Procedure

Biodiscovery Compliance

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1.0 Purpose

To ensure that Griffith complies with legislative obligations when conducting research involving native biological materials in Queensland.

2.0 Scope

This procedure applies to all areas of the University's operations, including its staff, appointees of the University, its controlled entities, and to all activities authorised and conducted by or on behalf of the University.

This procedure primarily addresses compliance with the *Biodiscovery Act 2004* (Qld) **(the Act)**, and it applies only to research that is being conducted using Native Biological Materials sourced from the State of Queensland. However, it also addresses requirements for areas in Queensland that are subject to Commonwealth laws. For research involving native biological materials sourced from outside Queensland, different laws will apply which of course must be observed by Griffith researchers. Refer to this Commonwealth Government website for information about accessing biological resources in other Australian jurisdictions.

The procedure applies to the below activities that constitute 'Biodiscovery':

- Collection of native biological material for the purpose of Commercialising the material,
- Analysis of the molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material, and
- Commercialising the native biological material or a product of research into the material.

The procedure does not apply to the below University activities:

- Using native biological material for education and training activities not involving commercialisation,
- Classifying native biological material scientifically, or verifying research results concerning the material, and
- Activities involving plants that are taken or used for a food or agricultural purpose in a way that is consistent with the International Treaty on Plant Genetic Resources for Food and Agriculture.

3.0 Procedure

In general terms, biodiscovery involves:

- i. collecting native biological materials (eg. from animals, plants or other organisms), and
- ii. using those materials for commercial activities, such as creating medicines, other therapeutic goods, or new chemicals such as pesticides or herbicides (these examples are illustrative only, any commercial activity would be captured).

Biodiscovery is regulated to ensure that the collection of native biological material is carried out appropriately; protecting the rights of the State and the custodians of the traditional knowledge and ensuring that benefits derived from the commercial application of native biological materials is shared equitably with key parties, specifically:

- the State of Queensland, in recognition of the sovereign rights vested in native biological materials sourced from public land, and/or
- the Custodians of traditional knowledge associated with native biological materials, in recognition of their right to benefit from their traditional knowledge being used.

Broadly, there are three key obligations that researchers are required to comply with under the Act:

- 1. obtain a collection authority to take native biological material from State land or waters,
- 2. be subject to a Benefit Sharing Agreement with the State when conducting biodiscovery research or engaging in commercialisation, and
- 3. take all reasonable and practicable steps to ensure that traditional knowledge is only used with the consent of and in accordance with an agreement with the custodians of the knowledge.

In addition, the University must report annually to the Queensland Government on its biodiscovery activities.

These obligations are subject to heavy penalties under Queensland law, including major fines, prosecution of senior leaders, and imprisonment of individuals.

3.1 Collection of Samples for Biodiscovery

3.1.1 Do you need a collection authority?

Important!

This section only refers to a permit/authority for collecting samples for biodiscovery. Other government permits will likely need to be obtained when collecting samples for scientific and educational research in Protected Areas or involving Protected Species. It is the responsibility of the researcher to identify and obtain all appropriate permits.

If your project involves collecting samples of native biological materials, you must obtain a collection authority from the Queensland regulator¹ when:

- the samples are taken from State Lands or Queensland Waters, and
- the collection is for research that will, or may be, commercialised. See the note below on circumstances where there is uncertainty about any commercialisation potential.

To determine if you need a collection authority for your project, undertake the steps below:

 Undertake due diligence on your planned collection site/s
 Collection on Land
 It is critical to identify the owner of the land to determine if it is State or non-State land. It will only be non-State land if the land is held privately (freehold land) or is subject to native title conferring exclusive possession.

¹ As at January 2024, this is the Department of Environment and Science.

		•	If the planned collection site is in a National Park or other Protected Area, it should be considered State land.		
		•	If you think the planned collection site may be privately owned, verify that this is the case by undertaking a title search which will confirm whether the land is freehold title (ie. privately owned). The easiest way to conduct a title search is online through the Queensland Titles Office. You can usually search by address but in some cases you may need details such as the Lot Number or Plan Number for the land.		
		•	Note: If the materials can be collected from privately owned land this means that the Act will not apply to the collection or use of the sample. However, the collection would still need to be negotiated with the landowner, who may exercise their right to impose conditions on the collection and use of material taken from their land.		
		•	If you think the planned collection site is subject to native title, you can use the maps provided by the National Native Title Tribunal to identify if this is the case. If so, the land may be exempt from requirements of the Biodiscovery Act, however you should seek legal advice in these circumstances as complicated factors may apply.		
		Col	lection from Waters		
		If collecting samples from a river, you will be collecting from Queensland waters.			
		If collecting from a marine area, use the Australian Marine Spatial Information System which identifies State water boundaries. Note that sites outside the Queensland boundary will likely be subject to Commonwealth permit requirements – for example particular requirements apply for collecting from the Great Barrier Reef Marine Park.			
2.	Decide whether there is any potential commercial application from the native biological materials	lf ye obt	ou are collecting samples for the purpose of biodiscovery, you <u>must</u> ain a collection authority.		
		When you are uncertain about whether there is commercial application, the preference of the University is to obtain a collection authority. This is because, if commercial application is later identified and no collection authority is in place, you will be legally barred from pursuing the commercialisation opportunity using the samples collected. Obtaining a collection permit in these circumstances provides a potentially valuable 'option to commercialise'.			
		Note: currently ² , the regulator advises that it can take up to 40 business days to process an application for a collection authority and may take longer if further information or consultation is required.			

² As at January 2024.



3.1.2 Once you have an authority

The collection authority will stipulate any conditions that apply to undertaking the collection activity.

The Compliance Code: Taking Native Biological Material under a Collection Authority will also apply and researchers must read this document (linked above) and ensure that the field work is conducted in accordance with the relevant standards that it sets.

Collection authorities must be kept readily available for inspection by the University and the regulator. A copy of the collection authority should be provided to the relevant Dean (Research) or Director (for Institutes) to ensure this. A copy of the collection authority must be available for immediate inspection when undertaking the fieldwork.

3.1.3 Historic collections

Samples collected prior to the Act coming into effect in 12 November 2004 are not subject to collection authority requirements. Provided there is clear documentation showing the collection date pre-dated the Act, a collection authority is not required to conduct biodiscovery work using that sample.

However, the requirement to be subject to a benefit sharing agreement will apply (see 3.2 below).

3.1.4 Obtaining samples from compound libraries

When a sample of biological material is being obtained from a library, the researchers should obtain details from the library about the origin of the sample.

If the compound is derived from native biological materials obtained from State land or Queensland waters, the requirement to be subject to a benefit sharing agreement will apply (see 3.2 below).

3.1.5 Collecting from Commonwealth areas

Some parts of Queensland are subject to Commonwealth legislation, notably the below world heritage sites:

- The Great Barrier Reef Marine Park
- Wet Tropics World Heritage Area

For these areas, the *Environmental Protection and Biodiversity Conservation Act 1999* (Cth) applies. You will be required to obtain a permit to access biological resources in these areas and the Commonwealth will not issue a permit until an agreement about the sharing of benefits with the Commonwealth is in place.

3.2 Benefit Sharing Agreements

The fundamental principle underpinning this section is that the State must be a potential beneficiary of any commercialisation of native biological materials sourced from State land or Queensland waters. The Act strictly prohibits biodiscovery where benefits are not shared with the State.

3.2.1 Working under the Griffith BSA

The University has entered into a Benefit Sharing Agreement (BSA) with the State of Queensland, allowing it to commercialise the outcomes from research on native biological materials, and setting out the terms in which the benefits will be shared with the State. The BSA is managed by Griffith Enterprise.

Consistent with the Griffith University *Intellectual Property Policy*, Griffith Enterprise must be advised of any planned commercialisation of native biological material, or a product of the biodiscovery research. Griffith Enterprise will coordinate the development of a specific biodiscovery project memorandum that is required by the BSA.



Under no circumstances can commercialisation of the native biological material proceed without the conditions of the BSA being applied to the project through the development of the project memorandum.

If Griffith engages another party to use the native biological material for the purpose of biodiscovery, that party must first enter into a 'Subsequent Use Agreement' (SUA) with Griffith that applies the prescribed terms of the Griffith BSA with the State. Griffith will be in breach of the BSA if it allows the other party to undertake biodiscovery work without first entering into a SUA with that party.

3.2.2 Application to Specific Scenarios

The table below describes some relevant scenarios where Griffith staff or students are undertaking biodiscovery work and describes relevant actions to be taken to ensure compliance with the benefit sharing obligation in the Act.

Biodiscovery Project Scenarios ³	Action required ⁴		
Griffith project with no external parties (apart from the State).	• The project must be subject to the Griffith BSA.		
Griffith is a participant in a collaboration arrangement with multiple parties such as a commercial research project or commercialisation agreement.	 One of the project parties must have an active BSA. If Griffith is the only party with a BSA, it should be used to provide the head agreement, with other parties entering into a Subsequent Use Agreement (SUA) with Griffith. Alternatively, if another party has a BSA with the State this could be used as the head agreement, with Griffith entering into a SUA with that party. 		
Griffith is undertaking a project under a government grant (on its own or in collaboration). For example, an ARC or NHMRC grant is funding research into native biological materials with intent to commercialise or the grant has an industry partner (e.g. ARC Linkage) who may derive some benefit from the research project.	 One of the project parties must have an active BSA. If Griffith is the only party with a BSA, it should be used to provide the head agreement, with other parties entering into a Subsequent Use Agreement (SUA) with Griffith. Alternatively, if another party has a BSA with the State this could be used as the head agreement, with Griffith entering into a SUA with that party. Advice from Legal Services should be sought as there could be complex interaction with the terms of the government grant and any agreement between the parties, especially if there is an industry partner who is a party to the grant agreement. 		

³ This is not intended as an exhaustive list.

⁴ Proper collection of native biological material is assumed for the purpose of the table.

Biodiscovery Project Scenarios ³	Ac	tion required⁴
A party is engaged to provide a specific service to a biodiscovery project (using the native biological material) for which they are paid a fixed fee and derive no other benefit other than that fee.	•	Griffith does not need to bind the party to the BSA with an SUA.
A HDR project.	•	A BSA must apply to the project for it to comply with the Act.
	•	The Griffith BSA may be used. The student will need to assign intellectual property to the University so that the Griffith BSA can apply to the project.
A HDR project with an industry partner.	•	A BSA must apply to the project for it to comply with the Act.
	•	The Griffith BSA would apply to the project unless the industry partner has a BSA and wishes to use their version. The student would need to assign intellectual property to Griffith for the Griffith BSA to be used.

3.2.3 Non-Commercial Sharing of Native Biological Materials with Third Parties

If native biological materials have been collected from State land or Queensland waters and are being transferred to a third party as part of non-commercial research, the standard agreement developed by Legal Services should be used. This agreement (called Griffith University transferring native biological material) is available on the Legal Services website and includes clauses to ensure compliance with the Act and the Griffith BSA if, during the progress of the research, commercial opportunities are identified.

3.3 Using Traditional Knowledge for Biodiscovery

The Act protects the traditional knowledge of Aboriginal and Torres Strait Islander peoples about native biological materials and requires that the free, prior and informed consent of the custodians is obtained to use their Traditional Knowledge.

If you are accessing or drawing on traditional knowledge to undertake biodiscovery, or in preparing to undertake biodiscovery, you must seek to enter into an agreement with the custodians that provides consent. In the absence of an agreement, work cannot proceed.

This obligation applies regardless of where in the State the native biological material was collected from.

Researchers seeking to use traditional knowledge for biodiscovery must read and comply with the Traditional Knowledge Code of Practice.

Researchers should be aware that consent from custodians can be withdrawn, at any stage. This needs to be recognised as a risk to a research project and managed accordingly.



4.0 Roles and Responsibilities

ROLE	RESPONSIBILITY
Researchers	Read, understand and comply with these procedures.
	Ensure that Griffith Enterprise is notified of all biodiscovery projects being undertaken.
	Ensure that any permits/authorities required for undertaking field work are identified and obtained correctly, prior to the collection and kept readily available for inspection and audit.
	When working on biodiscovery projects involving other parties (eg. other Universities or industry partners) ensure that responsibilities for biodiscovery compliance are agreed between parties, and where relevant, that appropriate agreements are in place.
Director, Griffith Enterprise	Responsible for the management of the University Benefit Sharing Agreement with the State.
	Support the development of Biodiscovery memorandums as required by the BSA, specific to the biodiscovery project.
	Ensure the inclusion of the relevant BSA terms in a Subsequent Use Agreement for the commercialisation of research utilising Native Biological Material.
	Notify the State of a Reportable Matter prescribed under the BSA.
Deputy Vice Chancellor (Research)	Overall accountability for the risk of non-compliance with biodiscovery requirements.
	Ensure that appropriate steps are taken to promote awareness of these procedures across the University research community, including through University processes for biosafety/biosecurity and/or ethics approval.

5.0 Definitions

Benefit Sharing Agreement means an agreement between the State and party undertaking biodiscovery which:

- grants the party the right to use native biological resources taken from State land or Queensland waters, for the purpose of biodiscovery, and
- agrees to provide benefits of biodiscovery to the State.

Biodiscovery means 'biodiscovery research' or the commercialisation of native biological material or a product of biodiscovery research.

Biodiscovery Research means the analysis of the molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material.

Commercialisation (or Commercialising), of native biological material, means using the material in any way for financial or non-financial gain. However, the term does not include using the material to obtain financial assistance from a State or the Commonwealth, including government grants.

Custodians, of traditional knowledge, means the Aboriginal or Torres Strait Islanders to who the knowledge relates.

Native Biological Material means a 'native biological resource'; or a substance sourced, whether naturally or artificially, from a native biological resource; or soil containing a native biological resource.

Native Biological Resource means a non-human living organisms or virus indigenous to Australia; or a living or non-living sample of the organism or virus.

Protected Areas means land or waters set aside for conservation or other public purposes. In Queensland they include:

- national parks (any type)
- nature refuge
- special wildlife reserve
- conservation park
- resources reserve
- coordinated conservation areas
- world heritage areas

Protected Species means a species of plant or animal that is subject to protection under the *Nature Conservation Act 1992* (Qld), *Environmental Protection and Biodiversity Conservation Act 1999* (Cth).

Queensland waters means all waters that are within the limits of the State or the coastal waters of the State.

Reportable Matter means any of the below which Griffith is required under its Benefit Sharing Agreement with the State to report to the State:

- the results of biodiscovery research carries out by or for Griffith under the agreement,
- the commercialisation activities carried out by or for Griffith under the agreement,
- the amount or value of the total consideration given or to be given to Griffith, or someone else at the Griffith's direction, for the commercialisation activities carried out under the agreement.

State Land means all land that is not:

- freehold land owned by a person other than the State or an entity representing the State or owned by the State, or
- land, including land in a freeholding lease as defined under the Land Act 1994, contracted to be granted in fee-simple by the State to a person other than the State or an entity representing the State or owned by the State, or
- land subject to a native title determination granting rights of exclusive possession.

Traditional Knowledge means information based on Aboriginal tradition or Torres Strait Island custom.

6.0 Information

Title

Biodiscovery Compliance Procedure



Document number	2024/0000033			
Purpose	To ensure that Griffith complies with legislative obligations when conducting research involving native biological materials in Queensland.			
Audience	Staff			
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Subcategory	Research			
UN Sustainable Developmen Goals (SDGs)	t This document aligns with Sustainable Development Goal/s: 10: Reduced Inequalities			
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Policy advisor	Director, Griffith Enterprise			
Approving authority	Deputy Vice Chancellor (Research)			
7.0 Related Policy [Documents and Supporting Documents			
Legislation	Biodiscovery Act 2004 (Qld)			
	Traditional Knowledge Code of Practice			
	Compliance Code: Taking Native Biological Material under a Collection Authority			
	Environmental Protection and Biodiversity Conservation Act 1999 (Cth)			
Policy	Intellectual Property Policy			
	Consultancy and Commercial Research Policy			

Responsible Conduct of Research Policy

Procedure Guide to the Responsible Conduct of Commercialisation Activities N/A

Local Protocol