

HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research

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Functional Sub group Corporate Administration - Finance
Clinical/ Patient Services - Research

Summary This Policy Directive sets out the fees to be charged by public health organisations for carrying out a research governance review of commercially sponsored research (site specific assessments) and review of commercially sponsored research by their Human Research Ethics Committees (HRECs).

Replaces Doc. No. HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research [PD2007_046]

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Ministry of Health, Public Health Units, Public Hospitals

Audience Human Research Ethics Committees, researchers

Distributed to Public Health System, Ministry of Health, Public Health Units, Public Hospitals

Review date 13-Jun-2013

Policy Manual Not applicable

File No. 05/914

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

HUMAN RESEARCH ETHICS COMMITTEES (HRECS) AND RESEARCH GOVERNANCE: FEE POLICY FOR THE REVIEW OF COMMERCIALY SPONSORED RESEARCH WITHIN NSW HEALTH

Mandatory policy

This policy directive sets out the fees to be charged by public health organisations for

- Carrying out a research governance review of commercially sponsored research (site specific assessments); and
- Review of commercially sponsored research by their Human Research Ethics Committees (HRECs).

Fees are to be charged in accordance with this policy directive.

Application

This policy directive rescinds PD2007_046.

This policy directive applies to all NSW public health organisations.

The objective of this policy directive is to apply a uniform fee structure for governance and ethics review of commercially sponsored research across NSW Health.

Fees for other kinds of research remain at the discretion of the Public Health Organisation.

Background

This new fee structure takes into account new arrangements for the ethics and research governance requirements for both single-site and multi-centre research (see PD2007_043 “Research – authorisation of proposals to conduct research on humans within the NSW public health system” and PD2007_072 “Research – model for single ethical and scientific review of multi-centre research”).

Implementation

This policy takes effect on 1 July 2008.

Enquiries regarding this policy should be directed to the NSW Health Research and Ethics Branch (02) 9391 9427.

Title: Human Research Ethics Committees (HRECS) and Research Governance: Fee Policy for the Review of Commercially Sponsored Research Within NSW Health

SCHEDULE OF FEES FOR ETHICS AND RESEARCH GOVERNANCE REVIEW OF COMMERCIALY SPONSORED RESEARCH

1. The following fees apply to applications to review commercially sponsored research made to all public health organisations, commencing 1 July 2008. That is, it applies to all ethics committee applications and all site specific assessment applications lodged with a public health organisation after 1 July 2008.

Table 1: Fees for review of commercially sponsored research by Human Research Ethics Committee (all figures are inclusive of GST)

2. These fees are payable to the public health organisations on lodgement of an HREC application or amendment, and are to be retained by the public health organisation for use in accordance with paragraph 11.

Application for research project with full industry sponsorship	\$3300
Application for research project with sponsorship from collaborative groups	\$150
Amendments to research projects with full industry sponsorship*	\$550
Addition of sub-studies to research projects with full industry sponsorship ^	\$1665

*Amendments include any changes to the protocol excluding minor administrative changes.

^Sub-studies will be reviewed and the fee determined on a case-by-case basis. The HREC may request that the sub-study be submitted as a new application and charge the full fee.

Table 2: Fees for governance review (site specific assessments) of commercially sponsored research by public health organisations, (all figures are GST inclusive)

3. The research governance fee covers costs involved in undertaking a site specific assessment fee including use of AU RED, the information technology platform that assists with the system of ethics and governance review of research implemented on 1 July 2007.
4. The Department of Health will recover monies for the use of AU RED from public health organisations annually in areas, based on activity over the previous twelve months.
5. Public health organisations are to retain the site specific assessment fee to cover Departmental invoices for AU RED and for use in accordance with paragraph 9.

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Site specific assessment application for research project with full industry sponsorship	\$3,740
Site specific assessment application for research project with sponsorship from collaborative groups	Nil
Site specific assessment application for amendments and additions of sub-studies (if required)	Nil

6. No charges are to be introduced at this time for applications to the Shared Scientific Assessment Scheme.
7. Public health organisations are free to determine fees charged for categories of research not contained in the fee schedule (for example, fully investigator-initiated clinical trials without any external sponsorship, external applications for access to medical records).
8. All fees are inclusive of GST. Public health organisations are to be aware that charges raised internally within the public health organisation are GST Free and therefore where this occurs the abovementioned charges should be reduced by 1/11th.
9. Revenue raised through the application of this policy must be used by Public Health Organisations to support their HREC and their research governance functions (including salaries, administrative support and training).
10. It is a matter for public health organisations to determine whether they will impose any additional charges to recover the costs of the conduct of the research project at their facility (as opposed to the cost of conducting ethics and research governance review).

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