



INTRODUCTION TO ACCESS AND BENEFIT-SHARING AND THE NAGOYA PROTOCOL:

What DNA Barcoding Researchers Need to Know

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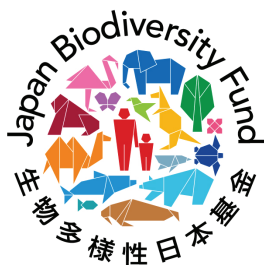
Introduction to Access and Benefit-Sharing and the Nagoya Protocol: What DNA Barcoding Researchers Need to Know

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Convention on
Biological Diversity



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Foreword

Research and knowledge development are critical to understand the complexity of Life on Earth and to make sound decisions on the conservation and sustainable use of biodiversity. In many parts of the world, however, we are faced with technical, scientific, and legal challenges to conduct such research and achieve the Convention's three goals, including facilitation of access to, and sharing the benefits arising from utilization of genetic resources, effectively.

The Global Taxonomy Initiative is one way to address these challenges. The Global Taxonomy Initiative has provided training opportunities for Parties to apply DNA-sequence based species identification method as a tool for biodiversity management that requires rapid species identification. The method of DNA barcoding has invigorated taxonomic research and is now applied in a wide range of areas, including environmental assessment, food inspection, disease control and public education. In addition, training has helped Parties improve specimen collections and biodiversity knowledge sharing and enhanced fundamental capacity of biodiversity research. DNA barcoding has proven to be a powerful tool for both taxonomists and all biodiversity stakeholders, including women and children, and indigenous peoples and local communities.

On the other hand, DNA barcoding practices have raised concerns among the public. These concerns include expatriation of biological specimens, sharing of digital sequence information and associated data with potential value, risks of unapproved changes of research purpose or benefits to be shared.

To address these concerns, the Secretariat of the Convention on Biological Diversity, in collaboration with the International Barcode of Life project and its partners, produced this e-book to provide practical advice on international collaborations that comply with the Nagoya Protocol and relevant national laws and regulations. I invite you all to use this e-book and work to promote active international capacity building and development and support activities to achieve Aichi Biodiversity Targets, and consequently contribute to the Sustainable Development Goals, and build the future we want.

Dr. Cristiana Paşca Palmer
Executive Secretary of the Convention on Biological Diversity

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I. Introduction

The Convention on Biological Diversity (CBD) facilitates international biodiversity research through provisions encouraging research and training (Article 12) and technical and scientific cooperation (Article 18), among others. It also addresses access to genetic resources and benefit-sharing (Article 15), which has been further elaborated in the 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 (**Nagoya Protocol**). These provisions have implications for international biodiversity research with regard to sourcing biological specimens, analyzing their genetic material and the subsequent use of the outcomes of this research.

This book explains the basic framework of **access and benefit-sharing (ABS)** under the Convention and the Nagoya Protocol. The book is intended for ‘DNA barcoders’ – researchers and practitioners using DNA-based approaches, such as DNA barcoding, for the identification of organisms. It aims to help them understand how access and benefit-sharing relates to their work and the steps to take to avoid problems. It also points to opportunities provided by the Nagoya Protocol for researchers and practitioners to raise awareness of their work and identify for themselves the specific practices within their field as these relate to access and benefit-sharing.

1. DNA-based Approaches as Tools for the Convention on Biological Diversity Implementation

a. DNA-barcoding and the Global Taxonomy Initiative

Baseline taxonomic knowledge is fundamental to human understanding of biodiversity. However, it is hampered by the limited resources available to governments and taxonomists, relative to the demand for species identifications. Historically, this limitation was compounded by the reliance of traditional taxonomy on interpretation of analog morphological diagnostic characters, which requires highly specialized knowledge and skills that take a long time to attain. This widely accepted shortfall is known as the ‘taxonomic impediment’ and is recognized by the Convention on Biological Diversity as a limiting factor to effective biodiversity conservation and sustainable use. To tackle the taxonomic impediment, Parties to the Convention established the **Global Taxonomy Initiative (GTI)** in 1998. This cross-cutting programme is designed to identify countries’ taxonomic needs, build taxonomic capacity, share information and raise policymakers’ awareness on imperative capacity development needs in the implementation of the Convention.

DNA barcoding is a concept that proposes using molecular analysis of short, standardized fragments of the genome (also known as ‘DNA barcode regions’) for taxonomic identification of organisms, with emphasis on species-level diversity. It provides an accurate, rapid diagnostic tool that works for whole organisms, as well as their fragments, tissues, cells, environmental DNA, and other derivatives lacking morphological diagnostic

features. The decreasing costs and growing automation of molecular analysis continually broaden the scope of its applications in areas of biodiversity mainstreaming (see Box 1 for examples) by facilitating the level of accuracy and throughput that cannot be sustained by conventional taxonomic approaches.

Box 1: List of confirmed and potential applications of DNA barcoding in areas of key public concern¹

- Invasive and alien species – identifying and monitoring invasive organisms and their ecological impact, improving early detection and regulatory measures to curb cross-border transfer of alien species;
- Endangered species – enhancing taxonomic and ecological knowledge about endangered species and creating a diagnostic framework for monitoring and curbing illegal harvest and trade through improving forensic approaches and streamlining regulatory frameworks;
- Agriculture and forestry – identifying and monitoring agriculture and forestry pests and biological control agents;
- Human health – identifying and monitoring human disease vectors and reservoirs; reconstructing disease transmission pathways; assessment and monitoring of natural-borne disease foci;
- Environmental surveillance/monitoring – helping extractive industries (e.g. oil, gas, mining), the natural resources (forestry, fisheries) and agriculture sectors to meet their environmental compliance requirements and to evaluate the efficiency of offset, restoration and remediation measures;
- Market surveillance, product ingredient authentication; detection of food contamination and substitution (e.g. seafood, meat and natural products).

DNA barcoding is now increasingly recognized, in particular, as a means to detect and monitor invasive alien species, linking the Global Taxonomy Initiative capacity development to invasive alien species programmes.

Conventional DNA barcoding approaches involve sequencing of individual organisms using low- and medium-throughput methods, such as Sanger sequencing. Recent advancements in next-generation sequencing platforms open vast opportunities for metabarcoding—high-throughput sequencing approaches that allow the detection of species of concern and screening whole species assemblages in bulk environmental

¹ DNA Barcoding and its role in building global capacity in molecular biodiversity: SBSTTA-18 Information document for the Parties UNEP/CBD/SBSTTA/18/INF/20; <https://www.cbd.int/doc/meetings/sbstta/sbstta-18/information/sbstta-18-inf-20-en.pdf>

samples. They also facilitate the detection of species from DNA traces in the environment (eDNA). A growing number of publications show that screening such samples using DNA-based approaches is faster, cheaper, more accurate, and less dependent upon specialized taxonomic expertise, compared to morphology-based approaches.

Box 2: Definition of technical terms used in DNA barcoding analysis

From an operational standpoint, it is practical to identify several key types of materials and data that correspond to the typical stages of DNA barcoding analysis:

Bulk sample or lot – a collection of multiple uncounted individuals sourced from the field that usually contains a mix of many different, often unidentified taxa. Most collections made during large-scale environmental surveys consist of bulk samples. These could be later sorted by taxonomy or by individual specimens (see below), or DNA from such samples can be extracted in bulk for the purpose of metabarcoding analysis. Soil, water, or air samples that may contain organisms and/or e-DNA would also fall into this category.

Specimen² – sorted biological individuals are a typical form of preparation for museum collections. They could be either individually collected or derived from bulk samples. Collection voucher specimens preserved in a DNA-friendly fashion (e.g., frozen, desiccated, or fixed in ethanol) are suitable for molecular analysis.

Tissue sample – a fragment of an individual organism preserved specifically for the purpose of molecular analysis and/or deposition in a genetic resources collection. This is the type of material most commonly analyzed by molecular laboratories doing DNA barcoding.

DNA³ extract – purified whole genomic DNA extracted from a biological sample. DNA extracts may be used for whole genome screening or analyzed using deep sequencing technologies, but such forms of analyses fall outside the scope of DNA barcoding and are not considered here. Depending on the source and end point of analysis, two categories of DNA extracts can be broadly defined:

- Bulk DNA extract – derived from a bulk sample or lot for the purpose of metabarcoding; contains DNA from multiple organisms, usually belonging to at least several different taxa;

² Note that the concept of species or taxon is excluded from this terminological framework. It is important to distinguish specimens (vouchers) – physical manifestations of individual organisms – from species and other taxa – operational units used to group organisms in biological systematics and to measure biological diversity.

³ Note that standard DNA barcoding approaches do not involve working with transcriptomes, therefore RNA is not considered here.

- Individual DNA extract – derived from a single specimen or tissue sample; typically contains DNA from a single target organism, but may include DNA from other organisms contained in or mixed with the sample (e.g., external contaminants, gut contents, symbionts, parasites, pathogens, or progeny).

PCR product (amplicon) – synthetic copy of a target DNA fragment generated in the laboratory in the course of a polymerase chain reaction (PCR amplification). Within the DNA barcoding context, PCR products represent amplified copies of the standard DNA barcode region(s) of the genome. During PCR amplification, genomic DNA is denatured multiple times and often degrades; however, leftover genomic DNA may remain within the reaction. Although theoretically possible, recovery of this non-target genomic DNA after PCR is difficult and impractical. PCR products may be generated for different purposes, such as:

- PCR amplicons synthesized from individual DNA extracts for the purpose of downstream analysis using Sanger-sequencing protocols – these products go through another round of PCR termed cycle-sequencing;
- PCR amplicons from bulk DNA extracts destined for metagenomic analysis;
- PCR products generated as a result of quantitative PCR analysis (qPCR or Real-time PCR) for the purpose of PCR-based detection of an organism – in this case, the PCR products do not undergo any subsequent analysis, but the amplification process is instrumentally monitored.

DNA sequence – information about nucleotide composition of the target area of the genome. This product of molecular analysis does not constitute genetic resources per se; however, it comprises the final output of most molecular analyses and is beginning to receive considerable attention in the context of the Nagoya Protocol and other international access and benefit-sharing instruments (see below). Two types of DNA barcode molecular data can be broadly defined:

- Raw data (chromatograms, trace files, BAM files) – these are machine-generated data that require further analysis/interpretation;
- Processed data (FASTA, FASTQ files) – product of machine-based or human interpretation of raw sequence data, usually depicted as a sequence of letters, corresponding to the four types of nucleotides (A – adenine, T – thymine, G – guanine, and C – cytosine).

Typically, Sanger-sequencing results in a single sequence corresponding to the target specimen/individual from which the sample was derived. By contrast, metagenomic data represent a slew of sequences recovered from DNA of the multiple organisms comprising a bulk sample.

2. Access and Benefit-Sharing and the Conservation and Sustainable Use of Biodiversity

Prior to the adoption of the Convention on Biological Diversity in 1992, genetic resources had largely been considered the common heritage of humanity, available to all and free for the taking. However, as technological and legal developments increased the commercial value of genetic resources, the countries that were the greatest store of diversity of these resources – predominantly developing countries – began to push for some control over how genetic resources were accessed and used and also for benefits from this use to be shared with them. This push coincided with the negotiation of the Convention and, as a result, access to genetic resources and the fair and equitable sharing of the benefits arising from their use were included as its third objective. Article 15 of the Convention further elaborates the basis on which genetic resources are to be accessed and benefits to be shared. It provides that States have sovereign rights over their genetic resources; therefore, the authority to determine access to genetic resources rests with national governments and is subject to national legislation.

The access and benefit-sharing provisions of the Convention are intended to create an equity relationship: access to genetic resources in exchange for the sharing of benefits derived from their use. Furthermore, the incentives created by access and benefit-sharing were intended to encourage the conservation and sustainable use of biodiversity, thus contributing to the other two objectives of the Convention.

In the years following 1992, a number of countries struggled to implement access and benefit-sharing provisions of the Convention. They faced challenges in tracking what happened to their genetic resources once they had left their jurisdiction. There was also a perception that benefits were not being shared. At the same time, users of genetic resources found it difficult, costly and uncertain to navigate the heterogeneous access landscape and achieve the legal certainty they needed to be able to use genetic resources without being accused of misappropriation. In response, the Parties to the Convention agreed, in 2002, to the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. The ABS provisions of the Convention were then further elaborated through the negotiations that led to the adoption in 2010 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance. The Nagoya Protocol applies to genetic resources that are covered by the Convention⁴, and to the benefits arising through their utilization. It also covers traditional knowledge associated to genetic resources that are covered by the Convention.

The Nagoya Protocol came into force on 12 October 2014 and, like the Convention on Biological Diversity, is legally binding on its members. As of 1 November 2017, the Protocol has 100 Parties⁵.

⁴ The discussion in this book focuses on genetic resources but many of the provisions and processes also apply to traditional knowledge associated with genetic resources.

⁵ Up to date information on the status of the Nagoya Protocol is available at <http://absch.cbd.int>.

3. DNA Barcoding and Access and Benefit-Sharing

This brief background can help to understand the sensitivities around genetic resources and access and benefit-sharing and why ABS measures exist. Initial reactions to access and benefit-sharing are often that it is too complicated or too burdensome and that it shouldn't apply to a particular sector.

Rather than approaching access and benefit-sharing as a hurdle to be overcome, it can be helpful to view it as an opportunity to develop collaborative relationships with the providers of genetic resources and to raise awareness of the work of DNA barcoders and how this might fit in ABS relationships. As will be described below, the Nagoya Protocol is a flexible instrument, which enables its provisions and requirements to adapt to different situations. The DNA barcoding community may wish to take advantage of this flexibility to develop tools and documents that present the practices of the sector as they relate to access and benefit-sharing.

DNA barcoding researchers and practitioners may also take the opportunity of the Nagoya Protocol to raise the awareness and build the knowledge among the public, including policy-makers. This is particularly important because the appeal and use of DNA barcoding spreads beyond biodiversity researchers and onto more applied practitioners, such as government regulatory bodies. The benefits of sharing data globally may become more apparent to such practitioners and, more broadly, to the parties as more real-world case studies reaffirm the utility of publicly accessible reference libraries. Researchers should still remain aware that trust may be fragile and will rely on demonstration of legal compliance, good practices and, whenever possible, targeted benefit-sharing.

DNA barcoding involves molecular genetic analysis of biological samples sourced from the environment or from collection repositories. This means that the genetic resources contained in these samples are accessed either *in situ* (in nature) or *ex situ* (from collections) and utilized for the purposes of recovering DNA sequences. DNA barcoding also requires access to a common global reference library of DNA barcode sequences. For this reason, it is important to ensure that international partnerships in DNA barcoding comply with national regulations on access and benefit-sharing, and to bear in mind that individual researcher's access to, and the use of, genetic resources are a global concern under the Convention.

II. An Overview of Access and Benefit-Sharing

1. What are genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol?

'Genetic resources' are defined in Article 2 of the Convention as "genetic material of actual or potential value", whereas 'genetic material' is "any material of plant, animal,

microbial or other origin containing functional units of heredity". The concepts in these definitions are changing with technology and with the introduction of new methodological approaches. When the Convention definitions were developed in 1988-92, "functional unit of heredity" could more or less be equated with the gene. The post-Convention development of genomics, proteomics and bioinformatics has shifted the boundaries of both functionality and value⁶.

DNA barcoding lies at the interface between biodiversity science and genomics. Most researchers understand the distinction between conventional DNA barcoding, which relies on a minimal amount of genomic information (gene fragments), and genomics, which employs screening large blocks of the genome. Given the relatively short, standardized fragments used for DNA barcoding, there is very little chance that the limited information in such sequences will be used for anything other than taxonomic identification. Among governments, however, there are different interpretations of the Nagoya Protocol, which reinforces the need for direct dialogue, transparency, and good faith.

2. Who are the actors in Access and Benefit-Sharing?

ABS in the context of the Convention and the Protocol is generally understood to operate on the basis of a bilateral relationship between providers and users of genetic resources:

- **Providers** are the entities that provide access to genetic resources. The Protocol recognizes that States have sovereign rights over natural resources, including genetic resources, in their jurisdiction; so a national government is the provider in many cases. However, laws within the provider country determine who has rights over genetic resources and who has the authority to grant access to genetic resources, therefore in some countries the provider may be indigenous peoples and local communities, private landowners, or sub-national governments.
- **Users** are those who seek access to genetic resources for different purposes. They are a diverse group and can include, for example, botanical gardens and industry researchers in the pharmaceutical, agriculture or cosmetic sectors.

Two other important actors in access and benefit-sharing are national focal points and competent national authorities:

- **National focal points** are responsible for making information available on access rules and procedures and relevant authorities.
- **Competent national authorities** are responsible for granting access or issuing written evidence that access requirements have been met and also for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms (see below).

⁶ For a detailed discussion of 'genetic resources', see Schei PJ & Tvedt MW (2010) 'Genetic Resources' in the CBD: The Wording, the Past, the Present and the Future. FNI Report 4/2010. Lysaker, Fridtjof Nansen Institute, 24pp. Available at: www.fni.no/publications/genetic-resources-in-the-cbd-the-wording-the-past-the-present-and-the-future-article815-290.html

Parties to the Protocol are required to designate a national focal point and competent national authorities and to publish information on these entities in the **Access and Benefit-sharing Clearing-House**.

The ABS Clearing-House is established by the Protocol as a platform for exchanging information on access and benefit-sharing. The ABS Clearing-House is a key tool for facilitating implementation of the Nagoya Protocol. As will be described further below, Parties are required to publish different types of information in the ABS Clearing-House to enhance legal certainty and transparency on procedures for access and for monitoring the utilization of genetic resources along the value chain.

3. The ABCs of ABS

The Convention's Article 15 sets out the basis on which genetic resources are to be accessed and benefits shared. These provisions have been elaborated and further developed under the Nagoya Protocol. The key requirements rest on three pillars: access, benefit-sharing and compliance – also known as the ABCs of ABS.

a. "A" is for Access

Users seeking access to genetic resources must get permission from the competent national authority of the provider country, unless otherwise determined by that country. This is known as **prior informed consent**, or **PIC**.

Prior informed consent is based on the principle that providers should be able to make an informed decision on whether or not to grant access. This requires the access seeker to provide sufficient information, in advance and in detail about the planned access activity, such as the genetic resources to which access is sought and the purposes for which the resources would be used, in order for the provider to make an informed decision on whether or not to allow access.

The Protocol's provisions on access go beyond the Convention by obliging Parties that require prior informed consent to establish clear and transparent procedures for accessing genetic resources and to issue a permit when access is granted. Parties must publish information on their access procedures and the permits they issue in the ABS Clearing-House. As will be described below, the publication of permits in the ABS Clearing-House is critical for the compliance system established by the Protocol.

The Protocol also specifies that it is access to genetic resources for their utilization that is regulated. The term 'utilization of genetic resources' is defined to mean "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology". Many countries are still working to translate this concept into their national measures and to understand which activities constitute utilization of genetic resources and which do not.

Countries have also taken different approaches to ‘access’ in their access and benefit-sharing measures (table 1). Other countries, such as Denmark, the Netherlands and the United Kingdom, have chosen not to require prior informed consent for access to genetic resources.

Table 1. National definitions of access.

DEFINITION OF ACCESS	COUNTRY/REGION	SOURCE, YEAR
Research or technological development carried out on genetic heritage sample	Brazil	Law no. 12.123, 2015
Acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol	European Union	Regulation 511/2014
Collection and use of genetic resources conserved in <i>ex situ</i> and <i>in situ</i> collections, of their derivatives or, if applicable, of their intangible components, for purposes of research, prospecting, conservation, industrial application or commercial use, among others, by signing an Authorization of Access to Genetic Resource Contract and its conditions, concluded with the Competent National Environmental Authority	Ecuador	Decreto 905, 2011 (builds on Andean Community Decision 391)
The collection, acquisition, transfer or use of genetic resources and/or community knowledge	Ethiopia	Proclamation 4852/2006
The taking of biological resources of native species for research and development on any genetic resource, or biochemical compounds, comprising or contained in the biological resources. Examples of access to biological resources include collecting living material or analyzing and sampling stored material, for various purposes including taxonomic research, other research and potential commercial product development	Australia	Environment Protection and Biodiversity Conservation Regulations, 2000

b. “B” is for Benefit-sharing

A provider and a user must negotiate an agreement to share benefits resulting from the utilization of a genetic resource as well as subsequent applications and commercialization in a fair and equitable manner. This agreement is known as **mutually agreed terms** or **MAT**.

Mutually agreed terms may be established following prescribed models, through individually-negotiated contracts, or through other forms of mutual agreement. These terms should be set out in writing and, in addition to terms on benefit-sharing, they should also address subsequent third-party use and changes of intent, as well as a dispute settlement clause. Although the Nagoya Protocol does not provide specific templates for such documents, a number of international organizations have developed template agreements⁷ that outline model contractual clauses that the provider and user may agree upon as a prerequisite for access to genetic resources. Model agreements are discussed in more detail in section III (d) of this book.

Benefits to be shared can be monetary or non-monetary. The Protocol includes an annex with examples of different types of benefits; many are relevant to DNA barcoding. Some of these benefits are also foreseen in the Convention, which provides that Parties should try to develop and conduct research (including molecular analysis) with the full participation and, where possible, in the countries providing the genetic resources.

Benefits from the utilization of traditional knowledge associated with genetic resources must also be shared. The Nagoya Protocol goes beyond the Convention by requiring measures to ensure that benefits are shared with indigenous peoples and local communities when those peoples and communities hold the resources, in accordance with national laws regarding those communities’ rights.

The Protocol also emphasizes the linkage between access and benefit-sharing and the other objectives of the Convention in its Article 9, which requires Parties to encourage both users and providers to direct benefits towards conservation and sustainable use.

c. “C” is for Compliance

Among the key innovations of the Nagoya Protocol are its provisions on compliance with providers’ access and benefit-sharing measures and with mutually agreed terms. As described above, this was intended to address the difficulties that countries granting access to genetic resources had in following what happened to the genetic resources once they left their borders.

The Nagoya Protocol requires that when a country grants access to a genetic resource, it also has to issue a permit (or an equivalent document) as evidence of the decision to

⁷ For example, the toolbox Agreement on Access and Benefit-sharing for Non-Commercial Research developed by the Swiss Academy of Sciences, available at <https://naturalsciences.ch/organisations/biodiversity/abs/toolbox>, and template Material Transfer Agreements developed by the Consortium of European Taxonomic Facilities (CETAF) for ex situ genetic resources collections, available at http://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf.

grant prior informed consent and of the establishment of mutually agreed terms. These permits demonstrate that the genetic resources were accessed in accordance with the country's access and benefit-sharing measures.

The provider country is also required to publish information on issued access permits in the ABS Clearing-House⁸; this information is used to generate an internationally recognized certificate of compliance. These certificates contribute to ensuring compliance with domestic ABS measures, while allowing downstream monitoring of the utilization of genetic resources and compliance with mutually agreed terms. In effect, internationally recognized certificates of compliance are permits that can be tracked and monitored internationally. See annex I for an example of an internationally recognized certificate of compliance.

Under the Nagoya Protocol, countries must develop measures to provide that the genetic resources utilized in their jurisdiction were accessed with prior informed consent and under mutually agreed terms, as required by the provider country. Specifically, the Protocol requires countries to take measures to monitor utilization and provides the framework for a new global monitoring system using checkpoints, certificates and the ABS Clearing-House.

Countries must designate checkpoints to collect or receive information on prior informed consent and the establishment of mutually agreed terms, the source and the utilization of genetic resources. Users are required to provide this information at a checkpoint. The information can be provided using an **internationally recognized certificate of compliance (IRCC)** where available.

The information collected or received by checkpoints must then be provided to relevant national authorities, to the Party providing prior informed consent and to the ABS Clearing-House. When this information is made available to the ABS Clearing-House, a checkpoint communiqué will be issued and will be sent to, among others, the national focal point and the competent national authority of the country that provided access to the genetic resource. This facilitates the flow of information between the user country and the provider country and enables the provider country to see how its genetic resources are being utilized and whether the utilization conforms with the prior informed consent and mutually agreed terms from the initial access to the genetic resource.

An internationally recognized certificate of compliance can help users provide the necessary information to checkpoints. Publishing information on permits in order to generate internationally recognized certificates of compliance is not only in the best interests of countries granting access to assist them in tracking how their genetic resources are being used but it is also helpful in providing legal certainty to users to demonstrate that genetic resources have been lawfully accessed.

Upon receiving a checkpoint communiqué, if the provider country feels as though its genetic resources are being utilized in a way that is not in accordance with the initial prior

⁸ <http://absch.cbd.int>

informed consent or mutually agreed terms, it may follow up and, if necessary, initiate legal proceedings. For this reason, Article 18 of the Protocol addresses compliance with mutually agreed terms and suggests that such terms should include provisions on the applicable jurisdiction for any dispute resolution process, the applicable law and options for alternative dispute resolution, such as mediation or arbitration.

III. Access and Benefit-Sharing and DNA barcoding: Practical Aspects

Researchers and practitioners conducting DNA barcoding are a diverse group. They may work for institutions that house specimen collections, such as natural history museums, zoos, aquaria, seed banks or botanical gardens. They may be part of a regulatory agency that helps enforce rules on trade in endangered species or other regulated organisms. They may be based in universities where they facilitate DNA barcoding analyses for partners as part of international research projects. As a result, DNA barcoders may have different roles in access and benefit-sharing relationships. In particular, DNA barcoders may be accessing genetic resources directly from provider countries or they may receive genetic resources through third-party transfers. These two methods of receiving genetic resources have their own particularities for what is needed to meet ABS requirements and both are addressed in the discussion that follows.

1. The relevance of DNA Barcoding to Access and Benefit-Sharing regulations

One of the first questions to ask is whether DNA barcoding constitutes ‘utilization of genetic resources’ as defined by the Nagoya Protocol (see section II).

Most standard DNA barcode markers represent either gene fragments, e.g. ribulose biphosphate carboxylase large chain (rbcLa) in plants and cytochrome C oxidase subunit I (COI) in animals, or non-functional elements of the genome, e.g., internal transcribed spacer (ITS1) in fungi. As such, they are not capable of producing functional transcripts and thus do not conform to a conservative definition of functionality. Furthermore, sending PCR amplicons to third-party laboratories for DNA sequencing analysis, for instance, is common practice among researchers.

At the same time, however, it is up to countries to interpret the provisions of the Nagoya Protocol and some include other molecules (e.g. proteins or oils) and information⁹ in their understanding of ‘genetic resources’. Looking at the original definition in the Convention and taking a dynamic approach to functionality and value, it could be expected that national ABS laws would at least cover any tangible biological material or its direct derivatives from which DNA (=genome) or RNA (=transcriptome) can be readily extracted. Examples include living or dead organisms, live cell and tissue cultures/propagules, germplasm, specimens deposited in natural history collections or in DNA banks.

In general, it may be advisable for DNA barcoding researchers and practitioners to take a precautionary approach when it comes to access and benefit-sharing. Assuming that requirements do not apply and proceeding without having the necessary information could limit the extent to which the results of the work can be used in the future. It can also damage relationships within research partnerships, because, for many countries, trust is a key consideration when they are granting access to their genetic resources.

2. Access

a. Access to Genetic Materials: Acquisition and Transfer

An institution (e.g. collection facility or laboratory) may gain custody of the material from a range of national or international sources (e.g. its own fieldwork, *ex situ* collections, commercial sources, individuals, or official bodies that have seized illegal material). Material may pass for permanent storage, or on a temporary basis (e.g. loans, or material provided for sequencing, or material brought by visitors). The transfer of material to the institution may or may not involve transfer of ownership. Institutions engaged in regular biomaterial transactions should appoint dedicated staff (e.g. collections managers) with adequate knowledge and expertise to ensure that material has been legally acquired, that its status within the institution is tracked, and that the conditions on which it has been acquired are being met.

b. Fieldwork

Compliance with national laws will require appropriate preparation and can be particularly challenging for an institution planning a collecting activity in another country. Therefore, it is vital to plan ahead. Useful resources for checking national requirements include the ABS-Clearing House, the national focal point and the competent national authority. Additional, non-ABS, permits for collection, research and/or export may be required and issued by different authorities. Colleagues with experience of working in the country may provide useful practical advice. However, depending on national laws, an access and benefit-sharing agreement may have to be negotiated directly with a government body or specified stakeholders, and certain agreement clauses may be mandatory.

⁹ For example, Brazil defines ‘genetic heritage’ as “genetic information of plant, animal and microbial species or species of other nature, ..., including substances derived from the metabolism of these living beings” (Law no. 13.123, 2015). Ethiopia defines ‘genetic resources’ as “any genetic material of biological resource containing genetic information having actual or potential value for humanity including derivatives” (Proclamation 482/2006).

In the context of DNA barcoding, there are several key issues that should be addressed in mutually agreed terms so that all involved parties know:

- if specimens or samples may be exported from the country of origin;
- if material will be destructively/consumptively sampled;
- if material will be sequenced;
- if data will be shared through a public domain;
- how and where voucher specimens and unconsumed material will be kept and used;
- if specimens or samples may be subsequently loaned or transferred between research groups or third parties.

If fieldwork involves an out-of-country institution, close partnership with an in-country host is advantageous both from an ethical and a pragmatic perspective, and may be a legal requirement in some jurisdictions. Permitting requirements for foreign partners may be different, particularly regarding the export of biological materials that contain genetic resources.

Collaborative research with in-country partners is a good practice, especially for longer-term projects. If the project partner is from the relevant government body, an access and benefit-sharing agreement may cover both prior informed consent and the particulars of the research partnership. However, all research partners should jointly determine ABS-relevant details of how material and data will be handled and benefits will flow from the partnership. These details should be formalized in a written collaboration agreement with clear responsibilities and expectations.

Institutions should keep records of their communication with authorities and partners regarding prior informed consent. An institutional policy or procedures for fieldwork may help to ensure that responsibilities are clear, laws are complied with, staff have adequate advice, benefits are agreed and shared, and material and data are managed appropriately afterwards, linked to permits and terms of use. Institutions can also develop their own 'statements of use' that explain their practices and how they use genetic resources in their work.

Given that DNA barcoding is most commonly done for non-commercial purposes, it may be possible to follow simplified access procedures to access genetic resources from a country. At the same time, however, it is important that prior informed consent and mutually agreed terms address the issue of change of intent in case circumstances change in the future.

c. Simplified Access Procedures

Nagoya Protocol implementation varies from country to country. Although many of the Nagoya Protocol's provisions focus on the creation of legal or administrative measures, the Protocol also recognizes that research is crucial for implementing the Convention and for the conservation and sustainable use of biodiversity.

To this end, Article 8 of the Nagoya Protocol provides for special considerations including the possibility of simplified access for non-commercial research to contribute to conservation and sustainable use of biodiversity and expeditious access for emergencies that threaten or damage human, animal or plant health.

Fast and reliable identification of species (e.g. keystone and indicator species in vulnerable natural ecosystems, invasive alien species, pests, parasites, disease vectors and economically important species) can be particularly critical in situations where there are threats to human, animal or plant health. Such identification could be greatly expedited and scaled up by using DNA-based diagnostic approaches. DNA barcoders seeking access to genetic resources from a country may wish to explore whether simplified access measures are available.

A number of simplified access measures appear in various national access and benefit-sharing laws. Examples include:

- access declarations rather than authorizations;
- lower, or waived, fees for access;
- simpler procedures or negotiations involving fewer parties;
- no requirement for benefit-sharing agreements;
- exemption from access and benefit-sharing laws (e.g. when ABS laws only cover bioprospecting and commercial uses).

Where simplified measures are in place, researchers using DNA barcodes in their work (in conservation and sustainable use) may be able to obtain facilitated access, but will need to be able to address any change of intent (from non-commercial research to other intent, including commercial use, see below). If originally non-commercial research develops a potential commercial angle, agreements (e.g. permits, research agreements, material transfer agreements) should be clear as to how new prior informed consent should be obtained and benefits shared.

d. Non-commercial vs. Commercial Use and Change of Intent

The distinction between commercial and non-commercial use is implied but not clearly defined in the Nagoya Protocol text. The issue was extensively discussed during the negotiation of the Protocol but the distinctions between commercial and non-commercial use, and the actors involved, are not always clear-cut. In general, non-commercial use can be understood as use to increase fundamental knowledge or understanding of the natural world; not primarily intended for or directed towards commercial advantage or monetary compensation¹⁰. Examples include taxonomic research and ecosystem analysis. In this context, it is relatively safe to assume that normal DNA barcoding activities fall in the non-commercial category; however, biological materials transferred as part of DNA barcoding workflows may also be suitable for other purposes, including commercial use.

Change of intent is an important issue to consider in non-commercial research projects, especially when genetic resources are obtained via simplified access measures. The same scientists, laboratories and analytical tools may be involved in both commercial and non-commercial research. The use of clear agreements can help set out the purpose of research. Such agreements should explicitly mention that any commercial use (e.g. clinical trials, intellectual property claims) is prohibited and that any such change of in-

¹⁰ This wording drawn from the Creative Commons Noncommercial License Element https://wiki.creative-commons.org/wiki/NonCommercial_interpretation.

tent must be negotiated between the provider and user (and other relevant parties and authorities) under a separate agreement. In such instances, it is critical to have robust collection management systems that link the individual specimens and samples housed within an institution to the individual agreements with different providers.

Whether working with partners or outsourcing analyses to external labs, institutions and researchers should look for indicators of possible or implied intent of the other party to commercialize the results. Such indicators may include:

- default agreement clauses providing for full transfer of ownership to materials and/or derivatives;
- restrictions on release of research findings;
- limitations placed on provider involvement;
- delays in public release of research data;
- separate fees for access to data/technology/materials resulting or remaining from research (excluding cost recovery fees);
- retention of monetary benefits from sale/lease for profit, patenting or licensing of research results;
- unauthorized transfer of biological material to commercial third parties;
- agreement terms reserving rights to file patents or maintain ownership of intellectual property rights (IPRs); and
- agreement terms allowing the user to investigate commercial applications, contract with a commercial body or project¹¹.

e. Using the ABS Clearing-House to Find Information

Keeping track of widely different access and benefit-sharing laws and procedures developed by different nations is challenging. DNA barcoding researchers can use the ABS Clearing-House platform to search information on national authorities and focal points in charge of ABS, national legislation and procedures for obtaining prior informed consent and negotiating mutually agreed terms. The platform also offers information on competent national authorities responsible for granting access or issuing evidence that access requirements have been met. Anyone can search the information on the ABS Clearing-House.

f. Third Party Transfers – Acquisition from Other Sources

Institutions may receive or work with material that was not directly collected by them or their project partners. Potential sources might include *ex situ* collections, commercial sources (e.g. pet shops, nurseries, markets, shops, and labs), individuals (e.g. donors to a collection, colleagues, visiting researchers and students, amateur taxonomists, the general public) or regulatory authorities (e.g. biosecurity authorities). Special consideration should be given to informal and accidental acquisition, such as material that is offered by conference colleagues or left behind by visiting researchers and students. Such material should not be accepted or used for molecular analysis.

¹¹ Drawn from Schindel DE, Bubela T, Rosenthal J, Castle D, du Plessis P, Bye R, PMCW (2015) The New Age of the Nagoya Protocol. *Nature Conservation* 12: 43-56. <https://doi.org/10.3897/natureconservation.12.5412>.

Before accepting material from such sources, measures should be taken to ensure that:

- the material has been collected legally;
- the potential supplier is entitled to supply or loan the material; and
- any terms and conditions of use are clear.

A material transfer agreement (MTA) or similar document¹² should be used for all transfers. It should set out the permitted uses of the material and also address issues such as further transfer to third parties, non-commercialization, benefit-sharing, as well as clear instructions for any change in intent, and any stricter terms as agreed with the original provider. Even if there are no restrictions on the transferred material, the material transfer agreement provides legal certainty for the recipient. The material transfer agreement should be unambiguously linked to the material being transferred, by referencing individual specimen/sample numbers and relevant permits. This link should be retained for any materials that remain in the custody of the user after analyses.

An example of terms in the template agreement used by the Canadian Centre for DNA Barcoding when accepting material for standard analysis is provided in Annex II.

If material originates from confiscation by police, customs, or other official government bodies, these authorities will likely set out the terms of use. If the material is of international origin, inquiries to the authorities of the source country should be made through the regulatory channels that supplied the materials.

Material obtained from commercial sources may have restrictions on transferring or distributing to others, on sampling for DNA or other chemicals. For example, utilizing a store-bought fruit for genetic or biochemical research, rather than eating it, entails a change of intent and might trigger access and benefit-sharing obligations.

3. Benefit-sharing

a. Benefit-sharing in Practice

Benefits arising from the utilization of genetic resources, as well as from subsequent applications and commercialization must be shared fairly and equitably with the provider country according to mutually agreed terms.

Benefit-sharing should be envisioned at the inception of a research project and formalized in applications for prior informed consent and collaborative research agreements with partners.

¹² E.g. the Consortium of European Taxonomic Facilities Code of Conduct and Best Practices (2014) includes model material transfer agreements for receipt of material with change in ownership (equivalent to a donation letter) and without change in ownership (equivalent to a loan agreement).

b. What Benefits Can Be Shared by Researchers?

In DNA barcoding-related projects, some non-monetary benefits arise directly from utilization of genetic resources. These benefits include sequence data used for particular purposes such as identification, bio-surveillance and authentication. In many cases important benefits arise from collaborative activities such as joint fieldwork and collaborative research, access to technology, and knowledge sharing. Co-authoring publications can help to build professional careers and open opportunities for research funding. Publications can also serve as a means of acknowledging providers and promoting collaborative aspects of the research.

By sharing barcode data globally via the Barcode of Life Data Systems (BOLD)¹³ and the International Nucleotide Sequence Database Collaboration (INSDC)¹⁴, DNA barcoding projects generate important environmental and societal benefits at the national and global levels. Countries of origin or partners may ask for some sequence data to be restricted or for delays in the release of results, but it is important to keep at least the core barcode reference library data in the public domain and openly accessible to anyone in the world.

Box 3: Benefit-sharing provisions of the Nagoya Protocol relevant to DNA Barcoding

Examples of benefits indicated in the Nagoya Protocol Annex that are relevant to DNA barcoding include:

- Sharing of research and development results;
- Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
- 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;
- Strengthening capacities for technology transfer;
- Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities.

¹³ <http://boldsystems.org>

¹⁴ <http://www.insdc.org>

DNA barcoding researchers may refer to the annex of the Nagoya Protocol, which indicates monetary and non-monetary values of genetic resources (see Box 3).

4. Compliance

a. How DNA Barcoders Can Comply with Access and Benefit-Sharing Requirements

It is important that DNA barcoding researchers and practitioners identify their role in the compliance process established by the Nagoya Protocol.

Where researchers are themselves accessing genetic resources from a provider country, they must follow the applicable regulatory procedures. From a compliance perspective, it is important that users keep records of the prior informed consent and mutually agreed terms. In particular, they should encourage the provider country to publish information on the access permit in the ABS Clearing-House. This will generate an internationally recognized certificate of compliance that will give the researcher the legal certainty they need to proceed with their work.

b. Complying with Access and Benefit-Sharing Requirements when Material is Received by Third Party Transfer

When a DNA barcoding analytical facility receives material to sequence, it may be a third party to an original access and benefit-sharing agreement. In these cases, certain core ABS information should be transferred with the material.

The analytical facility should verify with the sender that the material has been accessed with prior informed consent and that mutually agreed terms have been established, as required by the provider country. The terms of access should also indicate whether or not third party transfer is allowed. Internationally recognized certificates of compliance can assist in this regard. They will show that prior informed consent has been obtained and mutually agreed terms established. Depending on how much information is provided in the Internationally Recognized Certificate of Compliance (IRCC), it can also indicate specific uses that are allowed or restricted under the permit. It can also include information on conditions for third party transfer, e.g. whether such transfer is allowed and on what conditions.

c. Curation and Data Management

Proper curation of genetic materials and associated data is a vital part of the compliance process under Nagoya Protocol. The movements of a genetic resource can be complex, even within one institution. Original material may be sampled and subsampled over time, stored and used in different units or labs of the institution. For this reason, it is suggested to deposit material with a nationally recognized institution that possesses the proper facilities to store, curate and manage data. A robust data management system is a crucial tool for keeping long-term records of core ABS information such as:

- Country of origin and provider of the material;
- Prior informed consent, mutually agreed terms and related documents (agreements, permits, Internationally Recognized Certificate of Compliance);
- Specific terms of use, including any restrictions and benefit-sharing obligations;
- Unique identifiers supplied with the material, relevant to ABS and/or the material itself (collection voucher catalogue numbers, field numbers, sample container identifiers, strain identifiers, accession numbers, permit numbers, IRCC numbers).

Access and benefit-sharing information should follow the audit trail of the material as it is sampled, analyzed, or supplied to others, and should also be linked to subsamples. Restrictions should be flagged in specimen-associated database records.

ABS information should also be linked to sequence data and publications as much as possible. Good practice using the DNA-Barcoding community standard (BARCODE Data Standards)¹⁵ demands that barcode records are linked to voucher specimen information, including the biorepository housing the voucher(s). People checking the corresponding data records within these repositories should be able to see information on the country of origin, provider, and any applicable restrictions.

Good curation and data management will help researchers follow the measures that their own country has taken to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the provider country. This will enable DNA barcoders to provide the necessary information to checkpoints if they are required to do so.

We have now reviewed the whole process, beginning with the steps for accessing genetic resources through to what is needed to fulfill compliance requirements. The different steps are summarized in Figure 1.

5. Access and Benefit-Sharing and Unique Attributes of DNA Barcoding

The use of DNA-based identification of regulated articles in international trade by national regulatory agencies is increasing. For example, DNA can be used to authenticate the taxonomic provenance of foreign commodities, as well as inadvertent contaminants. DNA-based identification plays an increasingly important role in quality control of products, quarantine and enforcement. Another important group of organisms used for genetic analysis is invasive alien species. These species pose serious problems for the ecosystems and economies that they devastate. Some national ABS measures explicitly exclude non-native species (e.g. Australia and South Africa) while others do not.

In these, often time-sensitive, situations, it can be difficult to obtain prior informed consent and establish mutually agreed terms ahead of conducting the DNA barcoding analysis. Institutions working in these situations would be well-advised to develop

¹⁵ http://www.boldsystems.org/docs/dwg_data_standards-final.pdf

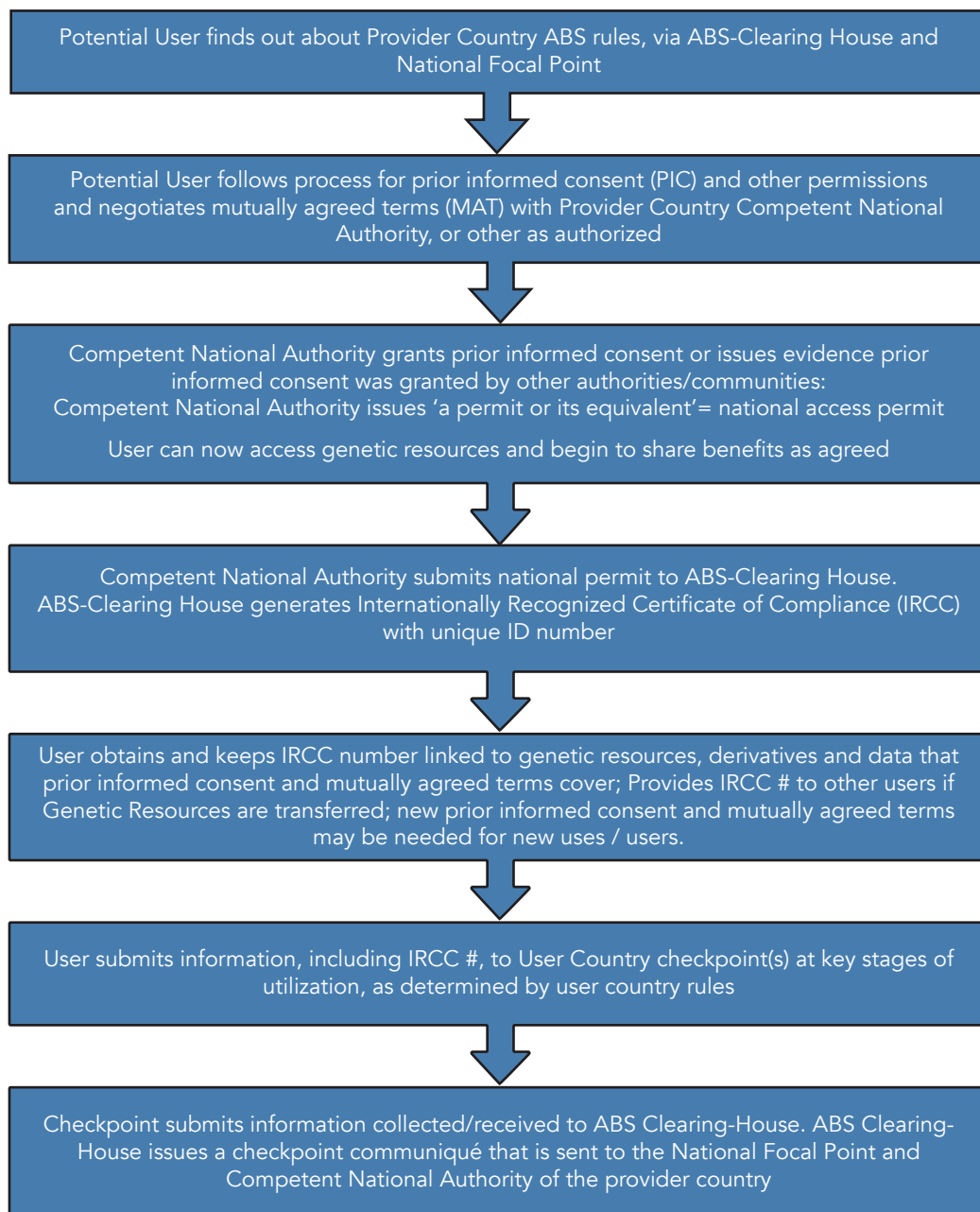


Figure 1. Overview of the steps that prospective users of genetic resources should follow to be in compliance with ABS requirements

policies or statements that clearly explain their role and activities and how they use genetic resources. Having these documents ready and available can help answer any questions that may arise. These institutions may also wish to engage with regulatory authorities in their own country to see what internal compliance measures are being developed or are in place to address the utilization of genetic resources.

Users of genetic resources are themselves highly diverse. The Nagoya Protocol recognizes that different sectors utilize resources for many different purposes and in different contexts. Thus, it provides room for the development of sectoral and cross-sectoral model contractual clauses, and voluntary codes of conduct, guidelines, best practices and/or standards.

The Nagoya Protocol's current flexibility in this area provides a good opportunity for research networks and institutions to develop realistic and usable models and standards, and to harmonize their work.

Barcode researchers and practitioners may be working in collections, in regulatory agencies, in academic research institutions, or in other environments. It is worth developing appropriate codes and best practices, or adapting existing ones to fit particular national circumstances, to build trust with potential providers. Model contractual clauses have been developed by sectors in communication with relevant governments to ensure that the agreements support compliance with national laws and work in practice. In the context of DNA barcoding, it is important to consider that an increasing number of users of DNA-based identification tools are located within provider countries. Best practices and model clauses should be developed to address these users' situations as well, to promote the growing engagement of developing country researchers and practitioners.

a. Access and Benefit-Sharing Tools for DNA barcoding researchers

ABS tools that may be useful for DNA barcoding researchers include:

- An overall ABS policy and/or Code of Conduct for the institution/facility, covering acquisition, use, supply and benefit-sharing;
- Standard operating procedures for ABS-sensitive points in workflows (e.g. field-work, accessioning into permanent custodianship, management of incoming and outgoing DNA and tissues, destructive sampling, research, data management and documentation);
- A policy for dealing with visiting researchers and students, particularly those coming from other countries and involved in research collaboration, material transactions, and/or data exchange;
- Standard/model documents (e.g. Statement of Use, material transfer agreement, donation letter, model or template agreements covering typical collaboration scenarios);
- If applicable, a separate policy on commercialization and supply to third parties that outlines actions to be taken if research intent changes;
- A data management system to record providers, prior informed consent and other permits, mutually agreed terms, unique identifiers, uses, loans and transfers, links to publications, and benefits.

To develop these tools and ensure staff awareness, it is useful for the institute to have:

- A member of staff with ABS knowledge and resources/authorization to handle issues and queries and gatekeepers for relevant points in workflow;
- A procedure for staff training, in-house guidance, and regular updates on current developments in the ABS policy area.

b. Codes of Conduct and Other Guidance

Developing and openly sharing a Code of Conduct, policies, and/or best practices helps both provider and user institutions to build trust at the grassroots level with their partnering organizations. Development of similar documentation at an inter-institutional level allows for greater harmonization between institutions that are part of international collaboration networks, facilitating greater recognition and trust-building between prospective providers and users. Examples of such codes and best practices post-Nagoya include the Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practices (for taxonomic collections institutions)¹⁶, the Global Genome Biodiversity Network (GGBN) Code of Conduct and Best Practices (for genome-quality collections)¹⁷ and the Transparent Users-friendly System of Transfer or TRUST (for microbial collections)¹⁸.

A Statement of Use can be developed to set out the institution's standard practices when seeking prior informed consent from government or other providers and sharing information with other interested stakeholders. It can also provide a practical baseline for terms of use when negotiating mutually agreed terms, with stricter measures added depending on the provider country and the particular project. As part of their codes of conduct, the GGBN and CETAF networks of *ex situ* collection networks have developed Statements of Use to describe their member institutions' standard non-commercial uses of biological material (see Box 5). Both reflect the needs and practices of *ex situ* collections. Elements from these models could be shared or adapted, depending on local situation and typical uses of individual institutions. Because many DNA barcoding practitioners are not based in major *ex situ* collection facilities, their Statement of Use would contain different typical uses.

Box 4: Excerpts from the GGBN Statement of Use

The Global Genome Biodiversity Network (GGBN) is an international network of biorepository institutions that share an interest in long-term preservation of genomic samples representing non-human biodiversity. The Statement of Use reflects the typical uses of material made by GGBN member institutions.

The Global Genome Biodiversity Network Statement of Use of Biological Material¹⁹

This document sets out the typical ways in which biological material, accessioned into the collections of [institution name] ("*[institution acronym]*"), may be used and genetic resources may be utilized. This includes use both in facilities managed or owned by the legal body and in facilities owned or managed by others but mandated for specific purposes (for example external DNA sequencing facilities). If Providers of biological material do not wish their material to be treated in this way or wish to place any specific restrictions, this needs to be expressly set out in

¹⁶ http://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf

¹⁷ http://www.ggbn.org/docs/ABS_Guidance/GGBN%20Guidance%20Code_of_Conduct_June_2015-Final.pdf

¹⁸ <http://bccm.belspo.be/documents/files/projects/trust/trust-march-2016.pdf>

¹⁹ See GGBN Code of Conduct Annex 1 for full text

writing when granting access, when donating or exchanging material, or providing unsolicited material such as for identification. If the Provider does not place any express written restrictions, then the material will be accessioned and used under the conditions set out below.

[*Institution*] is a member of the Global Genome Biodiversity Network (GGBN) and subscribes to the GGBN Code of Conduct on Access and Benefit-Sharing and Best Practice.

Use of Biological Material

Research at [*institution*]: Unless specified restrictions apply, any biological material, including its derivatives, at [*institution*] may be made available to its staff and authorised visitors for non-commercial research. Such analyses may result in complete destruction of the material.

Research results: Results of research will be made available through publication in printed or online form (such as books, scientific journals, publically-available databases, published images or internet sites). DNA sequence data [This also include raw reads from Next Generation Sequencing] will be deposited in publicly-available databases such as those run by the International Nucleotide Sequence Database Collaboration (INSDC) and, where possible, referenced to the respective biological specimens stored at [*institution*].

Information and images: As a scientific institution involved in biodiversity research and conservation it is important that [*institution*] makes its collections as accessible as possible to its direct counterparts and to the wider community. This may involve the publication of data, including place and date of access freely on the internet and in research publications, although it may be necessary to mask precise data for conservation purposes.

Loans: [*institution*] may lend biological material (specimens) to Third Parties contingent and consistent with the terms and conditions under which it was originally acquired from the Provider.

Transfer to Third Parties: [*institution*] may permanently transfer biological material or parts thereof to other scientific research institutions for scientific research or for educational purposes, including material obtained as donations or exchange for other specimens or samples, contingent and consistent with the terms and conditions under which the material was acquired from the Provider. Transfer will be take place only when the recipient institution or individual has signed a "Material Transfer Agreement" with [*institution*].

Traditional Knowledge associated with Genetic Resources

Any Traditional Knowledge associated with the Genetic Resources [Institution] will be managed and used according to the terms and conditions agreed with the Provider.

Commercialization

[Institution] is a not-for-profit institution and is only rarely involved in commercialization of collection-based genetic resources. However, as part of its mission, [institution] investigates genomic samples and their constituents for taxonomic and other scientific research. This research may lead to the discovery of potential commercial uses. In such cases, if not already covered by the terms and conditions agreed with the Provider, [Institution] will initiate renegotiation of the terms and conditions.

Benefit-sharing

Benefits may include any of those listed in the Annex to the Nagoya Protocol. However, due to the not-for-profit nature of the work of the [Institution] the most likely benefits will be non-monetary, inter alia: scientific training, education, capacity building, collaboration on scientific work programmes, and the mutual sharing of research results and publications.

[Institution] will aim at developing partnerships between scientists from all parts of the world to foster long-term collaborations helping to spread the benefits of genomic research and knowledge as broadly as possible.

c. Template Agreements

Model agreements can be used when developing an access and benefit-sharing agreement and/or a collaborative research agreement, although they will often offer more content and complexity than is useful for a particular project. National laws and regulations may mandate certain agreement clauses; other sources of ABS-relevant clauses include the Bonn Guidelines, the toolbox Agreement on Access and Benefit-sharing for Non-Commercial Research²⁰, and other models available on the ABS Clearing-House. It can be difficult to balance all of the potential inputs and achieve a legally-defensible document that is also readable by researchers. A decision-tree tool for collaborative agreements is in development for DNA barcode projects²¹. A succinct, focused document provides a good start towards building trust between collaborating parties and allows them to devote more effort towards addressing the overarching goals of the Convention on Biological Diversity.

²⁰ <https://naturalsciences.ch/organisations/biodiversity/abs/toolbox>

²¹ Schindel, DE et al. (2015)

Annex I

Example of an internationally recognized certificate of compliance from the ABS Clearing-House²²



ABSCH-IRCC-GT-206790-1
Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

General Information

Issuing country

GUATEMALA

Verification link (view latest version)

<https://absch.cbd.int/database/ABSCH-IRCC-GT-206790>

ABS-CH Unique Identifier (UID)

ABSCH-IRCC-GT-206790-1

Issuing Authority

National Council of Protected Areas (CONAP)
5ta ave 6-06 zona 1 Edificio IPM 6to Nivel
Guatemala
01001, Guatemala
Phone: +50224226700
Email: otecbio@conap.gob.gt

Details of the permit or its equivalent

Reference number of the permit or its equivalent

Contract of access to genetic resources for research purposes on Mahogany (Swietenia macrophylla King) and Cedar (Cedrella odorata L)

Additional national references or identifiers

Project Name:
Evaluation of the effect of forest management on genetic diversity of Mahogany (Swietenia macrophylla King) and Cedar (Cedrella odorata) forest concessions in the Maya Biosphere Reserve

Objectives:
Evaluate the genetic variability in Mahogany and Cedar
Evaluate the management effect and forestry on the genetic diversity in the Mahogany and Cedar populations of the community and industrial concessions

Date of issuance of the permit or its equivalent

09 Oct 2015

Reference to other internationally recognized certificate(s) of compliance that relate(s) to this permit

Project Name:
Evaluation of the effect of forest management on genetic diversity of Mahogany (Swietenia macrophylla King) and Cedar (Cedrella odorata) forest concessions in the Maya Biosphere Reserve

Objectives:
Evaluate the genetic variability in Mahogany and Cedar
Evaluate the management effect and forestry on the genetic diversity in the Mahogany and Cedar populations of the community and industrial concessions

²² <https://absch.cbd.int/database/IRCC/ABSCH-IRCC-GT-206790/1>

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted

YES

Provider The person or entity that holds the right to grant access to the genetic resources in accordance with domestic legislation.

National Council of Protected Areas (CONAP)

5ta ave 6-06 zona 1 Edificio IPM 6to Nivel
Guatemala

01001, **Guatemala**

Phone: +50224226700

Email: otecbio@conap.gob.gt

Entity to whom PIC was granted

Del Valle University of Guatemala (UVG)

Roberto Moreno Godoy

Principal and Legal Representative

18 av 11-55 zona 15 Vista Hermosa III

Guatemala

01015, **Guatemala**

Phone: +50223688353

Email: rmoreno@uvg.edu.gt

Additional documents or links about the prior informed consent

■ Acta Caoba y Cedro.pdf

■ Resolución aprobación de acceso RRGG.pdf

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established

YES

Additional information about the mutually agreed terms

Benefits derived from the utilization of genetic resources of Mahogany and Cedar on forest concession in Maya Biosphere Reserve:

- Complete access to the data base
- Ex situ follow up to the procedure, evaluate the procedures to be carried out within the framework of the project in order to verify the quality of procedures as DNA extraction, amplification and sequencing
- Transference of capacities
- Access to scientific information relevant for the conservation and sustainable use of the biological diversity
- Disclosure of information
- Deposit of three copies of the research work

Additional documents or links about the mutually agreed terms

■ Contrato CONAP_UVG Acceso a RRGG Caoba y Cedro.pdf

Subject-matter

Subject-matter or genetic resources covered:

Only two species included:

- Mahogany (*Sweetenia macrophylla* king)
- Cedar (*Cedrella odorata* L)

Location:

- Forestal concessions on the Maya Biosphere Reserve

Additional Genetic Resources Information Links:

Specmin data:

- http://www.conabio.gob.mx/conocimiento/info_especies/arboles/doctos/37-melia5m.pdf
- http://www.conabio.gob.mx/conocimiento/info_especies/arboles/doctos/36-melia2m.pdf

Information on the utilization of the genetic resource(s)

Type of use allowed by the permit or its equivalent

Non-Commercial

Specific uses covered by the permit or its equivalent or use restrictions:

Access to genetic resources on research purposes

Conditions for third party transfer:

The user is prohibited from allowing access and use by unauthorized persons to the gross or information derived from the analysis without the prior consent of the provider

Documents and Additional information

Copy of permit or its equivalent, or other relevant open-access document:

Acceso a Caoba y Cedro- Papeleria completa.pdf (<https://absch.cbd.int/api/v2013/documents/4EBE18FE-5420-8EA9-193A-18957A1709FA/attachments/Accesso%20a%20Caoba%20y%20Cedro-%20Papeleria%20completa.pdf>)

Certificate History

Date	Action	Author	Comment
30 MAR 2016 09:51 PM	PUBLISHED	Leslie Melisa Ojeda Cabrera (lojeda@conap.gob.gt)	Permit information published to the ABS clearing-house and certificate generated.

Further Information

Questions about the permit or its equivalent constituting an internationally recognized certificate of compliance should be addressed to the competent national authority issuing the permit or its equivalent. Additional information about the permit or its equivalent may be available in the Access and Benefit-Sharing Clearing House (<https://absch.cbd.int/>).

Questions about the Nagoya Protocol on Access and Benefit-sharing or the operation of the Access and Benefit-sharing Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity
413 rue Saint-Jacques, suite 800
Montreal, Québec, H2Y 1N9
Canada
Fax: +1 514 288-6588
Email: secretariat@cbd.int

Annex II

Canadian Centre for DNA Barcoding (CCDB)/Biodiversity Institute of Ontario Biological Material Analysis Agreement (BMAA) outlining standard Biological Material Transfer Conditions

Biological Material (hereafter referred to as the 'Material') includes biological specimens (whole collection vouchers, tissue samples, and/or bulk samples), as well as Genetic Material (sensu Nagoya Protocol - www.cbd.int/abs/) contained therein, transferred using the sample storage containers specified in this Biological Material Analysis Agreement (BMAA).

By signing this BMAA, the Provider (individual and/or institution) acknowledges the following:

- The Provider holds legal ownership/custodianship rights over the Material and has authority to transfer it to the Recipient for molecular analyses. The Provider shall inform the Recipient of any third-party restrictions on the storage and utilization of the Material, including those imposed by external permit-issuing authorities.
- The Material has been obtained under appropriate permits as required by its country of origin and is being transferred in compliance with all applicable national and international export/import requirements and shipping regulations. It is the Provider's responsibility to ensure that all export/import documentation required by relevant customs and conservation authorities has been obtained and attached to the shipment.
- The Material does not pose a biological or other hazard; and reasonable precautions (e.g. use of proper fixatives) have been taken to exclude potential risks to humans and the environment during shipment and processing.
- The provider should submit small (ca. 5 mg or less) tissue samples; no residual tissue will remain after consumptive analysis.
- Whole collection specimens, if submitted for processing, may be accidentally damaged or destroyed during sampling or DNA extraction ('voucher recovery'). The Provider should notify the Recipient prior to sending especially valuable (e.g. type) Material.
- Unless repatriation of specimens/tissues and/or genomic DNA has been requested in this BMAA under Special Conditions, any Material (including Genetic Material) remaining after analysis will be permanently stored by the Recipient as a permanent loan from the Provider, to ensure reproducibility of analytical results and/or taxonomic verification. If repatriation has been requested, the Provider shall assume applicable cost-recovery fees valid on the date of the request. If the Provider intends to donate the Material to the Recipient, applicable conditions would be negotiated under a separate agreement.

By accepting the Material for analyses, the Recipient (CCDB and its representatives) acknowledges the following:

- The Recipient shall respect the Provider's ownership/custodianship rights to the Material and the resulting obligations under the Provider's relevant institutional policies, national laws and international treaties (e.g., the Nagoya Protocol).
- The Recipient acknowledges that the original material and its derivatives will not be used in human subjects, in clinical trials, or for commercial purposes, and will not be forwarded to commercial organizations for the purpose of making profit.
- The Recipient will utilize the Material within the scope of analyses requested in this BMAA and in accordance with the work description, as specified below and overleaf. Unless explicitly negotiated otherwise and specified in writing, the Recipient will not use the Material for any other purpose (e.g., to analyze non-DNA barcode genetic markers). The Recipient may, however, re-analyze standard DNA barcode markers using different protocols, to attain improved results.
- Unless repatriation of the Material is requested in this BMAA, the recipient agrees to store residual Material (typically, genomic DNA only) indefinitely in a manner that excludes unauthorized third-party use. The Recipient will not transfer the Material (including Genetic Material) to any third party, without explicit written approval from the Provider; and will refer to the Provider any third-party requests to access the Material.
- Any third-party transactions of Material held in possession by the Recipient, if authorized by the Provider, shall be carried out under a separate agreement involving the Provider and the respective third party.
- If repatriation or third-party loan of the Material is requested by the Provider in this BMAA or at a later date, such requests will be fulfilled within a reasonable timeframe negotiated with the Provider.

Work Description and Pricing for Molecular Analysis – Research Projects

The CCDB agrees to perform sample processing, molecular analyses, and data validation, as per the Work Description specified in the attached Quote (referenced overleaf in this BMAA), or otherwise negotiated in writing, together with pricing and applicable conditions. Specimen data and corresponding genomic information will be submitted to the Barcode of Life Data Systems (BOLD; <http://boldsystems.org>). To qualify for discounted Reference Library pricing (if applicable), samples, provenance data and images must meet the reference library standards. Refer to <http://ccdb.ca/pricelist.php> for standard requirements, the corresponding pricing, and possible restrictions.

Data Ownership and Usage – Research Projects

As one of the leading analytical nodes of the International Barcode of Life Initiative, the CCDB is committed to the principles of rapid release and open sharing of reference DNA barcode data (including genomic data, specimen provenance information, and images) within the international research community. Contributors are encouraged to initiate pre-publication release of their data. The CCDB does not claim intellectual property over data submitted or over genomic information generated during analyses.

The Barcode of Life Data Systems (BOLD; <http://boldsystems.org>) is the standard data repository and analytical workbench used by the CCDB to submit reference DNA barcode data. BOLD is a project operated independently from the CCDB under a Creative Commons license. As such, BOLD implements its own standards and policies for storing and using the data submitted. Generally, information contained in BOLD data records (museum collection information, detailed geographic origin, DNA barcode sequences and other details) is not disclosed through BOLD, unless the corresponding project or dataset is published by its contributor.

IMPORTANT: Unless explicitly excluded from the reference library, sequence data contained in BOLD (including unpublished projects) may be used by the BOLD Identification Engine (http://www.boldsystems.org/index.php/IDS_OpenIdEngine) to provide DNA-based taxonomic identifications to public users. Reports generated by the ID Engine include similarity scores and neighbour-joining trees containing information on taxonomy and geographic origin. As well, provenance data and images submitted to BOLD become publicly visible through the public BOLD Taxonomy Browser (http://www.boldsystems.org/index.php/TaxBrowser_Home). This information may be used to generate summary statistics and illustrative distribution maps.

If you do not wish to disclose any data through the BOLD public interface, please contact the BOLD data management team at support@boldsystems.org or your CCDB representative to opt out. Such data may not qualify for discounted analytical rates.

