Where to Start

Human Research Ethics

Two-step Approval Process

Research being undertaken within a NSW Public Health Organisation (PHO) requires a two-step approval process, it requires a researcher to obtain both Human Research Ethics Committee (HREC) and Research Governance approval before it can commence.

What is HREC review?

The HREC will undertake an ethical and scientific review of the project and if approved will deem the project ethically and scientifically valid.

What is Research Governance?

Research Governance is a process whereby an institution determines whether their organisation or sites within that organisation have the resources or capacity to undertake a given project. This involves reviewing the appropriate Research Governance application HREC approved documentation, site specific documents, study budget, Clinical Trial Research Agreements (CTRA) (if applicable) and most importantly the insurance and indemnity arrangements. It also involves ensuring there is an appropriate monitoring framework in place for the conduct of research and ensuring there are the appropriate policies and procedures to support this.

The Research Governance review is really a risk assessment to ascertain whether research can be undertaken at a given site.

CCLHD & Ethical Review

CCLHD does not have a local or internal Lead NSW Human Research Ethics Committee (HREC) however CCLHD researchers and external researchers wishing to conduct research at a CCLHD site can chose to have their project/s reviewed by any of the current 17 NSW Lead HRECs (http://www.health.nsw.gov.au/ethics/Pages/contacts_hrecs.aspx) , or if conducting a multi-centre clinical trial one of the participating mutual acceptance states accredited HRECs (http://www.health.nsw.gov.au/ethics/Pages/mutual-acceptance.aspx).

Prior to commencing a research project it is important to determine what type of application is applicable. There are two types of ethics applications reviewable under the NSW system for single ethical review:

1. Low/Negligible Risk Research

2. National Ethics Application Form

Research projects which satisfy the classification of being a Multi Centre Low or Negligible Risk Research can be submitted on the NSW Health Low/Negligible Risk Research (LNR) Form and undergo an expedited review process when submitted to a Lead NSW Human Research Ethics Committee (HREC).

Research projects which are classified as requiring full Human Research Ethics Committee (HREC) review must be submitted on the National Ethics Application Form (NEAF) and undergo full Committee review.

Low/Negligible Risk Research

The National Statement on Ethical Conduct in Human Research (2007) (http://www.nhmrc.gov.au/guidelines/publications/e72) describes research as "low risk" where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

The National Statement on Ethical Conduct in Human Research (2007) (http://www.nhmrc.gov.au/guidelines/publications/e72 describes research as "negligible risk" where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

How to Apply

The form to complete for Low/Negligible Risk (LNR) Research Applications can be accessed through the Online Forms Website at: https://ethicsform.org/au/

You will need to create an account and wait to receive a confirmation e-mail before you can access the online system. Once you have done this please generate an LNR Research Form.

The Online Forms Website provides guidance on completing the form and supporting documents required for making an application. A copy of the form can be downloaded from the NSW Department of Health's Office of Health and Medical Research (OHMR) website:
http://www.health.nsw.gov.au/ohmr/pages/default.aspx

Any queries related to using the Online Forms Website should be directed to the help desk on:

Tel: +61 2 903 78 404 (available from 10am to 4pm AEST Mon to Fri)
E-mail: helpdesk@infonetica.net

If you are completing a **multi-centre** LNR Research Application (a project being undertaken within multiple NSW Health Local Health Districts) the completed form and supporting documents must be printed* and submitted to the Executive Officer of the Human Research Ethics Committee (HREC) that will review the application. LNR Research Applications are considered via expedited review by a Sub-Committee of the HREC usually consisting of a minimum of the Chair of the HREC and the Executive Officer; this however differs between HRECs/Institutions. Contact details for NSW HREC Executive Officers are maintained on the NSW Department of Health website at:
http://www.health.nsw.gov.au/ethics/Pages/contacts_hrecs.aspx

It is recommended that the Co-ordinating Investigator consult with the HREC Executive Officer to determine if the research project can be classified as LNR Research, before completing the form. The Executive Officer has the discretion to request that the research project is submitted for full review using the National Ethics Application Form if they consider the risk to participants to be greater than low risk. You can also discuss this with the CCLHD Research Office.

The HREC also has the discretion to request full review using the National Ethics Application Form following assessment of the application for expedited review if it considers the risk to participants to be greater than low risk.

If you are completing a **single site** LNR Research Application (a project being undertaken at one or more CCLHD sites only, with no additional sites external to CCLHD) it is recommended you contact the CCLHD Research Office for advice on the review and approval process.

In addition to the LNR Research Form an application for Site Specific Assessment is required.

***It is important to note that submission on the online system will not trigger notification in the relevant Research Office/Executive Officer's system. It is therefore recommended applicants contact the relevant person/office for specific details on the individual application requirements prior to submission.**

Research Requiring Full Ethical Review

In accordance with the National Statement on Ethical Conduct in Human Research (2007) (http://www.nhmrc.gov.au/guidelines/publications/e72) and PD2010_055 Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations (http://www0.health.nsw.gov.au/policies/pd/2010/pdf/PD2010_055.pdf), the following types of human research must be ethically and scientifically reviewed and approved by a Human Research Ethics Committee (HREC) before they take place in a NSW Public Health Organisation.

Research that involves more than low risk to participants and/or research that includes any of the following:

- Interventions and therapies, including clinical and non-clinical trials and innovations or new treatment modalities;
- Active concealment or planned deception of participants;
- Exposure of illegal activities; and
- Research specifically targeting Aboriginal or Torres Strait Islander peoples.

Research that includes any of the following, except where the project uses collections of non-identifiable data and involves only negligible risk to participants:

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

How to Apply

The National Ethics Application Form (NEAF) can be accessed through the Online Forms Website at: https://ethicsform.org/au/

The reason application is required via this portal is that it links to the IT system utilised by NSW HREC Executive Officers to manage and report on HREC applications to NSW Health. If you have already made your application via the National Health and Medical Research Council's (NHMRC) website please contact your nominated HRECs Executive Office for advice on how the form can be exported into the NSW Health system.

You will need to create an account and wait to receive a confirmation e-mail before you can access the online system. Once you have done this please generate a NEAF.

The Online Forms Website provides guidance on completing the form and supporting documents required for making an application.

Any queries related to using the Online Forms Website should be directed to the help desk on:

Tel: +61 2 903 78 404 (available from 10am to 4pm AEST Mon to Fri)
E-mail: helpdesk@infonetica.net

The completed form and supporting documents must be printed* and submitted to the Executive Officer of the HREC that will review the application. Contact details for NSW HREC Executive Officers are maintained on the NSW Department of Health website at:

http://www.health.nsw.gov.au/ethics/Pages/contacts_hrecs.aspx

It is recommended that the Co-ordinating Investigator consult with the HREC Executive Officer to determine if the research project does require full HREC review prior to completing the form. You can also discuss this with the CCLHD Research Office.

In addition to the NEAF an application for Site Specific Assessment is required.

***It is important to note that submission on the online system will not trigger notification in the relevant Research Office/Executive Officer's system. It is therefore recommended applicants contact the relevant person/office for specific details on the individual application requirements prior to submission.**

Single Ethical and Scientific Review of Multi-Centre Research within NSW
In 2007 NSW Health implemented a system of single ethical and scientific review of multi-centre research (http://www0.health.nsw.gov.au/resources/ethics/research/pdf/researchers_brochure_jun_2008.pdf), with the aim that every research project conducted within the NSW public health system is scientifically and ethically reviewed once only. The latest policy directive outlining the requirements of this initiative is PD2010_055 Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations (http://www0.health.nsw.gov.au/policies/pd/2010/pdf/PD2010_055.pdf).

Lead HRECs (http://www.health.nsw.gov.au/ethics/Pages/contacts_hrecs.aspx) are accredited to conduct a single ethical and scientific review of multi-centre research on behalf of all sites within the NSW public health system at which a research project is to be conducted, thereby eliminating the need for each local HREC to conduct its own review. Public health organisations (that is local health districts and statewide and specialist health networks) then retain the responsibility for authorising the research to be undertaken within their institutions via the Site Specific Assessment (SSA) process prior to its commencement.

Mutual Acceptance of the Ethical and Scientific Review of Interstate Multi-Centre Clinical Trials
In 2011, the NSW Ministry of Health and Queensland and Victorian Departments of Health signed a Memorandum of Understanding to introduce the Mutual Acceptance of Ethical and Scientific Review of Multi-Centre Clinical Trials (http://www.health.nsw.gov.au/ethics/Pages/mutual-acceptance.aspx) undertaken in public health organisations across the three states.
Under the Interstate Mutual Acceptance initiative, each proposal for a multi-centre clinical trial conducted across the participating states will be ethically and scientifically reviewed once only by a public health organisation HREC that has been certified by the NHMRC to review clinical trials.
On November 1st 2013 the MOU was re-negotiated in order to accommodate the other Australian jurisdictions into a National Mutual Acceptance (NMA) scheme for the review of Clinical Trials. South Australia signed the new MOU and is from this date a participating state under this model.

Research Governance

Two-step Approval Process
Research being undertaken within a NSW Public Health Organisation (PHO) requires a two-step approval process, it requires a researcher to obtain both Human Research Ethics Committee (HREC) and Research Governance approval before it can commence.

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The HREC will undertake an ethical and scientific review of the project and if approved will deem the project ethically and scientifically valid.

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Research Governance is a process whereby an institution determines whether their organisation or sites within that organisation have the resources or capacity to undertake a given project. This involves reviewing the appropriate Research Governance application, HREC approved documentation, site specific documents, study budget, Clinical Trial Research Agreements (CTRA) (if applicable) and most importantly the insurance and indemnity arrangements. It also involves ensuring there is an appropriate monitoring framework in place for the conduct of research and ensuring there are the appropriate policies and procedures to support this.
The Research Governance review is really a risk assessment to ascertain whether research can be undertaken at a given site.

CCLHD & Research Governance
CCLHD Research Office has a process for undertaking the Research Governance review of research projects prior to their commencement at a CCLHD site or associated Community Health Centre/ Service including;

Woy Woy Hospital
Gosford Hospital
Wyong Hospital
Long Jetty Hospital

The Research Governance process follows the ethical review process, with three different application options, which are dependent on the type of associated Human Research Ethics Committee (HREC) Application :

1. Site Specific Assessment (SSA) for Low/Negligible Risk Research
2. Site Specific Assessment (SSA) for National Ethics Application Form
3. Access Request

Each of the forms, like the Human Research Ethics Committee (HREC) Application must be completed on the NSW Health Online Forms Website (https://ethicsform.org/au/).

Site Specific Assessment for Low/Negligible Risk Research
Once approval has been received from a Lead NSW Health Human Research Ethics Committee (HREC) (multi-centre projects) (http://www.health.nsw.gov.au/ethics/Pages/contacts_hrecs.aspx) or CCLHD (single-site CCLHD projects) via the Low/Negligible Risk Research (LNR) Application Form an LNR Site Specific Assessment (SSA) is required. A separate application must be made for each site at which the research project is to be conducted. For example, even if the project is to be conducted at two sites under the control of a single Public Health Organisation (PHO), a separate application must be made for each site*.

This form, like the LNR Application Form, must be completed on the NSW Health Online Forms Website (https://ethicsform.org/au/). The two forms will be linked to one another in this system and once finalised will each have a unique Submission Code.

The reason application is required via this portal is that it links to the IT system utilised by NSW Research Governance Officers to manage and report on SSA applications to NSW Health.

The Online Forms Website provides guidance on completing the form and supporting documents required for making an application, however as each LHD is independently operated each site may have its own individual application requirements. Principal Investigators are therefore advised to contact the relevant Research Governance Officer and any individuals that need to provide a declaration and start to prepare an application at the earliest possible opportunity.

Any queries related to using the Online Forms Website should be directed to the help desk on:

Tel: +61 2 903 78 404 (available from 10am to 4pm AEST Mon to Fri)
E-mail: helpdesk@infonetica.net

The completed form and supporting documents must be printed** and submitted to the Research Governance Officer responsible for the site (for CCLHD please forward to the Research Manager. Contact details for Research Governance Officers and information on the facilities, locations and services covered by them are maintained on the NSW Department of Health website.

SSA authorisation must be granted at each individual Public Health Organisation (PHO) in which the research is to be undertaken and cannot commence at a given site until this process has been completed.

Please see the 'CCLHD- SSA - LNR Flowchart' to review the CCLHD process for the submission, review and authorisation of LNR SSA Applications.

The 'CCLHD - SSA - LNR- Checklist' has been drafted to assist with the submission of an LNR SSA Application Form for a CCLHD site, please use this and ensure all required documentation is supplied on submission. Completed applications for CCLHD sites should be submitted to:

CCLHD Research Office
Level 1, Health Services Building (inside the Library)
Hospital Road, Gosford Hospital
Gosford NSW 2250

***As processes vary between sites it is recommended you contact the relevant Research Governance Officer for individual submission requirements.**

****It is important to note that submission on the online system will not trigger notification in the relevant Research Governance Officer's system. It is therefore recommended applicants contact the relevant Research Governance Officer for specific details on the individual application requirements prior to submission.**

Site Specific Assessment for the National Ethics Application Form
Once approval has been received from a Lead NSW Health Human Research Ethics Committee (HREC) (http://www.health.nsw.gov.au/ethics/Pages/contacts_hrecs.aspx) or one of the participating Mutual Acceptance states accredited HRECs (if conducting a multi-centre clinical trial) (http://www.health.nsw.gov.au/ethics/Pages/mutual-acceptance.aspx) via the National Ethics Application Form (NEAF), a NEAF Site Specific Assessment (SSA) is required. A separate application must be made for each site at which the research project is to be conducted. For example, even if the project is to be conducted at two sites under the control of a single Public Health Organisation (PHO), a separate application must be made for each site*.

This form, like the NEAF, must be completed on the NSW Health Online Forms Website (https://ethicsform.org/au/). The two forms will be linked to one another in this system and once finalised will each have a unique Submission Code.

The reason application is required via this portal is that it links to the IT system utilised by NSW Research Governance Officers to manage and report on SSA applications to NSW Health.

The Online Forms Website provides guidance on completing the form and supporting documents required for making an application, however as each LHD is independently operated each site may have its own individual application requirements. Principal Investigators are therefore advised to contact the relevant Research Governance Officer and any individuals that need to provide a declaration and start to prepare an application at the earliest possible opportunity.

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SSA authorisation must be granted at each individual Public Health Organisation (PHO) in which the research is to be undertaken and cannot commence at a given site until this process has been completed.

Please see the 'CCLHD- SSA - NEAF Flowchart' to review the CCLHD process for the submission, review and authorisation of a NEAF SSA.

The 'CCLHD - SSA - NEAF- Checklist' has been drafted to assist with the submission of a NEAF SSA for a CCLHD site, please use this and ensure all required documentation is supplied on submission. Completed applications for CCLHD sites should be submitted to:

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***As processes vary between sites it is recommended you contact the relevant Research Governance Officer for individual submission requirements.**

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Access Request

An Access Request should be completed for those human research ethics applications which require support from a NSW Public Health Organisation (PHO) in the form of access to participants, tissue or data but do not involve the conduct of research at that Public Health Organisation (instead of a Low/Negligible Risk (LNR) Research or National Ethics Application Form (NEAF), Site Specific Assessment (SSA)).

For example, an Access Request should be used if the project involves one or more of the following activities at the PHO:

- Participant recruitment through posters, leaflets, handouts and letter of invitation but not recruitment through direct contact with potential participants or enrolment;
- Distribution of surveys and questionnaires through staff of the Public Health Organisation but not collation and analysis of responses at that Public Health Organisation; and
- Access to data or tissue held at the Public Health Organisation but not processing or analysis at that Public Health Organisation.

Prior to submitting an Access Request a researcher must first complete the appropriate Human Research Ethics Application .This must be on the LNR Research Application or the NEAF.

Once the appropriate ethical approval has been granted it is recommended contacting the relevant Research Governance Officer to ascertain whether an Access Request would be appropriate for submission to the given Local Health District/Health Service or whether the appropriate Site Specific Assessment will be required instead*. The Research Governance Officer has the discretion to request that the application is submitted on the relevant Site Specific Assessment if they consider that the project involves the conduct of research at a site.

Access Request authorisation must be granted at each individual PHO, where research support is required.

The completed form and supporting documents must be printed** and submitted to the Research Governance Officer responsible for the site (for CCLHD please forward to the Research Manager. Contact details for Research Governance Officers and information on the facilities, locations and services covered by them are maintained on the NSW Department of Health website at.

This form, like the LNR and NEAF, must be completed on the NSW Health Online Forms Website (https://ethicsform.org/au/). The two forms will be linked to one another in this system and once finalised will each have a unique Submission Code.

The reason application is required via this portal is that it links to the IT system utilised by NSW Research Governance Officers to manage and report on SSA applications to NSW Health.

The Online Forms Website provides guidance on completing the form and supporting documents required for making an application, however as each LHD is independently operated each site may have its own individual application requirements. Principal Investigators are therefore advised to contact the relevant Research Governance Officer and any individuals that need to provide a declaration and start to prepare an application at the earliest possible opportunity.

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***As processes vary between sites it is recommended you contact the relevant Research Governance Officer for individual submission requirements.**

****It is important to note that submission on the online system will not trigger notification in the relevant Research Governance Officer's system. It is therefore recommended applicants contact the relevant Research Governance Officer for specific details on the individual application requirements prior to submission.**

NSW Health Requirements

All human research that takes place in NSW Public Health Organisations must be reviewed, approved and conducted in accordance with the National Statement on Ethical Conduct in Human Research (http://www.nhmrc.gov.au/guidelines/publications/e72) (National Health and Medical Research Council (NHMRC), Australian Research Council (ARC) and Australian Vice-Chancellors Committee (AVCC) 2007).

This requirement must be met in order for Public Health Organisations to grant authorisation for the commencement of human research projects, in accordance with NSW Health Policy Directive PD2010_056 Authorisation to Commence Human Research in NSW Public Health Organisations (http://www0.health.nsw.gov.au/policies/pd/2010/PD2010_056.html).

Quality Improvement

When does a project qualify as QI?

The 'CCLHD- Application Checklist- CPI, QI & Research' has been primarily designed to assist Central Coast Local Health District (CCLHD) Staff in identifying when a Clinical Practice Improvement (CPI) or Quality Improvement (QI) Project entails ethical 'risks'.

If any of the answers to the questions on Page 2 are answered "YES", further advice should be obtained from the CCLHD Research Office about the need for ethical review and completion of the appropriate application. If you do

answer yes to one or more questions the project may still qualify as a quality project, these details can be discussed with the Research Manager if you find this is the case for your project.

If the answers to the questions are all 'NO' consultation is recommended with your Department/Divisional Manager for authorisation prior to proceeding.

Any questions about completing a CPI or QI that does not involve 'ethical risks' should be directed to the Clinical Governance Unit or appropriate Department/Divisional Manager.