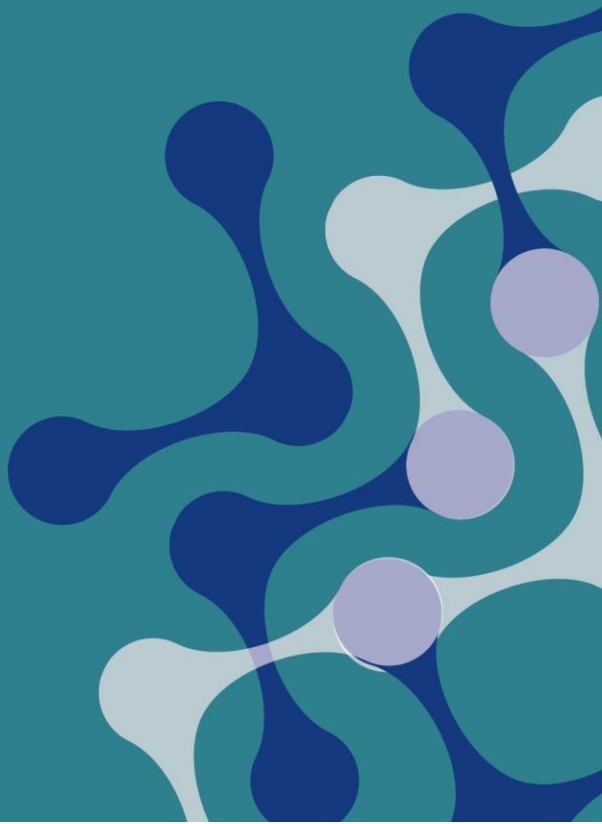
Office for Health and Medical Research

Medical Devices Fund Round 12

Guidelines

2024



NSW GOVERNMENT

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www.medicalresearch.nsw.gov.au

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Program Overview

The NSW Government established the Medical Devices Fund (the Fund) to help encourage and support investment in the development and commercialisation of medical devices and related technologies in NSW. Under the NSW Health Future Health Strategic Framework 2022-2032, NSW Health is committed to advancing and translating research and innovation with institutions, industry partners and patients. The Fund aligns with this commitment and the recommendation of the NSW Health and Medical Research Strategic Review that NSW be enabled to contribute to the discovery and application of new treatments and diagnostic techniques and devices that will be major contributors to health reform into the future.

The Fund supports individuals, companies, public and private hospitals, medical research institutes, universities, other public sector research organisations, and the medical devices industry. Through the Fund, NSW Health offers grants to drive the commercialisation of highly innovative ideas into new devices and technologies, addressing gaps in the product life cycle between early-stage research and mature investment opportunities.

Funding is provided on an open competitive basis, while maintaining commercial-in-confidence requirements.

Applicants will have approximately 5-6 weeks to complete and submit their application.

The Fund will be administered in accordance with the NSW Grants Administration Guide.

Objective

The Fund is funded by NSW Health and administered by the Office for Health and Medical Research (OHMR).

The Fund supports a cross-section of products across a range of applications throughout the medical device product life cycle. Funded projects must be capable of potentially improving patient care and/or health and wellbeing, and generating economic, social and/or environmental benefits to NSW.

Intended outcomes of the Fund are to:

- support individuals, companies, public and private hospitals, medical research institutes, universities, other public sector research organisations, and the medical devices industry, to take local innovation to market
- increase the uptake of NSW medical devices by the health system where they are cost effective and contribute to improved patient outcomes.

Applicant responsibilities

The Fund Guidelines (the Guidelines) contain information about the Fund, eligibility, and how to make an application.

Applicants must read these Guidelines before applying for a grant.

This document sets out:

- the purpose of the Fund
- the eligibility criteria
- the assessment criteria
- how applications are assessed
- how recipients will be monitored and evaluated
- responsibilities and expectations in relation to the Fund.

Applications close 10am AEDT Friday 29 March 2024 (late applications will not be accepted under any circumstances).

Indicative program timeline

Activity	Timeframe
Call for preliminary applications	Tuesday 20 February 2024
Preliminary applications close	10am AEDT Friday 29 March 2024
Fund Sub Group meets	April/May 2024
Fund Expert Panel meets	May/June 2024
Invitation to submit full application	June 2024
Full applications close	July 2024
Fund Expert Panel meets	August 2024
Interview with Fund Expert Panel	September 2024
Notification of outcome	October 2024

Program funding

Payment of grants awarded under the Fund will be made directly to the applicant's organisation.

Successful applicants will be awarded funds from a maximum pool of $8 million (excluding GST) with the final amount decided at NSW Health's

discretion. A minimum of $500,000 and a maximum of $5,000,000 can be awarded per application.

Funding will be provided following the execution of an agreement between the applicant and NSW Health.

Subject to the exclusions below, funding can be used for any purpose that meets the objectives of the Fund. Examples include but are not limited to:

- device development, including proof-of-concept, prototyping, and piloting studies
- manufacturing samples for product trials
- clinical assessment
- engaging a consultant to locate other national and international trials and research relevant to the product under development
- business planning, including conducting market and product assessments
- intellectual property management
- commercialisation
- capital raising.

The Fund will not support activities which do not meet the principles of the Fund. Exclusions include but are not limited to acquisition of land and buildings, capital works and general infrastructure costs, any costs directly related to research, PhD stipends, fees for visas, relocation, costs of dependents, insurance, and mobile phones, fees for international students or liabilities for students, donations and gifts, and fine or penalty payments.

The amount of funding awarded to successful applicants will depend on the overall quantity and quality of applications received. The Fund Expert Panel will have sufficient flexibility to tailor recommended funding support according to what it believes is required to assist the development and commercialisation of a medical device.

The majority of any funding provided to a project is to be expended in NSW.

Successful recipients are required to provide a financial acquittal following expenditure of the grant, demonstrating that grant funds were used in accordance with Fund Guidelines.

Eligibility Criteria

Applications that do not meet all the eligibility criteria will not be considered.

Who is eligible to apply?

Medical device definition

An applicant's medical device/technology must satisfy the definition of a medical device.

The medical devices industry is defined as including those companies and organisations that develop, produce or supply devices or parts of devices that are regulated as medical devices by the Therapeutic Goods Administration. The Therapeutic Goods Act 1989 (section 41BD), as amended, defines a medical device as:

a) any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

   i. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

   iii. investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

   iv. control or support of conception;

   v. in vitro examination of a specimen derived from the human body for a specific medical purpose;

   and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

   (aa) any instrument, apparatus, appliance, software, implant, reagent, material or other article specified under subsection (2A); or

   (ab) any instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection (2B); or

   b) an accessory to such an instrument, apparatus, appliance, software, implant, reagents, material or other article; or

   c) a system or procedure pack.

For the purposes of the Fund, the definition of a medical device includes those technologies that have a patient application which will impact the health system that are not considered to be drugs. Technologies such as 'omics' technologies, apps, virtual technologies, remote diagnostics, and nanotechnologies can be considered.

All submissions will be assessed against the Australian regulatory requirements for medical devices (TGA).

Applicants

Eligible organisations include public and private hospitals, medical research institutes, universities, start-ups and established small-to-medium enterprises (SMEs).

Applicants must be:

- A financially viable company or commercial enterprise with:
  - the parent company based in NSW (e.g., location of manufacturing jobs, headquarters based in NSW, NSW investment) and able to provide evidence that the proposal connects and benefits NSW
  - an Australian Business Number (ABN)
  - typically an annual turnover of less than $25 million
  - a legal entity; or
- An individual based in NSW who agrees to form such an entity so that NSW Government can enter into legally binding funding agreements; or
- A NSW public research organisation applying through its appropriate technology transfer office, or the CEO or equivalent of the research organisation.

Intellectual Property

An applicant's medical device/technology must be supported by NSW intellectual property (NSW IP).

Eligible projects

Projects throughout the medical device product life-cycle will be considered from a minimum Technology Readiness Level 3 (Technical proof of concept demonstration – see Appendix 1). Note that evidence must be provided to support the Technology Readiness Level.

Assessment Criteria

Eligible applications will be evaluated against information and evidence provided in relation to the below criteria.

Sufficient information and evidence must be provided by the applicants to enable the Fund Sub Group and Fund Expert Panel to undertake a diligent review of the applications without the need to source significant further data/information to evaluate the submission. Where relevant, letters of support from third party organisations are encouraged to be included.

Impact on health outcomes

- Applicants must demonstrate:
    - the impact of the device on the health system in NSW, Australia and globally
    - how the device will improve people's health and wellbeing.

Economic, social and/or environmental impact for NSW

- Applicants must demonstrate:
    - how the device has been and is developed in NSW
    - how the medical device will deliver economic, social and/or environmental benefits for NSW.

Impact on clinical practice

- Applicants must demonstrate how the medical device will assist health delivery in NSW including how it will result in:
    - improved clinical outcomes
    - improved practice efficiency or effectiveness
    - improved ease of use
    - improved quality
    - improved safety.

Innovation

- Applicants must demonstrate how the medical device is innovative (e.g., new to market, or new to world).

Commercialisation pathway

- Applicants must demonstrate how the project seeks to progress a medical device along the commercialisation pathway.

Funding need

- Applicants are required to demonstrate:
    - how the organisation will use the funding to complete project activities
    - how the funding requested is critical to the development and commercialisation of the device.
- A risk mitigation approach to funding will be undertaken as it is acknowledged that funding for a medical device at the technical proof of concept phase is a much higher risk from the point of view of return on investment than funding for a market ready product.

Applicant/Organisation

- Applicants must demonstrate:
    - the applicant is a NSW-based organisation, which is not a subsidiary, supportive of the technology applying for funding
    - the organisation's interest/involvement in the opportunity was initially derived from the activities of its researcher(s)/employee(s)
    - the organisation must benefit from the Fund investing in the opportunity, noting the benefit need not be financial
    - the organisation's researcher(s)/employee(s) have some ongoing role in the development of the technology
    - the organisation will derive financial benefit if the technology is commercialised
    - the organisation will gain recognition/kudos if the technology is commercialised.

Assessment Terms

Applications are screened in line with eligibility criteria and are put forward to the Fund Sub Group and Fund Expert Panel for assessment against the Assessment criteria set out in these Program guidelines. The Fund Sub Group and Fund Expert Panel assess each application on a case-by-case basis and the Fund Expert Panel puts forward recommendations for grant allocation to NSW Health. NSW Health will consider the recommendations before making a final decision regarding the funding allocation amount and successful applicants.

Membership of the Fund Expert Panel remains at the discretion of the Minister for Health and Medical Research. Membership of the Fund Sub Group remains at the discretion of OHMR. The Fund Sub Group and Fund Expert Panel may consult external subject matter experts as required. The decisions of the Fund Sub Group and Fund Expert Panel are governed by the Assessment Terms in these Guidelines.

Where appropriate, the Fund Expert Panel may consider the following in their recommendations:

- The requested funding amount in relation to the proposed project
- Whether the applicant has access to other avenues available to raise capital which may assist with the delivery of the project
- The total funding available in the Fund round

The amount of funding allocated to each successful applicant remains the decision of NSW Health.

Terms for successful applicants

Grant duration, size and repayment

Funding will be in the range of $500,000 to $5 million, depending on the product's stage of development and recommendation of the Fund Expert Panel.

NSW Health requires repayment of the grant once the recipient earns a profit through the commercialisation of the device. The specific terms of this repayment, such as time period, interest and other factors, will be agreed on as part of the funding agreement negotiations.

Organisations will be awarded funding for one Fund round at a time. While an organisation may apply in subsequent Fund rounds, the Fund Expert Panel will consider a range of factors including whether the organisation has fulfilled its obligations as set out in the funding agreement.

Reporting

Successful applicants will be required to undertake annual and final reporting requirements. This includes financial and return on investment reporting.

Other terms

All other terms are detailed in the funding agreement with successful recipients.

Application Process

The Medical Devices Fund application form is available at [https://www.medicalresearch.nsw.gov.au/medical-devices-fund/].

Applications are due by **10am AEDT Friday 29 March 2024**.

All applications must be submitted electronically to MOH-OHMRGrants@health.nsw.gov.au. This includes one electronic copy of the application form and attachments and video.

Filenames must follow the naming convention of: 'Medical Devices Fund2024_organisation name' for preliminary applications and 'Medical Devices Fund2024_organisation name_attachment' for attachments.

The application must be completed in its entirety to be eligible for consideration. Any confidential information should be clearly marked. The application must be signed by the applying organisation's CEO or appropriate delegate.

All eligible applications will be assessed on merit against the assessment criteria. However, NSW Health at its discretion may choose not to award or recommend funding to applicants under the Fund.

Applications received after the closing date will not be considered. Any late applications received will need to apply in a future round.

If the applicant finds an error after submitting the application, they should contact OHMR immediately at MOH-OHMRGrants@health.nsw.gov.au. OHMR is not obligated to accept any additional information and does not request applicants to correct applications after the closing date. Applications cannot be changed after the closing date and time.

Applications will be considered in a multi-stage process. NSW Health may request additional information from an applicant in relation to the eligibility and assessment criteria at any point during the assessment process. Where NSW Health considered an application is unsuitable or unsatisfactory against any criteria, the application may be excluded from further evaluation.

Assessment

Applications are called for once a year and there is a multi-stage application and assessment process. All applications and supporting material will be treated commercial-in-confidence.

OHMR will provide secretariat support for the Fund Sub Group and Fund Expert Panel.

All applicants are required to sign a declaration form regarding details about legal proceedings, research or financial misconduct in both the preliminary and full application. These details will not prevent the applicant from being considered for a Fund grant, however OHMR may request further information from successful applicants prior to entering into a funding agreement.

Eligibility check

The Fund Sub Group will conduct an initial eligibility check for all applications in line with the eligibility criteria in these guidelines. Applications which meet the eligibility criteria will progress to the Fund Expert Panel for assessment.

Preliminary application and assessment

Applicants are required to submit a preliminary application as an early screening document that allows the Fund Sub Group and Fund Expert Panel to determine eligibility, review the opportunity and assess the quality of the application.

The Fund Sub Group provides initial screening and advice to the Fund Expert Panel regarding the eligibility and quality of the applications against the agreed criteria.

The Fund Expert Panel will take this advice into consideration when reviewing the applications and determine which applications will proceed to full application. The Fund Expert Panel reserves the right to refer proposals to the Secretariat for further discussion and development with applicants.

Fund Sub Group and Fund Expert Panel members assess all eligible applications unless they have declared a conflict of interest for a certain application(s). Members individually assess all eligible applications against each criterion set out in these Guidelines.

Full application and assessment

The Fund Expert Panel will determine if a preliminary application proceeds to a full application. This is a more detailed application that covers all aspects of the opportunity.

To be eligible to be invited to submit a full application, applicants must submit a preliminary application.

For applications that progress to full application, an independent clinical expert review and an independent financial review will be undertaken. All parties will be required to agree to the same confidentiality undertaking when reviewing applications.

Interviews with the Fund Expert Panel

Following full application assessment, applicants may be required to present the proposal or be interviewed. This stage is by invitation only.

Approval

The Fund Expert Panel will agree on the ranking of eligible full applications that proceeded to interview and will put forward a recommendation on the suitability of each proposal for funding to NSW Health.

NSW Health will consider the recommendations from the Fund Expert Panel and will make a final decision on whether to support applicants and the funding amount allocated to each successful applicant.

Notification

OHMR will advise each applicant of the outcome of their application via email and/or letter in September 2024.

Successful applicants will be notified and advised on specific conditions of the grant opportunity.

Unsuccessful applicants will be notified and will be offered feedback if requested. If unsuccessful, applicants may submit a new application in a future Fund round and should include information that addresses feedback received on the previous application.

NSW Health may request that conditions of the grant opportunity be kept confidential prior to the execution of the funding agreement and announcement being made by OHMR in relation to the Fund and the grant.

Funding Agreements

Successful applicants will be contacted to execute a standard funding agreement.

The agreement will specify obligations in line with the terms outlined in these Guidelines, including NSW Health's obligations in relation to the flow of funds and the grant recipient's obligations in relation to reporting and accountability.

Funding agreements must be signed by an authorised signatory.

If the successful applicant is found to have provided dishonest or false information in their application, NSW Health has the right to terminate the funding agreement. If a Grantee becomes aware of a breach of terms and conditions specified under the funding agreement, they must contact OHMR immediately. After the funding agreement has been executed, the terms of the agreement remain in place should NSW Health choose to cancel or amend the Fund.

Enquiries

For all enquiries related to the Medical Devices Fund, please contact OHMR at MOH-OHMRGrants@health.nsw.gov.au.

Probity

OHMR will ensure the application and selection process is transparent and fair, in line with the published guidelines. If an applicant wishes to discuss the outcome of their application, they may submit a request for feedback to MOH-OHMRGrants@health.nsw.gov.au. Application outcomes cannot be appealed or contested.

Privacy and confidentiality

NSW Health will treat all personal information in line with the NSW Health Privacy Management Plan. Applicant and recipient personal information can only be disclosed for the primary purpose for which it was collected unless an exemption applies.

OHMR may share or disclose information about applicants and recipients for reporting purposes, administration, research, or service delivery with other NSW Government entities.

NSW Health will treat any information related to the applicant in line with the Privacy and Personal Information Protection Act 1998 (NSW). As part of the application, the applicant and any officers, employees, agents or subcontractors that are engaged with the project must declare their ability to comply with the Act.

NSW Health may request at any time that employees, agents, or subcontractors engaged with the project provide a written undertaking relating to non-disclosure of confidential information in a form provided by NSW Health.

NSW Health will treat any information related to an applicant's application or funding agreement as confidential should it meet all the conditions below:

- the information has been indicated as confidential and should be treated as such
- the information is commercially sensitive
- the information may cause unreasonable harm to the applicant or someone else.

The following instances will not indicate a breach of confidentiality if information is disclosed to:

- the Fund Sub Group, the Fund Expert Panel or any other NSW Government employees and contractors for the purposes of Fund administration and assessment
- OHMR employees and contractors who may research, assess, monitor and analyse the Fund and its associated activities
- NSW Government employees and contractors from other departments or agencies who may conduct activities related to government administration, research or service delivery
- any other Commonwealth, State, Territory or local government agencies who may form part of program reports and consultation
- the Auditor-General, Ombudsman or Privacy Commissioner
- a House or a Committee of the NSW Parliament.

Evaluation statement

OHMR will periodically assess the Fund to ensure it is meeting its objectives. NSW Health may contact funding recipients to supply additional information for up to three years following completion of the funding agreement.

OHMR reserves the right to undertake an audit of the Fund at the request of the NSW Audit Office. The constituents of any funding agreement may be tracked and reported.

Acknowledgement

Funding recipients should acknowledge any financial support offered by NSW Government in line with the Funding Acknowledgement Guidelines for Recipients of NSW Government Rebates.

For more information, please see the guidelines here.

Appendix 1 – Technology Readiness Level Scale

TRL	TRL Description	Evidence of Achievement
1	Basic principles observed and reported	Published research that identifies the principles that underlie this technology
2	Technical Device concept formulated	Practical applications (e.g. devices) of the basic principles are invented
3	Technical proof of concept demonstration	The basic performance of the invention is demonstrated in a laboratory setting and evidence of this is provided
4	Alpha prototype validation in laboratory environment	A simple prototype is developed and its performance is demonstrated in a laboratory environment. The performance indicates its potential for solving a clinical need
5	Beta prototype validation in clinical environment	A more advanced prototype is developed and its performance is demonstrated in a clinical environment and further clinical feedback is gained for the final design phase
6	Final Device design validation with clinical pilot study	The design of the device is frozen and a small number of devices are manufactured and a clinical pilot study is conducted by a key opinion leader. A pilot study report is prepared showing the results of the study
7	Device from pilot manufacturing line is being clinically trialled in multiple geographical locations	A larger sample of devices are manufactured and sent to multiple clinical sites in different geographical locations for clinical trials. The reports from these trials will be used for submissions to regulatory authorities (e.g. TGA, CE, FDA)
8	Device is partially approved and in clinical use	The device has been approved in limited geographical regions and is in clinical use in those regions
9	Device is fully approved and in clinical use worldwide	The device is approved for use worldwide and is in clinical use worldwide