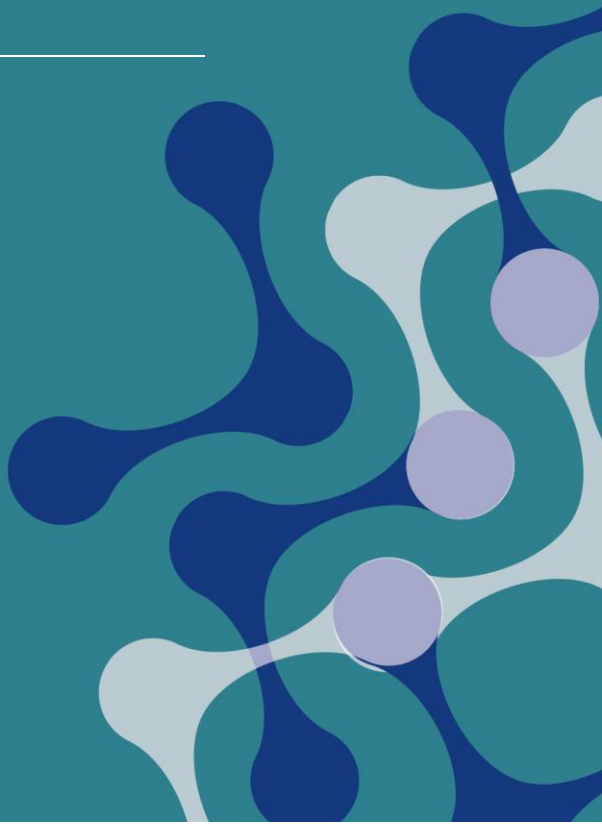
Office for Health and Medical Research

Medical Devices Fund Round 14

Program Guidelines

May 2026

Opening	5 May 2026
Closing date and time	5:00 PM AEST 9 June 2026
Enquiries	MOH-OHMRGrants@health.nsw.gov.au
Guidelines release date	May 2026
Type of grant opportunity	Open competitive



NSW GOVERNMENT

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Further copies of this document can be downloaded from the NSW Health website:
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 NSW Health Research and Innovation Strategy 2025-2030 commitment to bridge gaps in commercialisation and scaling of research and innovation.

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.

The Fund is 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 lifecycle. 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.

For Round 14, applicants with projects that address the following NSW Health Research and Innovation Strategy aligned priorities are encouraged to apply:

- Women's Health
- Female Entrepreneurs
- Aboriginal Health

Applicants with projects that do not address the above priorities are also able to apply. Where two applications successfully meet all other Assessment Criteria (as outlined on page 7), applicants that address one or more of the above priorities will be prioritised.

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 and assessment criteria
- how applications are assessed
- the application process and key dates
- how recipients will be monitored and evaluated
- responsibilities and expectations in relation to the Fund.

The Guidelines may be updated by OHMR at any time. If this occurs, links to the revised Guidelines or addenda can be accessed on NSW Health & Medical Research | Medical Devices Fund.

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 $8.2 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.

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

Successful applicants must repay the grant if the organisation achieves a specified level of economic success from the project outcomes. As part of funding agreement discussions, the Fund's independent financial advisor will take the applicant through the return on investment process and how and when repayment obligations begin. 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.

Successful applicants will be required to pay back grant funds where the corresponding spending was not in accordance with the funding agreement.

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 in their assessment including whether the organisation has fulfilled its obligations as set out in the funding agreement.

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 at the time of submitting the application.

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 covered by paragraph (a), (aa) or (ab); 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 that:
  - is headquartered in NSW (or will relocate to NSW during the application process)
  - has an Australian Business Number (ABN)
  - has an annual turnover less than $25 million
  - is a legal entity; or
- an individual based in NSW who agrees to form such an entity so that the 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.

Company or commercial enterprise applicants that intend to relocate to NSW during the Fund application process, must provide an explanation of

how and when the relocation will occur and what the applicant's connection is to NSW. No Funding Agreement will be entered into until relocation to NSW is complete.

You are not eligible to apply if you are:

- an international company or an Australian subsidiary of an international company
- a subsidiary of an Australian company (Note: the parent organisation needs to submit the application and will need to satisfy eligibility criteria)
- Australian Government agencies.

OHMR, at its sole discretion, can take publicly available information about an applicant into account that may cause the applicant to be ineligible for support, such as any personnel or business activities that could cause reputational damage or other risk to the NSW Government. OHMR may seek clarification from applicants in relation to their application, including seeking further information on the eligibility or assessment criteria.

OHMR reserves the right to assess the applicant's management, its Directors, Officers and entities or individuals that exercise control over an applicant against a fit and proper persons eligibility criterion.

Intellectual property

An applicant must hold the intellectual property or rights to commercialise the medical device/ technology.

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.

The majority of project activities should be based in NSW. In cases where project partners or project locations are outside NSW, the applicant should provide details as to why (e.g., providing a specific capability, expertise or technology that is not available in NSW).

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
- locating 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.

Applicants must demonstrate why sufficient funding for the entire project cannot be accessed from alternative sources and that the project would not proceed at the proposed scale in NSW without government support.

OHMR may seek clarification from any applicant in relation to its application, including seeking further information on the eligibility or assessment criteria.

At any time during the assessment process, if falsified or incorrect declarations are identified, the application will be deemed ineligible by OHMR and denied progress in the Fund.

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 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.

During the assessment process, OHMR may ask applicants to provide additional information, or may seek information from other sources, to assist in the assessment process. OHMR may seek to negotiate amendments to the application to maximise the public benefits from the project.

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, or will be further developed in NSW where an applicant intends to relocate
    - 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.

Team expertise and capability

- Applicants must demonstrate:
    - how the project team possess the requisite capabilities and expertise to successfully execute the project and/or will source those capabilities and expertise.

Assessment Terms

Applications are screened in line with eligibility criteria. OHMR, as secretariat, will access relevant technical expertise to complete initial eligibility, due diligence and screening of preliminary applications to provide to the Fund Expert Panel. The Fund Expert Panel will endorse eligibility and assess eligible preliminary applications against the Assessment criteria set out in these Program guidelines. The Fund Expert Panel assess each eligible application on a case-by-case basis and puts forward recommendations for grant allocation to NSW Health. NSW Health officials will consider the recommendations before making a final recommendation regarding the funding allocation amount and successful applicants for Ministerial approval, as the designated decision maker.

Membership of the Fund Expert Panel remains at the discretion of the Secretary, NSW Health. Members of the Expert Panel are listed on NSW Health & Medical Research | Medical Devices Fund. The Fund Expert Panel may consult external subject matter experts as required. The decisions of the 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 a Ministerial decision.

Application and Assessment Process

Before applying, applicants must read and understand the Program Guidelines.

Links to these documents, and any published alterations and addenda, may be accessed on NSW Health & Medical Research | Medical Devices Fund.

The Fund has a multi-stage application process. Applicants will submit a Preliminary Application electronically to MOH-OHMRGrants@health.nsw.gov.au.

If a Preliminary Application is shortlisted to proceed, the applicant will be invited to apply for a Full Application.

To apply, applicants must:

- Complete the Medical Devices Fund Preliminary Application form (links to access this document can be found on NSW Health & Medical Research | Medical Devices Fund)
- Provide all the information requested
- Address all the eligibility criteria
- Address all the relevant assessment criteria
- Include all necessary attachments as specified in the Preliminary Application form
- Submit the application by the timelines outlined in Key Dates.

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.

Note that applications cannot be submitted using file-sharing sites, including Google Drive, as they cannot be accessed from the NSW Health system.

The maximum application file size is 20MB. An acknowledgement of receipt of application will be sent within 3 business days of submission. Applicants should contact OHMR if they have not received an acknowledgment after this time.

Filenames must follow the naming convention of: 'Medical Devices Fund 2026_organisation name' for preliminary applications and 'Medical Devices Fund 2026_organisation name_attachment name' 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 recommend funding to applicants under the Fund.

Applications received after the closing date will not be considered except where OHMR is satisfied that the integrity and competitiveness of the Fund has not been compromised. Any late applications received will otherwise 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 are considered in a multi-stage process and 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 considers an application is unsuitable or unsatisfactory against any criteria, the application may be excluded from further evaluation.

Applicants should keep a copy of their application and any supporting documents.

Key dates

Expected program timeline

Activity	Timeframe
Preliminary applications open	5 May 2026
Information Session Webinar	13 May 2026
Preliminary applications close	5:00pm AEST 9 June 2026
Fund Expert Panel meets	August 2026
Invitations to full application, unsuccessful applications notified	September 2026
Full applications close	October 2026
Fund Expert Panel meets	November 2026
Interviews with Fund Expert Panel	December 2026
Notification of final outcome	February 2027

OHMR, at its absolute discretion, may vary these dates.

Assessment Process

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 as commercial-in-confidence.

OHMR will provide secretariat support for the 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

OHMR, as secretariat, will access relevant technical expertise to 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 Expert Panel to determine eligibility, review the opportunity and assess the quality of the application.

OHMR, as secretariat, will access relevant technical expertise to provide initial screening and to provide advice regarding the eligibility and quality of the applications against 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 Expert Panel members assess all eligible applications unless they have declared a conflict of interest for a certain application(s). Members assess all eligible applications against each criterion set out in these Guidelines.

Preliminary applications are given overall gradings of investable, potentially investable, or not currently investable in its current form. Only applications deemed as investable are invited to proceed further in the assessment process.

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. For applications proposing a commercialisation pathway into NSW Health, a health system expert review will also be undertaken. All parties will be required to agree to the same confidentiality and conflict of interest 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 recommendation on whether to support applicants and the funding amount allocated to each successful applicant for Ministerial approval, as the designated decision maker.

Notification of application outcomes

OHMR will advise each applicant of the outcome of their application in writing.

Unsuccessful applicants will be notified via email 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.

Successful applicants

Notification

Successful applicants will be notified via email within 30 business days of the final determination. Successful applicants will be notified of any specific conditions attached to the grant, which may include a 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.

The NSW Government will publicly announce funding for individual applications and provide information on the NSW Government Grants and Funding Finder.

Funding Agreements

Successful applicants who accept the offer of a grant will be required to enter into a formal Funding Agreement with the NSW Government relating to the grant. The Funding Agreement will specify obligations that relate primarily to the recipient's accountability for the grant, including using the grant for activities occurring in NSW, the return of unspent grant funds, reporting on the use of the grant and commercialisation progress for the duration of the term, and repayment of grant funds on economic success. The NSW Government makes no binding funding or support commitment to an applicant until both parties sign the Funding Agreement, including the lead applicant identified in the proposal.

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. 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.

Grant payment

The grant will be payable at the execution of the Funding Agreement. Invoices for grant payments will be submitted and paid in a single tranche, or as dictated by the Funding Agreement.

Successful applicants will be required to provide financial information to an independent financial advisor who will undertake annual financial monitoring of the organisation. This will monitor how the grant is expended against agreed milestones, identify any financial risks to the project or organisation, and determine if the applicant is required to begin repayment to NSW Health upon the specified level of economic success.

Payments will be GST inclusive. Applicants must be registered under the GST Law at the time of making any supply under this Funding Agreement on which GST is imposed. Grants are assessable income for taxation purposes, unless exempted by a taxation law. Successful applicants should seek independent professional advice on their taxation obligations. OHMR does not provide advice on successful recipients' particular taxation circumstances. The Fund is a grant that has repayment obligations tied to commercial outcomes specified in the Funding Agreement. If the successful applicant treats this as a liability in their financial statement, this treatment may not apply for income tax purposes.

Keeping OHMR informed

Successful applicants must inform OHMR of:

- any key changes to their organisation or business activities, particularly if they affect ability to complete the grant, carry on business and pay debts due
- any changes to their name, addresses, nominated contact details, or bank account details
- any breach of the terms and conditions under the Funding Agreement.

Requests for variations or changes to the project may be considered with regard to probity principles being upheld.

Reporting

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

During the term of the Funding Agreement, the Office, the successful applicant, and the independent financial advisor may meet to conduct a performance review and discuss the annual reports.

Evaluation

NSW Health will periodically assess the Fund to ensure it is meeting its objectives. NSW Health may use information from applications, reports and interviews with applicants for this purpose. NSW

Health may contact funding recipients to supply additional information for up to three years following completion of the Funding Agreement.

Successful applicants will be required to participate in program evaluation after the project has commenced.

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.

Enquiries

For all enquiries related to the assessment process or the outcome of an application for the Fund, please contact OHMR at MOH-OHMRGrants@health.nsw.gov.au.

Probity

The Office will ensure the application and selection process is transparent and fair, in line with the published guidelines. The application assessment process is guided throughout by the Fund's probity processes with advice from an independent probity advisor, including ongoing monitoring and measures to manage perceived or actual conflicts of interest. 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 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.

The Government Information (Public Access) Act 2009 (GIPA Act) provides for the proactive release of government information by agencies and gives members of the public an enforceable right to access government information held by an agency (which includes Ministerial offices). Access to government information is only to be restricted if there is an overriding public interest against disclosure. The NSW Legislative Council has the power to order the production of State papers by the Executive Government. Standing Order 52 provides that the House may order documents to be tabled by the Government in the House. The Cabinet Office coordinates the preparation of the papers – that is, the return to order. The return to order may contain privileged and public documents. Privileged documents are available only to members of the Legislative Council. Note that documents submitted as part of a grant application may be subject to an application under the GIPA Act or an order for papers under Standing Order 52.

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