Policy Directive

Ethics and Research Governance: Fee Policy

Document Number: SWSLHD_PD2017_032

Functional Sub-Group: Research and Ethics Office

Summary: This policy outlines the cost involved in terms of having commercially sponsored research reviewed by the organisations’ Human Research Ethics Committee.

Approved by: Clinical and Quality Council

Publication (Issue) Date: December 2017

Next Review Date: December 2020

Replaces Existing Policy: Fee Policy, V2

Previous Review Dates: August 2012
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Revision History

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<th>Amendment Notes</th>
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<tr>
<td>December 2007 SWSLHD_PD2017_032</td>
<td>This Policy has been amended to reflect the current SWSLHD Research and Governance Fees.</td>
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<tr>
<td>Fee Policy, V2 (Number not allocated)</td>
<td>Publication of policy document.</td>
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1. Introduction

Fees are charged by public health organisations for reviewing: commercially sponsored research by their Human Research Ethics Committee (HREC); and research governance review of commercially sponsored research (site specific assessments).

1.1. The risk addressed by this policy:

Discrepancy in costs for review of commercially sponsored research.

2. The Aims / Expected Outcome of this policy:

To ensure:
- A uniform fee structure for governance and ethics review of commercially sponsored research across NSW Health.

3. Policy Statement

Fees are charged in accordance with NSW Ministry of Health Policy Directive PD2008_030. The fee structure below does not apply to investigator initiated studies.

<table>
<thead>
<tr>
<th>3.1. Fees for review of commercially sponsored research by Human Research Ethics Committee</th>
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<tbody>
<tr>
<td>Ethics application for research project with full industry sponsorship</td>
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<tr>
<td>Ethics application for research project with sponsorship from collaborative groups</td>
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<tr>
<td>Amendments to research projects with full industry sponsorship*</td>
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<tr>
<td>Addition of sub-studies to research projects with full industry sponsorship**</td>
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<table>
<thead>
<tr>
<th>3.2. Fees for governance review (site specific assessments) of commercially sponsored research</th>
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<tbody>
<tr>
<td>Site specific assessment application for research project with full industry sponsorship</td>
</tr>
<tr>
<td>Site specific assessment application for research project with sponsorship form collaborative groups</td>
</tr>
<tr>
<td>Site specific assessment application for amendments and additions of sub-studies (if required)</td>
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</tbody>
</table>

*amendments include changes to the protocol and Investigator Brochure (or equivalent) 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.

### 3.3. Application of revenue

In accordance with the NSW Ministry of Health Policy Directive PD2008_030, all revenue raised through the application of this policy will be used by SWSLHD to support the functions of the HREC and the research governance functions (including salaries, administrative support and training).

### 3.4. Administration and Procedures for Payment

The Fee Policy will be administered by the District Finance Department via the SWSLHD Ethics & Research Governance Office as follows:

- Revenue receipts by way of Electronic Funds Transfer (EFT) must be paid into the SWSLHD Westpac General Fund bank account, and be accompanied by a remittance advice emailed to SWSLHD-Finance@health.nsw.gov.au.
- Cheques or money orders are to be made payable to the SWSLHD Ethics & Research Governance Office and must be submitted with the application or prior to approval. It should be accompanied by a statement of payment. The ABN for the SWSLHD is 46 738 965 845.
- The SWSLHD Ethics and Research Governance Office will forward the cheque and issue an appropriate GST compliant tax invoice, or alternatively a GST compliant tax invoice may be issued prior to submission.
- Should a request be made for a tax invoice to be issued prior to the payment of the fee, then the following details should be provided to the SWSLHD Ethics & Research Governance Office:
  - Name, mailing address and telephone number of the sponsor of the protocol
  - Name of contact person; and
  - Title and protocol number of research study.

Clearly state if the payment is for ethics review or Site Specific Assessment.

- The amount of the fee (GST included)
- These details will be forwarded to the Finance Department with the
  - Cost Centre: 485032
  - Entity code: 6001
  - Account number: 472100 Professional Fees and a Tax invoice will be forwarded directly to the sponsor by the District Finance Department.
- The cheque is deposited into the SWSLHD Ethics & Research Governance Office cost centre number 485032.

The fee may be refunded under the following circumstances:

- Full refund if the study is withdrawn prior to any preparation of the agenda
- Partial refund if withdrawn prior to the Committee meeting.

### 4. Principles

- All employees involved in commercially sponsored clinical trials should be aware of the fees for ethical and governance review. The fee structure should be included into...
early discussions with the commercial sponsors and also incorporated into the budget.

5. Performance Measures

- Number of commercially sponsored research
- Time taken by the commercial sponsor to pay invoices
- Time taken for review of commercially sponsored research

6. Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Collaborative Research Group</td>
<td>The Collaborative Research Group is an academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating the Study</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
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7. References and Links

**Related Policy Directives / Guidelines**

<table>
<thead>
<tr>
<th>Related Policy Directive / Guidelines</th>
<th>Description</th>
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<tbody>
<tr>
<td>MoH - PD2008_030</td>
<td>HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research</td>
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**Author:** Manager, Research and Ethics Office (Annamarie D’Souza)

**Reviewers:** Research and Ethics Office Steering Group Committee; Deputy Director Finance (Dimi Palamidas).