RESEARCH: GUIDELINES FOR INTERNAL APPROVAL OF PERINATAL RESEARCH AT THE ROYAL HOSPITAL FOR WOMEN (RHW)

1. PURPOSE:

The purpose of this document is to outline the steps that are undertaken in order to ensure that perinatal research that takes place in the RHW meets appropriate governance standards through an effective and efficient system of review.

It is also important that the research can be accommodated and that there is no conflict (with regard recruitment, space and resources) with existing research within RHW. For this reason all new research proposals will be reviewed by the Perinatal Academic Group (PAG).

2. REQUIREMENTS:

All human research that takes place in NSW Public Health Organizations must be reviewed and approved in accordance with the National Statement on Ethical Conduct in Human Research (2007) [National Statement]. Further information is available from: http://www.nhmrc.gov.au/guidelines/publications/e72.

Public Health Organisations must establish structures and practices consistent with:

- Policy Directive PD2010_055 *Research-Ethical and Scientific Review of Human Research in NSW Public Health Organizations.*
- Policy Directive PD2010_056 *Research – Authorisation to Commence Human Research in NSW Public Health Organisations.*

To conduct perinatal research within RHW, a project must be reviewed by the PAG in conjunction with relevant Ethical and Governance approval. This is a local rather than a NSW Health requirement.

Any Researchers involved in patient contact need to be appropriately credentialed to do so within RHW. This should be organised by the hospital administration. For further details, please contact Maria Combis on: 02 9382 6511. Email: maria.combis@health.nsw.gov.au

3. PERINATAL RESEARCH GOVERNANCE FLOW CHART:

The flow of the perinatal research ethics and governance process at RHW is summarised in the Perinatal Research Governance Flow Chart (attached). Further details regarding the individual documents and steps involved in this process are as follows:

3.1. Documents

STUDY PROTOCOL:

A study protocol is a document that describes, in detail, the plan for conducting the clinical study. The study protocol explains the purpose and function of the study as well as how to carry it out. Some specific elements of the protocol are: the reason for the study; the number of participants; eligibility and exclusion criteria; details of the intervention or therapy the participants will receive (such as frequency and dosages); what data will be gathered; what demographic information about the participants will be gathered; steps for clinical caregivers to carry out; the study endpoints.

To aid with completion of the study protocol, a local template is available from: http://www.health.nsw.gov.au/ethics/research/contactshrec.asp.

NATIONAL ETHICS APPLICATION FORM (NEAF):

The NEAF is a dynamic, interactive, web-based document for researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees (HRECs). The aim of NEAF is to increase the efficiency and quality of the ethical review process for both HRECs and researchers, by ensuring that HRECs are provided with consistent information to allow them to effectively assess applications for ethical review. The NEAF includes information from the study protocol, details of the investigators carrying out the research, accompanying documents including the Patient Information & Consent Form etc. To access the NEAF, please go to the independent NEAF website at https://www.ethicsform.org/au/SignIn.aspx.

SITE SPECIFIC ASSESSMENT (SSA):

The purpose of the SSA is to enable the Public Health Organization (PHO) to consider whether a research project to be undertaken within its jurisdiction meets the organisation's research governance requirements. These include issues such as availability of staff and resources, agreement by relevant Heads of Department, availability of laboratory and diagnostic facilities etc. These requirements are separate from the ethical considerations of a research project and can only be decided by each PHO. A separate SSA is required for each PHO.

This form is completed in conjunction with the NEAF, accessible at the same site as above. The details are available in the NSW Department of Health Policy Directive PD2010_056.

LOW NEGLIGIBLE RISK (LNR) FORM:

A number of research proposals are regarded as having lesser potential ethics issues (such as audits and case-note reviews). Relevant ethical approval may be gained by means of the Low or Negligible Risk Ethics Approval form which can be found at https://www.ethicsform.org/au/SignIn.aspx. Protocols are not required by the HREC for LNR projects.

If you have concerns whether your research study is appropriate for this low risk approval, then please contact the research support office on: 02 9382 3587. Email: ethicsnhn@health.nsw.gov.au

3.2 Committees and Review Involved in the Ethics & Governance Process

SCIENTIFIC REVIEW COMMITTEE (SRC):

SRC is a subcommittee of the HREC; members of this Committee review the scientific merit of research projects which require review by the full HREC i.e. an application which is submitted on a NEAF. SRC functions to assess the scientific rigour of research studies and does not aim to be a barrier for research. This requirement must be met in accordance with the NSW Department of Health Policy Directive PD20120_055.

The relevant HREC for RHW is the South Eastern Sydney Local Health District- Northern Sector (SESLHD-NS). This is based on the Randwick campus. The Research Support Office is able to assist with preparation and submission of any research applications to the HREC. The contact details for the SESLHD-NS HREC are:
http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp

HUMAN RESEARCH ETHICS COMMITTEE (HREC):

In accordance with the NSW Department of Health Policy Directive PD2010_055, the human research must be ethically and scientifically approved by an HREC.

The HREC of the SESLHD-NS reviews ethics applications for single and multi-centre research. The details are available at:
http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp

Executive Committee (EC):

The EC is a sub-committee of the HREC. This smaller committee meets fortnightly to review:

- Adverse Event Reports - Individual Event Report/Periodic Summary Event
- Report (see Reporting Guidelines)
- Amendments
- Authorised prescriber applications
- Low/negligible risk research applications
- Progress reports
- Requests for extensions of ethical approval - provide a progress report (above) with a letter stating the length of the extension (1-5yrs) and the reason for the request.
- Other miscellaneous items requiring ethics approval or acknowledgement

Ethical approval is valid for 5 years. It is the researcher's obligation to submit amendments, reports, notifications and extension applications to the Executive Committee.

Further details are available at:

http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp

GOVERNANCE REVIEW:

All Perinatal research projects commencing in the RHW must be authorised by the Local Health District Chief Executive, or their delegate, before the project can commence. Research Governance is the collective term for systems that promote, review, measure and monitor the quality of research. It provides a systematic and integrated approach to assurance and review of research responsibility and accountability that improves quality and safety in research.

Researchers are required to submit a SSA to the Research Governance Officer. The requirements are available in the NSW Department of Health Policy Directive PD2010_056.

PERINATAL ACADEMIC GROUP (PAG):

The PAG was convened in late 2011. It functions to provide oversight for research taking place within RHW. It does not aim to provide an additional barrier to research, however it acts to ensure that conflict between research studies and recruitment is minimised by having oversight of all current internal and external research. The PAG includes senior researchers and representatives of all clinical areas to give an overview of the clinical trials from logistics / infrastructure perspectives.

The PAG is able to advise when research can be accommodated in individual clinical areas. The PAG meets monthly and will be involved at the stage of governance approval. Members of the PAG are happy to advise on study conduct and design should this be required, as well as availability of resources. For further details please contact Anne Lainchbury on Anne.Lainchbury@health.nsw.gov.au.

3.3. Summary of the Flow Chart:

There are broadly three programmes of research application at RHW. Studies can be either:

1. Internal / Local Research; originating from researchers within the Hospital or from researchers outside of the hospital using RHW as the sole or lead site.

2. External Research with External Ethics Approval; where only local Governance is required.

3. Low and Negligible Risk Research; in which the risk to the participants is no more than discomfort or inconvenience.

1. Internal / Local Research:

- When research is proposed, two documents will be initiated as outlined above (Study Protocol; NEAF).
    - The Study Protocol can go to the PAG for review as well as being one of the documents included in the HREC submission.
    - The NEAF will be included in the HREC submission.

- The SSA form can be submitted at any time, the Research Support Office encourages parallel submission i.e. the SSA is submitted at the same time as the HREC submission. However this is up the researcher.

- The flow of research approvals:

    - Ethics Approval: Submission to Research Support Office (RSO) → Review by SRC → Review by HREC (Ethics) → Letter of HREC approval.

    - Governance Authorisation: Submission of SSA to PAG (obtain letter from PAG) → Submission of SSA (including letter from PAG) to RSO → Review by Research Governance Officer → Recommendation to CE or delegate → Letter of authorisation sent to Researcher → Project may commence.

- The PAG functions in two ways:

    - Reviewing and assisting with the Study Protocol as required: becoming aware of proposed studies.

    - Reviewing the Governance to see that proposed research fits with research that is currently taking place within the constraints of resources.

2. External Research with External Ethics Approval:

- When studies submitted to a HREC external to the SESLHD, the project does not need to be scientifically reviewed locally by the HREC.

- Whilst not a local ethics requirement, it may be beneficial for the Study Protocol to be reviewed by the PAG to ascertain local feasibility and timing.

- The flow of research approvals:

    - Ethics Approval: Obtain from HREC external to SESLHD.

    - Governance Authorisation: Submission of SSA to PAG (obtain letter from PAG) → Submission of SSA (including letter from PAG) to RSO → Review by Research Governance Officer → Recommendation to CE or delegate → Letter of authorisation sent to Researcher → Project may commence.

- The PAG functions in one way:

    - Reviewing the Governance to see that proposed research fits with research that is currently taking place within the constraints of resources.

3. Low and Negligible Risk Research (LNR):

- LNR application form will be submitted to the Human Research Ethics Executive committee (EC).

- The flow of research approvals for LNR projects:

- Ethics Approval: Submission to Research Support Office (RSO) → Review by Executive Committee of HREC → Letter of HREC approval.

- Governance Authorisation: Submission of SSA to PAG (obtain letter from PAG) → Submission of SSA (including letter from PAG) to RSO → Review by Research Governance Officer → Recommendation to CE or delegate → Letter of authorisation sent to Researcher → Project may commence.

- The PAG functions in one way:
  - Reviewing the Governance to see that proposed research fits with research that is currently taking place within the constraints of resources.