Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research

Summary This Policy Directive describes the processes for the management of research ethics and governance review fees in NSW Public Health Organisations and sets out the fees to be charged for processing research applications.

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Distributed to Ministry of Health, Public Health System, Divisions of General Practice, NSW Ambulance Service, Private Hospitals and Day Procedure Centres

Audience Research Office Staff;Researchers;Heads of Departments Hosting and Supporting Research;Directors of Research;All Chief Executives;Local Health District Accounts Personnel

Secretary, NSW Health

NSW Health

POLICY DIRECTIVE

Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research

POLICY STATEMENT

Application of fees for research ethics and governance review and approval must be uniform across the NSW public health system. This is intended to ensure researchers engaging with NSW Health will experience consistency in the amounts they are being charged for research ethics and governance processes, so they may have confidence in allocating budgets accordingly.

SUMMARY OF POLICY REQUIREMENTS

All NSW Health Research Offices are to apply this Policy Directive consistently to provide researchers with certainty in the fees they expect to be charged for ethics and governance submissions.

Research ethics and governance review fees described in this Policy Directive apply to clinical trial research applications. Research Ethics and Governance review fees vary by application type and project sponsor. Research Offices are not to charge fees for the review of research applications other than for clinical trials.

Researchers should be aware of the fees applicable to their submissions and provide correct details for invoices to be raised and ensure payment. Research officers are responsible for raising the invoices to the correct party. The fees are considered part of the cost of conducting research and are expected to be passed on to the project sponsor.

The fees charged for ethics and governance review in this Policy Directive is not intended to fund expenses a research office may incur.

REVISION HISTORY

Version	Approved By	Amendment Notes
PD2023_015 July-2023	Deputy Secretary, Population and Public Health	Advises fee policy to apply from 1 July 2023.
PD2008_030 June-2008	Director-General	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).

PD2007_046 June-2007	A/Director-General	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); and • Application fees for the use of AU RED.
PD2005_628 October-2005	Director-General	This policy directive sets out the fees to be charged by public health organisations for the review of clinical trials by their Human Research Ethics Committees (HRECs). Fees are to be charged in accordance with this policy.

CONTENTS

1. BACKGROUND

1.1. About this document

This Policy Directive describes the processes for applying research ethics and governance review fees for clinical trial research in NSW Health Organisations and sets out the fees to be charged for processing:

- Research ethics applications by a Human Research Ethics Committee
- Research governance applications (site specific assessments)
- Related administrative review processes.

It is the responsibility of NSW Health Organisations to ensure that the proper fees are invoiced appropriately.

1.2. Key definitions

Clinical Trial	A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to: • surgical and medical treatments and procedures • experimental drugs • biological products • medical devices • health-related service changes • health-related preventative strategies • health-related educational interventions.
Commercial External Sponsor	A commercial entity which is the sponsor of a clinical trial. For the purposes of this Policy Directive, such entities include all pharmaceutical and medical device companies.
Human Research Ethics Committee (HREC)	A committee constituted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* to review and, where appropriate, approve and monitor the ethical and scientific aspects of human research.

Institution Sponsor	A NSW Health Organisation which is the sponsor of a clinical trial. For the purposes of this Policy Directive, such entities include those public health organisations from other Australian jurisdictions as well as other government agencies and departments.
Non-commercial external Sponsor	A non-commercial entity external to NSW Health which is the Sponsor of a Clinical Trial. For the purposes of this Policy Directive, such entities include independent medical research institutes, collaborative or cooperative research groups and universities.
NSW Health Organisations	Public Health Organisations established under the *Health Services Act 1997* (NSW) and NSW Ambulance.
Site	A facility, location, or service where the clinical trial is being conducted.
Site Specific Assessment (SSA)	A component of research governance undertaken by NSW Health Organisations within NSW Health, to assess the suitability of the site(s) to be involved in the research.
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a Clinical Trial. The Sponsor has responsibilities under both Good Clinical Practice (GCP) and the Therapeutic Goods Administration's Clinical Trial Notification and Approval Schemes.

1.3. Legal and legislative framework

This Policy Directive must be read in conjunction with the following NSW Health Policy Directives and Guidelines:

Policy Number	NSW Health Policy Directive and Guidelines
(PD2010_055)	*Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations*
(PD2010_056)	*Research - Authorisation to Commence Human Research in NSW Public Health Organisations*
(GL2010_014)	*Operations Manual: Human Research Ethics Committee Executive Officers*
(GL2010_015)	*Operations Manual: Research Governance Officers*
(GL2013_009)	*Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations*

2. RESEARCH ETHICS AND GOVERNANCE FEES FOR CLINICAL TRIAL RESEARCH

Research ethics and governance fees are charged for the review of clinical trial research applications and amendments. Research ethics and governance fees vary depending on the type of submission and the project sponsor.

No fee is to be raised for research applications that are not for clinical trial research.

This Policy Directive requires the application of a uniform fee structure for ethics and governance review of research across NSW Health Organisations. These fees apply to both single-site and multi-centre research studies. These fees are payable to the NSW Health Organisations on submission of an ethics and governance application or amendment.

NSW Health Organisations must not charge review fees for items not contained in the fee schedule.

3. SCHEDULE OF FEES FOR RESEARCH ETHICS AND GOVERNANCE REVIEW

The fees set out in an information bulletin published separately and regularly, apply to the review of research ethics and governance applications submitted to all NSW Health Organisations.

Research Offices who host a Human Research Ethics Committee (HREC) reviewing a clinical trial are to charge the fees in the amounts set out in the related information bulletin.

Research Offices who host a clinical trial at a site under their control are to charge the fees in the amounts set out in the related information bulletin.

4. GUIDANCE ON APPLICATION OF FEES

This section provides some guidance to assist in interpretation of the application of fees in the tables in the related information bulletin. Further guidance is available on the Office for Health and Medical Research website.

4.1. Human Research Ethics Committee Review

A fee for Human Research Ethics Committee (HREC) Reviews must only be charged when a clinical trial submission is required to be reviewed by a full Human Research Ethics Committee. The fee covers all components of the review including any subcommittee or related committee review required to inform the Human Research Ethics Committee review. Such related committees include a drug committee, a scientific subcommittee, or any other institutional review.

4.2. Additional Site

A fee for an additional site is to be charged when a clinical trial adds a site to a clinical trial study after Human Research Ethics Committee approval has been granted.

4.3. Addition of a Sub-study

A sub-study is a study performed on a subgroup of the subjects included in the clinical trial. For example, a pharmacokinetics or pharmacogenetics sub-study may include a sample of the patients participating in the clinical trial.

A fee for a sub-study is to be charged when an already-approved clinical trial submits for approval a study related to the original clinical trial.

4.4. Amendments

An amendment is considered as any change to a research project or an approved application that occurs after ethics approval or governance authorisation, respectively. Where an amendment is submitted as a single batch of documents containing several items for review (by either the Human Research Ethics Committee or the Governance Office), only a single amendment fee may be charged.

4.4.1. Major Amendment

A major amendment is considered more than an administrative change and, in the case of an amendment submitted for Research Ethics Review under Table 1 of the related information bulletin, a full review by a Human Research Ethics Committee is required. Examples of major amendments include:

- protocol amendment
- contract amendment
- revision of the study design due to safety issues
- revisions in drug dosage, participant groups and numbers of study participants
- investigator brochure updates, where there are associated changes required to the Participant Information Sheet/ Consent Form (PISCF).

4.4.2. Minor Amendment

A minor amendment is defined as changes to the details of a research project that have no significant implications for the safety of participants or for the conduct, management, or scientific value of the research project. Examples of minor amendments include:

- Participant Information Sheet/ Consent Form amendments with changes not required to be reviewed by the Human Research Ethics Committee.
- Investigator brochure updates where there is no change required to the Participant Information Sheet/ Consent Form.
- Change of Principal Investigator/ Coordinating Principal Investigator.
- Minor updates to existing patient-facing documents, protocol clarification letters, advertising material and single-word changes.

4.5. Site Specific Assessment Review

A fee for a Site Specific Assessment (SSA) Review is to be charged when a clinical trial application is submitted to a research office for governance review. The fee covers all components of the review.

4.6. Non-Standard Contracts

While no fee may be charged for the presence of a non-standard contract for an institution-sponsored clinical trial, if a review of that contract by an external legal provider is required, research support offices may pass that cost on to the study team/ funder. This includes where an investigator-initiated clinical trial requires a 'contract for support' that is entered into with a funder or a provider of study product.

The NSW Health Policy Directive *Clinical Trial Research Agreements for Use in NSW Public Health Organisations* (PD2011_028) sets out a series of standard contracts approved for use with both commercial and non-commercial clinical trials. Use of these contracts will not attract a non-standard contract fee. Should a non-standard contract be used by either a commercial or non-commercial sponsor, a non-standard contract fee will be charged.

5. NSW HEALTH RESEARCH OFFICES

NSW Health Research Offices are responsible for appropriate invoicing of research ethics and governance review fees in accordance with this Policy Directive.

Researchers are responsible for ensuring that relevant research project invoicing details are included as part of research project budget planning and obtain appropriate clearances for the expenditure of any research projects funds and abide by provisions outlined within this Policy Directive.

Researchers must make themselves aware of all research review fees as outlined in section 3 of this Policy Directive prior to submitting a research ethics or governance application or amendment. The study team must provide appropriate invoicing details when submitting their research applications. The sponsor, principal investigator and/or relevant research project contact person is responsible for ensuring the invoice is paid in accordance with details included.

Research ethics and governance fees set out in this Policy Directive and related information bulletin represent part of the cost of conducting research and are expected to be passed on to the sponsor of the trial.

6. CONDUCTING A CLINICAL TRIAL AT NSW HEALTH ORGANISATIONS

The cost of conducting clinical trials in NSW Health Organisations is out of scope for this Policy Directive. Payments for the cost of a site conducting a clinical trial are to be agreed between the NSW Health Organisation and the clinical trial sponsor.