

# Background

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## Introduction

In this concept paper we describe the use of the national research permit system as a platform for administering ABS permits, monitoring compliance and realising non-monetary and monetary benefits arising from collaborations with non-commercial and commercial researchers and research organisations under the Nagoya Protocol. We describe a model for an online permit and monitoring system for the efficient administration of research permits that can be linked to monitoring of scientific literature, patents and commercial products.

The purpose of the model is to support the implementation of domestic access and benefit-sharing frameworks and implementation of the obligations under the following articles of the Nagoya Protocol:

1. Implementation of Article 6 on access to genetic resources,
2. Fair and equitable benefit-sharing in connection with research under Article 5,
3. Monitoring under Article 17
4. National reporting under Article 29 of the Nagoya Protocol.

The aim of this proposal is not to promote a one size fits all approach but instead to provide a model that is flexible and can be readily adapted to the specific needs of individual Parties to the Nagoya Protocol. We envisage the creation of an informal open coalition of countries with a common interest in an electronic permit and monitoring system that can be adapted to meet their particular circumstances and needs.

The core of this proposal is that Parties to the Protocol, and governments who intend to ratify the Protocol, may wish to adopt:

“A single electronic permit system that makes it easy to apply for permits and for government authorities to review and approve applications, monitor compliance and report on the access, benefit-sharing, compliance and reporting provisions of the Nagoya Protocol.”<sup>1</sup>

The majority of countries will already possess research permit systems. The available evidence suggests that in many countries there may be multiple permit granting authorities who administer research permits within their respective mandates. An important feature of this proposal is that *we do not suggest* that the administration of all ABS related research permits should be transferred to a single permit granting authority. Instead, recognising the diversity of legislative mandates of permit granting authorities within a country, we propose that a single online permit system should be implemented to serve the needs of multiple permit authorities. This approach can be described as *a single online permit system with multiple authorities*.

The aim of this model is two fold:

1. To provide a single electronic hub or platform for the administration of research permits that meets the requirements of permit authorities and simplifies administration, monitoring, and reporting in the fulfilment of their respective mandates.

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<sup>1</sup>Oldham, P (2015) Concepts for an Electronic Monitoring Tool. UNEP/GEF project “Strengthening Access and Benefit Sharing (ABS) in the Bahamas”

2. To simplify the research permit application and reporting process for non-commercial research under Article 8(a) of the Nagoya Protocol and for commercial research and development while enhancing the capacity of countries to realise non-monetary and monetary benefits under the terms of the Nagoya Protocol.

More specifically we anticipate that implementation of the model will:

1. Make it easier for Parties to the Protocol to review and administer permit applications;
2. Make it easier for applicants to apply for and receive a permit and obtain legal certainty based on compliance with the terms and conditions of the Party providing access;
3. Enhance the capacity of Parties to the Protocol to determine if a permit application triggers domestic access and benefit sharing requirements and obligations under the Nagoya Protocol;
4. Enhance the capacity of Parties to the Protocol to realise non-monetary and monetary benefits arising from both non-commercial research and commercial research and development involving genetic resources and associated traditional knowledge over the long term;
5. Enhance the capacity of Parties to the Protocol to determine the actual and potential value of their genetic resources through a long term electronic monitoring system;
6. Make it easier for Parties to meet national and international reporting requirements under the Nagoya Protocol and related international environmental agreements.

## Background

Researchers seeking to collect biological specimens, to work in protected areas, or to work with indigenous peoples and local communities are routinely expected to apply for a permit to carry out research. This is particularly true for researchers from foreign countries but is also true for domestic researchers.

Research permits frequently set out terms and conditions on the types of collections that may be undertaken and the geographic areas where research and collections may be conducted. It is quite common for research involving biological collections to require permission from more than one permit granting authority. Field research directed to commercial research and development may be subject to additional requirements and require export licences.

In the case of research involving human subjects, such as indigenous peoples and local communities, researchers will generally be expected to secure research permits from the relevant authorities, and to comply with standards for ethical conduct. In countries with indigenous peoples, specific provisions may apply for conducting research in indigenous communities.<sup>2</sup> Other conditions may apply to research with members of society who are may be classified as vulnerable (e.g. minorities, women, children, persons with disabilities). Professional researchers are accustomed to meeting requirements for research permits and recognise their importance for developing longer term research collaborations that both benefit their research careers and contribute to the knowledge base in the countries where they work.

In return for obtaining a permit, applicants will normally be expected to meet certain conditions. These conditions will vary from one country to another but for foreign researchers commonly include:

1. Requirements for collaboration with local research organisations as research partners.
2. The deposit of biological samples with national institutions (such as herbaria).
3. The provision or deposit of equipment used during the research with local partners.
4. Reports on activities and copies of publications.

Requirements for local research collaboration are important for the development of local research capacity in specialist areas and create the foundations for longer term research collaborations and interchanges between

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<sup>2</sup>Examples of such guidelines in the case of indigenous peoples include the Australian Institute of Aboriginal and Torres Strait Islander Studies, Guidelines for Ethical Research In Australian Indigenous Studies 2012 and Chapter 9 of the Canadian Research Councils Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

countries. Many countries, including the European Union, have developed special programmes to promote international research collaboration (such as the UK Darwin Initiative among others) that emphasise benefits for partner countries and communities.

The outcomes of research collaborations enabled by permits include:

1. Research funding for researchers and equipment in partner countries
2. Training, including schemes for researcher exchanges and degree or advanced level qualifications
3. Scientific publications, reports, datasets, deposits of samples etc. that improve the knowledge base about biodiversity and genetic resources in a country.

These outcomes are typically categorised as non-monetary benefits but are in practice supported by definable financial investments by external research agencies and contributions from local partner agencies and organisations. As such, there is a direct relationship between research permits and forms of benefit-sharing.

However, the extent to which the terms and conditions in research permits are legally-binding upon researchers once they are outside of national jurisdictions is open to question. For this reason, the use of ABS contracts establishing Mutually Agreed Terms (MAT) on benefit-sharing at the time when access is granted in accordance with the Convention and the Nagoya Protocol are regarded as necessary. Article 6 of the Nagoya Protocol establishes that Parties requiring prior informed consent will:

“Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly (Article 6.3(e))”

As this makes clear, under the Nagoya Protocol, there is a direct relationship between a research permit and the establishment of mutually agreed terms (MAT), with the MAT typically involving an ABS contract. In the paper we use the term research permit issued under the online system interchangeably to mean a research permit and associated MAT or ABS contract.

The permit providing evidence of prior informed consent and mutually agreed terms is linked to monitoring provisions under Article 17 of the Nagoya Protocol which, inter alia, specifies that:

“To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

2. 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.
3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.”

There is therefore a close relationship between a permit under the Nagoya Protocol as evidence of prior informed consent and the establishment of MAT and monitoring of compliance. However, it is also important to recognise that there are distinctions between types of research involving genetic resources and associated traditional knowledge that may trigger different procedures and MAT under the Nagoya Protocol.

## Permit Systems and Types of Research

As discussed during negotiation of the Nagoya Protocol distinguishing between types of research involving genetic resources and associated traditional knowledge is difficult because the distinction between non-commercial and commercial research is mainly located at the level of the *intent* of researchers rather than in methods, techniques and materials. Focusing on clarifying the “why” of particular research and identifying specific situations is in our view likely to lead to effective approaches to administration. Here we identify five broad situations that are likely to emerge over time in implementing the Nagoya Protocol.

### Non-commercial research

In practice, many (and possibly the majority) of cases of research involving biodiversity, genetic resources and indigenous peoples or local communities will be non-commercial. Article 8(a) of the Nagoya Protocol establishes that:

“In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

- (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;”

As this makes clear Parties will create conditions to encourage research contributing to conservation and sustainable use including simplified measures on access for non-commercial research.

The implication of this for the research permit system is that simplified measures could be developed to provide access using standard mutually agreed terms. Where an applicant agrees to the standard mutually agreed terms for non-commercial research (which might simply involve a tick to a check box signifying acceptance of such terms), and subject to acceptance of any other non-ABS requirements, a permit could simply be granted.

### Changes of Intent

However, as set out in Article 8(a) the negotiators of the Nagoya Protocol also recognised that what may begin as non-commercial research may become commercial research or “utilization” in the language of the Protocol.<sup>3</sup> It is therefore important that the terms and conditions of permits and associated standard MAT identify change of intent as a trigger for a requirement to return to the provider country for new or renewed prior informed consent and applicable mutually agreed terms for commercial research.

### Mixed Research

A third situation may arise where applicants apply for a permit to conduct both non-commercial research and commercial research, or, in other words, research of a mixed type. This situation is perhaps more likely to arise where *consortiums* of researchers from different public or private organisations are involved in applications for research permits. This situation may be more likely to arise where research locations are remote or involve extreme conditions (e.g. marine research at depth). In these circumstances it may be appropriate to attempt to clearly distinguish between prior informed consent and MAT for non-commercial aspects of the research and those involving commercial research and development (e.g. focusing on a specific

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<sup>3</sup>Article 2(c) specifies that: “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 as defined in Article 2 of the Convention

species). Alternatively, it may be appropriate to require MAT applicable for commercial research in the interest of certainty on the part of the provider country. This potential situation signifies that a research permit system should make provision for the possibility of permit applications for both non-commercial and commercial research.

## **Commercial Research**

The fourth situation involves cases of explicit commercial research and collection. Viewed from the perspective of the permit system it is likely to be desirable that commercial research is signalled at the application stage and triggers a procedure for the negotiation of MAT with the applicants within a reasonable period of time (Article 6.3(d)). While it may be desirable to develop a standard template for MAT for commercial research this is likely to serve as the starting point for a negotiation phase in arriving at mutually agreed terms and granting prior informed consent.

## **Research Involving Indigenous Peoples and Local Communities**

As noted above, research involving human subjects, such as indigenous peoples and local communities, is typically the subject of requirements for permits both from relevant authorities (such as Ministries for Indigenous Affairs or their equivalent), subject to requirements for ethical conduct (including by agencies funding the research) and the prior informed consent of the participating communities and research participants.

Article 6.2 of the Nagoya Protocol specifies that:

“In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.”

Article 6.3(f) further specifies that Parties shall:

“Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources.”

Article 5.2 of the Nagoya Protocol on benefit-sharing focuses on circumstances where indigenous peoples and local communities hold genetic resources:

“Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.”

Article 5.3 focuses on benefit-sharing in connection with the utilization of traditional knowledge associated with genetic resources:

“Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.”

The emphasis in the Protocol with respect to prior informed consent with respect to a permit and monitoring system is placed on ensuring, in the relevant circumstances, that prior informed consent is obtained and setting out criteria or process for obtaining prior informed consent. In this respect, the emphasis is likely to be placed on the provision of information on how an applicant for a research permit might go about obtaining prior informed consent from relevant indigenous peoples and local communities.<sup>4</sup>

### **Avoidance of prior informed consent and mutually agreed terms**

A final situation of relevance to an online permit and monitoring system is a situation where an individual researcher or organisations seeks to avoid requirements for prior informed consent and mutually agreed terms altogether. In this situation the permit system will normally be blind.

In this proposal we provide for a fall back position in the monitoring system that uses automated searches to capture publications, patent applications and other electronic materials making reference to a country and its biodiversity. While no system will be perfect, the growing availability of large scale digital data and digital methods will increasingly allow for the capture of cases of avoidance and, among member states of the European Union, failures to perform due diligence.<sup>^</sup>[EU Regulation No.511/2014)

The issue of avoidance of ABS regulations is however linked to enhancing the general capacity of Parties to know, in empirical terms, what is happening with genetic resources and associated traditional knowledge from within their jurisdictions.

### **Addressing the Capacity to Know through Monitoring**

A fundamental precondition for the successful implementation of the Nagoya Protocol on the national and international level is the capacity of Parties to know that the terms and conditions set out in permits and associated mutually agreed terms (ABS contracts) are being complied with by recipients. As noted above, Parties will also need to know when efforts are made to avoid requirements for prior informed consent and mutually agreed terms.

Research permit data provides the basic building blocks for identifying research activity involving genetic resources and associated traditional knowledge originating from a country that appears in data sources including:

1. Research publications on biodiversity, genetic resources and the traditional knowledge of indigenous peoples and local communities.
2. Patent applications and grants (as an indicator of commercial research & development).
3. Applications for market approval and products arising from utilizations of genetic resources and associated traditional knowledge.

The key to the use of the permit system as a tool for monitoring is to use the information provided by applicants (name, organisation etc.) and specifics of the permit data as inputs to search and compile information from other electronic data sources such as:

- Taxonomic data (e.g. The Global Biodiversity Information Facility, Encyclopedia of Life, Catalogue of Life, NCBI, The IUCN Red List etc.).
- Electronic literature sources (such as crossref or PubMed or Europe PMC using APIs (Application Programming Interfaces) providing free access to literature data such as author and organisation names, titles and abstracts.<sup>5</sup>

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<sup>4</sup>See for example the recently developed voluntary guidelines on prior informed consent from the Ninth meeting of the Working Group on Article 8j and related provisions sent for consideration by COP13 in document UNEP/CBD/COP/13/3 at 19/1

<sup>5</sup>Application Programming Interfaces are web services that use URL queries to obtain data directly from the electronic database sitting behind a web server. They are very similar to normal web queries except that larger amounts of data and specific data fields can be retrieved and the data is provided in either XML or JSON format.

- Patent data using services such as WIPO Patentscope or the European Patent Office Open Patent Services.
- Product information including product registration/marketing authorization data.
- The results of general web searches or searches of social media.

The combination of data from different electronic sources to address particular questions is a fundamental feature of the rise of informatics and analytics. Within the biodiversity informatics community, it is manifest in the creation of databases of basic taxonomic data that are linked to the scientific literature, images, video and georeferenced data in other databases. This trend is set to accelerate as more data sources become freely accessible using Application Programming Interfaces (APIs) and the funders of research promote open access to data as a condition of research funding for non-commercial research.

The model presented below would allow a Competent National Authority to perform regular automated searches in online databases. Based on information provided by applicants searches could be conducted for publications by a researcher, publications from a permit holding organisation, or searches linked to a specific species or genetic data linked to a permit. The growing use of electronic researcher IDs (such as ORCID, Researchgate or ResearcherID) could reduce the need for researchers to report on publications and provide data in an electronic format that can be shared with others and is more amenable to analysis. In a short space of time it would be possible for a Competent National Authority to compile an electronic archive on biodiversity and ABS related research in the country that could be publicly shared and help to demonstrate the benefits of research on biodiversity and genetic resources within the country.

While information provided by applicants provides the core data for monitoring the system would be able to perform automated searches of data sources for information on references to the country in publications in connection with a species. For example this search highlights publications containing a reference to Kenya and the word species recorded in the non-profit crossref database of over 81 million journals, books and datasets. This search does the same for the Seychelles. In short, the growing availability of large scale open access databases provides important opportunities for cost effective monitoring.

The use of electronic monitoring and analytics based on permit data and independent searches would allow Competent National Authorities to:

- Check compliance with MAT provisions related to information in publications
- Check compliance with MAT provisions related to information in patent applications
- Identify cases of utilization that appear not to be based on ABS permits and ABS contracts.

## **Enhancing Understanding of the Value of Genetic Resources and Traditional Knowledge**

One important challenge confronting countries involved in the negotiation of the Nagoya Protocol was the lack of reliable information on the economic value of genetic resources and associated traditional knowledge. Furthermore, as is now widely recognised, biodiversity and the knowledge, innovations and practices of indigenous peoples and local communities cannot be reduced purely to economic value. Rather, a broader approach to valuation, including ecosystem services, is required. A fundamental precondition for this type of analysis is data. The approach presented below would facilitate evidence based valuation of genetic resources and associated traditional knowledge over the long term and using a range of approaches to the definition of value.

## **Conclusion**

In this section we have explored the background to the proposed model for an online permit and monitoring system provided below. We have argued that the effective implementation of the Nagoya Protocol will require recognition of the importance of linking permit data with recognition of the possibilities for cost effective

monitoring opened up by the rise of large scale electronic data about biodiversity. This combination provides important opportunities to increase the confidence of provider countries in ABS and thus contribute to the successful implementation of the Nagoya Protocol. At the same time, permit systems and access and benefit-sharing require a vision that may span decades. For that reason in presenting the model system we encourage Parties to take a long term perspective.