Department of Health
CLINICAL QUALITY REGULATION AND ACCREDITATION

Tasmanian Government

Research Governance - Fee Policy

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Approval

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Revision History

Version	Approved By Name	Approved By Title	Amendment Notes
1.0	Health Executive	Secretary	

1. Policy Statement

- The Research Governance - Fee Policy (*Fee Policy*) requires the Tasmanian publicly funded health services to levy fees for human research projects that propose to be conducted within the Tasmanian publicly funded health service or propose access to participants (patients and/or Department of Health staff), data (medical and personal records of information) and/or tissue collections held within the authority of the Department of Health (DoH).

2. Purpose

- The *Fee Policy* is a consistent and standardised, whole-of-agency approach for the levying of fees to review human research projects (ethical and scientific reviews and the research governance review) and/or submissions for amendments to existing human research projects.
- The fees charged represent the total cost recovery (human and other resources) required to review new human research projects (ethical and scientific reviews and the research governance review) and/or submissions for amendments to existing approved human research projects.

3. Scope

- The *Fee Policy* applies to Sponsors and Investigators proposing to conduct human research within the Tasmanian publicly funded health service or where the proposed research requires:
    - Access or use of Tasmanian public health facilities
    - Access to participants (patients and/or Department of Health staff)
    - Access to data (medical and personal records of information) and/or;
    - Access to tissue collections held within the authority of the Department of Health (DoH).
- The term human research, includes all categories of research including clinical trials as defined in the National Health and Medical Research Council (NHMRC), National Statement on Ethical Conduct in Human Research (*National Statement*) and categories of research as defined in the NHMRC, Certification Handbook National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research (herewith referred to a 'research').
- The proposed research project must be for the benefit of the Tasmanian publicly funded health service, aim to improve the quality and safety of health care provided in the Tasmanian publicly funded health service and improve the health and wellbeing of the broader Tasmanian community.
- The DoH will **not be responsible** for the HREC review fee (including amendments) incurred by other Tasmanian public service agencies, private health service facilities, individuals not employed by the DoH, non-government organisations, private companies, and organisations who are Sponsors and wishing to conduct human research within the Tasmanian publicly funded health service or propose to access information held within the authority of the DoH and are seeking and/or granted ethics approval from the University of Tasmania (UTas), but not employed by DoH.
- The DoH will be responsible for the HREC review fee (including amendments) incurred by all DoH and THS staff, including officers, volunteers, and/or contractors and where the research is being conducted within the Tasmanian publicly health system or proposes to access information held within the authority of the DoH.

- Where a staff member employed by the DoH wishes to conduct multi-centre research and they will take on the role of the Coordinating Principal Investigator (CP1) and the Tasmanian publicly funded health service will act as the Sponsor, the DoH employee may seek ethical and scientific review from an NMA Certified HREC or another registered HREC. Refer Section: Other HREC Review Fees.

3.1 Policy Exclusions

3.1.1 Other Research Costs

- The *Research Governance - Fee Policy* does not apply to 'other research activity' costs. Other research costs include:
    - 'standard items associated with conducting clinical trials in Australia' provided by Supporting Departments (e.g. Pharmacy, Pathology, Medical Imaging, Health Information, Data Services or other Departments providing a service to the conduct of the research activity).
    - costs associated in the conducting the trial (e.g. staffing, training, equipment and consumables).
- Other research activity costs associated with conducting the research project can be determined using the Independent Hospital Pricing Authority (IHPA), Determination of standard costs associated with conducting clinical trials in Australia Standard List of Clinical Trial Items; the current IHPA Pricing Framework for Australian Public Hospital Services the Department of Health, Medicare Benefits Schedule Online (MBS); the current Tasmanian Industrial Commission, Health and Human Services Award Agreement; goods and services, including equipment and consumables procured by the DoH through Common-Use Contract arrangements; and/or approved departmental cost schedules.

3.1.2 National Mutual Acceptance (NMA)

- Tasmanian publicly funded health services are a formal member of the National Mutual Acceptance (NMA) Scheme. Refer to the DoH website for the NMA Guidelines: Tasmania for accepting the ethical and scientific approval from an HREC certified in accordance with the National Health and Medical Research Council (NHMRC), National Certification Scheme Institutions with certified ethics review processes (NMA Certified HREC) and the NHMRC National Health and Medical Research Council (NHMRC), Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research.

3.1.3 Grants

- Where a grant is administered, requests for exemption from governance fees as per Appendix 1 are to be submitted to the DoH Research Governance Office.

4. Mandatory Requirements

- This is a state-wide policy and must not be re-interpreted so that subordinate policies exist. Should discrete operational differences exist, these should be expressed in the form of an operating procedure or protocol.
- **Failure to comply with this policy**, without providing a good reason for doing so, may lead to disciplinary action.

- The ethics and governance fees as outlined in Appendix 1 – Fee Schedule (Table 1 & 2) apply to the ethical and scientific reviews and the research governance review and/or amendments for research projects.
- Fees where required will include GST. No other fees or levies are payable.
- Revenue raised must be held in a designated cost centre(s) and used to support research initiatives such as training and education of staff, provision of governance administrative support, and other operational costs eg. ICT/databases for research governance.

4.1 Commercially Sponsored (includes Contract Research Organisations CRO acting as a local Sponsor)

- For Commercially/CRO Sponsored research projects there **must** be full cost recovery from the Commercial Sponsor for ethical and scientific review and research governance review fees. **Fees to include GST**.
    - The HREC fee (including amendments) for human research that proposes to be conducted only in Tasmania **and does not have a HREC approval from an NMA Certified HREC** and is Commercially Sponsored will be sent a Tax invoice directly by UTas.
    - Where there is **an existing HREC approval from an NMA Certified HREC,** the Investigator is not required to submit the research to UTas for the ethical and scientific approval. Refer: *NMA Guidelines: Tasmania*. No further HREC fee is payable.
    - The Research Governance review fee (including amendments) for research that is Commercially Sponsored will be sent as a Tax invoice as per the terms of the Research Agreement by the DoH to the Commercial Sponsor on a "pass through basis".

4.2 Non-Commercially Sponsored Research

- The Sponsor may be an academic and/or a collaborative/cooperative research group (CRG) responsible for sponsoring, initiating, managing, developing and coordinating the Study.
- Non-commercial Sponsors can also include an individual institution, such as a university or public hospital. Non-commercial clinic trials are also referred to as academic investigator initiated clinical trials.

4.2.1 Collaborative/Cooperative Research Group (CRG)

- For Collaborative/Cooperative Sponsored research projects the Principal Investigator at the site **should** try to negotiate some funding toward the research governance review fees. It is the nature of collaborative/cooperative research that the research project is conducted in the 'spirit of collaboration' by the participating Institutions and there is generally no funding forthcoming to the site. There should be nil HREC fees if approved by a Lead HREC.
- In the event there may be some funding forthcoming for the site:
    - The Research Governance review fee (including amendments) for Collaborative/ Cooperative Sponsored research reviewed and approved by the THS will be invoiced by the DoH. **Fees to exclude GST**.

- The Research Governance review fee (including amendments) for Collaborative/ Cooperative Sponsored research reviewed and approved by the THS where there is no funding is not invoiced however must be recognised as an in-kind expense in the Financial Analysis and should be included as such.

4.2.1.1 Collaborative/Cooperative Research Group (CRG) between DoH/THS and UTAS - Contract for Services

- The Crown of Tasmania has a 'Contract for Services' with UTas to deliver ethics application review services to enable the DoH and THS comply with applicable ethical and scientific standards to conduct research activities within the Tasmanian publicly funded health services.
- The DoH staff are encouraged to participate in collaborative research that aims to improve the quality and safety of health care provided in the Tasmanian publicly funded health services and improve the health and wellbeing of the Tasmanian community.
- All collaborative research between DoH and UTas must have a research agreement, including research projects being conducted within the Tasmanian publicly funded health services.

Collaborative/Cooperative Research – DoH/THS is "Sponsor"

- For Collaborative/ Cooperative research where the Coordinating Principal Investigator (CPI)/Principal Investigator (PI) is a staff member of the DoH/THS and is conducting the project through their employment or on behalf of the DoH/THS, the DoH/THS is the "Sponsor".
  - The HREC review fee (including amendments) for research submitted to UTas will be invoiced to the DoH as per the 'Contract for Services'. The CPI/PI must ensure the ethical and scientific review fee is recognised as an in-kind expense in the Financial Analysis.
  - Where a UTas staff member is participating in the conduct of the research project the ethical and scientific review fee will be shared between the DoH and UTas in accordance with the 'Contract for Services'. UTas will send a Tax invoice to the DoH.
  - The Research Governance review fee (including amendments) for research reviewed by the Research Governance Officer (RGO) and approved by the relevant Chief Executive (or Delegate Authority) are not invoiced by the DoH under the terms of this policy but CPI/PI must ensure the cost is recognised as an in-kind expense in the Financial Analysis. **Fees to exclude GST**.

Collaborative/Cooperative Research – UTas is "Sponsor"

- For Collaborative/Cooperative Sponsored Research Projects, where the UTas is the "Sponsor" and the CPI is listed at being a UTas staff member and THS staff are collaborating as Investigators and/or the UTas proposes to conduct the research at a Tasmanian publicly funded health service site.
  - The HREC review fee (including amendments) for research submitted to UTas will be invoiced to the DoH as per the 'Contract for Services'. The ethical and scientific review fee must be recognised as an in-kind expense in the Financial Analysis. **Fees to exclude GST**.
  - Where a DoH/THS staff member is participating in the conduct of the research the ethical and scientific review fee will be shared. UTas will send a Tax invoice to DoH.

- The Research Governance review fee (including amendments) for research that is Sponsored will be sent a Tax invoice as per the terms of the Research Agreement by the DoH. DoH/THS staff participating in UTas "Sponsored" research project must ensure they inform UTas of the governance fee. Refer Appendix 1 - Table 2. **Fees to exclude GST**.

4.2.2 Investigator Initiated / Other External Sponsors

- Where an Investigator initiates and organises a research project without the involvement of an institution, he or she will take on the role of the "Sponsor" and will then be responsible for the initiating, management and conduct of the research project, including financial responsibility.
    - There should be nil HREC fees. The DoH will not be responsible for the submission of research for ethical and scientific review fees (including amendments) incurred by Investigators from other Tasmanian government agencies, private health services facilities, individuals not employed by the THS, non-government organisations, private companies, and organisations proposing to conduct health and medical research within the Tasmanian publicly funded health system and submit their research project for scientific and ethic review and approval at the University of Tasmania (UTas).
    - Where the Investigator proposes use of Tasmanian publicly health service facilities, access to participants (patients and/or public health system employees) and/or their data (medical and personal records of information) and/or tissue collections held within the authority of the DoH, the research project will require a research agreement and a governance review by the RGO and approval by the Chief Executive (or Delegated Authority).
    - The Research Governance review fee (including amendments) is outlined in Appendix 1 – Table 2. The Investigator will be sent a Tax invoice as per the terms of the Research Agreement by the DoH. **Fees are subject to type of Sponsor according to the Australian business registration**.

4.2.3 Student Researchers

- Where a Student is undertaking Honours, Masters, PhD coursework or completing research as part of a program of learning (eg. Medical, nursing student) initiates a research project in order to complete the required course it is deemed to be "Sponsored" by the tertiary institution in which they are enrolled. The Student must have a Supervisor within the tertiary institution and a delegated Site Supervisor who is a current DoH/THS employee as a point of contact.
    - There should be nil HREC fees. The DoH will not be responsible for the submission of research for ethical and scientific review fees (including amendments) incurred by Students employed by other Tasmanian government agencies, private health services facilities, individuals not employed by the THS, non-government organisations, private companies, and organisations proposing to conduct health and medical research within the Tasmanian publicly funded health system and submit their research project for scientific and ethic review and approval at the UTas.
    - Where the Investigator proposes use of Tasmanian publicly health service facilities, access to participants (patients and/or public health system employees) and/or their data (medical and personal records of information) and/or tissue collections held within the authority of the DoH,

the research project will require a research agreement and a governance review by the RGO and approval by the Chief Executive (or Delegated Authority).

- The Research Governance review fee (including amendments) is outlined in Appendix 1 – Table 2. The "Sponsor" will be sent a Tax invoice as per the terms of the Research Agreement by the DoH. **Fees are subject to type of Sponsor according to the Australian business registration**.

4.3 Amendments

- Amendments include any changes to the supporting documents e.g. protocol, investigator brochure or changes to research project investigators and/or any contractual amendments including the budget and contract revisions. Amendments are described in Glossary & Definitions and fees prescribed in Appendix 1 – Table 2.

4.4 Certified NMA HREC or Registered HREC Ethical Review Fees

- Where a staff member employed by the Tasmanian publicly funded health services proposes to conduct multi-centre research and they will take on the role of the CPI. The employee of the Tasmanian publicly funded health service may seek ethical and scientific review from an NMA Certified HREC or another registered HREC.
- CPIs seeking ethical and scientific review from an NMA Certified HREC or another registered HREC must clarify with that HREC as to any ethical review fees that may be leveraged by the HREC and ensure they have the funds to pay any ethical review fees and clarify if there are any agreements required in order to contract the ethical review services.
- CPIs seeking to conduct multi-centre research will need to discuss their project with the RGO if it is proposed that the Tasmanian publicly funded health services will act as the Sponsor of the research project to ensure the appropriate consideration of legal and insurance matters.

5 Roles and Responsibilities/Delegations

- **Secretary, Department of Health –** is responsible for ensuring the overall effective and responsible governance of research across the Tasmanian publicly funded health services.
- **Chief Executive (CE)/Chief Operating Officer (COO) (or equivalent) –** is responsible for ensuring awareness and compliance with this policy, ensures adequate resources and structures are in place to meet the requirements of this policy.
- **Department of Health (DoH)** – is responsible for providing policy leadership to establish a consistent fee schedule for the review of ethics applications and research governance applications and other associated monitoring fees.
- **Business Managers/Heads of Department/Divisional Directors -** ensure that the costs for ethics and governance fees are leveraged and documented in the Financial Analysis; and revenue generated from commercially sponsored trials is used within the scope of this policy, ensuring accountability and transparency and efficient use of the funds.

- **Coordinating Principal Investigator/Investigator/Principal Investigator (or equivalent) -** ensure the relevant fees for the ethics and governance applications are captured in the Financial Analysis and the fees for the governance review are fully disclosed when discussing prospective research with Sponsors.
- **Research Governance Officer/s –** ensure the relevant fees for the ethics and governance applications are captured in the financial analysis and the budget of the site-specific assessment form and invoiced for as required.

6 Risk Implications

- The ethics and governance fees as outlined in Appendix 1 – Fee Schedule represent revenue for the DoH. Failure to comply will risk insufficient financial support research initiatives such as training and education of staff, provision of governance administrative support, and other operational costs eg. ICT/databases for research governance.

7 Training

- The DoH Research Governance Office is responsible for providing training to DoH staff on the Research Governance Fee Schedule Policy.

8 Audit

- This policy will be included in the work program of the DHHS Internal Audit function. This work program is approved by the Audit and Risk Committee and will assess underlying systems and procedures for compliance with the requirements of this policy. The overall focus of this assessment will be one of continuous improvement to DHHS activities.

6 Glossary and Definitions

Amendment	A written description of a change(s) to, or formal clarification of, a protocol or the research project. An amendment may be major or minor.
Collaborative or Cooperative Research Group (CRG)	Is an academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating the Study. See also non-commercial sponsor.
Commercial Sponsor	The Sponsor or Contract Research Organisation (CRO) is a company or organisation that takes responsibility for the initiation, management, indemnity and financing of a clinical trial and endorses the Therapeutic Goods Administration form. The project protocol has been developed by the commercial entity, and it retains ownership of the product, project material and intellectual property. Consequently, the risks and liabilities associated with the trial are borne primarily by the Sponsor/CRO and they must provide indemnity and insurance.
Institution	Institution in which the research is being conducted.
Investigator Initiated	Where an investigator initiates and organises a trial without the involvement of an institution, he or she will take on the role of the trial sponsor and will then be responsible management and conduct of the trial. If the investigator is staff member of the Tasmanian publicly funded health services and is conducting the project through their employment or on behalf of the Tasmanian publicly funded health services, the Tasmanian publicly funded health services fills the role of the Sponsor.
Non-Commercial Sponsor	The Sponsor is an academic and/or non-commercial collaborative or cooperative research group responsible for sponsoring, initiating, managing, developing and coordinating the Study.
Major Amendments	Protocol amendments defined as changes to the protocol which includes any of the following: • Revision of the study design due to safety issues; • Revisions in drug dosage, participant groups and numbers of study participant; • Revision of the clinical trial research agreement; • Revision of the investigator brochure or protocol where there are associated changes to the Participant Information and Consent Form (PICF) that required HREC review and approval.
Minor Amendments	Protocol amendments defined as changes to the protocol which includes any of the following: • Correction of language, grammar and numbering • Minor amendments to the PICF (e.g. minor wording and administrative changes with no ethical significance) • Updates to existing recruitment material (e.g. flyers, advertisements, invitation letters) but not associated change to the PICF
National Mutual Acceptance (NMA)	National Mutual Acceptance (NMA) is a system for mutual acceptance of ethical and scientific review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. NMA reduces duplication in the conduct of ethical and scientific review of multi-jurisdictional research.

Multi-Centre Research	Research that is conducted by several investigators according to a single protocol at more than one study site either within the one state or across jurisdictions (also referred multi-jurisdictional).
Single-Centre Trial	Research that is conducted by one investigator at one site only (i.e. single-site research).
Study Site	The location(s) under the control of the Institution where the research is being conducted. See also Institution.
Sponsor	The Sponsor is responsible for the initiation, management, and financing (or arranging the financing) of the trial and carries the medico-legal responsibility associated with its conduct.

9 References

- Australian Government, Australian Business Register, Australian Business Lookup (ABN Lookup)
- National Health and Medical Research Council (NHMRC), Research Governance Handbook: Guidance for the National Approach to Single Ethical Review (December 2011).
- NHMRC, National Statement on Ethical Conduct in Human Research (*National Statement*)
- NHRMC, National Certification Scheme Institutions with certified ethics review processes.
- NHMRC, National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research (November 2012).
- Independent Hospital Pricing Authority (IHPA) Determination of standard costs associated with conducting clinical trials in Australia Standard List of Clinical Trial Items (2015)
- Tasmanian Industrial Commission, Health and Human Services Award Agreement
- Australian Government, Department of Health, MBS Online Medicare Benefits Schedule (MBS)
- Department of Health Research Governance Policy Framework and Research Governance Procedures

10 Appendix

- Appendix 1 - Fee Schedule (subject to annual revision)

Appendix 1 – Fee Schedule

Table 1: Fee Matrix

Sponsor Type	Multicentre/Single Centre	Governance Fee	HREC Fee
Commercial / Contract Research Organisation	Multicentre	100% Raise invoice – Refer Table 2	Nil NMA
	Single Centre	100% Raise invoice – Refer Table 2	NMA or Refer to UTas
Collaborative / Cooperative Research Group (CRG)	Multicentre	Nil In-kind in Financial Analysis	Nil NMA
	Single Centre	Nil In-kind in Financial Analysis	NMA or Refer to UTas
Investigator Initiated / Student	Multicentre/Single Centre	100% Raise invoice – Refer Table 2	N/A
Collaborative/Cooperative Research Group – DoH/THS and UTas			
Collaborative – DoH/THS as "Sponsor"	Multicentre / Single Centre	Nil In-kind in Financial Analysis	Refer to UTas or NMA HREC In-kind in Financial Analysis
Non-collaborative – DoH/THS as "Sponsor"	Multicentre / Single Centre	Nil In-kind in Financial Analysis	Shared Refer to UTas In-kind in Financial Analysis
Collaborative – UTas as "Sponsor"	Multicentre / Single Centre	100% Raise invoice – refer Table 2	Shared Refer to UTas In-kind in Financial Analysis
Non-collaborative – UTAS only as "Sponsor"	Multicentre / Single Centre	100% Raise invoice – refer Table 2	N/A

Table 2: Fee Schedule (Subject to Annual Review)

Ethical and scientific Review Fees	Refer to the University of Tasmania, Research Ethics and Integrity Unit Fee Schedule; or NHMRC National Certification Scheme for NMA Certified HREC contact information			
RESEARCH GOVERNANCE	Sponsor Type	Fee Description	GST Excluded	GST Included
	Commercial Sponsorship (includes Contract Research Organisations acting as a local Sponsor)	New application	$3579.00	$3937.00
		Additional site	$1789.00	$1968.00
		Addition of sub-study	N/A	N/A
		Major Amendment	$709.00	$780.00
		Minor Amendment	$269.00	$296.00
		Other Amendment	By negotiation	By negotiation
	Collaborative/Cooperative Research Group Sponsorship (includes Non-Government Organisations, Community and Participatory Groups)	New application	$3579.00	$3937.00
		Additional site	$1789.00	$1968.00
		Addition of sub-study	N/A	N/A
		Major Amendment	$709.00	$780.00
		Minor Amendment	$269.00	$296.00
		Other Amendment	By negotiation	By negotiation
	Low and Negligible Risk / Access Request (includes projects seeking waiver of consent)	New application	$2135.00	$2349.00
		Additional site	N/A	N/A
		Addition of sub-study	N/A	N/A
		Major Amendment	$532.00	$585.00
		Minor Amendment	$269.00	$296.00
		Other Amendment	By negotiation	By negotiation
	Investigator Initiated i.e. there is no commercial,	New application	$3579.00	$3937.00

	collaborative/cooperative sponsor and the investigator accepts responsibility for the conduct of the trial eg. Private consultants	Additional site	$1789.00	$1968.00
		Addition of sub-study	N/A	N/A
		Major Amendment	$709.00	$780.00
		Minor Amendment	$269.00	$296.00
		Other Amendment	By negotiation	By negotiation
	Students (includes Honours, Masters, PhD)	New application	$447.00	$492.00
		Additional site	$223.00	$246.00
		Addition of sub-study	N/A	N/A
		Major/Minor/Other Amendment	By negotiation	By negotiation