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Access and Benefit-Sharing for Australian Synthetic Biologists: A Tool for Risk Management

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CSIRO acknowledges the Traditional Owners of the land, sea, and waters of the area that we live and work on across Australia. We acknowledge their continuing connection to their culture, and we pay our respects to their Elders past and present.

Disclaimer

This Risk Management Tool provides a framework for thinking about ABS in your own research, based on the views and findings of the authors.

Because ABS laws are implemented differently in every country, this Tool cannot address every situation you are likely to encounter when dealing with ABS. Rather, it can help you to get to grips with the complex ethical and historical context in which ABS laws operate, understand ABS-specific language and highlight some ABS issues that may not be immediately apparent, so that you can make informed decisions.

This Tool should be treated as a starting point, so you have the background necessary to find and understand information that is specific to your R&D. It does not constitute legal advice, or necessarily reflect the views, policies and procedures of CSIRO, Griffith University and Queensland University of Technology. You will need to consult with your institution's legal advisers to settle any formal legal advice or legal obligations, such as ABS contracts or legislation interpretation.

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Foreword

In December 2022, the Parties to the Convention on Biological Diversity (CBD) adopted the Kunming-Montreal Post-2020 Global Biodiversity Framework and urged governments to help "bring about a transformation in our societies' relationship with biodiversity by 2030". The mission of the Framework is:

> *"To take urgent action to halt and reverse biodiversity loss to put nature on a path to recovery for the benefit of people and planet by conserving and sustainably using biodiversity and ensuring the fair and equitable sharing of benefits from the use of genetic resources, while providing the necessary means of implementation."*

Scientific research and development (R&D) utilising genetic resources (including associated Traditional Knowledge) from around the world will help in achieving the conservation of biodiversity and the sustainable use of its components. While there are significant potential benefits to the use of genetic resources, the distribution of these is not always balanced. At times, it may see the exploitation of vulnerable populations, or biopiracy whereby researchers or commercial enterprises take biological resources without appropriate permissions. Therefore, when a country's genetic resources are used in R&D activities, researchers may wish to consider engaging with the country of origin and their international policies and agreements that aim to articulate the sharing of benefits. This is about both equity and fairness in sharing the spoils of R&D, as well as liberating funds to address the market failure of conservation, hopefully to mitigate biodiversity destruction and decline. This is what "access and benefit-sharing" (ABS) policies are all about, and an understanding of these considerations can help to enable 'freedom to operate' for those intending on patenting and/or commercialising their science.

The Parties also decided, after half a decade of grappling with the issue of whether to regulate genetic sequence data – or "Digital Sequence Information" (DSI) – under the international ABS regime, that the use of DSI should result in fair and equitable benefit-sharing.

They therefore agreed to develop a multilateral solution for sharing the benefits from the use of DSI. It is hoped that the solution, which is yet to be developed, will generate both monetary and non-monetary benefits from the use of DSI to be shared fairly and equitably with the holders of genetic resources, including with Indigenous Peoples and local communities that have maintained and sustained biodiversity around the world.

Importantly for scientists, the Parties also agreed that whatever solution is eventually adopted should be consistent with open access to data, and not hinder research and innovation.

Given the growing emphasis on sovereign rights over genetic resources, as well as the development of international treaties aimed at safeguarding the equitable distribution of benefits, it is important for Australian researchers to understand the fundamentals of ABS laws and to stay up to date with changes that could impact their work. These developments are highly important for all the biological sciences, especially for a multidisciplinary field like synthetic biology, which utilises both physical genetic resources and genetic sequence data to modify naturally occurring genetic resources and to construct entirely new ones.

This Risk Management Tool is designed to give synthetic biologists (and those in related fields) an introduction to ABS laws implemented under the CBD and its Nagoya Protocol, and guidance on assessing risks when accessing and using genetic resources from different countries (including their own). This Tool outlines a risk framework to help users of genetic resources make decisions about ABS. The framework takes into account the complexities of modern scientific practice, helping users to weigh up their risks and responsibilities, in order to get on with the R&D needed to solve some of the world's greatest challenges through innovative science and technology.

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Executive summary

The Convention on Biological Diversity (CBD) and its supplementary Nagoya Protocol outline the minimum international legal standards for accessing genetic resources and associated Traditional Knowledge (TK) from other countries. Any researchers accessing or using genetic resources and/or TK associated with genetic resources from other countries will need to consider first whether they need to obtain the prior informed consent (PIC) of the originating country and come to mutually agreed terms (MAT) about how those resources will be used and how the benefits of the R&D will be shared with the originating country.

ABS was originally designed to regulate international bioprospecting activities, as scientific researchers from industrialised countries were collecting genetic resources and TK from less developed countries, conducting R&D, patenting the resulting products and processes and not necessarily sharing the profits and other benefits with the originating country. The purpose of ABS was to ensure that these lower-income countries were included in the R&D process and given the opportunity to benefit from the science conducted with their sovereign genetic resources.

Every country has the authority to implement their own laws about how they want to regulate access to their genetic resources and associated TK. Many countries have not implemented any laws, and those that have include complex, detailed and varied requirements that suit their national circumstances. That means there is no one-size-fits all approach to ABS and there is a patchwork of laws internationally. In the 30 years since its adoption in the CBD, ABS has become a tool for ensuring equity and fairness in more than just bioprospecting activities, but also any R&D using genetic resources and associated TK. This now includes synthetic biology research.

Synthetic biology, or advanced engineering biology, is a complex field of science that involves the disassembly of genetic resources, the reassembly of their parts in different combinations, a reliance on information technology (and digital genetic sequence information) and high levels of abstraction, none of which the CBD could have envisaged 30 years ago. This means that navigating the already complex ABS legal landscape is made even more complicated for synthetic biologists.

In dealing with ABS laws, synthetic biologists will come up against situations for which there is no clear answer, and they will need to make decisions about how to proceed based on imperfect and incomplete information.

This Risk Management Tool gives synthetic biologists a new way of approaching these difficult ABS decisions. Synthetic biologists require hundreds of genetic resources as inputs to the R&D process. Some of those inputs will be essential to the outcomes of the project, while others are incidental and can be substituted for similar inputs. These inputs can take the form of physical samples (including commercially available plasmids and enzymes), chassis organisms (including yeast and plants), and informational inputs (including genetic sequences). Researchers need to make an assessment about each of these genetic inputs, and decide when and how to proceed with negotiating ABS agreements.

Researchers who do not comply with ABS laws may find that they cannot publish their research, or that their project is terminated. They may be required to destroy samples or return genetic resources to the originating country. There's also a risk that they and their institution could suffer reputational damage. Some countries have implemented severe fines and even imprisonment for researchers that do not comply with their ABS laws. Therefore, this Risk Management Tool outlines considerations to help researchers identify the risks associated with the use of different genetic resources and associated TK in their R&D, and to manage them. In the form of a risk framework, it presents a series of questions for synthetic biology researchers to consider when making decisions about ABS, and offers an overview of the ethical, legal, and social context in which those decisions must be made. This risk framework will guide researchers through various ABS considerations related to research materials, data and information; research stakeholders and other interested parties; the intent of the R&D; potential legal pitfalls and benefits the R&D could generate. This will help researchers make informed decisions about the legal, ethical and social risks relating to ABS in their research.

Abbreviations/glossary

ABNJ: Areas Beyond National Jurisdiction

ABS: Access and Benefit-Sharing

ABSCH: Access and Benefit-Sharing Clearing House

AIATSIS: Australian Institute of Aboriginal and Torres Strait Islander Studies

BBNJ: Biodiversity Beyond National Jurisdiction. This is used to refer to a Draft Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable use of Marine Biological Diversity of Areas Beyond National Jurisdiction.

Bioprospecting: searching for plants, animals, microorganisms and other genetic resources that have properties that could be used in products with commercial value, such as cosmetics, pharmaceuticals and various agricultural applications. Note that some domestic laws will define bioprospecting differently, but this is the meaning of the term used in this Tool.

BLAST: Basic Local Alignment Search Tool

Bonn Guidelines: A precursor of the Nagoya Protocol, the Bonn Guidelines were adopted in 2002 as a set of non-binding recommendations for countries implementing their ABS requirements under domestic law. The Nagoya Protocol turned many of these requirements into voluntary but binding international law when it entered into force in 2014.

CBD: UN's Convention on Biological Diversity

CGIAR: Consultative Group on International Agricultural Research

CITES: Convention on International Trade in Endangered Species

CNA: Competent National Authority

Community Protocols (also known as Cultural Protocols or Biocultural Protocols): guidelines developed by Indigenous Peoples and local communities that inform visitors and collaborators of their responsibilities when entering and working with a given community.

COP: Conference of the Parties to the Convention on Biological Diversity

COP-MOP: Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol

DSI: Digital Sequence Information

EEZ: Exclusive Economic Zone

EPBC: Environment Protection and Biodiversity Conservation Act (Cth) 1999

EU: European Union

FMEA: Failure Modes and Effective Analysis

FAO: Food and Agriculture Organization of the United Nations

GISRS: Global Influenza Surveillance and Response System. The World Health Organisation's network of WHO-affiliated influenza laboratories around the world.

GSD: Genetic Sequence Data

GPS: Global Positioning System

ILBI: International Legally Binding Instrument (under the UN Convention on the Law of the Sea) that will determine how to deal with marine genetic resources sourced from areas beyond national jurisdiction.

INSDC: International Nucleotide Sequence Data Collaboration

IPLCs: Indigenous Peoples and local communities

IP: Intellectual Property

IRCC: Internationally Recognised Certificate of Compliance

ITPGRFA: FAO's International Treaty on Plant Genetic Resources for Food and Agriculture

MAT: Mutually Agreed Terms

MOU: Memorandum of Understanding

MTA: Material Transfer Agreement

Nagoya Protocol: Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

NFP: National Focal Point

NHMRC: National Health and Medical Research Council

NP: Nagoya Protocol

Plant Treaty: FAO's International Treaty on Plant Genetic Resources for Food and Agriculture

PIC: Prior Informed Consent

PIP Framework: WHO's Pandemic Influenza Preparedness Framework

R&D: Research and Development

SDG: UN's Sustainable Development Goals

SMTA: Standard Material Transfer Agreement

TK: Traditional Knowledge

UN: United Nations

UNCLOS: United Nations Convention on the Law of the Sea

WHO: World Health Organisation

Introduction

Why do synthetic biologists need their own ABS Risk Management Tool

There is an enduring assumption in the biological sciences that nature is free for the taking. Many researchers still collect environmental specimens or receive samples of genetic resources from collaborators on the assumption that they are free to use genetic resources in R&D, providing those resources have been taken from nature and are unmodified by humans. This is not the case.

Since 1992, the United Nations' (UN) Convention on Biological Diversity (CBD) recognised that countries have sovereign rights over the genetic resources that originate in their land, water and sea territories. The term "genetic resources" has a very broad possible meaning and in most places includes everything biological, from whole animals to derivative chemicals, and in some cases gene sequences too (see Box 1). This means that every time you collect or use samples of genetic resources (even samples collected decades and centuries ago), you may need to obtain permission(s) and agree to some terms and conditions, including about sharing some benefits with the originating country. This is even the case for foundational (non-commercial) research, depending on the law that applies in each situation.

The process of accessing or using genetic resources from other countries and coming to an agreement about how you will share benefits with that country is called "access and benefit-sharing" (ABS). The ideal is that any researchers accessing or using genetic resources and/or Traditional Knowledge associated with genetic resources from other countries obtain the prior informed consent (PIC) of the originating country and come to mutually agreed terms (MAT) about how those resources will be used and how the benefits of the R&D will be shared with the originating country (see Box 2). As each country has its own ABS laws, and intermediary countries have their specific laws, accessing and using genetic resources and associated Traditional Knowledge will need to satisfy each ABS jurisdiction.

Box 1

Terms defined in the Convention on Biological Diversity (CBD) and its Nagoya Protocol

Biological diversity means the variability among living organisms from all sources including inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems.

Biological resources includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Country of origin of genetic resources means the country which possesses those genetic resources in *in-situ* conditions.

Country providing genetic resources means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

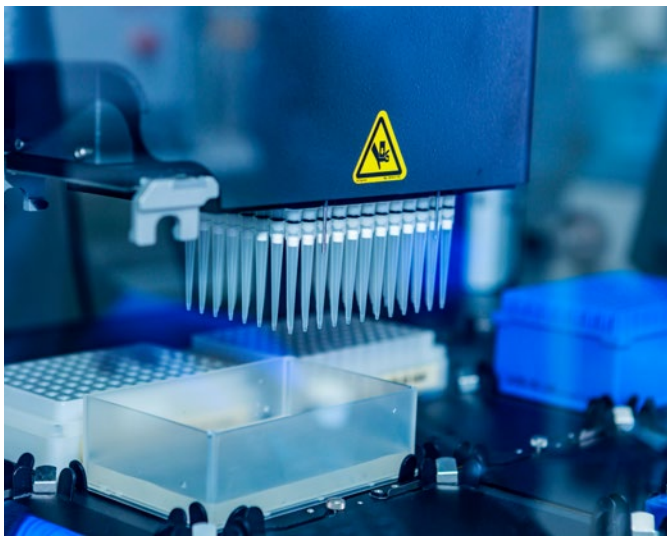
Derivative means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic resources means genetic material of actual or potential value.

Utilization of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

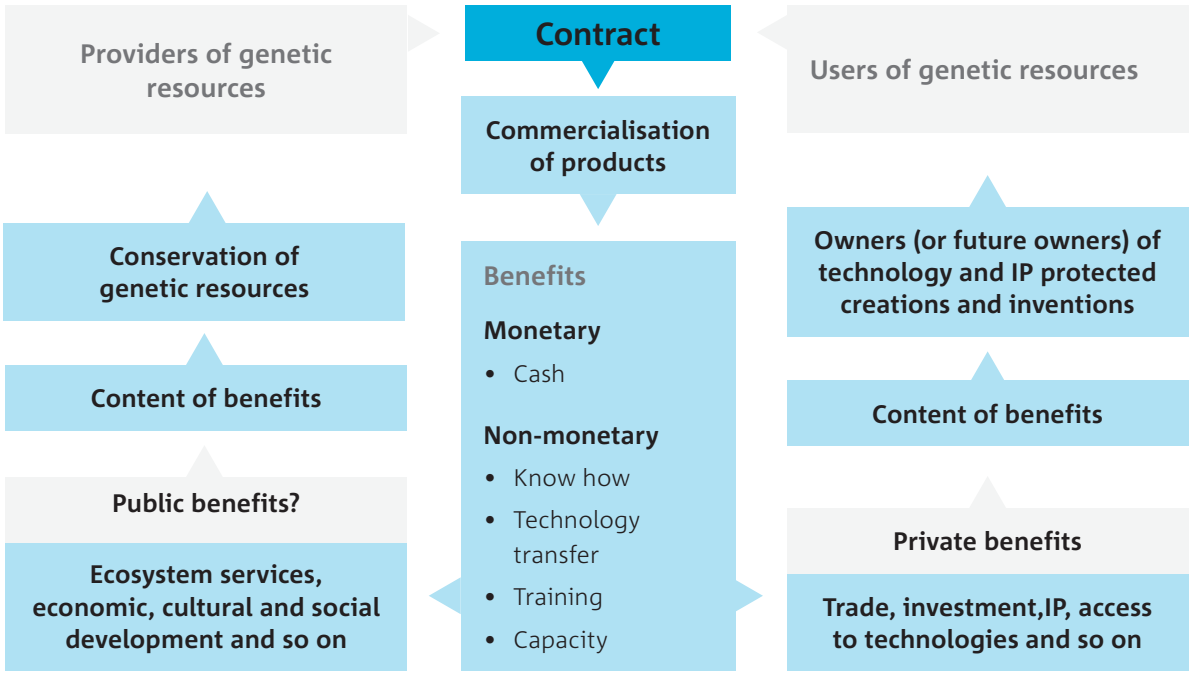
The Nagoya Protocol, a supplementary agreement to the CBD, was adopted by the parties to the CBD in 2010. It created some additional ABS requirements for accessing and using genetic resources, and extended ABS to include the access and use of Traditional Knowledge associated with genetic resources held by Indigenous Peoples and local communities. The resulting patchwork of laws, requirements, processes and obligations implementing the CBD and Nagoya Protocol in each country are complex and need to be carefully navigated for each and every use of a genetic resource. And this is made yet more complex by some countries having no formal ABS laws or processes, and others having different laws for provinces or states within a country.



Box 2

The ideal of access and benefit-sharing under the CBD and its Nagoya Protocol.

Providers of genetic resources deal with the owners of finance, technology and intellectual property (IP) to give them access to genetic resources through an ABS contract. The genetic resources are then used to develop commercial products, processes and services. The commercial returns and non-monetary benefits can then be shared between the providers and owners of the technology and IP.



Adapted from Lawson, C. and Pickering, C. 2021. Scientometric review of the literature about genetic resources access and benefit-sharing under the Convention on Biological Diversity: Current research and future directions. *Journal of Science & Law*, 7(1): 1-30. doi:10.35005/daen-sd52

This Tool seeks to provide Australian synthetic biologists with an approach and a framework for thinking about ABS obligations under the CBD and Nagoya Protocol, smoothing the path from foundational research to the development of commercial products, and ensuring that the benefits of synthetic biology are appropriately shared with all parties involved in the stewardship of genetic resources and associated Traditional Knowledge. At its heart, the ABS process is about establishing the provenance of genetic resources and making decisions that can be defended in a matrix of complicated and often uncertain laws, requirements, processes and obligations.

In many ways, ABS has gone unnoticed by the synthetic biology community. This is, in part, because ABS was originally intended to regulate "bioprospecting" activities, where researchers (often from pharmaceutical companies) would travel to biodiverse countries and collect samples of genetic resources from the environment in the hopes that they would discover the next blockbuster drug. Many countries rich in biodiversity (but without the technological resources to conduct this research themselves) were concerned that companies from industrialised countries were patenting their natural wealth and making vast sums of money without their involvement. The regulation of these sorts of activities meant that biodiverse countries could capture some of the benefits of this research and use them to increase their own capacity to conserve their biodiversity and conduct biological research themselves.

Most synthetic biologists do not conduct fieldwork or collect new biological samples from the environment. Thanks to the use of model organisms collected many decades before the introduction of ABS laws, ready access to physical biorepositories, and online genetic sequence databases, synthetic biology is a field of science that has not had regular encounters with ABS laws. Whenever synthetic biologists require particular genetic resources (or parts thereof), they are just as likely to synthesise them rather than acquire physical samples. Furthermore, there is a high level of abstraction in synthetic biology compared to many other biological sciences. Unlike R&D associated with bioprospecting activities, synthetic biology rarely leads to an innovation that can be traced back to an easily identifiable genetic resource collected from the environment. Sometimes it can be difficult to determine where the (potentially hundreds of) inputs to the synthetic biology R&D process have originated and where, therefore, to start negotiations about sharing any benefits.

While ABS laws have existed in some form for 3 decades, researchers may have only recently noticed increasing restrictions on accessing genetic resources from other countries. Some countries have also started applying access restrictions to information about genetic resources, including genetic sequence data. This is due, in part, to pressures to commercialise many aspects of the R&D process, but also due to increasing awareness about the CBD and Nagoya Protocol, the important role of Indigenous Peoples and local communities (IPLCs) in conserving biodiversity, and the growing sense that the benefits of science are not being shared in a fair and equitable way. ABS is no longer just about regulating bioprospecting activities. It has also become a tool to deliver equity and fairness in science.

These issues have become more high-profile in recent years, and many biodiverse countries are more inclined to enforce their ABS laws than in previous decades. This means that there is a growing degree of scrutiny on R&D and researchers' compliance with the CBD, Nagoya Protocol, and various domestic laws about accessing and utilising genetic resources. Non-compliance with ABS laws can have serious consequences, including being unable to publish research results, research projects being terminated, serious reputational damage and even fines and imprisonment in some countries. Working around ABS requirements is no longer a viable approach. But for synthetic biologists using hundreds of physical and informational genetic inputs for R&D, ABS can pose a time consuming and expensive compliance obligation. This is further complicated because some countries have no ABS laws, others have no institutional architecture or governance frameworks to implement their ABS laws, and it is difficult to establish the provenance of many orphan and legacy samples. Even where an originating country can be identified, the relevant holder – such as an Indigenous or local community – may be difficult to identify and properly engage. That is why **this Risk Management Tool takes a "risk framework" approach to ABS compliance, specifically designed for Australian synthetic biologists, which takes into account their unique circumstances.** This Tool will also be useful to other practitioners in the biological sciences that use hundreds of genetic resources as inputs to their R&D where a separate ABS agreement with every country contributing any genetic resource would become an unreasonable impediment to actually conducting the research.

How to use the Risk Management Tool

This Risk Management Tool has been written for the users of genetic resources in synthetic biology R&D and therefore takes a very user-centric approach to these issues. This means their focus is on navigating ABS laws and dealing with barriers to access as they arise. However, it is important to stress that ABS laws were never intended to be an impediment to R&D; they are about sharing the benefits of R&D and using genetic resources in a fair and equitable way with the originating countries. In many ways, most scientists are already sharing the benefits of their R&D. Collaboration with scientists from the country of origin, joint authorship and international capacity building activities like education and training are all the sorts of benefit-sharing activities that the CBD and Nagoya Protocol try to encourage. This Risk Management Tool will equip users of genetic resources with the information required to make important decisions about ABS, and ensure the benefit-sharing activities that stem from R&D are in line with international expectations and obligations. Researchers in Australia frequently use genetic resources from other countries, but also often provide Australian and other countries' genetic resources to researchers based overseas. Therefore, this Tool will be helpful for addressing issues that arise for researchers providing genetic resources as well.

Part I of this Risk Management Tool will provide the legal background required to understand ABS and its overarching intent. It covers the terminology you are likely to encounter while trying to assess and comply with your ABS obligations. **Part II** will outline the process for accessing and/or utilising genetic resources from other countries and the sorts of considerations necessary to effectively engage in this process. Because every country has its own ABS laws (based on, but not always the same as, the requirements of the CBD and Nagoya Protocol), the process for accessing and/or utilising genetic resources is different from country to country. This usually necessitates researching the laws of every relevant jurisdiction and coming to an ABS agreement with every country that has contributed any amount of genetic material or information to the R&D process. Because this approach is not viable for many synthetic biology projects, **Part III** outlines a risk framework to help users make difficult decisions about what to do when the way ahead is uncertain.

Many ABS situations are not clear-cut, and you will need to minimise the legal risks to your research, yourself and your institution. This is why it is so important to understand the background and intent of ABS laws: your decisions will need to be made with the intent of the laws in mind. The goal of this Risk Management Tool is to provide a framework for thinking about ABS-related administrative and legal obligations, so that you have a better chance of getting your research underway! Finally, **Part IV** will outline some additional considerations for those looking to ensure ABS compliance at the institutional level. Again, it is written for institutions that are predominantly users of genetic resources in synthetic biology, but will also provide information about acting as an authorised provider of genetic resources from Australia, and potentially other countries.

You can read this Risk Management Tool from start to finish, or just the parts that are relevant to your needs. For instance, if you already have a basic understanding of the legal background of ABS, you may want to skip ahead to Part II. Because each section of the Risk Management Tool needs to be comprehensible in isolation, the use of legal terminology and acronyms is avoided unless already defined within the specific section.

NOTE: This Risk Management Tool provides a framework for thinking about ABS in your own research. Because ABS laws are implemented differently in every country, this Tool cannot address every situation you are likely to encounter when dealing with ABS. Rather, it can help you to understand the complex ethical and historical context in which ABS laws operate, understand ABS-specific language and highlight some ABS issues that may not be immediately apparent, so that you can make informed decisions. This Tool should be treated as a starting point, so you have the background necessary to find and understand information that is specific to your R&D. You will need to consult with your institution's legal advisers to settle any formal legal obligations like ABS contracts or legislation interpretation.

A note about Intellectual Property

Intellectual Property (IP) and ABS are not the same thing, but they are related. IP rights include patents, copyright, trademarks, plant breeder's rights and trade secrets. For the purposes of this clarification, we will focus on patents which are a time-limited monopoly right to exploit a novel and non-obvious invention (products, devices, methods or processes). Patents are issued by the country in which the invention will be used and/or marketed. In Australia, the patent period is up to 20 years for a standard patent, and extendable up to 25 years for some pharmaceutical patents. In the 1980s, many rich countries started patenting biotechnological inventions that were based on genetic resources. Patenting is now a common form of legal protection and a part of the R&D strategy of many commercially oriented research institutions.

The international regime on ABS (i.e., the CBD and Nagoya Protocol) can be seen as something of a backlash to rich countries patenting inventions based on the genetic resources of poorer countries. There were particularly egregious examples of industrialised countries using patents to protect innovations based on the traditional practices and cultural knowledge of Indigenous Peoples and local communities. Traditional Knowledge (TK) is the result of communal engagement with the land and nature over millennia, and does not fit neatly into Western ideas of knowledge generation and IP protections.

Therefore, many poorer countries fought for recognition of their sovereign rights over genetic resources. The implementation of ABS laws was an attempt to protect natural and cultural resources by using the same kinds of property laws that had been used by industrialised countries to protect individual innovations or commercial property.

When thinking about these different types of property regimes (i.e., sovereign rights and IP rights) it can be helpful to think about them in reference to the innovation pipeline. Countries have sovereign rights over the raw natural inputs to the innovation pipeline ("genetic resources"). R&D can be said to occur within the pipeline, and the outputs of that pipeline can be subject to IP rights if they are sufficiently novel, useful, inventive and creative. In this sense ABS and IP are complimentary. There is conflict, however, if the benefits derived from commercialisation through IP (such as the royalties from a patented product or process) are not shared in a fair and equitable way with the country of origin of the sovereign genetic resources.

Box 3

The Innovation Pipeline

This simplified representation of the innovation pipeline shows the difference between where in the R&D process sovereign rights apply to genetic resources, and where IP rights apply. Note that there is rarely a 1:1 relationship of inputs to outputs. That is, R&D on a single genetic resource (input) will rarely lead to a single commercially viable product (output), nor is that necessarily the aim of most R&D. Also note that some patented outputs can be licensed for use as inputs to other R&D processes.

Certainly, the innovation pipeline is nowhere near as linear as it is represented in the above image. The point is simply to differentiate between the types of resources that are subject to sovereign rights of the originating country (and therefore ABS laws) and the outputs of R&D that are subject to IP rights. The inputs include a lot more than genetic resources; they can also include equipment, proprietary laboratory tools, test animals, personnel time, etc. The outputs are also more complex than is represented here, and may include data, information, research publications, genetic sequences, modified genetic resources, laboratory tools, computer programs, machinery and commercial products. But, as a generalisation, it is the genetic resource inputs that are subject to sovereign rights (and therefore ABS processes) and the outputs that are subject to IP protections.

Many of the IP-protected outputs of one R&D process will later become the inputs to other R&D processes. Therefore, it is important to remember that **some genetic resources that are inputs to R&D could be subject to both IP protections and ABS obligations.** This could therefore result in two parallel legal negotiations for the use of a particular type or sample of a genetic resource in your R&D: negotiating an ABS agreement, and separately, a commercial licence. This could result in two benefit-sharing/payment obligations to different entities (e.g., the authorised provider for ABS purposes and the patent holder).

Part I – Legal background

Laws are the combination of duties, obligations and standards that guide acceptable practices. Synthetic biology, and science more generally, operates within a complex landscape of laws at every stage of the R&D process, and these laws together make up the ethical, legal and social obligations expected of modern-day scientists. As an international endeavour, synthetic biology now spans the planet, which means that the scope of these ethical, legal and social obligations needs to be carefully planned and administered to comply with the many laws at different levels. These levels include international laws (e.g., treaties of the United Nations and its organs), regional or supranational laws (e.g., treaties of the European Union), domestic laws of countries, sub-national or provincial laws (e.g., states and territories), local laws (e.g., local councils) and even sub-local laws (e.g., private title lands).

Access and benefit-sharing (ABS) is just one type of law that impacts synthetic biology. Every synthetic biology R&D project using genetic resources will need a bespoke consideration of the jurisdictions involved, the array of potential stakeholders involved in each stage of the project, the kinds of physical genetic samples to be collected, obtained and/or used, the sorts of data and information that will be used as inputs to the R&D process, and the kinds of products to be delivered as outputs to that process (including new data, information and knowledge, publications and products). Given the nuances involved in every synthetic biology project and the differences in ABS laws across jurisdictions, there is no quick fix solution or universal way to approach ABS.

Instead of viewing ABS obligations as a set of fixed elements, it is better to approach ABS as a set of principles and considerations, and to apply these principles and considerations in a "risk framework". A risk framework is a way of balancing and weighting different factors to make a decision about using a particular genetic resource in a synthetic biology project. This approach accepts that there is a matrix of relevant factors in making any decision and considers: (1) a complex patchwork of laws, requirements, processes and obligations implementing the CBD and Nagoya Protocol in each country; (2) the needs of each project are not the same, with projects engaging different elements of genetic resources (such as sequences, compositions, combinations, and so on); and (3) a range of possible stakeholders including collaborators, national research objectives, Indigenous Peoples and local communities, and so on. This is more than just a minimum compliance obligation and requires engagement by researchers with the spirit and intent of ABS as a tool for equity, justice, and conservation.

Box 4

What is meant by operating in a "risk framework"?

This Risk Management Tool acknowledges that ABS laws are highly complex and difficult to navigate. Not only are ABS laws jurisdiction-specific, they are also sample-specific. This Tool therefore takes the approach that some questions of ABS compliance will pose greater legal risks to your research than others, and suggests that a starting point for approaching ABS compliance is by identifying the highest legal risks to your research, yourself and your organisation. This will require you to balance various risk factors. For instance, if you wanted to collect samples from multiple countries to build a library of genetic resources, it is reasonable to inform the country of your intent with enough time for them to consider your request and negotiate an ABS agreement with you. If, however, you must screen existing sample libraries to determine if any contain compounds with an effect on a novel virus posing a current pandemic threat, it is reasonable to start screening the compounds and simultaneously check that the associated ABS paperwork is in order.

What is Access and Benefit-Sharing?

The term "access and benefit-sharing" (ABS) is short for access to genetic resources and the sharing of benefits associated with their use in R&D. The international regime on ABS comes from the United Nations' (UN) Convention on Biological Diversity (CBD) and the Nagoya Protocol, with subsidiary schemes under other international agreements for some plant materials and some influenza viruses (see "Specialised International ABS Laws"). Not all countries are party to these agreements, and not all countries have implemented policies, rules and administration to give these international agreements effect in their own jurisdiction. **But every country has the right to regulate access to their genetic resources as they see fit and there are always some laws that apply to accessing biological materials.** This means that even if you want to access genetic resources from a country that is not party to any of these agreements, you should still check to see if they regulate access to their genetic resources under their domestic laws. At a minimum, the process of accessing genetic resources or associated Traditional Knowledge (TK) from another country will usually require the provider party's "prior informed consent" (PIC) and you will need to come to "mutually agreed terms" (MAT) about how the genetic resources will be accessed and/or used and how associated benefits will be shared. This will be documented in an ABS agreement.

The international ABS legal architecture

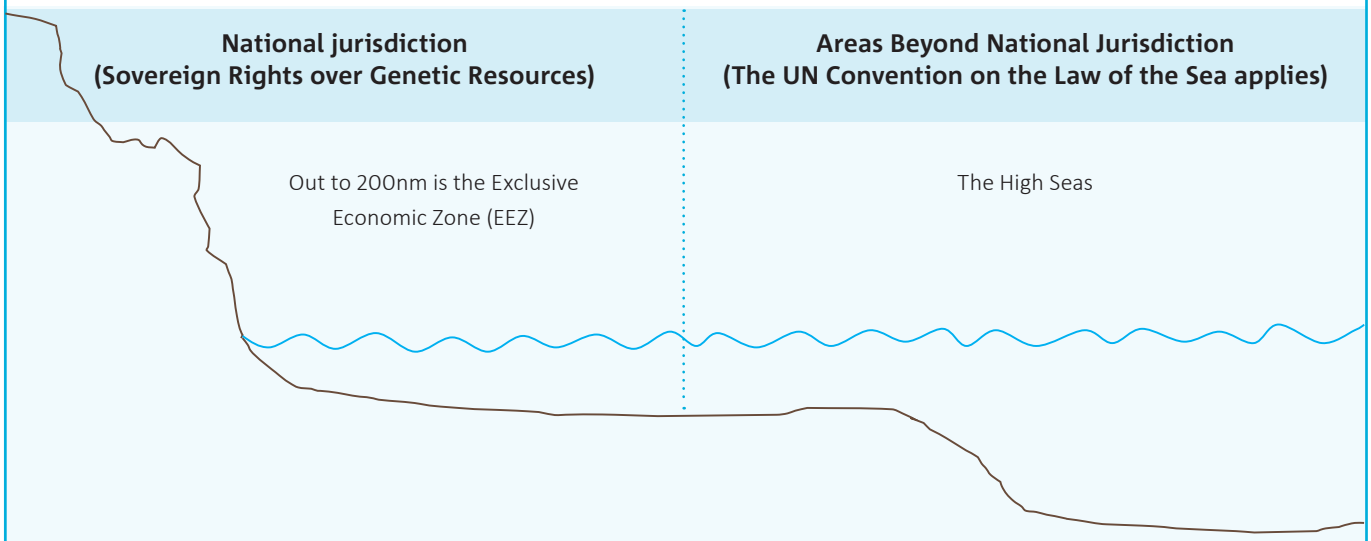
The complex landscape of international ABS laws includes sometimes overlapping international ABS schemes for different parts of the planet. Fundamentally, the CBD and Nagoya Protocol apply to sovereign "genetic resources" of the land territory and waters, adjacent seas and air column of UN member countries. Within those spaces there are specific schemes for some plants and some influenza viruses (see "Specialised International ABS Laws"). Beyond those spaces there are separate schemes for Antarctica and outer space, and there is a new scheme for accessing marine genetic resources from the high seas in areas beyond national jurisdiction (See Box 5).

Usually when people refer to "international ABS laws" they are talking about the rules contained in the UN's CBD and its Nagoya Protocol, which affirm that countries have the sovereign right to regulate access to their genetic resources. These rules are given effect in the national jurisdiction of UN member countries by passing domestic laws that cover the genetic resources in their land territory and waters, adjacent seas or air column. Sometimes countries choose not to regulate access to their sovereign genetic resources. Each country will take different approaches to ABS, and it is important to remember that ABS laws apply in addition to all other relevant ethical, legal and social obligations in any given country.

Box 5

Where can countries exercise sovereign rights over genetic resources?

A simplified schematic of jurisdiction of the areas where countries have sovereign rights over genetic resources under the CBD and Nagoya Protocol ("national jurisdiction"). Note that countries have full sovereignty (exclusive legal authority) out to 12 nautical miles (their territorial sea) but only "sovereign rights" (more limited authority) in the Exclusive Economic Zone (out to 200nm).



NOTE: Remember that there are other laws (at all levels) about genetic resources that may impact your research, including the Convention on International Trade in Endangered Species (CITES) and national import and export controls. Laws about accessing genetic resources and sharing the benefits associated with their use in R&D (ABS) is just one category of laws you will need to consider when designing and conducting your research.

The Convention on Biological Diversity (1992)

The Convention on Biological Diversity (CBD) is a UN treaty that has been adopted by 196 parties, including every country except for the United States of America and the Holy See (Vatican City). The CBD was adopted in 1992 and entered into force on 29 December 1993. It has three key objectives:

1. "the conservation of biological diversity";
2. "the sustainable use of its components"; and
3. "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources".

It is this third objective that creates international minimum standards for accessing and using genetic resources. Under the CBD, users of genetic resources from other countries should first seek the permission of the authorised provider country ("prior informed consent", PIC) (this is normally in the form of a permit issued by the government) and make an agreement with the provider country about the terms of access and/or utilisation ("mutually agreed terms", MAT) (this may be a condition or term of the permit). These terms can include an agreement to share the benefits that users generate through their R&D using those genetic resources ("benefit-sharing agreement"). The benefit-sharing agreement is usually in the form of a contract.

NOTE: In some circumstances, there may be more than one "authorised provider". E.g., in some instances, you will require the permission of multiple levels of government and/or multiple groups of Indigenous Peoples and local communities.

The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization to the Convention on Biological Diversity (the "Nagoya Protocol") is a supplementary agreement to the CBD that came into effect on 12 October 2014. It provides further guidance about ABS, including some new rules about accessing and using Traditional Knowledge (TK) associated with genetic resources that is held by Indigenous Peoples and local communities (IPLCs). Not all countries that are party to the CBD have signed up to the supplementary Nagoya Protocol.

NOTE: The notion of ownership in science is complex. Just because you collected samples from the environment, stored them and used them in your R&D, does not mean you own those samples in the same way you might own your shoes. There are a bundle of rights over those samples, some of which will have nothing to do with you or your lab group. When it comes to samples of genetic resources, it may be appropriate to think of yourself as something of a caretaker who – if you have appropriately engaged in the ABS process – has the right to use those genetic resources in R&D activities, but may also have the responsibility to share the benefits associated with their use.

Who are the "Contracting Parties"?

In the context of the CBD and Nagoya Protocol the Contracting Parties to the treaties are national governments. National governments sign onto the international treaty, and they are responsible for putting the rules of the treaty into their domestic laws. National governments (and subnational governments, such as provinces and territories) can implement their own ABS measures as they see fit, and they will often have different interpretations of terms such as "utilisation", "commercial research" and even "genetic resources". This means the laws are different around the world and this is why a Risk Management Tool such as this can only provide general ABS information.

Who are the provider parties and user parties?

When obtaining prior informed consent (PIC) and negotiating mutually agreed terms (MAT) for the access and/or use of particular genetic resources, there are **provider parties** (e.g., the country of origin) and **user parties** (e.g., scientific researchers or organisations). The provider party is often the country's Competent National Authority or another government department, but it can be communities, private organisations, or individuals under some laws. It could be an *ex-situ* biorepository (e.g., biobank, culture collection or seed bank) that has authorisation from the **country of origin** to provide the genetic resources to other parties. This is why language like "country of origin", "provider party" and "authorised provider" are often used to mean the same thing in ABS documents. There may be more than one provider party if you obtained genetic resources or sequence information from several countries (or subnational jurisdictions), each of which may also require PIC and MAT.

NOTE: The user party must have the legal authority to enter into a contract to access and use genetic resources. This would not normally be an individual scientist, but instead their research organisation or institution. This will ensure the agreement is formed under the legal authority of the organisation and survives a change of personnel.

Remember that once your organisation has obtained samples, you may have permission to send those samples to other research institutions. This would make your organisation an authorised provider for the purposes of that arrangement. This does not mean, however, that your organisation will receive any benefits. ABS laws are about ensuring the country of origin is the beneficiary. That is, ABS is not like buying something, owning it, and then selling it to another party.

In practice, a benefit-sharing agreement is likely to be concluded between a government department (e.g., Ministry of the Environment or similar) or an IPLC and a research institution. When the research institution has authorisation from the country of origin or IPLC to act as a provider of those genetic resources, the agreement might be between two research institutions in different countries.

Country of Origin

The concept of "origin" is difficult to define for genetic resources which may have evolved their specific genetic characteristics over millennia and across large geographical areas. Remember that this a regulatory term rather than a scientific one. The CBD defines the country of origin as "the country that possesses those genetic resources in *in-situ* conditions". The definition of ***in-situ* conditions** is "where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties". **For the purposes of ABS, the country of origin may be the country where a given sample of the genetic resource was collected (i.e., the country of extraction).**

However, if a country has a strong cultural affinity to a particular species and/or is known to be the site of evolutionary origin of a particular subtype or strain of genetic resource, then it would be appropriate to negotiate ABS terms with that country (e.g., the country of evolutionary origin), even if you are sourcing a particular sample of that genetic resource from a biorepository or separate country where the genetic resource also exists within its ecosystem.

NOTE: Remember that some countries will implement different ABS laws in different sub-national jurisdictions and will therefore require more detailed information than just "country of origin" to determine which ABS laws apply. Be sure to get detailed data about the collection location whenever possible (e.g., GPS coordinates).

Utilisation of Genetic Resources

The CBD does not define what it means by "utilisation" but the Nagoya Protocol defines utilisation of genetic resources as the "conduct [of] **research and development** on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology". Biotechnology is defined in the CBD as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

NOTE: The utilisation of genetic resources for reasons other than R&D are not covered by the CBD and/or Nagoya Protocol. This includes commodities such as grain and livestock that will be used for food. The key here is the intended use of the genetic resource: if it is originally exported as a commodity but is later used in R&D, then this change in intended utilisation brings the activity within the scope of the CBD and Nagoya Protocol.

Timing is an element of access and utilisation that can cause some confusion. Obviously, the CBD could not have applied to any samples or specimens that were collected prior to the existence of the CBD. These laws cannot be applied retroactively. Some countries have interpreted this to mean that any samples collected before this date are exempt from ABS obligations. Others, however, have determined that while the samples may have been "accessed" before the CBD entered into force, any new utilisations of the sample occurring after the CBD entered into force do require ABS obligations to be met. In these confusing situations it is important to remember the intent of ABS laws: that they are here to ensure that the benefits of R&D on genetic resources are shared with the countries from where those genetic resources originated. As a matter of best practice, start by assuming that new uses of pre-CBD samples fall within the scope of the CBD and Nagoya Protocol, and then check to see if your relevant jurisdiction applies a narrower definition.

Genetic resources and derivatives

ABS laws apply to **"genetic resources"**. The CBD defines genetic resources as "genetic material of actual or potential value" and then defines "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity". Genetic resources may take the form of whole animals, animal tissue or faecal matter, plant material, environmental samples containing microorganisms (e.g., water or soil), extracted DNA or RNA – **essentially anything that is being analysed or used based on any of its genetic properties.** As a matter of best practice, start by assuming anything biological or derived from something biological is a genetic resource, and then check to see if the relevant jurisdictions apply a narrower definition.

NOTE: Human genetic resources are not specifically covered by the international ABS laws, but they might be covered by domestic ABS legislation. The use of human genetic resources in R&D generally comes with additional ethical, legal and social obligations. In Australia, the use of human genetic resources in R&D is covered by human research ethics (see the NHMRC's National Statement on Ethical Conduct in Human Research, available at https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018).

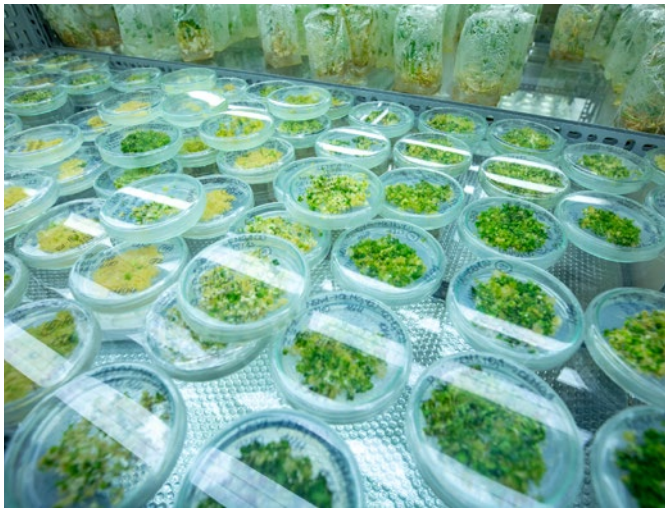
The Nagoya Protocol expands ABS to include **"derivatives"** which it defines as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity".

It is important not to get too hung up on the technicalities of the terms "genetic resources" and "derivatives". Under international law, countries have sovereign rights over all the natural resources in their territories. In practice this means that countries can apply ABS laws to whatever genetic resources or derivatives (and any definition of those terms) they see fit. For instance, the parties to the CBD have agreed not to apply ABS to human genetic resources, however, some countries (e.g., Malaysia) still include human genetic resources in their domestic ABS laws.

Modified or synthetic genetic resources

In the course of your synthetic biology R&D, you are likely to be using genetic resources that were originally sourced from the environment (to which ABS obligations applied) but have now been modified in the laboratory. It is not clear how different a synthetic genetic resource needs to be from a wild-type genetic resource before ABS laws no longer apply to the synthesised resource. This is the sort of categorical problem that inspires philosophical debates and that laws cannot easily address.

You will need to follow the guidance of your institution where it's provided, or else use your discretion about the contribution that synthetic genetic resources are making to your R&D, the extent to which they resemble wild-type genetic resources and what ethical, legal and social risks you may be exposed to if you continue the R&D as planned. For example, if you are working with a protein coding sequence and have changed some codons to optimise protein expression in a particular chassis, then it is reasonable that you would still inform the country of origin (the original source of the wild-type protein coding sequence) about your R&D. If, however, you are feeding all of the known sequences of a particular family of proteins into an artificial intelligence algorithm to develop an entirely synthetic optimised protein that does not closely resemble any of the input sequences, then (as the laws are currently formulated) it would not be reasonable to negotiate an ABS agreement with every country of origin. But, consistent with the spirit and intent of ABS laws, it may be appropriate to clearly identify the broader benefits of the project outputs and share those benefits, for example by making the results publicly available, engaging PhD students from developing countries on the project, and so on.



In-situ sampling and *ex-situ* collections

The CBD distinguishes between collecting genetic resources from *in-situ* (in place) conditions and using genetic resources from *ex-situ* (out of place) collections:

In-situ (field collection)

If you are collecting wild-type genetic resources from the environment, then you are accessing genetic resources from *in-situ* conditions. The CBD defines *in-situ* conditions as those places "where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties".

Ex-situ (biorepository)

The CBD refers to "the conservation of components of biological diversity outside their natural habitats" as *ex-situ* collections. You would know these as seed banks, biobanks, biorepositories, microbial culture collections, tissue banks and the like. Any time you receive genetic resources that were collected earlier by another party (i.e., you are not the party collecting the samples from *in-situ* conditions) you are accessing genetic resources from *ex-situ* collections. If you also provide samples that you have collected to other researchers, then your laboratory is also a provider of *ex-situ* genetic resources (see Part IV).

NOTE: The storage of genetic sequences in digital databases are sometimes referred to as *in-silico* collections.

Digital Sequence Information (DSI)

The term "Digital Sequence Information" (DSI) is used in the ABS regulatory space to refer to genetic sequence data and associated information. While the precise scope of this term (in the legal sense) is yet to be determined, it more than likely covers nucleic acid sequences (genomic and transcriptomic data), amino acid sequences (proteomic data) and the metadata associated with that sequence information. The term could also cover annotations, additional information about metabolites and information about epigenetic modifiers.

At this stage, the parties to the CBD have not decided whether DSI should be regulated like a physical genetic resource or derivative, and some countries have therefore made their own decision on the matter. In your research, you are likely to both use DSI and generate DSI.

This means DSI could become part of the terms and conditions in your ABS agreements. Some countries already include DSI in their definitions of genetic resources, and those laws need to be complied with where applicable.

NOTE: The term DSI more than likely does not cover Traditional Knowledge (TK) associated with genetic resources held by Indigenous Peoples and local communities (IPLCs) which is already covered by ABS minimum requirements (i.e., prior informed consent and mutually agreed terms).

Generating Genetic Sequence Data/DSI

If you are generating genetic sequence data from your R&D, you will need to determine if the country of origin of the genetic resource wants you to publish that data in an open access sequence repository like GenBank. You will need to comply with the repository's terms and conditions, and as a matter of good practice include all relevant metadata information, such as country of origin tags. This will likely form part of the terms of the ABS agreement.

Using Genetic Sequence Data/DSI

At this stage, there might be an assumption that there are no ABS impediments to you accessing data from GenBank or any of the other open access sequence repositories of the International Nucleotide Sequence Database Collaboration (INSDC) or similar.

However, it is best practice to consider whether the specific characteristics of a particular nucleic acid or amino acid sequence that can be traced back to a country of origin are materially contributing to your research. If so, you should consider getting in touch with the Competent National Authority (CNA) of the country of origin to discuss your R&D and determine if their ABS rules apply. If you are simply conducting a BLAST or are otherwise comparing your target sequence with others in the database, it would not be considered reasonable to negotiate an ABS agreement with the countries of origin of the sequences in the open access database.

NOTE: In December 2022, the Parties to the CBD and the Nagoya Protocol decided to develop a multilateral system for sharing benefits that are generated through the use of DSI. It is not clear what this system will look like at this stage, or what types of access and utilisation it will cover. This is an active issue in the ABS field, so keep an eye out for changes.

Specialised International ABS Laws

If you work with plant genetic resources used for food and agriculture, or influenza viruses with human pandemic potential, or marine genetic resources from international waters you also need to be aware of resource-specific ABS rules under the following international agreements:

International Treaty on Plant Genetic Resources for Food and Agriculture ("Plant Treaty")

The Plant Treaty is an international treaty that covers **plant genetic resources for food and agriculture** and the fair and equitable sharing of the benefits arising from their use. It was specifically made to be "in harmony" with the requirements of the CBD. The Plant Treaty includes the "Multilateral System" that facilitates access to plant genetic resources on 64 of the world's most important crop species, including yams, chickpeas, rice, maize, and wheat. This includes a range of other materials that have been contributed and become a part of the Multilateral System. All these plant genetic resources are provided to researchers according to the terms of a Standard Material Transfer Agreement (SMTA), where users agree to share benefits back into the Multilateral System, including a percentage of profits if their research results in a commercial product. You will probably know whether plant genetic resources you have requested from an *ex-situ* repository are Plant Treaty materials, as you will be asked to sign a SMTA. If not, then you will need to consider the CBD and Nagoya Protocol ABS matters.

Pandemic Influenza Preparedness Framework (PIP Framework)

The Pandemic Influenza Preparedness Framework is governed by the World Health Organisation (WHO) and applies to the sharing of **H5N1 and other influenza viruses with human pandemic potential** that are shared with (and accessed through) the Global Influenza Surveillance and Response System (GISRS), an international network of WHO-affiliated influenza laboratories. Any parties that wish to access influenza samples with human pandemic potential through this network will need to sign a Standard Material Transfer Agreement (SMTA) that requires different types of benefit-sharing according to the capabilities of the party.

Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable use of Marine Biological Diversity of Areas Beyond National Jurisdiction (High Seas Treaty)

Under the 1982 UN Convention on the Law of the Sea (UNCLOS) benefit-sharing from **marine genetic resources from areas beyond national jurisdiction** (the high seas and the seabed and ocean floor beneath the high seas) was not considered. Any marine genetic resources collected from international waters (called "areas beyond national jurisdiction", ABNJ), where countries do not have sovereign rights to the waters and resources within, were essentially free for the taking. If marine genetic resources are sourced from within 200 nautical miles of a country's coastline (i.e., within their "Exclusive Economic Zone", EEZ), then the country can exercise their sovereign rights over those marine genetic resources under the CBD and Nagoya Protocol (see Box 5).

In June 2023, UN countries agreed to set up a new international agreement for the collection and utilisation of marine genetic resources in ABNJ and benefit-sharing arrangements. Key features of this new agreement are a notification mechanism, requiring information about collection and utilisation activities concerning marine genetic resources from ABNJ, fair and equitable benefit-sharing requirements and an ABS Committee that will establish guidelines for benefit-sharing and transparency. How the notification and benefit-sharing system will work in practice is yet to be determined by the Conference of the Parties to this new agreement.

This agreement for marine genetic resources outside of national jurisdiction sits outside of, and is complementary to, the CBD and Nagoya Protocol rules which apply to genetic resources within national jurisdiction (including marine genetic resources within national jurisdiction).

Pandemic Treaty (forthcoming)

The Pandemic Treaty is currently being negotiated at the international level and is likely to impact the management of pathogenic genetic resources.

The World Health Organisation (WHO) is currently negotiating a new convention, agreement or accord to address some of the shortcomings with pandemic preparedness and response that were seen during the COVID-19 pandemic. While the terms of this "Pandemic Treaty" are yet to be agreed, it is likely that the Treaty will include some rules about accessing pathogens with human pandemic potential (other than pandemic influenza viruses), and sharing the benefits associated with their use in R&D. These terms will likely be negotiated to be compatible with the ABS requirements of the CBD and Nagoya Protocol.

NOTE: You may have heard of a health exemption or exception to the Nagoya Protocol when it comes to pathogenic genetic resources, but this is a misunderstanding. Article 8(b) of the Nagoya Protocol states that Parties shall:

"Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries."

So, when implementing laws about health emergencies, Parties to the Nagoya Protocol can take the need for faster ABS agreements into account. There is no health exemption to the ABS requirements of the CBD or Nagoya Protocol.

Access and Benefit-Sharing (ABS) Agreement

This is any agreement (usually in the form of a contract) between the provider party (e.g., country of origin) and user party (e.g., researcher) that outlines the terms and conditions around accessing and/or utilising genetic resources and/or associated Traditional Knowledge (TK). At a minimum, the ABS agreement will cover "prior informed consent" (PIC) and any "mutually agreed terms" (MAT) including about sharing the benefits of R&D with the provider party, all in accordance with the laws of the jurisdiction in which you are collecting or from which you are accessing samples of genetic resources or associated TK.

Prior Informed Consent

Prior informed consent (PIC) means that you have sought permission from the provider party to access and use their genetic resources, that you have given the provider party information about how you intend to use those genetic resources before starting your planned R&D activities, and that permission has been given freely (as in, without force or political pressure). Usually, PIC is given by the Competent National Authority (CNA) of the country of origin of the genetic resource of interest (see "Competent National Authorities") .

Mutually Agreed Terms

Mutually agreed terms (MAT) means the terms and conditions that are agreed upon by both provider and user parties to the ABS agreement. These can be standard terms and conditions, like those found in some Standard Material Transfer Agreements (SMTAs), where the provider party determines the terms and conditions and the user party can receive the genetic resources under those terms. Sometimes coming to an ABS agreement with MAT will involve a negotiation process, where both provider and user can determine the terms and conditions together. It can also be the case that an ABS agreement will contain a combination of standard, non-negotiable terms, as well as some room for negotiation on other terms. Remember that it is not whether the terms and conditions are mutually negotiated, but whether they are mutually agreed that matters.

Model Contracts

Model contracts are template ABS agreements that can give you an indication as to how ABS agreements can be structured. Model contracts can be found on the ABS Clearing House and some research institutions have made their model contracts available online. They can cover the terms and conditions around the transfer, storage and duplication of samples, data sharing arrangements and comeback clauses (that require users to return to provider party in the event that their intent changes from non-commercial research to commercial R&D). Model contracts are often useful for provider parties developing their own institutional ABS agreements. You may not wish to use the entire model contract and take the individual clauses that suit your needs or those of your institution. The Australian Government provides a model contract that addresses many of the relevant considerations (including Traditional Knowledge) for materials collected in Commonwealth Areas (available at https://www.wipo.int/tk/en/databases/contracts/texts/australiaprovider.html).

Non-commercial and Commercial Research

The CBD states that provider countries should facilitate access to their genetic resources for use in R&D, providing that use does not go against the objectives of the CBD (i.e., the R&D does not contribute to environmental degradation). The Nagoya Protocol then makes a distinction between non-commercial and commercial research, stating that there should be **simplified access measures** for users undertaking non-commercial research. In practice, some countries' ABS laws have procedures in place to manage changes of intent where non-commercial research becomes commercial research.

NOTE: Neither the CBD nor the Nagoya Protocol define non-commercial and commercial research. Many countries will not differentiate between the two, meaning that access measures for all utilisation types will be regulated in the same way.

Monetary and Non-monetary Benefits

The whole point of ABS laws under the CBD and Nagoya Protocol is to share the benefits of R&D using genetic resources with the country of origin. There are a range of benefits that researchers can share with the providers of genetic resources. These will be determined in the mutually agreed terms (MAT) of the ABS agreement. The Nagoya Protocol makes a distinction between **monetary benefits** which can include direct up-front payments for access to genetic resources, joint ownership of any intellectual property created through the R&D, or the payment of royalties from the sale of products developed through the R&D. Monetary benefits are often associated with commercial R&D. **Non-monetary benefits** include collaborating with the provider country to conduct the R&D; sharing research results and data; ensuring joint authorship in publications and acknowledgement in presentations; and helping to build scientific research capacity in the provider country by delivering education (e.g., post-graduate students) and training in the provider country or bringing researchers from that country to train in your laboratory. These are usually associated with non-commercial research.

Box 6

Examples of Monetary and Non-monetary Benefits.

Listed in Annex 1 of the Nagoya Protocol (available at https://www.cbd.int/abs/text/articles/?sec=abs-37).

1. Monetary benefits may include, but not be limited to:

a. Access fees/fee per sample collected or otherwise acquired;
b. Up-front payments;
c. Milestone payments;
d. Payment of royalties;
e. Licence fees in case of commercialization;
f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
g. Salaries and preferential terms where mutually agreed;
h. Research funding;
i. Joint ventures;
j. Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

a. Sharing of research and development results;
b. Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;
c. Participation in product development;
d. Collaboration, cooperation and contribution in education and training;
e. Admittance to *ex situ* facilities of genetic resources and to databases;
f. Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
g. Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
h. Institutional capacity-building;
i. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
j. Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
k. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
l. Contributions to the local economy;
m. Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
n. Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
o. Food and livelihood security benefits;
p. Social recognition;
q. Joint ownership of relevant intellectual property rights.

Traditional Knowledge Associated with Genetic Resources

NOTE: The terms "Traditional Knowledge" and "indigenous and local communities" come from the CBD and the Nagoya Protocol. In 2014, the Conference of the Parties to the CBD decided to change the term "indigenous and local communities" to "indigenous peoples and local communities", and this is the term that is therefore used in this Tool.

It is important to remember that these terms reflect the language that is currently used in relation to the CBD and Nagoya Protocol at the international level. Other forums, jurisdictions and Indigenous groups will use different terminology for different but sometimes overlapping concepts. This includes terms like "free and prior informed consent" (FPIC) where the CBD and Nagoya Protocol refer only to "prior informed consent" (PIC). You should be mindful of the preferred terms you are using when dealing with specific groups.

The CBD and Nagoya Protocol both recognise the importance of Traditional Knowledge (TK), cultural practices and innovations of Indigenous Peoples and local communities (IPLCs) for the conservation of biodiversity and the sustainable use of its components. If your R&D involves the use of any TK associated with genetic resources, accessed from a country of origin that is a party to the CBD and Nagoya Protocol, you must seek the prior informed consent (PIC) and involvement of the IPLC holding that knowledge and establish mutually agreed terms (MAT) about how that TK will be used and how benefits will be shared. This is held to be best practice, even when the country of origin is not party to the Nagoya Protocol.

There is no current universally accepted definition of TK. This means that it is for the TK custodians to determine what they consider their TK to be. This can include knowledge, innovations and practices, and it can also include the biological things that are a part of the landscape. Again, this is about more than just a minimum compliance obligation and requires a genuine engagement by researchers with the issues at hand, as well as with the spirit and intent of ABS as a legal mechanism to encourage equity, justice and conservation. The best practice is to engage with IPLCs and genuinely consider their legitimate needs and interests before coming to any agreement.

NOTE: It is unclear what level of association needs to exist for TK to be considered associated with a particular genetic resource for the purposes of ABS, and therefore, when it is appropriate to enter into an ABS agreement for the use of that TK. This is yet another area where you will have to follow institutional advice where provided, or else use your discretion (remembering that ABS is about fairness and equity) and document your decision and interactions with the country of origin's Competent National Authority (CNA).

If there are multiple communities holding the same TK, then you may need to seek the involvement and approval of all associated IPLCs. These groups could be in multiple countries, and their involvement would therefore necessitate contact with all the relevant countries' Competent National Authorities (CNAs). The CNAs should be able to help you contact representatives of IPLCs and guide the process of obtaining PIC and establishing MAT.

NOTE: Some IPLCs have designed **Community Protocols** (also referred to as Cultural Protocols or Biocultural Protocols) that provide helpful information about how a specific community undertakes the ABS process. These documents sometimes outline their expectations and values as providers of TK for use in R&D. This can guide your interactions with the IPLC that created the Community Protocols.

Remember that all communities will approach this process slightly differently, hence the need for community-specific protocols. Do not assume that because one community does things a particular way, other communities will be the same. The Australian Government and the Queensland Government have provided guidance about engaging with IPLCs in Australia: Australian Government's A Guide to applying the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (at https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf) and NHMRC's Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (at https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities).

See also the Queensland Government's "right people for right country" in the Traditional Knowledge Code of Practice and Traditional Knowledge Guidelines (at https://environment.des.qld.gov.au/__data/assets/pdf_file/0028/246907/traditional-knowledge-cop.pdf).

ABS Clearing House

The ABS Clearing House (ABSCH) is an online platform for users and providers of genetic resources, and your first port of call for all things ABS (available at https://absch.cbd.int/). Each country has a profile on the ABS Clearing House with the contact details of their Competent National Authority (CNA), their national ABS legislation and other relevant data published by the country's ABS National Focal Point (NFP). It is important to remember that the records on the ABS Clearing House are not always complete, up to date or written in English. In these instances, it is worth considering a partnership with collaborators from the host country so that they can help you navigate the ABS laws in their country and participate in the project. This is also an important aspect of benefit-sharing.

The ABSCH is essentially a library of written resources for providers and users. It includes guidelines, community protocols and model contract clauses. The ABSCH is updated all the time so keep an eye on the records that are relevant to your project.

NOTE: If information in the ABSCH is not up to date you can report the record to the ABSCH and they will ensure that the record is updated.

National Focal Points (NFP)

National Focal Points are responsible for updating the information on the ABSCH. Their contact details are available on the ABSCH and they are a great place to start if you want to clarify anything general about the ABS process in the country of origin.

Competent National Authorities (CNA)

Competent National Authorities (CNAs) are the bodies in each country that provide access approvals and permits. They are the national government body that is authorised to give prior informed consent (PIC) and negotiate ABS agreements with potential users of genetic resources from the country of origin. They should be able to give you more information about the specifics of your case.

NOTE: The differences between the NFPs and CNAs are not always clear cut and their duties can overlap. In some countries, the NFP is the same person or body as the CNA.

Checkpoints

Some countries have designated checkpoints embedded within other government processes to ensure that their ABS laws (and the laws of other provider countries) have been complied with. For instance, some countries may require you to declare that you have met ABS requirements when submitting a patent application for biotechnological inventions.

There can be other informal checkpoints that may ask you to declare that you have complied with ABS laws, or to show evidence that you have complied with ABS laws. Some journals are now requiring researchers to declare that their research is compliant with the CBD and Nagoya Protocol (e.g., *Molecular Ecology*). These sorts of ABS declarations will be similar to ethics declarations, where some journals require researchers to provide an ethics approval reference number. Similar requirements may become commonplace in other scientific journals and funding bodies as the CBD and Nagoya Protocol become better established. Even if the journal does not require this sort of declaration, you may like to include your own declaration to that effect in the text of your research publications. This is a form of self-reporting by the research community that shows you were acting with an awareness of ABS laws and take your benefit-sharing obligations seriously.

Internationally Recognised Certificate of Compliance

Internationally Recognised Certificates of Compliance (IRCCs) are documents issued by the country of origin that confirm you have obtained the listed genetic resources in accordance with their ABS laws. The IRCCs are posted publicly on the ABS Clearing House (ABSCH) and can be used to demonstrate to that you obtained prior informed consent (PIC) and have come to mutually agreed terms (MAT) with the provider country. Even if you have received a permit to collect and/or a permit to use the genetic resource of interest, you can still ask for an IRCC to be registered on the ABSCH so that you have approval recorded on an international portal. IRCCs are given a unique identifying number when they are registered on the ABSCH by the provider country. You should keep a record of this number with the rest of the data about the sample and the number can be quoted in publications if journals ask for evidence that you have met your ABS obligations.

NOTE: Because IRCCs are posted on the ABSCH, you need to be prepared for the information you provide during this process to be made public. If there is information you would like to remain confidential, you will need to make this clear with the provider party.

Box 7

Case study of ABS laws in Australian Jurisdictions

In response to the signing of the United Nations *Convention on Biological Diversity* (CBD) in 1992 and its ABS obligation, all Commonwealth, State and Territory governments endorsed the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (2002) that was reflected in the *National Strategy for the Conservation of Australia's Biological Diversity* (1996) for consistent regulation and management of access to genetic resources across Australia. The basic principles were that access to publicly owned and managed biological materials should require prior permission, that any benefits should be shared with the access providers, there should be certainty by providing a legal basis for ABS, and that any regulation should facilitate continued access for non-commercial scientific research. Genetic resources on private lands are subject to agreement with the relevant land holders (and Traditional Knowledge custodians in Queensland and the Northern Territory). While Australia is yet to adopt the Nagoya Protocol, most jurisdictions apply those standards, recognising that those standards essentially implement the earlier ideals of the Bonn Guidelines (https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf) about ABS standards.

The CBD is implemented in Australia's Federation consistent with the allocation of powers under the Commonwealth's *Constitution*. The Commonwealth under the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) (EPBC Act), *Queensland under the Biodiscovery Act 2004* (Qld), the *Northern Territory under the Biological Resources Act 2006* (NT), Western Australia under the *Biodiversity Conservation Act 2016* (WA), and the Australian Capital Territory under the *Nature Conservation Act 2014* (ACT). The Commonwealth's EPBC Act also applies in the territories of Ashmore and Cartier Islands, Australian Antarctic Territory, Christmas Island, Cocos (Keeling) Islands, Coral Sea Islands, Jervis Bay Territory, Norfolk Island and the Territory of Heard Island and McDonald Island, and the seas to the EEZ (except the coastal waters of the States and Territories).

In some Commonwealth areas (e.g., the Antarctica Treaty Area and the Great Barrier Reef Marine Park), administrative responsibility for ABS lies with the relevant department/authority and associated legislation for the area, so there are different procedures. Victoria, New South Wales, South Australia and Tasmania have administrative arrangements and do not have dedicated ABS laws, other than general laws applying to accessing biological resources on State lands, waters and seas based on tenures (such as national parks, historic sites, nature reserves, and so on) or resources (such as all native Australian fauna, listed flora, and so on).

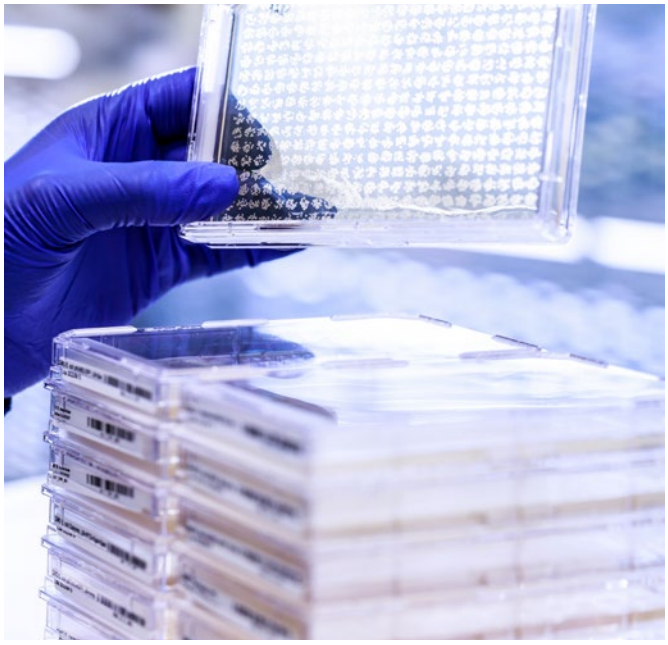
The reach of all these ABS schemes and general laws is different, with significant areas not covered by any ABS laws. Where these ABS schemes and general laws do not apply, or apply in addition to other arrangements (such as native title claims), then those seeking to access resources on land, water or sea need to negotiate a private agreement with the land owners and current title holders (except the Northern Territory that applies to all territory lands, waters and seas), including reaching agreements with private land owners, private lease owners, native title owners, and so on, that manage the various forms of land, water and sea titles.

In addition to these dedicated ABS legislative, administrative and policy arrangements, there are a range of other often overlapping legislative, administrative and policy arrangements variously requiring authorisations, permits, licences, permissions, and so on, according to the kind of land holding and the kind of sample collecting involved. For example, New South Wales requires authorisations under the *National Parks and Wildlife Act 1974* (NSW) to collect in national parks, historic sites, nature reserves, the Karst conservation reserve, state conservation areas, regional parks, Aboriginal areas, wildlife refuges or conservation areas, or plants in nature reserves or the Karst conservation reserve, under the *Fisheries Management Act 1994* (NSW) to collect fish or marine vegetation in State waters and seas and under the *Marine Estate Management Act 2014* (NSW) to collect biological materials in identified marine park or marine reserves. There are similar parks, wildlife, fisheries and resources laws in each Australian State and Territory.

Part II – Accessing Genetic Resources Originating from Overseas

The CBD and Nagoya Protocol outline the international minimum standard for domestic ABS laws and policies around the world. Parties to the CBD and Nagoya Protocol then implement these laws at the national level and sometimes at a more granular level, with laws implemented by sub-national jurisdictions (like regions or provinces) and even local jurisdictions (like local councils). This means that the most important part of the ABS process (and sometimes the most difficult) is to work out the country of origin for the genetic resources of interest, sometimes down to the precise location where the sample was collected. This will determine what jurisdiction you will need to deal with and what laws will apply. Remember that some countries will exercise their right to determine ABS processes on a case-by-case basis, and ABS can therefore look different for every country, every species and every sample you wish to access and/or utilise in your R&D.

Part II will answer some questions about the process of navigating these laws: the who, what, when, where and why of the ABS process and the sorts of problems you are likely to encounter. Like the rest of this Risk Management Tool, Part II has been written for researchers doing their utmost to meet their ethical, legal and social obligations when those obligations are unclear, and the associated science is complex.



When should you be engaging in the ABS process?

Ideally, you should be thinking about ABS in the planning stages of any project that utilises genetic resources from other countries. Remember that collaborators and partner research institutions in the country of origin can help you navigate the ABS laws in their country (particularly when the laws and procedures are in a different language). They also bring their local knowledge to the project and can help make the science itself more robust.

If the project has already started, it may be possible to obtain retroactive consent from the country of origin. If you do not have prior informed consent (PIC) and have not come to mutually agreed terms (MAT) with the country of origin – and the country of origin requires an ABS process – best practice in this scenario is to stop the R&D activities using those genetic resources and start the ABS process.

Where are your genetic resources from?

You need to determine the country of origin of a sample that has already been collected (*ex-situ* genetic resources from a biorepository), or from where you would like to obtain samples (*in-situ* genetic resources from fieldwork). This will determine the jurisdiction and government authority you are supposed to be dealing with at the national level, at least at the start of the process. Go online to the ABS Clearing House (https://absch.cbd.int/) and look up the relevant country profile. The country may have "Legislative, Administrative or Policy Measures" that you can read to get a sense of what the process will be like, or indeed actually start the process online. If you are requesting samples from an *ex-situ* collection, you should enquire about the ABS terms and conditions that are associated with those samples.

NOTE: Some biorepositories and other *ex-situ* collections will have their own standardised forms and procedures to address their legal requirements under the CBD and Nagoya Protocol. Completing their procedures may be sufficient to meet your ABS obligations. But remember, these procedures and forms have been designed to meet their legal obligations, not yours. It is always worth double checking that their procedures fulfil the minimum requirements of prior informed consent (of the country of origin) and mutually agreed terms.

Be aware that when requesting samples from biorepositories in the European Union, they might stipulate that they are compliant with the EU Regulation 511/2014 on the Implementation of the Nagoya Protocol, but this only means that they have met the EU's requirements. They may not necessarily have met the legal requirements of the country of origin. Different biorepositories will have different ideas about who is responsible for compliance with the ABS laws of the country of origin. Remember: even if you have received samples from a biorepository, you are ultimately responsible for complying with the laws of the country of origin.

Who are you dealing with?

Once you have established where the genetic resources of interest are from, you should contact the country level Competent National Authority (CNA) or National Focal Point (NFP) of the country of origin of the samples. You can find this information on the ABS Clearing House (ABSCH). You may only need to deal with the country-level authority, however, there may be other stakeholders with claims over the genetic resources in question. The CNA/NFP should guide you through the next steps and let you know whether there are subnational jurisdictions and/or Indigenous Peoples and local communities (IPLCs) you need to discuss your sample collection and R&D activities with.

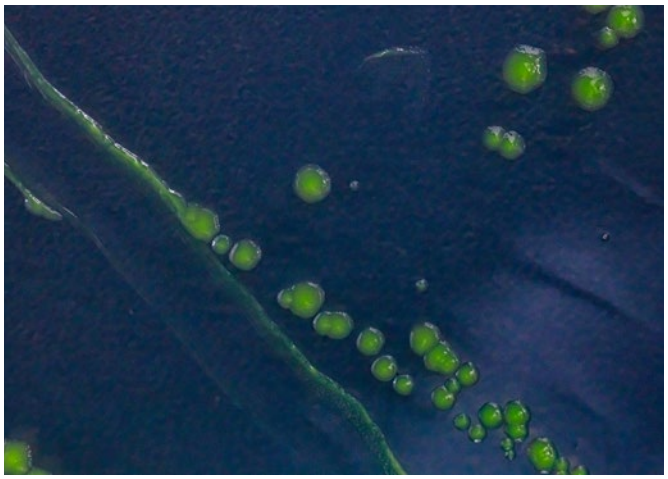
What will ABS look like for you as a user of genetic resources?

ABS processes are different in every country and can vary from jurisdiction to jurisdiction and even sample to sample. The following are examples of what the ABS process might look like for you after you have approached the Competent National Authority (CNA) or the National Focal Point (NFP):

- The samples of genetic resources could be **exempt from ABS.** This may be the case for samples collected prior to the introduction of ABS laws (but not always). If you are told that the genetic resources are exempt from ABS, you should have this confirmed in writing (e.g., a letter or email should suffice). This is where the ABS process will end for the use of these particular samples of genetic resources.
- You may simply need to **register your intended use** of the genetic resources on a country-level online database. This may be the case when you are using the genetic resources for non-commercial research purposes. If your research leads to a commercial product, you may also need to register a change of intent (from non-commercial research to commercial R&D) and then negotiate a new ABS agreement with the country of origin. Make sure you keep a record of the registration number from the country's online portal.

- You may need to **sign a Material Transfer Agreement (MTA) with ABS terms and conditions** contained within it when you receive the genetic resources or export them from the country of origin. This is sometimes the process for dealing with an authorised provider of genetic resources that is not the country of origin (e.g., a biobank that has permission to send genetic materials to third parties). Remember that an MTA is not the same as an ABS agreement, but an MTA can contain ABS clauses. Do not assume that just because you have signed an MTA that you are automatically compliant with ABS laws.
- You may need to **collaborate with a partner organisation in the country of origin.** That is, your project may require formal collaboration with a researcher or research institution at the country of origin.
- You may need to **negotiate a bilateral ABS agreement** with the country of origin's relevant government body. Some countries will have standardised agreements where the terms (or some of the terms) are non-negotiable. This means you can either agree with their terms, or decide not to use the genetic resources of interest.

The process will be different again when accessing Traditional Knowledge (TK) associated with genetic resources from IPLCs, although as a minimum it is still expected that you seek PIC to access and/or use the TK and come to MAT about benefit-sharing. The country-level CNA or NFP should be able to guide you through this process and some communities have developed their own Community Protocols to assist with this process.



Why are you engaging in this ABS process?

The immediate procedural purpose of engaging in the ABS process is to obtain the prior informed consent (PIC) of the country of origin (either directly from the government of the country itself, or indirectly from another authorised provider) and to come to mutually agreed terms (MAT) about how their sovereign genetic resources will be used in your R&D. It is also about ensuring that you can demonstrate that you have obtained PIC and negotiated MAT in compliance with the law (i.e., record keeping).

The overarching purpose of engaging in this process is to ensure that the benefits of global R&D are being shared in a fair and equitable way with all peoples of the world. It can be easy to lose sight of this when you are dealing with the bureaucracy to obtain samples you were once able to obtain quite freely. Keeping the overarching intent of ABS at the fore of your ABS dealings can help solve problems that emerge during this bureaucratic process. By showing that you are aware of the equity and fairness goals of the CBD and Nagoya Protocol, and that you are willing to engage in ABS in good faith, you will be better able to find solutions to procedural problems that are suitable to both you and the provider party. Remember this process is also about building trust through communication (letting provider parties know what you are doing with their genetic resources) and scientific collaboration (including the provider country and its scientists in the R&D process) where possible. This process can also make your R&D better by incorporating other types of knowledge and local expertise and building robust networks of scientists from diverse backgrounds around the world.

NOTE: Some of the problems that users of genetic resources have encountered when dealing with ABS procedures is that the laws are complex and unclear, it can be difficult to identify the point of contact at the relevant government authority you are supposed to be dealing with, there are multiple authorities at multiple levels of government you may need to deal with, some of the access requirements overlap, there is sometimes a high turnover of the staff working in these government bodies and some countries have few resources to dedicate to guiding you through their ABS process.

Record keeping

Your records need to be able to show that you have authorisation to access and/or use the genetic resources in your possession. You should retain your ABS records for at least as long as you continue to store the associated genetic resources, and keep them in an archive thereafter. These records may be required when you publish your research, submit a patent application, provide the genetic resources to other researchers for validation or other R&D, and when your organisation or the provider country conducts ABS compliance checks. Some scientific journals require researchers to declare that they will make the genetic materials they used in their research available to other scientists for the purposes of validation. This may not be possible if those genetic resources are covered by an ABS agreement that states that you cannot provide the genetic resources to third parties without the consent of the provider party. You may need to inform the journal's editor and stipulate this in the article.

If you are collecting samples from *in-situ* conditions (field collection) you should assign a unique identifier for the sample as it is collected from the environment, assign unique (but connected) identifiers for each of the following: sub-samples that are separated from the original environmental sample (e.g., when isolating microorganisms from a soil sample), any genetic material that is extracted from the original sample, and genetic sequence data that is generated from the sample.

NOTE: When submitting samples to an *ex-situ* repository or genetic sequences to an online database, a unique identifier is likely to be assigned to the accession. Remember to keep records of how these accession numbers are connected to your own identifiers.

The point is to ensure that by the time you are analysing genetic sequences you will be able to trace one genetic sequence to all connecting records and the originating (physical) sample (assuming the sample has not been consumed in the process). This should be possible using internal records (e.g., a computer backed-up laboratory notebook).

Part III - Decision Making Using a Risk Framework

Synthetic biology operates with a high degree of fragmentation and abstraction. Synthetic biology R&D has many inputs, and experiments can go through many hundreds of iterations. Often it is not clear at the outset where a project might be leading, and some research paths may prove to be false starts and dead ends. This scientific complexity, combined with the legal uncertainty involved in dealing with ABS laws around the world, mean that synthetic biologists need a novel way of thinking about how ABS applies to their R&D. It's not effective to apply a simple checklist of ABS elements. Rather, applying the relevant ABS legislative, administrative and policy arrangements according to their spirit and intent requires a "risk framework" that balances compliance against the uncertainty. A risk framework is a rubric to assess the likelihood and consequence of various legal measures, and help identify those that are of consequence based on their likelihood. The idea here is that identifying risks, assessing their severity, and considering how to mitigate them will deliver better ethical, legal and social outcomes. The severity of the risk might be assessed using the Risk Calculator in Table 1.

Table 2 outlines various scenarios that may apply to your R&D and associated ABS considerations. It forms a framework for thinking about balancing legal and reputational risks to you, your research, your funders (if applicable), and your organisation, through the conduct of your research activities. The ideal for assessing risks in science is to consider the potential risks at the early planning stages and then monitor these as the project progresses, recognising that any new developments may have consequences for the risk profile of the project. The following is a possible project planning risk framework where a "yes" answer points to the need for a closer consideration of the circumstances. For each "yes" answer, the risk assessment may be useful to clarify the kinds of risks and the likely severity of risks.

A risk framework is essentially a way of identifying risks and then managing those risks to mitigate their adverse effects. There are many ways to do a risk assessment and the common ways to assess risk that have been developed include: (1) risk matrix; (2) decision trees; (3) what-if analysis; and (4) failure modes and effects analysis (FMEA). While there is no perfect way to guarantee all risks have been identified, at least considering the potential risk factors means that many of the risks can be mitigated.

Table 1: Risk Calculator. Determine whether any given ABS risk requires your immediate attention based on any potential consequences versus the likelihood of those consequences occurring. Use the Risk Calculator to fill in the final columns of the Risk Considerations table below.

		LIKELIHOOD			
		CERTAIN	VERY LIKELY	LIKELY	UNLIKELY
Consequences	Critical	Requires actions	Requires actions	Requires actions	Consider action
	High	Requires actions	Requires actions	Consider action	Consider action
	Medium	Requires actions	Consider action	Consider action	No action
	Low	Consider action	Consider action	No action	No action

Table 2: Risk Considerations and Risk Assessment Activity. Think about the specifics of your project and fill in the potential consequences and likelihood columns based on the Risk Calculator table above. Make a plan for further action on any risk considerations that require it. If the particular risk consideration does not apply to your project, strike out the potential consequences and likelihood sections, and indicate that no further action is required in the final column.

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Materials	Will the project use genetic resources (biological materials or genetic sequence data/digital sequence information)?	To avoid ambiguity and contrived definitions, anything biological should be considered relevant for the purposes of ABS. This includes genetic resources that were collected prior to the entry into force of the CBD and Nagoya Protocol.			
Materials	Will project materials be collected in the field specifically for this project?	New (*in-situ*) collections require a consideration of potential new stakeholders and their long-term interests. Remember to collect as much metadata for the samples as possible so that proposed future uses and change of intended use (from non-commercial research to commercial product development) can be traced back to the originating sample.			
Materials	Will the genetic resources be collected or sourced from multiple countries?	Every country of origin (i.e., the country of sampling or country of extraction) will need to be consulted. If there is a country with a particular cultural affinity with the genetic resource of interest (e.g., a national emblem), it may be worth informing their Competent National Authority (CNA) as well, even if the particular sample you are using was not taken from that country.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Materials	Are you obtaining genetic resources from an *ex-situ* collection (e.g., tissue bank, culture collection, botanic gardens or museum)?	Check if the *ex-situ* collection has been given the authority from the country of origin to provide the samples to third party users. Obtain a record of this. If not, you may need to approach the country of origin. Note that when an *ex-situ* collection states that they are compliant with the CBD and Nagoya Protocol, that means they have met their legal requirements, not yours. You should check that the *ex-situ* collection is an authorised provider of genetic resources (i.e., has the consent of the country of origin to act as a provider of the genetic resources). You may be required to negotiate an ABS agreement with mutually agreed terms (MAT) which may include benefit-sharing obligations, particularly if you are engaging in commercial R&D.			
Materials	Could the materials be collected somewhere else?	This raises tricky questions about alternative sources of genetic resources and whether those alternatives should also be considered as a part of the project. While obtaining samples from the most legally permissible country is a legitimate approach to ABS, there may be reputational risks if you are seen to be sidestepping social and ethical obligations to share benefits, particularly with poorer countries. Being seen to avoid ABS laws could have negative consequences if you intend to work with international organisations or commercialise your research in the future.			
Materials	Is the project using materials collected before the entry into force of the CBD and/or Nagoya Protocol?	It is best practice to treat all genetic resources collected prior to the entry into force of any ABS laws as if the laws do apply. This is because even if the genetic resources were accessed prior to the CBD and Nagoya Protocol, your use of the materials is occurring after the entry into force of these laws. The use of older samples can also raise tricky questions about how the materials were originally collected (i.e., ethical collection practices) and whether the new uses are considered appropriate by the country of origin.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Materials	Will the materials be stored by you?	Consider how and where the materials will be stored, for how long, whether there will be duplications, access by others, repatriations, and so on. You may not wish to store the materials once the project is complete, so you should negotiate with the country of origin about how long you intend to store the samples, whether they will be returned to the country of origin or whether they will be destroyed at the end of the project. One form of benefit-sharing you may wish to consider is the donation of freezers or other equipment needed to adequately store the samples at an institution in the country of origin.			
Materials	Will the materials be stored by others?	This raises questions about limitations on how and where the materials will be stored, for how long, duplications, access by others, repatriations, and so on. You and the provider party may wish to submit the samples to an *ex-situ* conservation facility (e.g., a culture collection or museum). Be sure to collect as much metadata about the samples as possible (including latitude and longitude coordinates) and provide a record of the ABS agreement to the accessioning collection.			
Materials	Will the materials result in harm to or the death of the organism (destructive sampling)?	This requires consideration of ethical collection protocols, such as animal ethics guidelines. You should consider whether the same or similar data can be obtained using less destructive sampling methods.			
Materials	Are the materials endangered, dangerous or import/export restricted?	This requires consideration of relevant laws in addition to ABS (e.g., international laws such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the Biological and Toxin Weapon Convention (BWC) and UN Security Council Resolution 1540 and Australian regulations under the Department of Agriculture, Fisheries and Forestry (DAFF)).			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Materials	Are the materials human genetic resources?	While the CBD and Nagoya Protocol do not specifically cover human genetic resources, most countries will have laws about accessing and utilising human genetic resources under human research ethics policies. Note that if the ultimate intent of accessing human samples is to test for, isolate, sequence or otherwise conduct R&D on human pathogens, then those pathogens will be subject to the ABS rules of the CBD and Nagoya Protocol. Influenza viruses with human pandemic potential are also covered under the WHO's Pandemic Influenza Preparedness (PIP) Framework.			
Materials	Are the materials plant genetic resources relevant to food and agriculture?	You may be able to access these types of plant genetic resources under standard ABS terms and conditions from the "Multilateral System" of the International Treaty on Plant Genetic Resources for Food and Agriculture (see the Plant Treaty's Annex 1 that lists the crops covered by the Multilateral System).			
Materials	Are the materials influenza viruses of human pandemic potential?	You may be able to access influenza viruses with human pandemic potential under standard ABS terms and conditions under the World Health Organization's Pandemic Influenza Preparedness Framework.			
Materials	Are you accessing or using marine genetic resources from areas beyond national jurisdiction (e.g., the high seas)?	If you are collecting or using samples of marine genetic resources that were collected more than 200 nautical miles from the coastline, then those activities are covered by the new High Seas Treaty.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Materials	Do you have free, prior and informed consent to collect and use the genetic resources?	This requires consideration of who may have sovereign (or other ownership-style) claims over the genetic resources and that they have freely and fully agreed to your collection and use. Remember that claims may not be limited to the country of origin and may include sub-populations within the country of origin, such as Indigenous Peoples and local communities (IPLCs). If IPLCs are involved, you need to comply with the relevant governmental policies and community protocols.			
Materials	Do you have mutually agreed terms to collect and use the materials?	Remember that the terms do not have to be mutually negotiated, just mutually agreed. Some countries may offer ABS agreements with non-negotiable terms and conditions.			
Materials	Do you need a Memorandum of Understanding (MOU) with stakeholders associated with collecting and using genetic resources?	If you are partnering with an organisation or research institute in the country of origin, it is worth outlining how various ABS responsibilities will be met and which party will meet them. If you are accessing and/or using many samples of genetic resources, it may be more efficient to negotiate an MOU with ABS terms and conditions included for all samples associated with the collaboration, rather than ABS agreements for each sample.			
Materials	Will there be intellectual property claims over the genetic resources or innovations based on R&D using those resources?	If you are conducting R&D with commercial intent, you should include terms about intellectual property claims in the ABS agreement. Remember that shared intellectual property rights can be considered a form of benefit-sharing.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Materials	Will you be publishing genetic sequence data from the genetic resources you use?	This raises tricky questions about how genetic sequence data/digital sequence information may be used by other researchers to conduct R&D without having to access physical samples of the genetic resourecs (and therefore without entering into an ABS agreement). This is why the country of origin may wish to protect the data or information associated with its genetic resources. You may need express permission to post the genetic sequence data/digital sequence information on online sequence repositories/ databases.			
Materials	Have you been donated an historical collection from another researcher, comprising samples from different countries and collected at different points in time?	Keep as much information about the samples and collection as possible. Ask for copies of the laboratory notebooks or other records associated with the origin, collection and characterisation of the samples. It may not be possible to obtain retroactive permission to have these samples, but you should get prior informed consent (PIC) from the provider country before any new uses of these samples in R&D. Keep in mind that often countries will not know of the existence of the samples and may ask for their repatriation. If records have not been appropriately kept, you should consider rejecting the donated collection. Without reliable provenance information, the samples may have reduced scientific value anyway.			
Intent	Is this research intended to generate commercial outcomes (e.g., patent applications, licensing deals, product development)?	If the project is likely to generate monetary benefits, then the providers of the genetic resources may expect monetary benefit-sharing. Be ready to negotiate terms about sharing intellectual property and payments or royalties based on gross turnover, for example.			
Intent	If the research is non-commercial in nature, is it possible or likely that the intent of the research will change if it produces promising results?	Some provider countries will include “come back clauses” in their ABS agreements if parties have agreed to simplified ABS measures for non-commercial research but there is a change of intent and the research shows commercial promise. In some cases, the user needs to initiate a fresh application with the provider but in other cases, it may only require a renegotiation of the benefit-sharing agreement.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Intent	Are you conducting R&D on behalf of another party? Or are you outsourcing some parts of the R&D process to another service provider (e.g., a biofoundry)?	Ensure that the parties involved have a clear understanding about who is responsible for complying with any ABS obligations associated with the genetic resources being used, and that this understanding is recorded in writing.			
Data and information	Will the project use publicly accessible data and information?	While data might seem to be openly accessible this may not be so, and increasingly other stakeholders may make sovereign (or other ownership-style) claims over the data and information. Can you identify those possible stakeholders and what they might claim? If you are using genetic sequence data/digital sequence information, you should consider how much of a particular sequence you are using, whether the sequence is unique to an organism found in a particular part of the world, and whether it is making a material contribution to your R&D and any outputs.			
Data and information	Will the project be sequencing genetic materials?	There may be some restrictions on sequencing genetic resources and/or publishing those sequences on publicly available genetic sequence repositories like GenBank. These restrictions may be outlined in the ABS legislation of the country of origin, or they could become part of the mutually agreed terms (MAT) in the ABS agreement. Make sure you include the country of origin and any other identifiers that are associated with the accession in the metadata of the entered sequence.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Data and information	Will the project be utilising Traditional Knowledge (TK) associated with genetic resources and held by Indigenous Peoples or local communities (IPLCs)?	Even if a country does not have specific laws for ABS, you should check to see if there are other laws about native title or the like. Note that some countries do not have robust protections for the cultures and knowledge of IPLCs. While you may not have a specific legal obligation to negotiate ABS terms with the relevant community, you should consider whether you have an ethical or social responsibility to do so.			
Data and information	Do you have an appropriate system in place to manage data and information?	Data and information management is generally expected to comply with the standards of FAIR Principles – Findable, Accessible, Interoperable and Reusable https://datascience.codata.org/articles/10.5334/dsj-2020-043			
Participants	Can you list the in-house research team?	Some countries may require the CV of every person working on a particular project involving their genetic resources.			
Participants	Are there members of the research team that are not employed by your organisation (e.g., students) that will be conducting R&D on genetic resources on your premises?	You may be responsible for making sure that the people working with genetic resources are suitably qualified and understand their obligations under the CBD, Nagoya Protocol and any national legislation that may impact their R&D activities.			
Participants	Can you list the external research team?	Some countries may require that you list all people involved in R&D using their genetic resources.			
Participants	Will the project involve stakeholders?	You should consider conducting a stakeholder mapping exercise to make sure that you have considered the claims of every group that might be impacted by your research, including IPLCs. This can help understand where your legal obligations lie and with whom you should be negotiating ABS agreements.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Participants	Are you conducting research on behalf of another party (e.g., another institution or research group)?	Make sure you have discussed ABS issues with the other party and document which party in this arrangement has the responsibility to undertake the ABS process.			
Participants	Are IPLCs involved in any aspect of the project or research?	If IPLCs are involved, you need to comply with the relevant governmental policies and community protocols. It is also important to consider that IPLCs other than the one from which the materials or knowledge is derived may have an interest as well.			
Governance	Is there a MOU with the external research team?	Make sure it is clear in the MOU which party has responsibility to undertake the ABS process. Other considerations may include storage and destruction of materials, storage of data and the assignment of intellectual property rights.			
Governance	Is there a MOU with the stakeholders?	Make sure it is clear in the MOU which party has responsibility to undertake the ABS process.			
Governance	Do you maintain laboratory books that are stored into the future?	If your laboratory notebooks are necessary for tracing the origin of samples and subsamples, make sure they are appropriately (digitally) backed up.			
Governance	Are you splitting or duplicating samples and will you be using subsamples (e.g., extracts and or derivatives) throughout the project?	If you divide samples, extract DNA, amplify the DNA or otherwise split subsamples from the original sample of the genetic resource, you need to be able to trace those subsamples back to the original sample (or information about the original sample) in your records. Tracking the use of subsamples is particularly difficult in synthetic biology where genetic resources (and genetic sequence data) are fragmented and combined with other fragments of genetic resources and information. You do not need to be able to trace every nucleotide back to the originating sample, but if a significant portion of a genetic resource is making a material contribution to your R&D, you should be able to identify its origin. You will need to use your discretion about what you consider to be a “material contribution”.			

RISK CATEGORY	RISK CONSIDERATION	COMMENT	POTENTIAL CONSEQUENCES	LIKELIHOOD	FURTHER ACTION REQUIRED (YES/NO)
Governance	Do you have appropriate accounting arrangements to accommodate the interests of those who will receive benefit-sharing payments in the future?	Projects and research involve the expenditure of money and other resources. While most institutions have adequate accounting arrangements, it is best to make sure that any benefit-sharing obligations are appropriately accommodated in the accounting arrangements. This is important as the people reaching agreement may not be the same as those implementing the benefit-sharing commitments, and record keeping is important.			
Benefit-Sharing	Is your research likely to generate non-monetary benefits?	Non-monetary benefits can include the results of R&D (e.g., data, publications and presentations), education and training, contributing samples to *ex-situ* collections, capacity building and technology transfer. It is worth considering how you can involve the provider party in producing these benefits (i.e., so that scientists from the provider country can also receive credit for the work) as well as sharing the benefits with the country of origin.			
Benefit-Sharing	Is your research likely to generate monetary benefits like licencing fees for the use of intellectual property, research funding or profits from the sale of a product?	Ensure that you have a clear arrangement with the provider party about how these monetary benefits are to be treated, and over what time period. Consider including researchers from the country of origin as part of the R&D team so they have an opportunity to benefit from enhanced research funding opportunities.			
Benefit-Sharing	When are benefit-sharing obligations triggered (e.g., at the point of access, the point of first use, or the point of commercialisation)?	Remember that benefit-sharing may occur in stages, at multiple points in the innovation pipeline. Keep records of approved uses for each sample, when benefit-sharing obligations triggered and when benefit-sharing has actually occurred.			
Benefit-Sharing	Are you collecting or using lots of genetic resource samples where benefit-sharing obligations attached to each individual sample are unmanageable?	See if you can negotiate benefit-sharing for the R&D project as a whole, as opposed to the use of the samples themselves. This may entail coming up with an agreement with the authorised provider that includes mutually agreed ABS terms and conditions covering all the genetic resources involved in the project.			

Table 3: Troubleshooting. This table lists some of the common problems you may have when trying to navigate ABS laws.

PROBLEM	APPROACH
There is no information on the ABS Clearing House regarding who to contact about accessing genetic resources, or I am unable to make contact with the Competent National Authority (CNA) or National Focal Point (NFP).	Contact a related government department that may be able to help (e.g., Ministry of the Environment or Department of Health). Alternative approaches can be made through diplomatic channels (e.g., Embassy contacts) or research institutes in the country. You can also contact the Australian National Focal Point (NFP) for advice (details available on the ABS Clearing House).
The project has already started without obtaining the prior informed consent (PIC) of the provider country, nor coming to an ABS agreement with mutually agreed terms (MAT).	Check any documentation you have about the samples (e.g., collection permits or Material Transfer Agreements). It may be the case that these documents stipulate the permitted use of the samples and benefit-sharing obligations. If you do not have such documents, or they do not stipulate ABS terms, and you have already started the project, you should stop research activities using those genetic resources until you have received informed consent from the provider party.
It is not possible to identify the country of origin for a particular sample, or the origin of the sample is disputed.	There are some instances where you will still want to use a genetic resource for which the origin is unclear or disputed. This makes obtaining prior informed consent (PIC) to use the genetic resource impossible. You need to be able to demonstrate that you have made meaningful efforts to identify the authorised provider of a genetic resource.
The country of origin does not have any information in the ABS Clearing House or is not a party to the CBD and/ or Nagoya Protocol.	Do not assume that just because a country does not have any information on the ABS Clearing House or is not party to the CBD and/or Nagoya Protocol that they do not have laws and regulations about accessing their genetic resources. The USA, for instance, is not party to the CBD or Nagoya Protocol, but it does have some federal laws about collecting samples in national parks, and certain state laws that may impact collection activities. You will need to be able to show that you have made reasonable attempts to contact the relevant authorities in the provider country before you begin using genetic resources in your R&D.
The genetic resource I need to access originates in or is native to two or more different countries or jurisdictions.	Ideally you would approach all countries in which that genetic resource can be said to have originated. However, practically speaking, the laws around ABS tend to treat the country of origin as the country of extraction for the particular sample that you are using. If you can identify that country, then it is best to approach their National Focal Point (NFP) for further information. If there is a country that is known to have a particular affiliation with or relationship to the species or resource you are dealing with, then you should also approach their NFP, even if they are not the country from where the specific sample was collected.
The "genetic resource" I am using is entirely synthetic and novel. There is no analogue in nature.	There is no clearly defined line between synthetic and natural genetic resources. While the genetic resources or sequences you are using may be synthetic, if they used a naturally occurring genetic resource as a starting point or drew from nature as a source of inspiration, there may be cause to enter into an ABS agreement. You will need to make a determination about whether a naturally occurring (wild-type) genetic resource made a material contribution to the design and/or construction of your synthetic genetic resource. Remember that synthetic genetic resources may also be considered "derivatives" under the Nagoya Protocol. Again, you will need to make a determination about the level of contribution the natural genetic resource has made to your R&D.

Part IV – Considerations for Institutional Policy Approaches to ABS Compliance

This section lists some considerations for implementing and managing compliance for existing and ongoing operations as users of genetic resources. This is not as comprehensive as the considerations listed in Part III because the principles are often the same, just scaled up to apply to multiple projects.

NOTE: If you have a large R&D operation it may be worth putting on dedicated personnel to manage ABS issues and assist individual researchers to meet their requirements and manage field collection activities. Ideally this would be someone who can maintain contacts, meet reporting requirements, conduct staff training, and negotiate ABS agreements on behalf of the institute or organisation. It is also worth budgeting for ABS requirements. This may include requirements for extra time, personnel, money, and data management capabilities.

If ABS is something your institution has not dealt with before, you should assess all the projects your laboratory, research group, facility or organisation is currently undertaking to determine if you are using genetic resources that could be subject to the ABS laws of other countries. It is worth involving individual labs and research groups in this initial ABS audit because it can help raise awareness about the ABS requirements they need to meet when organising future R&D projects. Other awareness-raising activities can include induction training on ABS issues for new staff members and annual refresher courses.

The aim of the institutional ABS audit is to ensure you have the prior informed consent (PIC) of the providers of genetic resources to conduct ongoing R&D activities. When this is not the case, you will need to prioritise which projects you will seek to achieve ABS compliance for based on a risk assessment. That is, if not having obtained PIC for particular uses of genetic resources from other countries can expose the institution to reputational risks, or threaten funding or intellectual property applications, obtaining PIC for those projects will be your next priority. On an institutional level, the ABS audit may help to identify areas where the institution can improve its ABS processes. Are there ways you can make the ABS processes more systematic, or ways that you can highlight your benefit-sharing activities to existing stakeholders (including the public)? Your institution should consider keeping a list of the monetary and non-monetary benefit-sharing you are engaging in, so that you can demonstrate your contributions to meeting ABS obligations under the CBD and Nagoya Protocol.

You should consider creating record-keeping systems for institutional ABS matters. Ideally, the records will be centralised but accessible to all staff members, systematic and standardised. It can include form templates (checklists for accepting materials from providers, risk matrices for decision-making, outgoing Material Transfer Agreements), the provenance details of samples in the institution's possession (including GPS coordinates for any of the samples your institution has collected), and any relevant protocols or Community Protocols from the Indigenous Peoples and local communities (IPLCs) you have worked with.

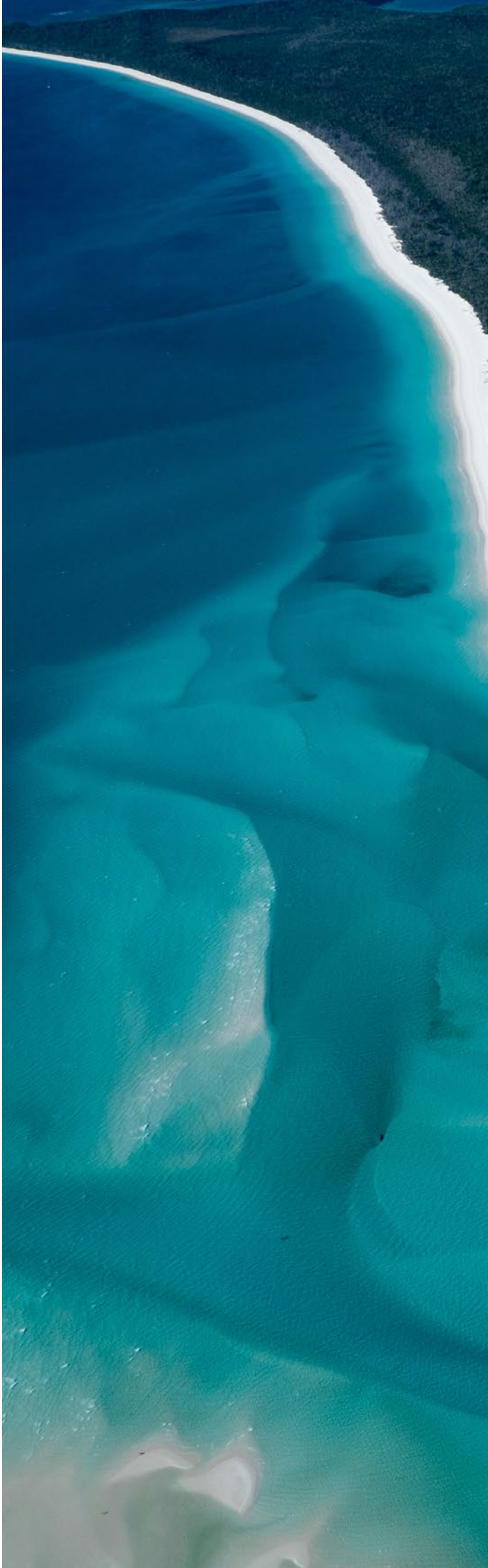
Are you a provider of genetic resources?

If you store samples on site, then your institution is acting as an *ex-situ* conservation collection. It is possible that other researchers from around the world will want to access and use your samples. Remember that the ABS obligations associated with samples of genetic resources do not necessarily stop with the first access and use. There can be terms and conditions that travel with the genetic resources.

Sometimes you will be asked to share genetic resources (or derivatives) used in your R&D for the purposes of validation of results or to extend your research findings. If you have obtained genetic resources in accordance with the country's ABS rules, you may be authorised to provide these genetic resources to a third party. Make sure you check with the original provider first.

If you have made substantial changes to the genetic resource, such that it now constitutes a novel (synthetic) genetic resource, then you will need to consider the extent to which it is a different resource for the purposes of ABS. Again, you may want to check with the country of origin if this is unclear from your original ABS agreement.

There is no one way to approach ABS and you should seek professional legal advice if you are unsure of how to proceed. ABS was never specifically designed to regulate synthetic biology, but the principle of fair and equitable benefit-sharing in R&D is important for all scientists, and can help unlock a better future for everyone.



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