MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

COVERSHEET

Minister	Hon Dr Shane Reti	**Portfolio**	Science, Innovation and Technology
Title of Cabinet paper	Transitioning health research funding from the Health Research Council to Research Funding New Zealand	**Date to be published**	9 April 2026

List of documents that have been proactively released

Date	Title	Author
November 2025	Transitioning Health Research Funding from the Health Research Council to Research Funding New Zealand	Offices of the Minister of Science, Innovation and Technology, and of the Minister of Health
12 November 2025	Transitioning Health Research Funding from the Health Research Council to Research Funding New Zealand ECO-25-MIN-0185 Minute	Cabinet Office
5 November 2025	Future of Health Research Funding: Decision Making and Allocation RIS	MBIE and MOH
5 November 2025	RIS Annex 2 - Cost Recovery for a Fast-track Research Ethics Review Process	MBIE and MOH
3 December 2025	RIS Quality Assurance Feedback Form and QA Criteria	MBIE and MOH
14 August 2025 – 5 November 2025	Briefings on the Future of Health Research Funding	MBIE and MOH

Information redacted **YES**

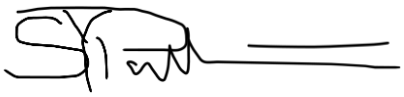
Any information redacted in this document is redacted in accordance with MBIE's policy on Proactive Release and is labelled with the reason for redaction. This may include information that would be redacted if this information was requested under Official Information Act 1982. Where this is the case, the reasons for withholding information are listed below. Where information has been withheld, no public interest has been identified and that would outweigh the reasons for withholding it.

Some information has been withheld under the grounds of commercial information, confidential advice to Government, and confidential commercial information (trade secret).

Annex 2: Stage 1 Cost Recovery Impact Statement

Cost recovery for a fast-track research ethics review process

Coversheet

Purpose of document	
Decision sought:	Analysis produced to inform Cabinet's decision to provide for fees to recover the costs of fast-track research ethics review.
Advising agencies:	Ministry of Health
Proposing Ministers:	Hon Simeon Brown, Minister of Health Hon Dr Shane Reti, Minister of Science, Innovation and Technology
Date finalised:	4 November 2025
Responsible Manager	
Saskia Patton Manager, Ethics Regulatory Services Ministry of Health  4 November 2025	
Quality Assurance	
Reviewing agencies:	Ministry of Business, Innovation and Employment & Ministry of Health
Panel assessment & comment:	The joint Regulatory Impact Analysis Review Panel from the Ministry of Business, Innovation and Employment and the Ministry of Health have reviewed the Regulatory Impact Assessment (*Future of health research funding – decision making and allocation)*, and supporting Stage 1 Cost Recovery Impact Statement (*Cost recovery for a fast-track research ethics review process)*, and we have determined that the papers **meet** the criteria.

Stage 1 Cost Recovery Impact Statement

Cost recovery for a fast-track research ethics review process

Status quo

1. Ethics review of health and disability research is critical for protecting study participants. Independent ethics committees provide external, impartial review of research applications, ensuring ethical standards are upheld. This is especially important when researchers may have conflicts of interest or be subject to institutional pressures.

2. New Zealand has a centralised system for the ethics review of health and disability research. The system was designed to ensure transparency, accountability, and protection of participants, and has evolved in response to historic inquiries such as the Cartwright Inquiry (1987-88).

3. There are currently four Health and Disability Ethics Committees (HDECs), which are ministerial committees established under the Pae Ora (Healthy Futures) Act 2022. The HDECs are responsible for reviewing and approving health and disability research where there is more than minimal risk to participants. Each committee assesses research applications against standards developed by the National Ethics Advisory Committee (NEAC). When an application does not meet these standards, the HDEC will advise the applicant of the necessary changes in order to meet the standards.

4. The HDECs are independent from the Ministry of Health, however the Ministry provides secretariat support for the committees. Responsibilities of the Ministry include:

    a. Managing the HDEC website and IT platform used to submit applications;

    b. Reviewing applications initially to determine their validity and scope;

    c. Preparing HDEC meeting agendas, assigning committee members to applications, hosting committee meetings, and recording committee decisions;

    d. Issuing decision letters to applicants and responding to queries;

    e. Monitoring the activity of approved applications;

    f. Recruiting and training HDEC members, and;

    g. Annual reporting to the Health Research Council (HRC) and Minister of Health.

5. The HDECs review approximately 600 applications annually, covering a wide range of clinical and health- and disability-related studies. Over the past decade, the number of applications being reviewed by the HDECs has increased by 101.5%. On average, the HDECs have experienced an annual growth rate in applications of 8.4%. This is expected to continue, and industry stakeholders have signalled a growing need for ethics review in the future.

6. In addition to ethics review and approval, a separate regulatory approval process is required for clinical trials involving new medicines. Decisions on whether to approve these trials are made on the recommendation of the HRC via two standing committees:

SCOTT (for pharmaceutical-type medicines) and GTAC (gene and other biotechnology therapies). Both committees are funded through cost recovery.[1]

7. New Zealand's average timeframe of 35 days for ethics review is comparable to many international jurisdictions and generally meets the requirements of the public research sector. Commercial Information Stakeholders in this sector have indicated a strong preference for a review timeframe of 20 days, noting that such a shift would require more investment in system capacity and resources. Commercial sponsors have also expressed willingness to contribute through cost recovery mechanisms, as is standard practice in other jurisdictions, and is already the case in New Zealand for regulatory approval of clinical trials involving new medicines.

8. Currently, the HDECs do not charge for ethics review, and there is no legal authority to do so. The ethics review system is funded by the Crown. In September 2025, the Minister of Health, Hon Simeon Brown agreed to progress work to enable the HDECs to charge for the ethics review of research applications. In October 2025, the Minister of Science, Innovation and Technology, Hon Dr Shane Reti and Hon Simeon Brown agreed to legislative changes that relate to ethics and scientific review functions, including adding a regulatory power for cost recovery for fast-track ethics approval.

[1] The current fee for an application for regulatory approval of a clinical trial is $9,843.

Policy Rationale: Why a user charge? And what type is most appropriate?

9. The proposal for full cost recovery will enable a fast-track research ethics review process to be implemented. Research applicants who are willing to pay for faster ethics review would be able to do so. For all other research applicants, ethics review would continue to be free of charge, although this would be slower than the fast-track process.

10. Ethics review of health and disability research attracts both public and private benefits. Accessible, independent, and robust ethics review supports high-quality health and disability research to occur in New Zealand. In turn, evidence from health and disability research informs health care decision-making and is a key tool for improving health outcomes for all New Zealanders. Early-stage scientific discoveries are made accessible over time—such as the introduction of new medicines and medical devices—benefitting patients.

11. In most cases, ethics review is necessary for the publication of research, which has reputational benefits for individual researchers. Faster ethics review can provide direct, often time-sensitive benefits to commercial research applicants—such as regulatory approval and market access—and may yield proprietary or commercial advantage. Such private benefits are evidenced by commercial stakeholders indicating that they would be willing to pay for faster ethics review of their research applications.

12. The dual nature of the benefits of ethics review justifies a differentiated approach to funding:

    a. Ethics review of *all* health and disability research warrants Crown funding due to the broader societal benefits, whereas;

    b. Cost recovery for *fast-track* ethics review is justified due to the benefits of this process being largely constrained to individual research applicants.

13. Internationally, the combination of public and private benefits of ethics review is recognised and accounted for. Many comparable jurisdictions—such as Australia, Canada, Germany, and the Netherlands—employ mixed or full cost recovery models, in particular for commercial research.

14. A fee is the most appropriate type of charge for the proposed cost recovery model as it closely associates those who pay with the benefits of faster ethics review. It is also the easiest to implement (e.g. a fee already exists for clinical trial applications involving new medicines).

15. It is anticipated that commercial research applicants will be most likely to pay for the fast-track ethics review process. Currently, approximately one-third of studies reviewed by the HDECs are commercially sponsored.

High level cost recovery model (the level of the proposed fee and its cost components)

16. The following costs have been modelled on the assumption of establishing an additional ethics committee, thus allowing for more frequent meetings, plus additional resources for considering amendments and corrections to applications.

17. The fast-track research ethics review process will leverage the existing structure of New Zealand's ethics review system. It is anticipated there will be an additional committee established, increasing the number of permanent HDECs to five. This will allow for up to 12 additional meetings each year, and all HDEC meetings will consider fast-track applications. Further to this, a 'floating' committee will be implemented. The floating committee will be responsible for fast-track applications with provisional approval as well as any amendments to fast-track applications following approval. New chairpersons and committee members will have clinical trials expertise, given most fast-track applications are expected to be clinical trials.

18. Additional secretariat capacity will be purchased. Ministry of Health staff will work directly with fast-track research applicants, including screening and processing applications. New standard operating procedures (SOPs), guidance, and application forms for the fast-track review process will be developed. Existing IT infrastructure (e.g. application management software) will be updated to accommodate fast-track applications.

19. There will be at least one HDEC meeting every week, with the ability to respond to any surges in demand throughout the year (e.g. in December and January) without delaying review timeframes. Across all five HDECs, research applicants who pay for the fast-track review process will be prioritised. As a result, it is expected that fast-track research applicants will have their applications reviewed within **20 days** (cf. 35 days for all other applicants).

20. A separate model to the existing HDEC system was also considered for the fast-track review process. However, this was determined to be inefficient and would require higher charges for research applicants. In order to achieve a 20-day review timeframe under a separate model, additional HDEC-equivalent committees would be needed.

21. Leveraging the existing HDEC system for the fast-track review process will also indirectly benefit research applicants who do not pay for ethics review. For instance, committee training modules developed for the fast-track review process would be made available to all HDEC chairpersons and members, thereby improving the quality of ethics review overall. However, research applicants who choose to pay for faster ethics review would not be directly subsidising the existing ethics system. Rather, cost recovery would ensure enough capacity in the system for these applicants to be prioritised, resulting in significantly shorter review timeframes.

22. A memorandum account will be established to support transparency and accountability in administering cost recovery for the fast-track ethics review process. It will record annual surpluses and deficits by comparing fee revenue with actual service delivery costs. Over time, the account should reflect a net balance close to zero, meaning fees collected should approximately match costs incurred across multiple years. This enables the Ministry to monitor financial performance and adjust fees when needed, ensuring fairness and sustainability. The account also helps demonstrate that cost recovery is managed in line with Treasury and Auditor-General guidance, and that no cross-subsidisation occurs between the fast-track and standard review pathways.

23. Cost estimates for the fast-track ethics review process are listed in **Table 1** below.

Table 1: Fast-track ethics review cost estimates (per annum)

No.	Category	Item	Cost estimate ($)
1	Secretariat	Committee operation: 4 FTE[2]	375,000
2		System development & maintenance: 2 FTE[3]	210,000
3	Committees	5th HDEC (1 chairperson, 8-10 committee members)	95,000
4		'Floating' committee (1 chairperson, 4-6 committee members)	60,000
5	Infrastructure	IT	90,000
6	Overheads	Legal, communications, office expenses, etc. (6 FTE)	300,000
7	Implementation costs	New SOPs, guidance, application forms Development of committee training modules New committee appointments	50,000[4]
8	Other	Training for research sector	50,000
Total			**1,230,000**

24. Confidentiality

[2] 1 Senior Advisor, 2 Advisors, 1 Administrator.

[3] 1 Senior Advisor, 1 Advisor. Committee training, stakeholder engagement, and system monitoring and reporting.

[4] One-off cost ($250,000) distributed over 5 years.

[5] Respondents answered on the understanding that the service would be funded through cost recovery and be privately delivered. Based on comments from respondents, NZACRes estimated that between 145 and 228 applications would be submitted to this service.

[6] It is assumed that the same percentage of commercial research applicants would be willing to pay for faster ethics review of 'major' application amendments, however fewer (25%) commercial applicants would be willing to pay for other types of application amendments as these tend to be less urgent.

25. Sector stakeholders have indicated that they would expect to pay the equivalent of the Australian service (up to $10,000). There is also a new social sector ethics committee established in New Zealand that is currently charging applicants $3,000. Therefore, we think a fee in the range of $3,000-10,000 per application would be acceptable from an applicant perspective.

26. Estimated charge levels (fast-track ethics review process):

    a. New HDEC research application: $5,350

    b. HDEC research application 'major' amendment (incl. full committee review): $5,350[7]

    c. HDEC research application amendment (sub-committee review): $1,785[8]

27. Estimated revenue for each of the charge levels is given in **Table 2** below.

Table 2: Estimated revenue from cost recovery for fast-track ethics review (per annum)

Charge	$ amount	No. applications[9]	Revenue ($)
New HDEC research application	5,350	146	781,100
HDEC research application 'major' amendment	5,350	34	181,900
HDEC research application amendment	1,785	151	269,535
Total	**N/A**	**331**	**1,232,535**

28. As with any new cost recovery initiative, there are risks associated with demand uncertainty and system capacity. These risks will be explored further during stakeholder consultation and addressed in detail in the Stage 2 Cost Recovery Impact Statement.

29. There is a risk that actual demand for the fast-track review process may be lower than anticipated, particularly if research applicants are unwilling to pay the proposed charge levels. To mitigate this, consultation will include targeted engagement with commercial and non-commercial research applicants to test willingness to pay and refine demand estimates. This will inform the development of a more robust financial model in stage 2.

30. On the other hand, if demand exceeds expectations, there is a risk that the fast-track service may be under-resourced, potentially impacting service quality or creating pressure on the standard review pathway. To manage this, the fast-track service will be designed with scalable components. Committee costs are variable and directly linked to application volumes, as HDEC chairpersons and members are paid per review. Other costs such as secretariat staffing, infrastructure, and overheads include both

[7] Same fee as new HDEC research application due to similar committee and secretariat resources required.

[8] Approximately one-third of the cost of HDEC research application 'major' amendment.

[9] In FY2024-25, there were 195 commercially sponsored applications (195 x 0.75 = 146), 45 'major' amendment applications (45 x 0.75 = 34), and 604 other amendment applications (604 x 0.25 = 151). 'Major' amendment applications were defined as having ≥ 20 attachments.

fixed and variable elements. These will be scaled in line with actual demand, allowing the Ministry to ramp up resources and associated expenditure as needed.

31. Demand for ethics review is increasing over time. Stage 2 will include sensitivity analysis to identify thresholds at which additional resourcing (e.g. increased FTE) would be triggered. These thresholds will be informed by consultation feedback and operational modelling. The use of a memorandum account will support financial monitoring and adjustment of fees or resourcing over time.

Consultation

32. To date, there has been no formal consultation on the proposal for cost recovery for a fast-track research ethics review process. However, over the past year, Ministry of Health officials have informally engaged with industry stakeholders in response to calls for improved timeliness of ethics review. Stakeholders have expressed willingness to pay for certainty of ethics review timeframes, in particular comparable timeframes to Australia (20 days). Stakeholders have indicated that they would expect to pay similar fees to those in Australia.

33. Confidentiality

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36. Subject to Cabinet approval, Ministry of Health officials will consult with the following stakeholders on the proposal for cost recovery:

    a. Commercial stakeholders (e.g. sponsors, contract research organisations), and;

    b. Public researchers (e.g. NGOs, universities).

37. In the first half of 2026, officials will engage with stakeholders to better estimate expected demand for the fast-track ethics review process. The information gathered from these engagements will be used to refine the estimated charge levels for the fast-track review process.

38. In the second half of 2026, officials will formally consult with stakeholders on a draft cost recovery framework, including the estimated charge levels, timeframes for ethics review, exceptions, and waiver powers.