review of Low and Negligible Risk Research.

SSA Form: Site Specific Assessment Form (for research in which the risk to participants is more serious than discomfort).

LNR SSA Form: Site Specific Assessment Form for Ethical and Scientific Review of Low and Negligible Risk Research.

Access Request Form: for research projects which only require access to participants, their tissue or data through a NSW Public Health Organisation and does not involve conducting research at any facilities, locations or services under the control of that Public Health Organisation. (Note that a new form must be completed for each Public Health Organisation involved but not for each individual location).

The Guidance section of the Online Forms website provides a matrix summarised below to help determine which forms you may need to submit:

<table>
<thead>
<tr>
<th>Research conducted at a NSW Public Health Organisation</th>
<th>Research involving more than low risk</th>
<th>Low and Negligible risk research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• NEAF&lt;br&gt;• SSA Form</td>
<td></td>
<td>• LNR Application Form&lt;br&gt;• LNR SSA Form</td>
</tr>
<tr>
<td>Research which only involves access to participants, their tissue or data through a NSW Public Health Organisation</td>
<td>• NEAF&lt;br&gt;• Access Request Form</td>
<td>• LNR Application Form&lt;br&gt;• Access Request Form</td>
</tr>
</tbody>
</table>

It is important to reiterate that a SSA Form is required for each site at which the research will be conducted (a site may be a facility, location or service).

STOP! By this point you should have already confirmed what additional documentation the HREC you will be applying to requires. Most require a research protocol and other documentation such as recruitment and enrollment letters and specify that you must use their templates. There is often considerable overlap between the NEAF or LNR Application Form, SSA Forms and the additional documentation required by the local HREC. You will also be required to submit certain documentation such as participant information and consent forms via the Online Forms website. Most HRECs insist you use their templates for the participant information and consent forms. The SSA, NEAF or LNR application forms will be much easier to navigate through if you have already created a clear protocol document which contains the prescribed language as found in many provided HREC templates.

Once you are satisfied with your online application and have gathered the necessary electronic authorisation from the various department heads and supervisors, locked your form and generated a submission code you get to print it all off and repeat the process in hardcopy! Happy days. Note that any changes made, even to uploaded supporting documents, voids the electronic authorisation and you will have to get everyone to sign-off again.

Documentation ad infinitum

Below is an example of the type of supporting documentation which may be required for a typical LNR application. As has been repeatedly stressed throughout this guide – you must confirm with the local/lead HREC exactly which documentation they require specifically. Be prepared to have to submit
copies both electronically and in hardcopy. Hardcopies usually have to be originals, signed by all involved such as student investigators, supervisors and heads of departments and occasionally in multiples (up to 12 copies for some HRECs).

- LNR Application form – as found on the Online Forms website
- LNR SSA form
- Study protocol – often based on a supplied template
- Participant Information Sheet and Consent forms – often based on a supplied template
- All documents to be used in the study – e.g. questionnaires, recruitment flyers, letters of invitation, telephone scripts etc.
- Cover letter
- Researcher CVs
- Method of payment form

As you can imagine – this list is considerably longer for a full ethical and scientific review, particularly if it is a sponsored study or involves intervention under the purview of the Therapeutic Goods Administration.

**LNR Application Form**

Frustratingly, you cannot easily navigate to subsequent pages on the online form without having entered the required fields first (you can go back though). Below is a brief overview of the online LNR application form to give you an idea of the sort of information you’ll need.

This particular online form is to be completed by the Co-ordinating Investigator with sections including;

1. Project Title and Type
2. Research Personnel
3 – 4. Project Summary Information
5. Project Detailed Information
6. Consent
7. Data, Privacy, Storage and Security
8. Declaration by Investigators
9. Declaration by Head of Department

There is a bit of a clue here in that the very first check box on the form asks you to confirm that you have read the online guidance section and have discussed the project with an HREC Executive Officer. You will also need to indicate if your research is a “single-centre” or “multi-centre” project and if it is low or negligible risk – it is at this point you should be really grateful you have done your homework! (see page 8).

The project title section should be fairly self explanatory (if not, then perhaps you had better head back to the drawing board) as is the personnel section. Do note, however, you will be asked if the Co-ordinating Supervisor is a student and if so to complete your supervisors details. The catch is, if it is a multi-centre project you must nominate a supervisor for each site. If it is a single-centre project then the Co-ordinating Investigator and the Principal Investigator will be the same person (with one supervisor).

The Project Summary section involves questions about whether the project has undergone previous ethical review or peer review – bear in mind that you must provide documentation so if you have picked up a previously approved project be sure to get all the details from your supervisor first. You will also need to have details of any funding, conflict of interest issues and details on how you plan to disseminate your results.
The Project Details and Consent sections include things like research aims and methodology, potential risks and benefits and informed consent. Here there is considerable overlap with most of the protocol templates so be sure to have yours on hand for some cheeky copy-paste action.

Section 7 on Data, Privacy, Storage and Security is actually quite involved and can throw young players if you are not prepared. Although this should also be covered in your project protocol there are a few detailed questions such as how you will secure your stored data, the duration of storage and how you will destroy it that must comply with the relevant institution’s guidelines. If you haven’t already done so you need to look at Section 2 of this document:


Section 2.1.1 indicates that

*In general, the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:*

- for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient

Obviously you must confirm with your relevant institution what the specific policy on data management is but the Australian code for the Responsible conduct of Research is a good place to start if you are floundering.

**National Ethics Application Form (NEAF)**

In addition to the sections included on the LNR application this long form (in excess of 60 pages!) has many more probing questions regarding things like funding, risk to participants, the type of participants involved, recruitment, data/information ownership and so forth. There is also a series of detailed questions which are project specific and deal with aspects such as ionizing radiation, use of human embryos/gametes, stem cells, clinical research and novel interventions. It is unlikely that a student project will require a NEAF but if you do find yourself involved in such research then perhaps you should be asking whether you are the most appropriate person to be the Co-ordinating Investigator.

**LNR SSA Form**

The sections in the LNR SSA form will look very familiar to the LNR application form so get ready more copy-paste action. Remember that the SSA form goes to the Research Governance Officer, not the HREC Executive Officer so you do have answer each question again in full.

1. Project Title
2 – 3. HREC, Governance Jurisdiction & Site
4 – 5. Project Summary & Duration
6. Research Personnel
7. Departments & Services
8. Research Participants
9. Budget & Funding
10. Declaration by Investigators
11. Declaration by Head of Department
12. Declaration by Head of Supporting Department
13. Declaration by Nominated Authority for Data Provision
14. Declaration by RGO

There aren’t too many surprises here as it really covers the logistical side of things rather than ethical aspects. You will need to be clear on whether a supporting department is involved and what their role is in addition to getting the okay from the Head of the Department in which your research will be undertaken (sections 7, 11 & 12).

Don’t get caught out...Tracking is your friend

Hopefully this is a bit of a no-brainer for most but for those haven’t experienced the unparalleled joy of working on process documentation before you must...

No excuses, you MUST keep an accurate version control of all of your documentation. There are several ways of doing so, the least technical of which simply renaming the document with the version number in the title every time you open it to work on it.

Microsoft Word® and Word for Mac® have a “Track Changes” button in the “Review” tool bar which simplifies things greatly. Using this feature also allows you easily toggle between showing the review markup and hiding it which is handy when submitting a “clean” (no markup) and “tracked” (markup shown) versions.

More information on Microsoft Word® version control can be found here:


Apple iWork® similarly has a Track Changes feature but Apache OpenOffice™ is a little more complex when it comes to version control. Users familiar with the open source software, however, should find these instructions fairly straightforward:


If you are unsure of how to go about keeping accurate version records and producing tracked and clean copies of a document then you should seek advice as soon as possible - the medical library is a good place to start.
Paying for an ethics review – is that ethical?

The National Statement indicates that institutions which establish a HREC should adequately resource and maintain them and that the resources should be sufficient to enable the HREC to *not charge fees where doing so would discourage research the institution has an obligation to support*. HRECs in NSW charge a centrally determined fee for ethical and scientific review of commercially sponsored research. Individual HRECs determine the fee for non-commercially sponsored projects. Most embrace the spirit of the National Statement and charge only a nominal (or no) fee for student projects. Be warned, however, some HRECs may withhold a letter a approval until the fee is received so be sure to have your credit card ready.

“This sst! Can I run your ethics committee?”

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On Second Thoughts...

Amending an Approved Project

Generally, just about any change to a project will require formal approval prior to implementation. The only exception seems to be corrections to typos or amendments to contact details which won’t affect the version number or date of the study documents. Anything and everything else which might affect any of the aspects below requires an amendment application to the approving HREC:

- The rights, safety and welfare of the participants of the research;
- The scientific value of the research;
- The conductor management of the research;
- The monitoring requirements; or
- The quality or safety of any investigational medicinal product/device used in the research

NSW Health stipulates that a signed request for an amendment will include a brief description and rationale of the changes and implications for the ongoing project. Most HRECs have produced an Amendment Application Form that covers the requirements succinctly. Don’t overlook the technical specifications - electronic and hardcopies in both tracked and clean versions.

When the HREC receives an amendment application they initially review it to determine if it needs to be referred for a full HREC review. In some instances such as a change in the primary objective the HREC may reject the amendment application and request a new application for ethical review be submitted. Alternatively, a modification suggestion or request for more information will be issued by the reviewing HREC.

Changes in Personnel or Sites

You must notify your local/lead HREC and RGO if there are any changes to the Co-ordinating Investigator or a Principal Investigator at a site. Again most HRECs have simplified the process by producing a form template and that along with the new guy’s CV is usually sufficient.

Changes to site/s are a little more tricky. If a single centre research project needs to become a multi-centre project it the degree of difficulty largely depends on whether the reviewing HREC was a lead HREC or not. If the original reviewing HREC is a lead HREC then it may review the new proposed sites. If the original HREC was not a lead HREC then a whole new application must be made to the relevant lead HREC. Generally, copies of correspondence with the original local HREC are included in the new application and the project may continue at the original site whilst the new application including more sites is considered.

Adding more sites to an already approved multi-centre project is more straightforward. The Co-ordinating investigator is responsible for applying in writing to the lead HREC that approved the original submission whilst the Principal Investigator at the additional site is responsible for submitting the SSA application to the Research Governance Officer.

Keeping Tabs

Annual Progress and Final Reports

The NHMRC likes to keep tabs on all registered HRECs to make sure they’re fulfilling their obligations and appropriately monitoring all research undertaken in their jurisdiction. In turn, your HREC need to know what you’re up to so brace yourself for more forms. Submission of annual reports is a condition
of approval and they are due every year on the date the study was approved until the study is completed. Each HREC produces its own form or template but generally they all include the following:

- Project details
- Progress/delays/need for extension
- Compliance
- Serious Adverse Events
- Monitoring/audit
- Insurance claims

Once your project is completed you will need to submit a Final Report which is typically the same form as an annual progress report with an extra section at the end. “Completion” in this sense means that the results have been published or presented or that data analysis has been finished and you can provide a “lay summary of findings.” Be prepared with an explanation if you have no plans for publication.

Once again you will be required to submit everything in multiple hard and soft copies along with 3 camels and your first born child to your local HREC and research governance office.

**Key Point:** Submission of annual reports is a condition of approval and they are due every year on the date the study was approved until the study is completed.

---

**Pitfalls and Echo Chambers**

There are a few common pitfalls and hurdles which students seem to come up against time and time again. Some are avoidable, some inevitable, but all are soul-crushingly frustrating. Here are a few hints to help ease the way—

*In cyber space nobody can hear you caps lock...*

One common complaint from students is a lack of timely response to email. It is extremely difficult for a student to jump up and down and demand a response from higher up the pecking order. The echo chamber that a series of unanswered emails creates can become overwhelming when you are up against the clock. Fear not—just need to go a little old school.

- **Pick up the phone and call.** In all likelihood you probably won’t get to speak to the head honcho you need to but leave a detailed message with your phone number and politely asked to be called back. Your request may still go unheeded but it is more likely to cross their radar than a skimmed email languishing in an inbox.

- **Schedule a little face-time.** Here you must be a little flexible and if it means a 6:30am meeting before rounds then it’s a case of sucking it up and ordering a double-shot latte. Decisions can be reached quickly with no back and forth lag time, you can suss each other out and avoid misunderstandings and you’ve shown you are serious about the matter in hand. Be punctual, dress well, shave or at least brush the brioche crumbs out of your hipstertastic beard and offer a firm handshake. Boom—you’re a person and far more likely to get a favourable reply than an anonymous eight letter-numeral combination email address.

- **EAs are your best friends.** Executive assistants are not only the gate keepers but they have considerable power when it comes to signing off on all things administrative. The current system of online application involves a tedious electronic authorisation process (see the [Online Forms Website](#) section) which requires any and every change, no matter how minute, to be authorised by all listed on the form. As the final submission requires hardcopies with original signatures many EAs are able to facilitate the electronic authorisation to enable you to lock and print the necessary forms—a huge time saver in terms of turnaround. They are also very good at putting things under noses or moving things to the top of pile so it is definitely worth getting to know them.
• **Plan ahead.** As in months ahead. The ideal situation is one where you are submitting your ethics application several months before you plan to commence your project. Even if you are only mulling over the possibility of doing a project start your literature review now and have everything in place ready to go as soon as you get the all clear. Have a reminder system in place for important dates, if you know you exams coming up and won’t be able to spend hours filling out forms have your drafts ready to go. Medical students by default tend to be fairly reasonable at time management but you will have to become an expert.

I’d like to thank the Academy...

If you’re one of the persistent few who successfully applies for and gains ethics approval don’t be surprised if you find yourself practicing your acceptance speech in front of the bathroom mirror. It really is a considerable achievement and frankly the lack of statuettes and black-tie awards ceremony is a massive oversight. The experience itself, however, is extremely valuable and certainly any investigator-initiated research you have undertaken is worthy of a line or two in your curriculum vitae. Research experience becomes even more important when you are a resident trying to get on to a competitive training program which may seem light years away now but will be here before you know it.

The advantage of undertaking a research project as a student is that you have access to an absolute goldmine of knowledge and experience at your fingertips. People in the employ of a university are generally there because they have an interest in teaching and fostering a love of academia and inquiry in aspiring neophytes (it certainly isn’t the pay). Be proactive, seek out expertise, ask for help and make the most of an exceptional opportunity to pursue your interests. If you hit a road block there is almost certainly another way around it but you’ll probably have to stop to ask for directions first.

So good luck, keep swearing to a minimum and remember you can always become a pharmaceutical rep if the whole medicine thing doesn’t work out!
## Appendix 1: The Who’s Who of Ethical Review

### Table 1: Contact Details of likely relevance to SMP students

<table>
<thead>
<tr>
<th>Organisation</th>
<th>HREC</th>
<th>Code</th>
<th>Website</th>
<th>Address</th>
<th>Lead HREC</th>
<th>Research Governance Officer Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aboriginal Health and Medical Research Council</td>
<td>Aboriginal Health and Medical Research Council HREC</td>
<td>EC00342</td>
<td><a href="http://www.ahmrc.org.au/index.php?option=com_content&amp;view=article&amp;id=127:ethics-committee-further-information&amp;catid=3:what-we-do">http://www.ahmrc.org.au/index.php?option=com_content&amp;view=article&amp;id=127:ethics-committee-further-information&amp;catid=3:what-we-do</a></td>
<td>Phone: (02)9212 4777 <a href="mailto:ethics@ahmrc.org.au">ethics@ahmrc.org.au</a></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Adventist HealthCare Limited</td>
<td>Adventist HealthCare Ltd Human Research Ethics Committee</td>
<td>EC00141</td>
<td><a href="http://www.sah.org.au/ahcl-ethics-committee">http://www.sah.org.au/ahcl-ethics-committee</a></td>
<td>Research Governance &amp; Ethics Officer Adventist HealthCare Limited 185 Fox Valley Road WAHROONGA NSW 2076</td>
<td>Jenelle Quick Research Governance &amp; Ethics Officer Adventist HealthCare Limited 185 Fox Valley Road Wahroonga NSW 2076 Australia M +61 417 042 300 P +61 2 9487 9604 F +61 2 9487 9615 E <a href="mailto:jenelleq@sah.org.au">jenelleq@sah.org.au</a></td>
<td></td>
</tr>
<tr>
<td>Cancer Institute NSW</td>
<td>NSW Population and Health Services Research HREC</td>
<td>EC00410</td>
<td><a href="http://www.cancerinstitute.org.au/research-grants-and-funding/ethics/nsw-population-health-services-research-ethics-committee">http://www.cancerinstitute.org.au/research-grants-and-funding/ethics/nsw-population-health-services-research-ethics-committee</a></td>
<td>Ethics Coordinator Cancer Institute NSW PO Box 41 Alexandria NSW 1435</td>
<td>Yes N/A</td>
<td></td>
</tr>
<tr>
<td>Greater Western Area Health Service</td>
<td>Greater Western Human Research Ethics Committee</td>
<td>EC00399</td>
<td><a href="http://www.healthinfonet.ecu.edu.au/key-resources/organisations?oid=784">http://www.healthinfonet.ecu.edu.au/key-resources/organisations?oid=784</a></td>
<td>c/o: Ethics and Research Governance Officer Western NSW Local Health District PO Box 143 BATHURST NSW 2795</td>
<td>Yes Ma Suzanne Degiorgio A/Senior Administration Officer T: 02 6339 5601 F: 02 6339 5606 E: <a href="mailto:Suzanne.degiorgio@gwahs.health.nsw.gov.au">Suzanne.degiorgio@gwahs.health.nsw.gov.au</a></td>
<td></td>
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<tr>
<td>Nepean Blue Mountains Local Health District</td>
<td>Nepean Blue Mountains Local Health District</td>
<td>EC00151</td>
<td><a href="http://hrep.nhmrc.gov.au/hrec/nepean-blue-mountains-local-health-district-human-research-ethics-committee">http://hrep.nhmrc.gov.au/hrec/nepean-blue-mountains-local-health-district-human-research-ethics-committee</a></td>
<td>Research Office Ground Floor Court Building PO Box 63 PENRITH NSW 2751</td>
<td>Yes Ma Yasoda Sathiyaseelan Research Governance Officer Nepean Blue Mountains Local Health District Executive Unit Nepean Hospital (PO Box 63) PENRITH NSW 2751 T: 02 4734 1998 E: <a href="mailto:yasoda.sathiyaseelan@swahs.health.nsw.gov.au">yasoda.sathiyaseelan@swahs.health.nsw.gov.au</a></td>
<td></td>
</tr>
<tr>
<td>North Shore Private Hospital</td>
<td>North Shore Private Ethics Committee</td>
<td>EC00443</td>
<td><a href="http://www.northshoreprivate.com.au/Our-Doctors/ethics-committee.aspx">http://www.northshoreprivate.com.au/Our-Doctors/ethics-committee.aspx</a></td>
<td>North Shore Private Hospital Ethics Committee Executive Suite North Shore Private Hospital 3, Westbourne St ST LEONARDS NSW 2065</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>NSW Justice Health and Forensic Mental Health Network</td>
<td>NSW Justice Health Human Research and Ethics Committee</td>
<td>EC00119</td>
<td><a href="http://www.justicehealth.nsw.gov.au/research/justice-health-human-research-and-ethics-committee-hrec">http://www.justicehealth.nsw.gov.au/research/justice-health-human-research-and-ethics-committee-hrec</a></td>
<td>Galia Guirguis Executive Officer PO Box 150 Matraville NSW 2036 P: (02) 9344 4151 E: <a href="mailto:chrc@justicehealth.nsw.gov.au">chrc@justicehealth.nsw.gov.au</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sydney South West Area Health Service (RPA)</td>
<td>SLHN Ethics Review Committee (RPA Zone)</td>
<td>EC00113</td>
<td><a href="http://www.cs.nsw.gov.au/rpa/research">http://www.cs.nsw.gov.au/rpa/research</a></td>
<td>C1: Research Development Office Level 3, Building 92 Royal Prince Alfred Hospital Missenden Road CAMPERDOWN NSW 2050 Yes</td>
<td>Ms Lesley Townsend Research Development Office Suite 210A RPAH Medical Centre 100 Carlton Avenue NEWTOWN NSW 2042 T: 02 9515 6766 F: 02 9515 7176 E: <a href="mailto:lesley.townsend@sswahs.nsw.gov.au">lesley.townsend@sswahs.nsw.gov.au</a> Alternative contact: Ms Maree Larkin T: 02 9515 7899 F: 02 9515 7176 E: <a href="mailto:maree.larkin@sswahs.nsw.gov.au">maree.larkin@sswahs.nsw.gov.au</a></td>
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<tr>
<td>Sydney South West Area Health Service</td>
<td>SLHN Human Research Ethics Committee</td>
<td>EC00118</td>
<td><a href="http://www.cs.nsw.gov.au/concord/Ethics/default.htm">http://www.cs.nsw.gov.au/concord/Ethics/default.htm</a></td>
<td>Research Office Level 1 Building 75 Concord Repatriation General Hospital Hospital Road CONCORD NSW 2139 Yes</td>
<td>Ma Virginia Turner Research Office Level 1, Building 75 Concord Repatriation General Hospital CONCORD NSW 2139 T: 02 9767 5622 F: 02 9767 6569 E: <a href="mailto:ethicscrgh@email.cs.nsw.gov.au">ethicscrgh@email.cs.nsw.gov.au</a></td>
<td></td>
</tr>
<tr>
<td>The Sydney Children's Hospitals Network (Randwick and Westmead)</td>
<td>Sydney Children's Hospitals Network Human Research Ethics Committee</td>
<td>EC00130</td>
<td><a href="http://www.chw.edu.au/research/ethics/">http://www.chw.edu.au/research/ethics/</a></td>
<td>The Children's Hospital at Westmead Research &amp; Development Office Level 2, Kerry Packer Building Corner Hawkesbury Rd &amp; Hainsworth St, WESTMEAD NSW 2145 Yes</td>
<td>Ms Carolyn Casey Research Governance Manager Research Office, Clinical Sciences Building The Children's Hospital at Westmead Locked Bag 4001 WESTMEAD NSW 2125 T: 02 9845 1272 E: <a href="mailto:governance.schn@health.nsw.gov.au">governance.schn@health.nsw.gov.au</a> Ms Sabine Giesebrecht Research Governance Officer T: 02 9845 3084 E: <a href="mailto:sabine.giesebrecht@health.nsw.gov.au">sabine.giesebrecht@health.nsw.gov.au</a> Ms Asatina Viviani Research Governance Officer T: 02 9845 3029 E: <a href="mailto:asatina.viviani@health.nsw.gov.au">asatina.viviani@health.nsw.gov.au</a></td>
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<tr>
<td>Western Sydney Local Health District</td>
<td>Western Sydney Local Health District Human Research Ethics Committee</td>
<td>EC00152</td>
<td><a href="http://www.wslhd.health.nsw.gov.au/Research---Patient-Safety/Human-Research-Ethics">http://www.wslhd.health.nsw.gov.au/Research---Patient-Safety/Human-Research-Ethics</a></td>
<td>Research Office Room 1072 Education Block Level 1 Westmead Hospital Cnr Hawkesbury &amp; Darcy Roads WESTMEAD YES</td>
<td>Ms Margaret Piper Westmead Hospital Rm 1072, Level 1, Education Block WESTMEAD NSW 2145 T: 02 9845 9634</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2: The Ethics Cheat Sheet (FAQ)

Do I even need ethics approval, its not like I’m trialing a cancer drug!
Yes, you need ethics approval. Even if your supervisor says you don’t – you probably still do. You need to contact your local Human Research Ethics Committee to get written confirmation that you do not need ethics approval to cover yourself.

I’m not starting my project until next year, when do I need to start the application process?
Now. Ethics approval takes a really long time so start as soon as possible. People are not exaggerating when they say it took 18 months to get ethics approval.

What’s an HREC?
Human Research Ethics Committee – this is a committee established by an institution to assess proposed research in the context of participant rights, welfare, and dignity in a process of formal ethical and scientific review.

How do I find my local HREC?
Contact the Research Officer at the institution in which you hope to undertake your research project. If you can’t find the information internally a list of HRECs registered with the NHMRC can be found here:

Someone said I might be able to get an expedited review for Low or Negligible risk – what’s that?
Most (but not all) HRECs offer a process for expedited review of low or negligible risk research. Theoretically it means less paperwork and a faster turnaround. The reality is it still takes a really long time and involves lots of paperwork (but it is better than a full review). You must confirm with your local HREC that your project satisfies the definition of “low or negligible risk”.

So I just get ethics approval and I can start, right?
Nope. Before you begin your project you need 2 things:
1. Ethics approval
2. Site Specific Assessment (SSA) (also known as a “research governance review”)

What’s an SSA?
Site Specific Assessment (SSA) is undertaken by a Research Governance Officer (RGO) and assesses whether a particular project is appropriate for that institution. This assessment looks at aspects such as funding, resources and regulations. This goes hand in hand with the ethics review performed by the HREC. You cannot begin without ethics approval from your local HREC and SSA approval from the RGO.

Sydney Uni has a HREC – can’t I apply to them?
No need. Research undertaken in a public health organisation must have ethics approval from the local/lead HREC. If the approving HREC is registered with the NHMRC (as most hospital HRECs are) then Sydney University does not require an application to the university HREC. You don’t even need to let the uni HREC know you have ethics approval from a NHMRC registered HREC. Happy days.

My project spans more than one site – is this considered multi-centred research?
Multi-centre research means the project is conducted at more than one site where those sites are within the jurisdiction of more than one NSW Health HREC. Don’t sweat – you still only need one ethics application but it must go to a “Lead HREC” accredited to conduct review of multi-centre research. You will need to get SSA approval for each site involved, but you should be able to foist that job off to the Principal Investigator for each site.

Do I have to pay for an ethics review?
Generally yes – but HRECs tend to charge investigator-initiated and student research only a nominal (or no) fee.
Which participants/data require special consideration when it comes to research in NSW?
People in a “correctional environment” (people in custody as well as those employed by the Justice & Forensic Mental Health Network), aboriginal people or communities and data collections owned or maintained by NSW Health. You will need to contact special HRECs to undertake research concerning these groups.

My research involves aboriginal participants – are there any special rules?
Yes. You will need to seek ethics approval from the Aboriginal Health and Medical Research Council (AH&MRC) HREC in addition to your local HREC. More information can be found here: www.ahmrc.org.au/ethics2.php

I just want to re-examine data owned by NSW Health – surely I don’t need ethics approval for that?
Oh yes you do. Access or linkage to state-wide data collections owned or managed by NSW Health or the Cancer Institute NSW must be reviewed by the NSW Population and Health Services Research HREC (NSW PHSREC). What’s more, you will need to have your research proposal reviewed by the relevant Data Custodian BEFORE applying to the NSW PHSREC. More info here: www.cancerinstitute.org.au/research-grants-and-funding/ethics/nsw-population-health-services-research-ethics-committee

I’ve been told I must reference the “National Statement” in my application – what’s that?
The National Statement on Ethical Conduct in Human Research is a series of guidelines regarding research governance put out by the National Health and Medical Research Council (NHMRC). It is essential reading when applying for ethics approval. You can find it here: www.nhmrc.gov.au/guidelines/publications/e72

Can I apply for ethics approval/SSA online?
Yes – in part. In fact you must use the online form to apply in NSW. You will also need to supply copious amounts of supporting documentation and soft and hardcopies of your forms to your local HREC as well. The online forms can be found here: www.ethicsforms.org/au

Where do I find information Australian standards for research?
The Australian Code for the Responsible Conduct of Research is the framework upon which individual institutions must base their policies for research conduct. You can find the code here: www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39.pdf

What’s an annual report and why do I have to do one?
Submission of an annual report is a condition of approval and are due every year on the date the study was approved until the study is completed.
Appendix 3: Project Approval Flowchart

1. Develop Proposal
2. Obtain support for project from Supervisor/Dept Head & SMP Research Office/Honours Coordinator
3. Determine level of risk to participants
4. Discuss with HREC/RGO
5. Determine if additional review requirements (indigenous participants, access to state databanks etc)
6. Discuss with Speciality HREC
7. Low & Neglibile Risk Research
   - Expedited HREC review (LNR application)
   - Site authorisation (SSA LNR application and/or Site Access form) by RGO
   - HREC Approval
   - Chief exec/delegate approval
8. Research involving more than Low Risk
   - Full HREC review (NEAF)
   - Site authorisation (SSA application and/or Access Request form)
   - HREC Approval
   - Chief exec/delegate approval
9. Project Commencement (pending approving from SMP Evaluations Unit or USYD HREC as appropriate)
### Appendix 4: Glossary and List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>AU RED</td>
<td>Australian Research Ethics Database</td>
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<tr>
<td>AH&amp;MRC</td>
<td>Aboriginal Health and Medical Research Council</td>
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<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>Co-ordinating Investigator</td>
<td>The individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. For single-centre research this is the same person as the Principal Investigator</td>
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<tr>
<td>Lead HREC</td>
<td>HREC accredited to conduct the ethical and scientific review of multi-centre research</td>
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<td>LNR</td>
<td>Low and Negligible Risk research</td>
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<td>Local HREC</td>
<td>A HREC associated with the research site which can grant ethics approval for research at that site only</td>
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<tr>
<td>Low risk research</td>
<td>Research in which the only the only foreseeable risk is one of discomfort</td>
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<td>Multi-centre research</td>
<td>Research that is conducted at more than one site within the NSW public health system, where those sites are within the jurisdiction of more than one NSW Health HREC</td>
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<td>National Statement</td>
<td>National Statement on Ethical Conduct in Human Research 2007 (Updated December 2013). The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors’ Committee. Commonwealth of Australia, Canberra</td>
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<td>NEAF</td>
<td>National Ethics Application Form</td>
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<td>Negligible risk research</td>
<td>Research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NSW PHSREC</td>
<td>New South Wales Population and Health Services Research Ethics Committee</td>
</tr>
<tr>
<td>OH&amp;S</td>
<td>Occupational Health and Safety</td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>The individual responsible for research conducted at a site and submits the research project for site authorisation</td>
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<td>SAE</td>
<td>Serious Adverse Event</td>
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<td>SSA</td>
<td>Site Specific Form</td>
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References


5. Harris, S. “That’s it, in a nutshell”. Digital image 2482x2033 pixels (unwatermarked).


17 National Statement on Ethical Conduct in Human Research 2007 (Updated December 2013). 5.1.26 Establishment of HRECs. The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors’ Committee. Commonwealth of Australia, Canberra.


19 Grizelda. “Pssst! Can I run your ethics committee?” Digital image 1419x1811 pixels (unwatermarked).

