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;Research Directors;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 must be aware of the applicable fees for their submissions and provide correct invoicing details to ensure timely payment. Research officers are responsible for issuing invoices to the correct party. The fees are considered part of the cost of conducting research for 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
PD2025_017 May-2025	Deputy Secretary, Clinical Innovation and Research	Advises fee policy to apply from 1 July 2025.
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	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 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. Examples of interventions in clinical trials are: • surgical and medical treatments and procedures • experimental drugs • biological products • medical devices.
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 (2023)* 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 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 the 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 Directives 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 a standardised fee structure for the ethics and governance review of research across NSW Health Organisations. These fees apply to both single-site and multi-centre research studies and are payable to the NSW Health Organisations upon submission of an ethics and governance application or amendment.

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

3. Schedule of Fees for Research Ethics and Governance Review

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

Research Offices hosting a Human Research Ethics Committee (HREC) reviewing a clinical trial must charge the fees specified in the related information bulletin.

Research Offices hosting a clinical trial at a site under their control must also charge the fees specified in the related information bulletin.

The National Health and Medical Research Council (NHMRC) *Direct Research Costs Guidelines* directly permits the allocation of grant funds for the payment of ethics and governance fees.

4. Application of Fees

This section offers guidance to interpret the application of fees in the related information bulletin tables. 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 requires a full Human Research Ethics Committee review. The fee encompasses all components of the review process including any subcommittee or related committee review required to inform the Human Research Ethics Committee review. These related committees include a drug committee, a scientific subcommittee, or any other institutional review.

4.2. 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 to commercial external sponsors only, when an already-approved clinical trial submits for approval a study related to the original clinical trial.

4.3. 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, that requires review by a full committee.

Where an amendment is submitted to the Research Office as a single batch of documents containing several items for review, only a single amendment fee may be charged.

Examples of amendments are:

4.3.1. 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).

4.3.2. 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.

4.3.3. Amendment Classification Post 30 June 2025

Effective 1 July 2025, the classification of amendments into "Major" and "Minor" categories will be discontinued.

All amendments submitted for research ethics and governance review will be treated uniformly under the general term "Amendments." This change aims to streamline the review process, providing a more efficient framework that positively impacts non-commercial sponsors by reducing administrative complexity and potential delays. For commercial sponsors, this adjustment is not expected to significantly alter the review process, as the rigorous standards applied to their submissions will continue to be upheld.

4.3.4. Amendments Post 30 June 2025

From 1 July 2025, the amendment fee applies to:

- protocol 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).

Examples of amendments that do not require review by a full committee and do not attract a fee 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.

4.4. 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.

4.5. Non-Standard Contracts

While no fee may be charged for the presence of a non-standard contract for an institution-sponsored clinical trial, the costs of external legal review of the contract may be passed on to the study team or funder, at the discretion of the Research Office. 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 *Research Agreements in NSW Health Organisations*

(PD2023_017) outlines a series of standard contracts approved for use with both commercial and non-commercial clinical trials. Use of these standard contracts will not incur a non-standard contract fee. However, should a non-standard contract be used by either a commercial or non-commercial sponsor, a non-standard contract fee will be applied.

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 must ensure that sufficient funds 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 the related information bulletin prior to submitting a research ethics or governance application or amendment. The study team must provide appropriate invoicing details with 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.

The fees charged for ethics and governance review are not intended to fund all the expenses a Research Office may incur.

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.