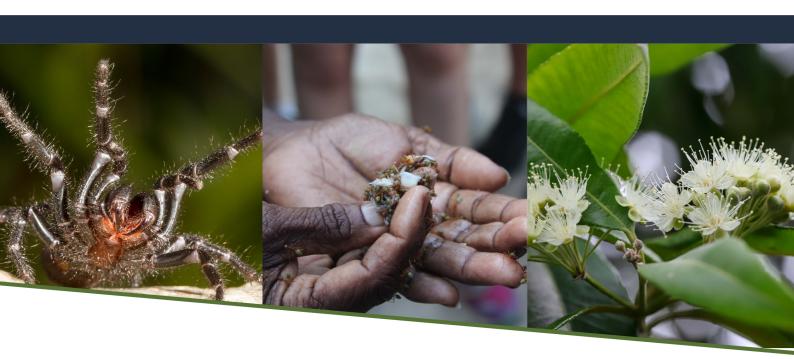


# Traditional Knowledge Guidelines

Using publicly accessible traditional knowledge

Biodiscovery Act 2004





# **Acknowledgement of Country**

The Department of Environment, Science and Innovation acknowledges the Country and people of Queensland's First Nations. We pay our respect to Elders, past and present.

We acknowledge the continuous living culture of First Nations Queenslanders—their diverse languages, customs and traditions, knowledges and systems.

We acknowledge the deep relationship, connection and responsibility to land, sea and sky Country as an integral element of First Nations identity and culture.

This Country is sacred. Everything on the land has meaning and all people are one with it. We acknowledge First Nations peoples' sacred connection as central to culture and being.

First Nations people speak to Country, listen to Country, sing up Country, dance up Country, understand Country and long for Country.

We acknowledge and thank First Nations people for the enduring relationship connecting people, Country and ancestors—an unbreakable bond that safely stewarded and protected the land, waters and sky for thousands of generations.

The Department of Environment, Science and Innovation has consulted with First Nations peoples, biodiscovery entities and other stakeholders in the development of these guidelines.

Prepared by: Science Development, Department of Environment, Science and Innovation

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The Department of Environment, Science and Innovation acknowledges Aboriginal peoples and Torres Strait Islander peoples as the Traditional Owners and custodians of the land. We recognise their connection to land, sea and community, and pay our respects to Elders past and present.

The department is committed to respecting, protecting and promoting human rights, and our obligations under the Human Rights Act 2019.

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# 1. Introduction

This guideline aims to assist biodiscovery entities to meet the minimum requirements in the <u>Traditional Knowledge Code of Practice</u> (the code) when seeking to use publicly accessible traditional knowledge for biodiscovery under the *Biodiscovery Act 2004* (the Act), where the custodians of the traditional knowledge <u>cannot be identified</u>. The code requirements are outlined in Appendix 1 of this guideline.

Biodiscovery involves the collection and analysis of native biological material for commercial purposes, such as the development of pharmaceuticals and insecticides. The Act's traditional knowledge obligation requires that a person does not use traditional knowledge for biodiscovery other than under an agreement with the custodians of the knowledge.

Established under the Biodiscovery Regulation 2021, the code aims to assist biodiscovery entities meet the traditional knowledge obligation. The <u>Traditional Knowledge Guidelines</u> support entities to meet the code and provide best practice advice for entities to engage with First Nations peoples in a culturally appropriate way. This material is also relevant to engagement between biodiscovery entities with First Nations peoples concerning this guideline.

The code defines publicly accessible traditional knowledge as information that has been published, broadcast, or otherwise made accessible for public consumption or is accessible to the public on request. Protecting the use of publicly accessible traditional knowledge recognises that this knowledge may have been shared without the consent of custodians, and that the benefits of using traditional knowledge are to be shared fairly and equitably with First Nations peoples.

Where the custodians of publicly accessible traditional knowledge cannot be identified, a biodiscovery entity must provide funds to build the capacity of First Nations peoples to use or negotiate the use of their traditional knowledge for the benefit of their communities. This can be achieved by directing funds to a project that supports First Nations peoples' engagement in biodiscovery. This applies where the biodiscovery project generates monetary benefits above a minimum threshold. Appendix 2 outlines these thresholds.

These guidelines provide an indication of the processes to be used to identify and assess project proposals. Biodiscovery projects typically involve long research and development timeframes before monetary benefits are generated, if at all. Therefore, it is uncertain as to whether a biodiscovery project using publicly accessible traditional knowledge will generate monetary returns, and if so, when, in terms of triggering the requirement to fund a project. As such, the Department of Environment, Science and Innovation (the department) will develop specific project identification and assessment processes at that point in time where a biodiscovery entity is required to fund a project.

# 2. Project delivery principles

The following principles should guide the delivery of projects that support First Nations peoples' engagement in biodiscovery:

- Projects represent the priorities, needs and aspirations of First Nations peoples for engagement in biodiscovery.
- Projects demonstrate First Nations people's leadership in the design, governance and conduct of the project.
- Projects represent the highest quality in approach and ethics, respecting cultural and customary protocols and decision-making timeframes and processes that incorporate the principle of free, prior, and informed consent when engaging with First Nations peoples.
- Projects have relevance and impact.

- Project outputs meet the highest standards for the recognition and protection of First Nations cultural and intellectual property.
- Where practical, projects benefit First Nations peoples in the geographic area the traditional knowledge comes from.
- Projects achieve value for money, directing funds to activities that will have the most impact per dollar spent.

# 3. Project objectives

The objectives of funded projects are to strengthen the ability for First Nations peoples to use, or negotiate the use of, their traditional knowledge for biodiscovery for the benefit of their communities.

Project outcomes may include:

- Supporting First Nations peoples and communities to determine what would be required to enable them to lead or participate in biodiscovery projects.
- Building awareness and understanding of First Nations peoples and communities about their rights concerning the use of traditional knowledge in biodiscovery.
- Ensuring First Nations peoples have the skills, tools and resources needed to negotiate the use of their traditional knowledge for biodiscovery, identify and pursue biodiscovery opportunities, or participate in biodiscovery projects. This includes but is not limited to the skills, tools, and resources to support:
  - o the development of community protocols and processes,
  - o engaging and negotiating with researchers and commercial entities,
  - o forming partnerships with researchers and commercial entities,
  - o scientific research by community members,
  - building networks of trusted advisors with appropriate expertise and cultural knowledge,
  - obtaining intellectual property protections for the benefit of the community,
  - o negotiating the terms of benefit sharing agreements,
  - o gaining or sourcing business skills related to planning, and establishing systems, processes, and models for biodiscovery activities.

Funded projects can benefit a particular community or communities or be for the general benefit of First Nations communities in Queensland. Communities may encompass place-based localities or may be with a group of Traditional Owners, or be determined by other factors, such as involvement in the research sector.

Funding does not have to be used for new projects. It may be used to amplify the outcomes of existing projects, provided it can be shown that the funding is additional to the contribution that would otherwise have occurred.

# 4. Project funding

The amount of project funding must be determined with reference to Appendix 2 of this guideline. The funding required, and the point at which the funding obligation is triggered, varies depending on the type of product produced and the amount of revenue generated by the biodiscovery activity.

A biodiscovery entity may choose to exceed the minimum threshold set out in Appendix 2. There is no limit on the amount of funding that can be directed to a project. In-kind support can also be provided to maximise project benefits, but this must be additional to the minimum funding threshold required from the biodiscovery entity.

Where a project is co-funded by another partner, funding from any partners must be in addition to the minimum funding required from the biodiscovery entity.

# 5. Project identification and selection – processes and criteria

A biodiscovery entity should contact the department when reasonably certain that there will be a monetary benefit from its biodiscovery activity. This allows a project identification and assessment process to be established, and an indicative timeframe determined for project endorsement. The department will develop relevant material to guide these processes.

The key steps in the project identification and selection process are:

- Step 1 Project identification Projects may be identified through two avenues:
  - o The department may source projects on behalf of the biodiscovery entity.
  - The biodiscovery entity may submit projects to the department.
- <u>Step 2 Eligibility check</u> The department will screen project proposals against the project eligibility requirements.
- <u>Step 3 Assessment</u> Eligible proposals will be referred to an assessment panel with a majority of members who are First Nations people. The assessment panel will recommend suitable projects to the department for endorsement.
- <u>Step 4 Endorsement</u> The department will provide endorsed project proposals to the biodiscovery entity for consideration.
- <u>Step 5 Selection and funding</u> The biodiscovery entity may choose which project to fund or may fund multiple projects. The biodiscovery entity is to enter into relevant agreements to fund the project(s) within 12 months of project endorsement.
- <u>Step 6 Reporting</u> the department may request information from the biodiscovery entity over time on the:
  - o amounts retained and used to benefit First Nations peoples
  - governance and administrative arrangements to manage the retention and use of commercialisation receipts<sup>1</sup> to benefit First Nations peoples
  - o impact of the project, including outputs and outcomes for First Nations peoples.

Figure 1 provides an overview of the broad parameters of the project identification and selection process to guide tailored processes on a case-by-case basis. More detail on each of the steps is provided below.

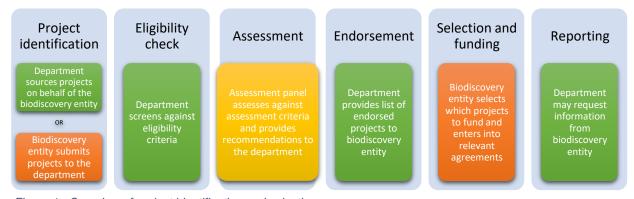


Figure 1 - Overview of project identification and selection process

# 5.1 Project identification

Project funding proposals are to be sourced from organisations who wish to undertake a new project or obtain support for an existing project that aligns with the project principles and

<sup>&</sup>lt;sup>1</sup> Refer to Appendix 2 for the definition of commercialisation receipts.

objectives in sections 2 and 3, above. A biodiscovery entity can be an active project partner and/or a funding source for a project.

A biodiscovery entity may already be aware of a suitable project and seek to have it directly endorsed, provided the entity can demonstrate that the proposed project meets the eligibility and assessment criteria in line with Steps 2 and 3 above, in Figure 1.

# 5.2 Eligibility check

# 5.2.1 Who is eligible to deliver a project?

An organisation is eligible to provide a project funding proposal where they:

- Have an Australian Business Number (ABN) or Indigenous Business Number (IBN).
- Are registered for the purposes of GST, if required by the Australian Tax Office.
- Hold an account with an Australian financial Institution.
- Have no outstanding reports, acquittals or serious breaches relating to any Commonwealth, State or Territory funding (a serious breach might be one that has resulted in termination of a project because of having outstanding reports or acquittals).
- Are not bankrupt or subject to insolvency proceedings.
- Are one of the following:
  - o an organisation established through specific Commonwealth or Queensland Government legislation
  - o a company incorporated in Australia
  - o a company limited by guarantee
  - o an incorporated association
  - o a not-for-profit organisation
  - o a publicly funded research organisation

Proposals from community groups, individuals such as scientists and researchers or unincorporated associations are to be made through an eligible organisation that agrees to manage the funding and take responsibility for the project.

## Joint (consortia) project proposals

Some organisations may provide a project funding proposal as a group, so that they can work together to deliver the project or contribute to an existing project. Where this is the case, a lead organisation should be nominated. Only a lead organisation can submit the project funding proposal and agree to manage the funding and take responsibility for the project.

## **First Nations organisations**

Funding is to be used to commission or support projects with demonstrated First Nations people's leadership and governance in project delivery. As such, First Nations groups and organisations are encouraged to provide project funding proposals themselves or in partnership with other organisations.

# Project proposals sponsored by an eligible auspice body

A project proposal by an individual, group or organisation that does not meet the eligibility criteria in this section can be sponsored by an auspice body that meets this criterion. The project is undertaken with the support and approval of the auspice body, who will be responsible for entering into a funding agreement for the project with the biodiscovery entity. This type of arrangement could be used to provide one-off projects that have a smaller revenue source.

# Who is not eligible to submit a project funding proposal?

The following organisations are not eligible to provide a project funding proposal:

- A Commonwealth or State or Territory Government (including portfolio) agency
- An individual or sole trader
- An unincorporated association
- An organisation based outside of Australia.

# 5.2.2 Eligible expenditure

Funds are only to be spent on the agreed activities that make up a project, as defined within an agreement between the biodiscovery entity and lead organisation responsible for delivering the project.

The funding for projects should only be used for:

- The engagement of researchers, consultants, specialists, experts, or contractors to work directly on the project.
- Scholarships, traineeships, mentorships and/or other support to participate in formal education courses.
- Facilitation of workshops and/or community meetings.
- Domestic travel for researchers to engage with community and/ or key stakeholders for the project.
- Communicating project results.
- Project specific resources, including any capital works or capital purchases or purchase of land or buildings that is directly relevant to the objectives of the project.
- Remuneration for community members, such as Traditional Owners in recognition of the value of their contributions, particularly where significant time or expertise is provided beyond normal project contributions.
- Access to independent legal advice by First Nation peoples or communities, where applicable.
- Project administration (a maximum of 20 per cent of total annual funding amount) for items such as project management, report-writing, book-keeping, audits, and financial management.
- Costs incurred in the preparation of project proposals, at the discretion of the biodiscovery entity.

## 5.2.3 Ineligible expenditure

The funding available for a project should not be used for:

- Purposes and activities that do not clearly align to the objectives of funded projects outlined in section 3 above, including payment of fines or loans, purchase of gifts, personal debts, or sitting fees.
- Activities of the organisation/s delivering the project, that are already funded by governments or are part of their normal responsibilities.
- Activities for which governments or Local Government bodies have primary responsibility.
- Capital works or capital purchases or the purchase of land or buildings that are not directly related to the objectives of the project.
- Operational funding or ongoing administration and employment within an organisation.
- Activities with a political or lobbying focus or intent.

#### 5.3 Assessment

# 5.3.1 Assessment panel

An assessment panel will be formed using nominations from First Nations peoples and others with relevant expertise who are both internal and external to the Queensland Government. The number of assessment panel members and the depth and breadth of their experience, the panel nomination process, and the assessment process to be used, will be confirmed on a case-by-case basis.

The assessment panel will have a majority of First Nations members. Where possible, the First Nations people on an assessment panel will be from the geographic area where the traditional knowledge comes from. It is departmental policy that First Nations peoples are remunerated regarding their time and expertise.

The department will provide secretariat support to the panel. The department will provide an assessment guide to the panel to assist them in their decision making, ensure the rationale for recommended projects is documented, and all other relevant records are kept and provided to the department. The department will also ensure that appropriate measures are followed to manage any panel member conflicts of interest. Confidential and personal information must also be handled appropriately in relation to departmental policy and relevant legislation, including the *Information Privacy Act 2009*.

The assessment panel will recommend suitable projects and any relevant conditions for endorsement by the department.

# 5.3.2 Project assessment criteria

Table 1 outlines the project assessment criteria to be used by an assessment panel to assess project proposals.

Table 1: Project assessment criteria

Table 1. Project assessment chiena							
Assessment criteria							
First Nations	The project proposal demonstrates:						
people's leadership,	First Nations people's leadership in the design, governance, conduct and evaluation of the project.						
governance,	<ul> <li>Collaboration and partnerships with First Nations people's</li> </ul>						
and	organisations and communities including the incorporation of free,						
collaboration	prior, and informed consent processes, which are executed in a culturally appropriate manner.						
Project quality	The project proposal demonstrates:						
	Clear objectives.						
	The capabilities and experience of the project team to undertake the project, or mechanisms to develop capabilities to undertake or contribute to the project.						
	The capability of project partners to engage and undertake tasks in a culturally competent way related to the cultural context within which the project will be embedded.						
	Best practice project design, planning, risk management, performance monitoring and evaluation commensurate with the nature and scale of the project.						
	<ul> <li>Sound governance and administrative arrangements for managing project funding.</li> </ul>						

Assessment criteria							
	<ul> <li>Commitment to the implementation of relevant cultural protocols, or the development of them to guide project delivery.</li> <li>The ethical management of information and data generated by the funded project in accordance with cultural protocols and respect for Indigenous data sovereignty.</li> <li>How any intellectual property rights generated through the project will be shared between project partners and with participants, recognising First Nations peoples as the equal inventors and joint owners (where applicable).</li> </ul>						
Impact and contribution	<ul> <li>The project proposal demonstrates:</li> <li>Alignment with one or more of the stated project outcomes in section 3 above and addresses a need and/or unmet demand for the target community, or First Nations communities in Queensland to engage in biodiscovery.</li> <li>How it will ensure that it continues to meet its intended outcomes, including through planned monitoring and evaluation activities.</li> <li>How its intended outcomes are to be achieved with the available funding.</li> <li>That the activities to be funded represent value for money.</li> <li>How project outputs can collectively benefit First Nations peoples and communities.</li> </ul>						

# 5.3.3 Evidence of support for the project

The following supporting information is to accompany project proposals:

- Community support letters demonstrating the need or demand for the project.
- A letter of support from each project partner, providing:
  - an overview of how the project partners will work together to deliver the project, including roles and responsibilities,
  - o an outline of the relevant experience and/or expertise of the project partners,
  - the funding contributions and or other resources from project partners such as in-kind support, in addition to the funding being provided by the biodiscovery entity.

# 5.3.4 Supporting material to guide project proposals

The department will develop supporting material to guide the development and submission of project proposals, and their assessment. With reference to the DES Grants Administration Framework, supporting material should include:

- A clear and concise statement of the objectives of project funding and the amount of funding available.
- The project submission process including the decision-making processes to be used.
- How project submitters will be advised of the assessment outcome.
- Anticipated timeframes for submission and assessment processes.
- A feedback protocol for unsuccessful projects.
- Whether late project proposals will be accepted and under what circumstances.
- Procedures related to how personal and confidential information will be dealt with.

The department will consult with the biodiscovery entity as needed, to guide the development and submission of project proposals.

# 5.4 Project endorsement

The department will endorse project proposals taking into consideration the recommendations made by the assessment panel, any relevant conditions, and the principles outlined in section 2. The department will provide a list of endorsed project proposals to the biodiscovery entity.

Departmental endorsement of projects will align with the delegations for financial expenditure, related to the level of funding to be provided for the project. The higher the funding threshold for the project, the more senior the level of project endorsement required.

# 5.5 Project selection and funding

The biodiscovery entity will determine which of the endorsed project proposals to fund or may choose to fund multiple projects.

The biodiscovery entity is to enter into an agreement to fund the project within 12 months of project endorsement and inform the department when an agreement has been executed.

Agreements should include, and not be limited to:

- Governance and administrative arrangements to manage project funding and in-kind contributions, including how costs are to be attributed and accounted for.
- Providing a project description, milestones, deliverables, intended outcomes, and monitoring and mitigation strategies to address project delivery risks.
- The obligations that apply to each party, including the consequences and actions if a party fails to meet its obligations.
- The possibility of the withdrawal from the project by a project partner, and what this
  means for the project.
- Outlining protocols, including cultural protocols for project delivery.
- Specifying the management of information and data generated by the funded project in accordance with cultural protocols, and respect for Indigenous data sovereignty.
- Specifying processes in relation to the attribution, dissemination, and publication of any First Nations people's traditional knowledge.
- Ensuring that any arrangements with First Nations peoples that relate to the use of their cultural or intellectual property are based on their free, prior, and informed consent
- Ensuring any intellectual property rights generated through funded projects establishes First Nations peoples as the equal inventors and joint owners of these rights (where applicable).
- Review and evaluation activities to monitor the efficiency and impact of the project, to support project improvements.
- How complaints can be made, and complaints and disputes are handled.
- Record keeping requirements.

# 5.6 Project reporting

The department may request information from time to time, on the:

- Amounts retained and used for project funding,
- Governance and administrative arrangements in place; and
- Impact of the project, including outputs and outcomes for First Nations peoples.

# 6 Significant changes to the project, or project completion

Any significant change to an existing project may require referral to an assessment panel to ensure the criteria for project endorsement will continue to be met. A biodiscovery entity should contact the department to discuss the scale of the variation to the project to

determine whether this is necessary. Where a project is completed, a new endorsed project is to be funded from the monetary benefits of the biodiscovery activity using the publicly accessible traditional knowledge.

# 7 Subsequent claims of custodianship

The code outlines requirements to address any later claims of custodianship for publicly accessible traditional knowledge after a biodiscovery project using the knowledge has commenced. In accordance with performance outcome 5.2 of the code, a biodiscovery entity can choose to cease funding the project where a benefit sharing agreement commences with the custodians of the publicly accessible traditional knowledge.

Given the typically long timeframes before biodiscovery research and development activities generate monetary benefits, if at all, any late custodianship claims could arise and be addressed before any monetary benefits are generated. This would negate the requirement to fund a project in accordance with performance outcome 4.2 of the code.

If a project is underway, and a benefit sharing agreement is entered into with the traditional knowledge custodians, the biodiscovery entity may choose to continue to fund the project until its completion. Alternatively, an entity could choose to establish other funding arrangements and or in-kind support for the continuation/ completion of the project.

# Appendix 1 – Traditional Knowledge Code of Practice requirements

The Traditional Knowledge Code of Practice (the code) allows a biodiscovery entity to use publicly accessible traditional knowledge where performance outcomes 4.2 and 6 of the code are met through relevant code compliance measures. These are outlined below.

## Performance outcome 4.2: Custodians cannot be identified

Where the custodians of the publicly accessible traditional knowledge cannot be identified, the biodiscovery entity directs a fair portion of the proceeds of commercialisation to build the capacity of First Nations communities to engage in biodiscovery.

## Code compliance measures

If a biodiscovery entity seeking to use publicly accessible traditional knowledge for biodiscovery has followed the steps in requirement 1 (refer to performance outcome 1.1 of the code) but cannot identify a custodian with authority to speak for Country about the knowledge, the biodiscovery entity may use the traditional knowledge for biodiscovery.

If the biodiscovery entity chooses to use the traditional knowledge, the entity must:

- Document and retain evidence of the measures undertaken to find the custodians (refer to performance outcome 6 of the code).
- As a minimum, retain the percentage of gross commercialisation receipts received from biodiscovery each year—as set out in the State's model benefit-sharing agreement (refer to Appendix 2 of this guideline).
- Use these funds to build the capacity of First Nations peoples to use or negotiate the
  use of their traditional knowledge for the benefit of their communities. This can be
  achieved by directing these funds to capacity-building projects demonstrated to
  achieve the desired outcomes, through projects identified by:
  - o the Queensland Government, or
  - o the biodiscovery entity and endorsed by the Queensland Government.

The State's model benefit sharing sharing agreement is available on the Business Queensland biodiscovery webpage.

# Performance outcome 6: Evidence of compliance

Provide evidence to the State that the biodiscovery entity has complied with the traditional knowledge obligation prior to using traditional knowledge for biodiscovery and keep and maintain records of compliance.

# Code compliance measures

Prior to using traditional knowledge for biodiscovery, a biodiscovery entity must:

• If using publicly accessible traditional knowledge, that the custodians of which cannot be identified, provide the State with evidence of the measures taken to identify the custodians of that knowledge.

In addition, an entity using traditional knowledge for biodiscovery must keep, and provide to the State upon request, documentation on:

- If retaining commercialisation receipts from the use of publicly available traditional knowledge:
  - o information on the amounts retained and used to benefit First Nations peoples
  - governance and administrative arrangements in place to manage the retention and use of commercialisation receipts to benefit First Nations peoples.

# Appendix 2 – Minimum project funding thresholds

Table 1 below outlines the minimum project funding thresholds. The Traditional Knowledge Code of Practice requires that as a minimum a biodiscovery entity is to retain the percentage of gross commercialisation receipts received from biodiscovery each year—as set out in the State's model benefit-sharing agreement (Schedule 3), for project funding. The model benefit sharing agreement is used for agreements between the State and biodiscovery entities.

Columns 1-3 in Table 1 provide the thresholds in the State's model benefit sharing agreement. Column 4 provides the minimum project funding amounts with reference to these thresholds. For example, if the biodiscovery activity results in a commercially viable pharmaceutical, nutraceutical or agricultural product, a biodiscovery entity must set aside 2.5% of the annual gross revenue per annum as a minimum for project funding, where this revenue hits \$500,000 up to \$5,000,000.

Table 1: Minimum project funding thresholds

1 1	Column 4		
Purpose of Product*	Gross Commercialisation Receipts# received by the Biodiscovery Entity in one calendar year (\$AUD)	Payment (% of gross Commercialisation Receipts)	Minimum project funding amount/ calendar year
Pharmaceutical,	< 500,000	0	0
Nutraceutical or Agricultural	500,000-5,000,000 > 5,000,000	2.5 5.0	\$12,500 \$250,0000
Chemical and	Option 1:		
Diagnostic	>200,000	1.5	\$3,000
	Option 2:		
	< 100,000	0	0
	100,000-3,000,000	1.0	\$1,000
	> 3,000,000	2.0	\$60,000
Other Research	Option 1:	0.5	<b>Ф</b> Е 000
	>200,000	2.5	\$5,000
	Option 2:		
	< 100,000	0	0
	100,000-3,000,000	1.0	\$1,000
	> 3,000,000	3.0	\$90,000

Under the *Biodiscovery Act 2004* (the Act), biodiscovery includes the biodiscovery research or the commercialisation of native biological material or a product of biodiscovery research.

Under the State's model benefit sharing agreement, commercialisation receipts include reference to the value of any monetary benefits or consideration provided to, received by or for the benefit of the biodiscovery entity (or on its behalf) after the commencement of the Act in relation to, or in any way connected with commercialisation involving native biological material, including, but not limited to:

- Transferring, delivering, or providing access to Intellectual Property, samples, or products; or
- Assigning or granting rights in Intellectual Property, samples, or products; or
- Disposing of any Intellectual Property (arising from biodiscovery of the native biological material)

In respect of Products, commercialisation receipts refer to sales of those products occurring after the commencement of the Act.

Commercialisation receipts does not include funds received for the explicit purpose of research.