Policy

Fee Policy for Review of Human Research at NSLHD

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Intranet location/s	Support: Research
Summary	A Fee Policy has been implemented in order to provide sufficient funds to support the administration of the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee and Governance review of research applications.
Author Department	Research Office
Contact (Details)	Research Manager NSLHD-Research@health.nsw.gov.au PH:99264590
Endorsed By	Dr Tamsin Waterhouse, Medical Executive Director NSLHD
Sector/Service	District Research & Medical Workforce/Services
Audience	All clinical and non-clinical staff who conduct research in NSLHD
Date Created	2014; Reviewed July 2014, November 2019
Review date	December 2023
Previous Reference No.	PO 2014_002 - Fee Policy 4 May 2014 Fee Policy- Version 3 dated 3rd July 2008 (amended November 2013)
Related Policy/s	Policy Directive PD2008_030, "HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research".
National Safety Quality Health Safety (Accreditation) Standard	Standard 1.7
Key Words	Research; Ethics, Governance
Status	Active

Title: Fee Policy for Review of Human Research at NSLHD

1. Scope of Practice

A Fee Policy has been implemented in order to comply with NSW Ministry of Health (MoH) policy and provide a mechanism to fund the necessary operational and service improvement for the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC) and Research Governance review to meet NSW MoH Key Performance Indicators (KPIs).

1.1 Application

This policy applies to all researchers who submit documents to the NSLHD Research Office for review and approval to conduct research projects. This policy should be used in conjunction with the NSW MoH HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research PD2008_030.

2. Expected Outcome

The policy has been implemented in order to ensure sufficient funds are available to deliver timely services that support the activities of the NSLHD HREC and NSLHD Research Governance.

The funds supplement the supports provided by the NSLHD and are used to ensure good governance and operational compliance (including salaries, administrative support and training) by the NSLHD HREC and Research Governance to its obligations as directed by the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Research Involving Humans and the Australian Code for the Responsible Conduct of Research.

3. Definitions

The NSLHD has adopted the definitions from PD2011_006, 'Clinical Trials: Insurance and Indemnity'.

3.1 **A commercially sponsored research project has the following characteristics:**

- It is initiated by a pharmaceutical/device company or other commercial entity and not by an investigator at a NSW public health service site.
- The research is conducted to investigate a medication/device for commercial exploitation by its manufacturer/sponsor.
- The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.

3.2 **A sponsored (non-commercial) research project has the following characteristics:**

- The research must address relevant clinical questions and not pharmaceutical/device industry or commercial needs.
- The sponsor (non-commercial) must declare any/in-kind support (e.g. provision of medicines, devices, funds) from any organisation.
- The sponsor (non-commercial) must be the primary author and custodian of the clinical trial protocol
  - Examples of groups that may fall under this category are;

  a) Research institutes external to NSW Health;
  b) Collaborative or cooperative research groups external to NSW Health; and
  c) Universities.

3.3 **An investigator initiated (NSLHD sponsored) research project has the following characteristics:**

- A pharmaceutical/device company is not acting as the Sponsor for the purposes of the CTN Scheme application
- A pharmaceutical/device company is not directly funding the conduct of the study that is making payment to the relevant hospital or investigator
- The clinical trial addresses relevant clinical questions and not industry needs
- The Principal Investigator and NSLHD is the primary author and custodian of the clinical trial protocol

Note – Investigator initiated trials can receive some industry funding or industry contribution, (e.g. educational grants, or supply of medication). However, the support must be declared in the protocol submission to ensure that the clinical trial retain its 'investigator initiated' status.

3.4 **Amendments to approved research**

Fees are applied to *each* version change to Investigators Brochures (or equivalent) and protocol documents (or equivalent). No additional fee applies for Participant Information Sheet and Consent Forms (PISCFs) submitted in conjunction with an updated protocol or IB; if PISCFs are submitted separately, the fee applies.

Amendment definitions

- **Complex:** Substantial changes to the project requiring review by the full HREC, e.g. Change of aims and objectives, addition of a sub-study or open-label extension which was not part of the originally approved protocol.
- **Regular:** Most amendments fall into this category, e.g. IB updates, protocol revision to modify visit schedule, revision in risk section of PISCF following IB update, extension of follow-up from 3 to 5 years, addition of new questionnaire**.**
- **Minor:** Correction of typographical errors without movement of text, update to contact details. There is no fee for minor amendments.

4. Policy

The policy has been implemented in order to ensure sufficient funds are available to deliver timely services that support the activities of NSLHD HREC and NSLHD Research Governance and in no way compromises the system of ethical or scientific review.

The NSLHD's Research Office is required as delegated by the Chief Executive to provide reports to the NSW Office of Health & Medical Research and the NHMRC's Research Integrity Office that describe the type and complexity of research project and review & approval times for all valid applications.

4.1 **How to Pay the Levy**

- A completed method of payment (MoP) form **MUST** be uploaded to REGIS with the application. Applications submitted without the MoP may be rejected by the Research Office.
- Upon receipt of the MoP form, an invoice will be raised for external applicants, or journal transfer processed for internal applicants.
- For journal transfers, cost centre details must be provided along with a signature from the cost centre manager and date.
- A receipt will be issued once payment is received.
- Cash, cheques and credit card payments are not accepted by the NSLHD Research Office.

Without a complete methods of payment form your application is not valid.

The policy can be accessed at the following locations:

Intranet Research Office:
http://intranet.nslhd.health.nsw.gov.au/AreaGov/NSGovSys/AreaPPGLibrary/Research/PO2014_002.pdf#search=research%20office
Internet Research Office:
http://www.nslhd.health.nsw.gov.au/AboutUs/research
Intranet Research MOH policies:
http://intranet.nslhd.health.nsw.gov.au/AreaGov/NSGovSys/Pages/A-ZPPG.as

5. References

Use the Referencing for Policies, Procedures and Guidelines referencing guide to assist with the correct format for reference lists

6. Risk of Policy Non Compliance (list risks)

- Insufficient funds to support the administration of NSLHD HREC and site governance review.
- Delay in approving research studies by HREC and/or site governance.

TABLE OF FEES – Human Research Ethics Committee (HREC) Service Delivery

HREC Administration Fees		
Greater Than Low Risk Projects	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$3400
	Sponsored (non-commercial) research project with commercial funding/support ≥$50000 *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$3400
	Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$310
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$155
	Student research projects	$155
Amendments To Approved Projects (Greater Than Low Risk projects)	Complex amendment to commercially sponsored study or study with ≥ $50000 commercial funding. * Complex amendments require review by the full HREC, example; change of aims and objectives, addition of a sub-study or open-label extension which was not part of the originally approved protocol.	$1710
	Regular amendment to commercially sponsored study * Examples include Protocol, IB. No additional fee applied to PISCFs if submitted in conjunction with protocol or IB update. If PISCFs are submitted separately, fee applies.)	$565 per amended document
	Regular amendment to research project with commercial funding ≥$50000 * No additional fee applied to PISCFs if submitted in conjunction with protocol or IB update. If PISCFs are submitted separately, fee applies.	$565 per amendment document
	Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$155
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$105
	Student projects	$105
Low/Negligible Risk (LNR) Projects	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$3400
	Research project with commercial funding/support ≥$50000	$3400
	Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$205
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$105
	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$565
	Research project with commercial funding/support ≥$50000	$565

HREC Administration Fees		
LNR Amendments	Sponsored (non-commercial) *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$105
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$80
	Student projects	$80

External Entity Agreement (EEA) for HREC to extend approval to Private/External Institution – executed for the duration of the HREC approval or 5 year term for non-project specific agreements.	
Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$1000
Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$500
Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$250
Non project specific (5 year term)	$1000

TABLE OF FEES – GOVERNANCE SERVICE DELIVERY

Governance Administration Fees		
Site Specific Assessment (SSA): Greater Than Low Risk	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$3840
	Research project with commercial funding/support ≥$50000	$3840
	Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$515
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$155
Regular Amendment (HREC is not NSLHD) When the reviewing HREC is NSLHD there is no charge.	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$515
	Research project with commercial funding/support ≥$50000	$515
	Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$155
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$105
	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$1710
	Research project with commercial funding/support ≥$50000	$1710

Governance Administration Fees		
Low/Negligible Risk SSA	Sponsored (non-commercial) *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$260
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$155
Regular LNSSA Amendment (HREC is not NSLHD) When the reviewing HREC is NSLHD there is no charge.	Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$515
	Research project with commercial funding/support ≥$50000	$515
	Sponsored (non-commercial) *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$105
	Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$80

Material Transfer Agreements – executed for the duration of the HREC approval.	
Commercially sponsored research project * The protocol has been developed and is the responsibility of a pharmaceutical/device company or other commercial entity.	$1000
Sponsored (non-commercial) research project *Examples of sponsored (non-commercial) research includes research where the sponsor is a research institute, university or collaborative group.	$500
Investigator Initiated research project (NSLHD employees only) * The Principal Investigator and NSLHD must the primary author and custodian of the protocol.	$250

Fees are inclusive of GST

Without a complete method of payment form, your application is not valid.