Consortium of European Taxonomic Facilities (CETAF)

Code of Conduct and Best Practice for Access and Benefit-Sharing

In Memoriam

This Code of Conduct and Best Practice has been developed by the CETAF Legislation and Regulation core team, who wants to expressly dedicate it to Johan Bodegård, deputy Director of the Natural History Museum of Stockholm (SE) whose wise guidance, permanent support and judicious advice have made this possible. Our respected colleague passed away on 31st August 2017.

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Introduction

CETAF, the Consortium of European Taxonomic Facilities, is a networked consortium of non-commercial scientific institutions in Europe formed to promote training, research and understanding of systematic biology and palaeobiology. Together, CETAF institutions hold very substantial biological (zoological and botanical), palaeobiological, and geological collections and provide the resource for the work of thousands of researchers in a variety of scientific disciplines.

CETAF has developed and adopted this Code of Conduct for Access and Benefit-Sharing, together with the annexed Best Practice, as a response to Article 20 in the Nagoya Protocol, *Regulation 511/2014 of the European Parliament and Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of*

Benefits Arising from their Utilisation in the Union (hereafter the 'EU Regulation') and the subsequent *Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices* (hereafter the 'Implementing Act') and specifically in response to Articles 8 and 13 of the EU Regulation. Throughout the Code of Conduct, Best Practice and other annexed documents, the term 'Biological material' is to be read as including the genetic resources that are within that material.

The principles and practices stated below are designed to fully support CETAF members' operations as taxonomic collection-holding and non-commercial biological research institutions in complying with Access and Benefit Sharing (ABS) legal and ethical requirements[1]. The documents (i) outline the Code of Conduct governing principles under which collections are managed and collection-based research conducted in CETAF member institutions; (ii) provide details of best practices to ensure implementation of those principles, and guidance on ABS-relevant actions to be taken by institutions and individuals in common workflows (Best Practices, **Annex 1**); (iii) provide a selection of tools and check lists to support the advice given (Practical Guidance, **Annex 5**).

The CETAF Code of Conduct was developed by CETAF's *Legislations and Regulations Liaison Group*. They drew on their understanding of the processes and practices of their institutions, their understanding of the Nagoya Protocol and its implications, and a wide range of existing Codes of Conduct and Best practice documents, including particularly the *Principles on Access to Genetic Resources and Benefit-Sharing* for Botanic Gardens[2], the Swiss Academy of Sciences model Agreement on Access and Benefit Sharing for Non-Commercial Research[3], and the Code of Conduct of the International Plant Exchange Network (IPEN)[4].

[1)] For EU members, enabling them to comply with the EU Regulation and subsequent Implementing Act
[2)] http://www.bgci.org/resources/article/0007/
[3)] http://abs.scnat.ch/downloads/index.php
[4)] http://www.bgci.org/resources/Description_of_IPEN/

The Code of Conduct document below has several mutually-supporting sections annexed:

The Code of Conduct. This sets out the basic principles to which CETAF members will abide.

Best Practice (**Annex 1**)**.** This provides detail of how the Code of Conduct should be implemented in practice to manage ABS inside institutions.

Use of Biological Materials statement (**Annex 2**). This is a tool for use when seeking permission to access biological material, whether for utilisation or not. If proposed clauses are inapplicable or fail to meet the particular needs of either contracting party, or are rejected by the Providing country, they may be deleted. Annexing this statement to an agreement is intended to provide legal certainty over possible use of any material acquired.

Glossary (**Annex 3**). This explains the terms used elsewhere in the document.

Non-monetary benefits (Annex 4). Non-exhaustive but indicative list from the Nagoya Protocol Annex.

Practical Guidance (**Annex 5**). This provides a set of checklists as a tool to help users and their institutions be sure that compliance requirements are met.

Complementary Documentation (A): Material Transfer Agreements. These are models for use in acquiring material or transferring it temporarily or permanently to third parties. They may be modified according to the individual needs of an institution.

Complementary Documentation (B): Data use statement. This may be included in any publication to inform subsequent users that the original material was accessed under conditions that might preclude a change in use.

CETAF Code of Conduct on Access and Benefit-sharing

CETAF Member Institutions commit themselves to the following Code of Conduct on access to genetic resources and benefit-sharing. This Code of Conduct applies to biological material[5] that is accessed, i.e. acquired newly from a Providing Country, after the entry into force of the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity* (hereafter referred to as the *Nagoya*

[5)] The term '*biological material*' is used throughout the documents because it describes all material in CETAF Member Institution collections, regardless if it contains 'functional units of heredity' or not. 'Genetic resources' is used when specifically referring to 'utilisation' within the scope of the Nagoya Protocol. The CBD and the Nagoya Protocol define '*genetic resources'* as 'genetic material of actual or potential value', and '*genetic material'* as 'any material of plant, animal, microbial or other origin containing functional units of heredity'.

Protocol). Participating institutions are encouraged to apply this Code of Conduct, as far as reasonably possible, also to all other biological material in their collections[6].

Convention on Biological Diversity and laws related to access to genetic resources and associated traditional knowledge and benefit-sharing

Participating institutions will:

- Honour the letter and spirit of the Convention on Biological Diversity (CBD), The Nagoya Protocol (NP), and other relevant international agreements.
- Abide by international and national laws and regulations relating to Access and Benefit-sharing[7].
- If Genetic Resources (GR) and particularly Traditional Knowledge associated with Genetic Resources (TKaGR) is obtained from indigenous and local communities, the views and position of the indigenous and local communities holding the GRs or TKaGR should be taken into account and may be reflected in mutually agreed terms, even if this is not required by the national legislation.
- Comply with Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and other agreements entered into with the Providing Country and Providers within that country.

Acquisition of biological material

Participating institutions will:

- In order to obtain Prior Informed Consent (PIC), provide a full explanation of the purposes for which biological material will be used and how genetic resources will be utilised (within current technical understanding).
- When acquiring biological material from *in situ* conditions, obtain information on the Providing Country's access laws.
- If required by legislation or regulation in the Providing Country, (i) obtain information on the Providing Country's procedures for obtaining Prior Informed Consent and relevant permits and for agreeing Mutually Agreed Terms (MAT), and (ii) obtain Prior Informed Consent and relevant permits from the Government of the Providing Country and other relevant stakeholders as required under national law, and (iii) agree terms, according to applicable law and best practice.
- When acquiring biological material from *ex situ* collections, agree terms with the body governing the *ex situ* collection under which the material can be used.
- When acquiring or otherwise receiving biological material for purposes other than utilisation of genetic resources from *ex situ* sources, whether from scientific collections, commercial

6) While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

7) In case of conflict between national law in the home country of the institution and the CETAF Code of Conduct, national law will take precedence.

sources or individuals, evaluate provenance and available documentation. Where necessary, take appropriate further steps to ensure that the biological material was acquired in accordance with applicable law and that the legal status of the material is clear. For subsequent utilisation see first bullet point under *Utilisation of genetic resources* below; requirements are explicit.

- When receiving genetic resources for the purposes of utilisation from *ex situ* sources, whether from scientific collections, commercial sources or individuals, evaluate provenance and available documentation and, where necessary, take appropriate further steps to ensure that the genetic resources were accessed and can be utilised in accordance with applicable law.

Utilisation of genetic resources

Participating institutions will:

- Only utilise genetic resources after performing due diligence[8] to ensure that they were accessed in accordance with applicable ABS legislations or regulations and can legally be utilised, and obtaining documentation to demonstrate this.
- Utilise genetic resources on terms and conditions consistent with those under which they were accessed or otherwise acquired.
- Renegotiate Prior Informed Consent and Mutually Agreed Terms if the participating institution wishes to utilise genetic resources in a different way to those set out in the original agreements.

Supply of biological material to Third Parties

Participating institutions will:

- Supply biological material to Third Parties on loan only on terms and conditions consistent with those under which it was acquired.
- Supply biological material for subcontracted work on genetic resources, such as to sequencing companies, only in compliance with the terms and conditions under which they were acquired, and set conditions in a contract that prohibit independent utilisation.
- Supply biological material permanently to Third Parties only on terms and conditions consistent with those under which they were acquired and with copies of the documentation showing agreements with the Providing Country, where applicable, including Prior Informed Consent, Mutually Agreed Terms or other relevant documents.

Use of written agreements

Participating institutions will:

[8] In the context of the EU Regulation

- Acquire biological material using written agreements providing legal certainty and ensuring that there is a record of relevant documents such as Prior Informed Consent and Mutually Agreed Terms.
- Supply biological material to Third Parties using written Material Transfer Agreements (MTAs), setting out the terms and conditions under which the biological material may be acquired, used and supplied and resulting benefits shared.

Traditional Knowledge associated with Genetic Resources

Participating institutions will:

- Acquire Traditional Knowledge associated with genetic resources using written agreements providing legal certainty and ensuring that there is a record of relevant documents such as Prior Informed Consent and Mutually Agreed Terms.
- Use and supply Traditional Knowledge associated with Genetic Resources only in accordance with the terms and conditions under which it was acquired.

Benefit-sharing

Participating institutions will:

- Share benefits arising from their utilisation of genetic resources and associated Traditional Knowledge fairly and equitably with the Providing Country and other appropriate stakeholders[9].
- Strive to share benefits arising from the new utilisation of genetic resources accessed or otherwise acquired prior to the entry into force of the Nagoya Protocol, as far as reasonably possible, in the same manner as for those acquired thereafter[10].

Benefits may include any of those listed in the Annex to the Nagoya Protocol, although because of the not-for-profit nature of the work of the Participating Institutions are most likely to be non-monetary, *inter alia*: scientific training, education, capacity building, transfer of technologies, collaboration on scientific work programmes, and the mutual sharing of research results and of associated publications (see **Annex 4** to this document).

Curation

Participating institutions will develop appropriate internal mechanisms and procedures based on information in this Code of Conduct and its annexes to:

[9] as agreed in Prior Informed Consent and Mutually Agreed Terms at the time of Access, or as renegotiated following a subsequent change of use

[10] While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

- record the terms and conditions under which biological material is accessed or otherwise acquired, but always including the original Prior Informed Consent and Mutually Agreed Terms / permit conditions, when such agreements were issued by the Providing country;
- record relevant information on their utilisation of genetic resources or traditional knowledge associated with genetic resources, and benefits arising from that utilisation;
- record supply of biological material to Third Parties permanently or on loan, including the terms and conditions of supply; and
- record when and how biological material or traditional knowledge associated with genetic resources passes permanently out of custodianship, including complete consumption of samples or disposal.

Policies

Participating institutions will:

- Prepare, adopt and communicate institutional policies setting out how the Participating Institution will implement this Code of Conduct.
- Prepare a transparent policy on utilisation of genetic resources and traditional knowledge associated with genetic resources.

Consortium of European Taxonomic Facilities (CETAF)

ANNEX 1 to the CETAF Code of Conduct on ABS

CETAF BEST PRACTICE on Access and Benefit-Sharing

This Best Practice on Access and Benefit-Sharing (the "Best Practice") has been produced in response to Article 20 of the Nagoya Protocol and Article 8 of *Regulation 511/2014 of the European Parliament and Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union* (hereafter the "EU Regulation") and the subsequent *Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices* (hereafter the "Implementing Act") to guide Institutions on the implementation of the Code of Conduct. It supports CETAF members to establish ABS measures[11], the policies and practices herein are not, however, restricted in applicability to the EU Regulation[12].

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11) CETAF General Meeting approved the CoC and BP in October 2015

12) CETAF Members are from EU countries as well as from EU associated countries

Preamble

These Best Practice components are designed to assist institutions in implementing the CETAF Code of Conduct on Access and Benefit-Sharing. The Best Practice gives practical guidance for the day-to-day work of the institution, so that:

- it can fulfil its legal obligations and understand its rights and responsibilities resulting from the implementation of the Nagoya Protocol on Access and Benefit Sharing in the Provider and User Countries in which it operates;
- it can negotiate and enter into relationships with Providers of genetic resources, biological material and associated Traditional Knowledge, and deal with any contractual matters that may result from such agreements;
- its staff, authorised visitors and associates abide by appropriate national and international laws and regulations when working in or on behalf of the Institution. If Genetic Resources (GR) and particularly Traditional Knowledge associated with Genetic Resources (TKaGR) are obtained from indigenous and local communities, the views and position of the indigenous and local communities holding the GR or TKaGR should be taken into account and may be reflected in mutually agreed terms, even if this is not required by the national legislation[13]
- the Institution, its staff, authorised visitors and associates[14] comply with the EU Regulation, the Implementing Act, and the relevant National legislation;
- biological material and associated Traditional Knowledge[15] entering the collections is obtained with appropriate legal certainty and can legally be retained;
- temporary and non-temporary supply of specimens to any Third Parties is documented as required to meet relevant legal and contractual obligations; and
- the documentation legally required in this process is managed effectively to enable its retention, rapid retrieval and compliance with its terms.

[13] The requirements of Providing countries in regard to indigenous communities and the legal status and official recognition of customary laws of such local communities may differ from country to country. *In-situ* collecting in areas with indigenous communities should only be carried out with prior consent of such communities.

[14] i.e. staff, whether onsite or elsewhere, including when working as a visitor in another institution; students attached to the Institution; associates (e.g. Research Associates, Honorary Associates); volunteers; visitors working in the Institution, and anyone authorised to use the name of the Institution in their activities.

[15] Although the wording of the Nagoya Protocol refers to 'traditional knowledge associated with genetic resources' such TK tends to be accessed into collections associated with biological material, irrespective of whether that material contains functional units of heredity, or not.

Tools in this Best Practice fit closely to the requirements of the EU Regulation, while offering necessary flexibility for adaptation under national laws of the home countries of CETAF Members inside and outside the EU.

In order to comply with ABS regulations and function effectively, Institutions[16] and their staff[17] should:

1. **Acquire** only biological material and associated Traditional Knowledge (TKaGR) that has been legally accessed[18] (whether from *in-situ* or *ex-situ* sources);
2. **Manage** collections and associated data in a way that the Provider of the biological material, including any subsamples, can be traced and that any related terms and conditions are easily accessible;
3. **Use**[19] biological material and TKaGR only in a way that is consistent with the terms and conditions under which it was acquired;
4. **Supply biological material and associated traditional knowledge** to Third Parties for their use only on terms and conditions that are consistent with those under which the material was acquired, and with relevant documentation;
5. **Share benefits** with the Provider as agreed in Mutually Agreed Terms (MAT), permit conditions and analogous contracts;
6. **Seek new Prior Informed Consent** (PIC) and **renegotiate Mutually Agreed Terms** (MAT) in case of proposed change in utilisation from that previously agreed;
7. **Develop institutional policies;** and
8. **Train their staff** and inform authorized visitors and associates.

This Best Practice applies to biological material accessed after the entry into force of the Nagoya Protocol (12 October 2014). CETAF members and other participating institutions are encouraged to apply this Best Practice, as far as reasonably possible, also to all other biological material in their collections[20].

Tools to assist organisations and individuals understand ABS and the Nagoya Protocol are given on the Practical Guidance (**Annex 5**) Sections *"Getting Started"* and *"Institutional Management"*.

1. Acquisition of biological material

There are different ways of acquiring biological material: collecting in the field (*in-situ*) and acquisition from *ex-situ* sources (e.g. collections inside or outside the original Providing Country), either by permanent (e.g., exchange, donations, sharing of tissue or DNA samples) or temporary supply (e.g., loans).

16) In the following the term "Institution(s)" refers to those bodies adhering to the CETAF Code of Conduct and Best Practice.

17) In the following the term "staff" is used as a general term, but Institutions should make sure that not only employees but also associates and any other individuals authorised to act in the name of the Institution are informed and abide by relevant ABS policies, regulations and legislation.

18) See Annex 3 - Glossary for a definition of "Access".

19) See "Statement of Use of Biological Material" for a description of the spectrum of "use".

20) While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

Institutions should exercise due diligence to ascertain that Genetic Resources (GR) and Traditional Knowledge associated with Genetic Resources (TKaGR) which they utilise have been accessed in accordance with applicable ABS legislation or regulatory requirements[21]. Section 2.1 lists the information required to be able to exercise due diligence in this regard according to the EU Regulation and Implementing Act.

When signing agreements such as MAT or Material Transfer Agreements (MTA), Institutions should refer to the legal framework governing the collections and ensure that it can accommodate requirements of those agreements, including persistent obligations (i.e. those which will persist for the lifetime of the specimens being in the custody of the Institution, which may extend indefinitely).

In order to facilitate this, Institutions should designate one or more individuals (e.g. director, conservator or any other technical staff) to handle such legal matters and authorise agreements such as MAT or MTAs[22].

Institutions should make sure that their internal policies and procedures relating to material entering their premises cover the following ABS aspects, if applicable:

a. Field Collecting (see Section 1.1.)
b. Object Entry[23], governing what legal documentation is required by the Institution when biological material is received, either unsolicited (see Section 1.4), temporarily (see Section 1.2) or permanently (see Section 1.3).

For practical guidance see **Annex 5** Section *"Acquiring GR from in-situ or ex-situ sources in Providing Countries (including field collecting)"*.

1.1. Acquisition from *in-situ* sources (fieldwork)

Permission from the Providing Country to undertake fieldwork and collect biological material will typically include Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), which may be combined in a permit. Staff may have to negotiate and agree these with the Providing Country prior to the start of fieldwork, depending on the applicable laws and regulations of the Providing Country, and whether or not the fieldwork is taking place as part of a larger project for which negotiations have already taken place. Institutions should develop systems so that staff are aware of the permissions and legal documentation required[24], and seek to obtain the relevant documentation

21) Note that the term "access" has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations. Therefore it is recommended to include an agreed definition in all legal documents.

22) For example, the Natural History Museum in London (NHMUK) requires Memoranda of Cooperation to be signed by the Director of Science, but individual staff may be permitted to sign collecting permits (or PIC and MAT) in Providing Countries. NHMUK also has a Registrar with the responsibility of overseeing all legal agreements and providing advice to staff.

23) Objects may include biological material but also substances that could contain biological material, such as soil samples.

24) Set procedures should include use of the ABS Clearing House and seeking advice from National Focal Points, among others. For example see recommendations at the following link: http://nagoyaprotocol.myspecies.info/node/16

from the Competent National Authority within the Providing Country [25]. Institutions and staff should be aware, when contacting the Competent National Authority, that other offices might need to be contacted as well (e.g. separate export or research permits may be required), depending on the Providing Country's legislation. If a Providing Country grants free access, institutions are advised to positively document that access was not restricted and that no permits for access of biological material were required or have been issued[26].

Indigenous and Local Community customary laws and community protocols should be taken into account and reflected in mutually agreed terms, even if this is not required by the national legislation.

Staff should not start any fieldwork until the required permits are agreed and finalised, or appropriate written guarantees received. Fieldwork in a Providing Country is to be carried out only in accordance with the laws and regulations of that country.

Institutions should draw up guidelines to assist staff in this formal process, including clear rules on who is authorized to sign any agreements. Staff should only sign MAT (e.g. conditions in permits) if the Institution is able to meet the terms agreed. When negotiating PIC and MAT, the Institution or its staff must be clear about the purposes for which the material will be used at the Institution[27]. Institutions and their staff are encouraged to refer to the CETAF "Statement of Use of Biological Material", because it sets out the typical ways in which biological material may be used by CETAF members. This document (see **Annex 2**) is intended for use in discussions with Providers of biological material when seeking access. It might also be used in donations or exchanges of material, or when material is provided unsolicited such as for identification. By its use ambiguities or uncertainties regarding uses of the material can be avoided. It should be provided to Competent National Authorities in Providing Countries, and with their agreement annexed to an agreement. If Providers do not wish their material to be treated in a way listed in the document, or wish to place any specific restrictions, staff should ensure that this is expressly set out in writing in the agreement or permit, or (and) the relevant elements of the document deleted. Written restrictions and conditions in a permit or equivalent will always take precedence over the text of the use statement.

Where possible and appropriate, fieldwork should be conducted as part of a collaborative venture with a museum, botanic garden, university or other recognized scientific research organization in the

25) With pending international and national ABS legislation inside and outside the EU, Institutions and particularly individual researchers and curators should carefully check and compare laws as soon as they enter into force to determine if specific access restrictions and reporting obligations need to be considered. Relevant information on national ABS legislation and Competent Authorities can be obtained from the ABS clearing house website (https://absch.cbd.int/).

26) e.g. by recording positive replies of respective Competent National Authorities.

27) It is advisable to consider and cover – as far as foreseeable and possible – any potential future uses beyond current specific research projects for which PIC & MAT are negotiated. The proposed use should be as broad as possible and not be limited to a specific technique, keeping in mind that samples persist in collections (if not consumed by the current project). This could help to avoid new negotiations being triggered due to novel analytical and technical advances even though the purpose of the research is unchanged.

Providing Country. Such collaboration can be included in the MAT as a direct benefit arising from the fieldwork[28]. In cases where an institution conducts long-term or repeated projects in a Providing Country, it might be beneficial to develop framework agreements with the Competent National Authority of that country.

Activities that involve collecting specimens or samples by staff and associates, and any other individuals using the name of the Institution, should be carried out only for and in the name of the Institution responsible for the fieldwork; any additional acquisition of biological material for private or other use, including on behalf of or for sale to Third Parties, should be prohibited by the Institution[29].

1.2. Temporary acquisition from *ex-situ* sources

This covers all cases where material is not transferred into ownership of the Institution and/or is not accessioned into its collections.

Internal policies or procedures should set out conditions under which loans of material from outside the Institution received by staff or associates of the institution can be accepted in the context of ABS. Staff should not utilise such genetic resources[30] if the original permit conditions of the material are unclear, in which case clarity from the source should be sought. This will reduce the risk of breach of terms under which genetic resources were accessed if appropriate documentation is not transferred with the material, or of utilising genetic resources if they were illegally collected.

Two additional scenarios regard (I) material brought in by guest scientists for examination in the Institution including through research falling within scope of the EU Regulation, and (II) material sent in for sequencing from users not associated with the Institution, where the Institution is acting purely for others[31] or as a collaboration partner offering established analytic pipelines. In neither of these cases does the material pass under the ownership of the Institution. While the broad solution is the same for each, they can be considered separately:

I. Visiting scientist bringing material for examination. If the material is to be utilised within the scope of the EU Regulation or other appropriate legislation[32] there should in all cases be a formal agreement between the visitor and the host Institution setting out (i) who has the responsibility to ensure that due diligence has been done in regard to the material being utilised; (ii) who has responsibility to submit a due diligence declaration, if required. It should also specify what is to happen to any material left by the visitor (see 1.4 below). This

28) It is advisable to list under the MAT all benefits that are to be delivered and to record all benefits being delivered.

29) Institutions are advised to develop or revise procedures to train and inform independent or contracted individuals or organisations who collect and supply biological materials or who do fieldwork for and in the name of that institution.

30 Utilisation in the sense of Nagoya Protocol as defined in the Glossary

31 Including formal subcontracting

32 Where the institution implementing these Best Practices is outside the EU.

should be set out in a written agreement[33] or covered in MoUs between the hosting and home Institution of the guest researcher as discussed in Section 3.3. below.

a. If the utilisation is part of a collaborative project involving the Institution, the host Institution should ensure that due diligence is carried out (i.e. by delegating this responsibility to an individual staff member hosting collaborators), or through a written agreement[23] with external collaborators that obliges them to meet all necessary legal ABS requirements when utilising in the Institution. If a due diligence declaration is required, the person responsible for the submission must also be agreed; the submission should be made by either (i) the supervising custodian within the institution, (ii) the Project Co-Ordinator, if based in another EU institution[34], or (iii) the hosted external collaborator, as appropriate. If the external collaborator is deemed to be responsible but is based outside the EU, a submission of a due diligence declaration is still required if the utilisation is in scope of the EU Regulation[35]. The Institution should satisfy itself that the responsible user for submitting a declaration is named clearly in the written agreement.

b. If the host Institution (i) has no collaborative interest in the research and has not received research funding for it, or (ii) the guest researcher is not employed via external funding by the host Institution or its agents, the host Institution can reasonably take the view that due diligence obligations in relation to the research carried out and any submission of a due diligence declaration is the responsibility of the visitor. However, this needs to be supported by a formal agreement. It is important that visitors are made aware that if the utilisation happens inside the EU, their utilisation may be within scope of the EU Regulation and, if so, they are legally bound to carry out due diligence and submit a due diligence declaration if required. The host Institution should support visitors in undertaking due diligence, providing information on the requirements and the means of fulfilling them[36]. Annex 6.4 provides a template for the agreement between host and visitor.

II. When the host Institution is sequencing on request for an external user[37] and has no involvement in the research, and the relationship between the host Institution and the legal person carrying out the research is governed by contract, the host Institution is not regarded as a user, but the legal person contracting the work is. The contract between this legal person and the host Institution should make clear who is legally responsible to exercise due diligence and submit due diligence declarations if required for compliance with the Nagoya Protocol under user country Regulations. The contract should also specify that there is no transfer in rights to the host institution, and state either the return or the destruction of any material left.

[33] See also Annex 6.4: Agreement for guest researchers bringing biological material to facilitate their own research at hosting institutions
[34] As set out in the EU Implementing Regulation Art 5(3)
[35] See Implementing Regulation Art 5(1)
[36] See also Annex 5: Practical Guidance on GR Entering the Institution Section F
[37] Often termed 'subcontracting'

1.3. Permanent acquisition from *ex-situ* sources

This covers all cases where material is not collected in the wild by the Institution, but is transferred from other collections or any other *ex-situ* sources into the ownership or custodianship of the Institution, by means such as purchase, donation, bequest, exchange, submission as unsolicited samples, etc.

Institutions must exercise due diligence (see Section 1 "*Acquisition of biological material"* above) so that they do not acquire biological material without being confident that they can retain the material legally.

Institutions should not knowingly acquire, by any direct or indirect means, any biological material that has been collected, sold or otherwise transferred in contravention of any national or international law or treaty at the time of original collection or thereafter. For biological material accessed after the Nagoya Protocol came into force[38], Institutions should accept biological material only with appropriate documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit sharing legislation or regulatory requirements and, where relevant, with Mutually Agreed Terms (see also Sections 1 and 2.1). An exception may be appropriate when material known or suspected to be illegally obtained is submitted by an outside authority such as police, customs or quarantine officials for temporary or permanent deposition.[39]

If biological material is acquired from a commercial supplier and might be utilised immediately or in the longer term, the Institution should be aware that this could constitute a change of use which could require seeking PIC and MAT from the original Provider. Institutions are advised to check the provenance and legal status of this material before acquiring it.

Institutions will need to ensure their policies and procedures address management of documentation associated with acquisition of material from *ex-situ* sources. The Institution will need documents covering requirements and permissions associated with the material and demonstrating its provenance e.g. the number of an Internationally Recognised Certificate of Compliance, or PIC and MAT (or a statement as to why they were not required if they are not provided). These might usefully be attached to a document confirming transfer of title to the Institution, including any conditions. A tool to facilitate this is a "Material Transfer Agreement"[40] for use with any material not collected by staff (see Section 1.1 *"Acquisition from in-situ sources"*). This is also of use in cases where material is offered to the Institution and a commitment to accept is required prior to donation.

1.4. Unsolicited acquisition

Objects may arrive at the Institution without being solicited. Examples include submissions for identification, donations from researchers in other institutions, and material abandoned by visitors.

38) 12th of October, 2014 (http://www.cbd.int/abs/)
39) NHMUK has developed a separate MTA explicitly for the receipt of such material.
40) See CETAF MTA templates, here specifically MTA 3 (Annex 6.3)

The Institution should develop or adapt policies and practices to address each circumstance. To reduce risks of potential non-compliance, the Institution should in all cases exercise due diligence, which will include (but not necessarily be limited to) requiring from the donor appropriate documentation (permit or equivalent) or a statement providing clarification why such documentation was not required. Annex 6.3 provides a template to file and document such information on the condition. Material left by visitors should be returned to the visitors or clarity on its legal provenance sought as for unsolicited donations[41].

Material sent for identification or analysis similarly cannot be retained without appropriate documentation (including, if appropriate, clarity that it was not legally obtained in the first place but for some reason, such as submission by national border authorities, it can be legally held by the Institution). Sequence or other data from objects submitted for identification should not be published without clarity on whether this is legally appropriate.

2. Curation and Data management

Institutions should make sure that their internal policies and procedures consider ABS aspects where relevant. Internal policies may need to address:

a. Harmonisation of policies, management and record keeping protocols across all collections and research groups in the Institution. Separate or newly-developing collections (e.g. frozen tissue and DNA collections) and public exhibition collections may have different protocols and policies from the more traditional collections; harmonising policies will reduce management problems and uncertainty among staff.
b. Living collections – Special conditions may apply to living collections, including utilisation of cultures and other captive-bred and propagated organisms in collections. These will need to be recognised in policies.
c. Research and ABS. Policies may be needed to govern internal access to and utilisation of Genetic Resources and publication of results, during research activities by Institution staff and others. This may be covered by other ABS policy elements, or in a separate policy, depending on how closely research and collection management are integrated.
d. Destructive and invasive sampling – covers any form of sampling or subsampling including that intended for DNA extraction. It is particularly important to manage restrictions and requirements agreed with the Providing Country (MAT).
e. Traditional Knowledge associated with genetic resources – covering aspects of the Institution's acquisition, documenting, digitization, archiving and release of TKaGR. This should include how it is stored, who can access it, and conditions under which it can be made public.
f. Databasing, data (including images) and document management, publication of data associated with biological material (see Section 2.1); digital linkages between collection data records and corresponding MAT, PIC and MTAs.
g. Internal Collections Audit – Monitoring or audit system (preferably digital) in order to determine if the Institution is managing its ABS documentation effectively, compliance with agreements and associated processes, and improvements, if required and feasible.

[41] See also CETAF MTA 4, warranty of guests bringing material to an institution for research / analysis (Annex 6.4)

It is advisable to register and store relevant legal documentation at one central point (e.g. with a registrar or in the central administration), especially if subsamples of a single individual organism (Genetic Resource) are stored in separate collections, different buildings, etc. An accessible digital archive of these documents can offer valuable support, and has been developed by some CETAF members. Digital images of permit documents can be held within specimen or other collection management databases in some implementations. During planning of such electronic systems, institutions should carefully check the legal requirements under national and European law to archive such sensitive data in electronic form and which measures must be taken to protect such data from illegal access of third parties.

See Section 6 "*Institutional Policies*" for further details.

2.1. Record-keeping and data management

Institutions must manage their collections and associated information so that biological material is used only in a way consistent with the terms and condition under which the material was acquired from the Providing Country. The items below may be considered as outline requirements of such a system.

For that purpose, Institutions should **keep records** on

- acquisition of biological material, including core data associated with Genetic Resources such as[42]
    - *a description of the GR* (at appropriate taxonomic level)
    - *the date*[43] *and place of access of GR and TKaGR*
    - the *Provider* from whom the GR or the TKaGR were directly obtained
    - references to associated legal documentation (*Number of the Internationally-Recognized Certificate of Compliance (if issued), permits, PIC, MAT*, etc.) and scanned or physical copies where possible, including the *authority responsible for granting PIC, the date of its granting and the person or entity to whom PIC was granted*. There should be a flag or indicator inside the documents that PIC was granted.
    - Conditions of the Prior Informed Consent / permit
    - *Mutually Agreed Terms*, including benefits shared
    - *Presence or absence of rights and restrictions, including commercialisation and third party transfer.*
- the *utilisation of Genetic Resources and Traditional Knowledge associated with Genetic Resources* and, if utilised, *the person or entity utilising them*[44] at the Institution or through a

42) In this list the items in italics are those that are required for submitting a due diligence declaration to a Competent Authority (Checkpoint) under the EU Implementing Act, and for transmission to other users under the EU Regulation (see Article 4, paragraph 3). Outside the EU, the same information may be required by Checkpoints.

43) Retain both the date of actual access and the date when the permit was given.

44) The EU Implementing Act refers to the recipient of research funding for utilisation of genetic resources, while the ABS Clearing House *Checkpoint Communiqué* refers to the person or entity utilising the GR. Where these are different (e.g. in the case of PhD students) the record should record who had responsibility for due

subcontracted entity (see also point 3) and whether this was funded by external sources (grants) or internal resources[45];

- utilisation carried out at the Institution when the Institution was sequencing on request from an external user, including relevant contracts (see section 1.2. above – to evidence that due diligence was not the responsibility of the Institution);
- any *supply to Third Parties*, whether on loan or permanent supply (see also point 4);
- any benefits derived from the use/utilisation as agreed in MAT and shared with the Provider/Providing Country (see also point 5);
- de-accessioning, disposal and loss, including consumption of tissues or DNA for analysis or degradation of material.

and are advised to **implement appropriate data management** systems that allow the Institution to

a) keep records of the origin, provenance and Provider of any sample or specimen of biological material and TKaGR that is in the Institution's collections, and provide staff or authorized visitors with information on any terms and conditions of use;
b) track the use of biological material and any associated traditional knowledge that entered the collections (including utilisation or supply to Third Parties).

To accomplish this, the data management system should provide the following elements:

- Means to discover rapidly what legal documents, requirements and restrictions are associated with a specimen or sample (as set out, for example, in the MAT) and, if necessary, efficiently transfer this information to a user in another institution when the specimen or any subsample, part or derivative of it is transferred;
- Means to discover rapidly all records on the use of biological material that entered the collections (including utilisation or supply to Third Parties); this should include the establishment of unique identifiers (e.g., collection catalogue numbers) that allow tracking of specimens or samples;
- Means to link different data and information obtained from the use of biological material (such as DNA sequence information, images, or other digital representation) to the original sample or specimen;
- Means to retain all relevant records and legal information covering Genetic Resources for an appropriate period of time (e.g. to comply with the EU Regulation, those shall be kept at least 20 years after "end of utilisation").

diligence and thus is named on a submission of due diligence. If the research was not funded by a grant the institution should still keep a record of the user.

[45] The source of funding might have relevance in combination with the ABS Implementing Act or the EU Regulation and should be critically reviewed for each utilisation (including multiple use of same samples)

2.2. Deaccession and Disposal of collections

As with other aspects of collection management, one or more harmonized internal policies and/or procedures will be helpful here (see Section 6). Disposal should only take place if it is in accord with the terms and conditions agreed with the Providing Country.

Mutually Agreed Terms may require that specimens be destroyed after use (e.g. DNA sent for sequencing to a third-party laboratory) or returned to the Provider. Destruction should only be carried out if congruent with all restrictions or requirements. Institutions should have a process in place to manage destruction of Genetic Resources in line with the original PIC, MAT or MTA where this is required.

3. Utilisation of Genetic Resources

This section, as well as the entire document, addresses occasions which institutions should consider as response to applicable ABS laws, e.g. how to manage uses of genetic resources which would constitute utilisation[46]. While the text provides guidance for compliance with the EU Regulation, it is suitable for CETAF members and others outside the EU.

3.1. Clarification of conditions affecting utilisation

Biological material should not be sampled for utilisation of Genetic Resources if this is prohibited by Prior Informed Consent or Mutually Agreed Terms. Institutions should therefore develop means to associate any data indicating restrictions on the use of biological material (including utilisation of Genetic Resources) with each individual (sub)sample of this material. They should also put mechanisms in place so that staff and other users, such as partners in collaborative projects, are informed about and can abide by terms and conditions regarding GR and TKaGR. Such mechanisms might require addition of labels indicating the restrictions, barcodes or document numbers or similar IDs on the specimen labels linking to respective database entries and filed documents, or simply procedures requiring users to check the records.

If the information associated with the material is insufficient, clarification of the legal status of the biological material should be sought, e.g. by contacting the National Focal Point of the original sourcing country of the biological material in question. If so required for legal access, additional permits such as an access permit or its equivalent might be needed and Mutually Agreed Terms established with the Providing Country; these should be established before utilisation takes place.

3.2. Inappropriate utilisation

If utilisation is taking place but the information is found to be insufficient to provide certainty about the legality of access and utilisation, individuals should discontinue utilisation. Insufficient information might be indicated if the relevant information required to submit a due diligence declaration under Article 7(1) of the EU Regulation is not all available [see also EU Regulation Article 4(5)].

[46] As most CETAF members have to respond to the EU Regulation, “utilisation” should be understood to refer to the activities within scope of the EU Regulation.

An Institution should have clear and robust policies and procedures on how it handles inappropriate utilisation (whether inadvertent or deliberate) by staff and other users. Policies and procedures should be put in place to halt the inappropriate utilisation when discovered, prevent its reoccurrence, and address any problems it may have caused with the Providing Country. Such systems might include the following structured response:

a. In all cases utilisation ceases until it is clear that it can be done legally.
b. In cases where attention has been drawn to apparent non-compliance by the Providing Country:
    i. The situation is reviewed to discover whether the concern is justified.
    ii. The complaint is responded to with an explanation, and apology if an infringement has taken place.
c. PIC is sought and MAT agreed with the Providing Country for the utilisation undertaken, and covering further utilisation if required.
d. If the utilisation is being carried out by a third party on material borrowed from the Institution, inform the third party of the situation and request that utilisation ceases, referring to EU Regulation Article 4(5) if appropriate;
e. If an infringement has taken place, review policies and procedures to avoid its recurrence. If helpful, discuss with National Competent Authority of your country.
f. If internal policies and procedures reveal obvious gaps arising from the implementation of these Best Practices, inform CETAF of the issues, so they can be addressed.

3.3. Reporting on utilisation

Institutions should be aware that any utilisation[47] of GR within their facilities may fall under the reporting responsibility of that Institution, both to the Providing Country and under user country regulations, including submitting a due diligence declaration under Articles 7(1) and 7(2) of the EU Regulation[48]. Section 2.1. above lists the information that will be required to submit a due diligence declaration in the EU. Because the EU submission is based on Article 17 of the Nagoya Protocol, the information required by Checkpoints[49] in other Parties to the Nagoya Protocol to complete a "*Checkpoint Communiqué*"[50] is likely to be the same. Declarations are required in the EU when utilisation concerns GRs:

i. that were accessed from a country that was a Party to the Nagoya Protocol at the time of access,
ii. from a Party that exercises its sovereign rights over GR and TKaGR inside their national territory,
iii. that has implemented its national access laws

47) "Utilisation" here is used in the sense of the Nagoya Protocol (see **Annex 3** - Glossary)
48) The Commission Implementing Regulation for the implementation of Regulation (EU) No. 511/2014 sets out the requirements for reporting due diligence at the stage of research funding and at the stage of final development of a product, specifying the provisions of Articles 7(1) and 7(2) of the EU Regulation.
49 In this document the term 'Checkpoint' refers to authorities identified by Parties to the Nagoya Protocol under Article 17 of the Nagoya Protocol inside and outside the EU.
50 This will be relevant to users of these Best Practices based in Parties to the Nagoya Protocol outside the EU.

iv. the utilisation is carried out inside the EU and is funded by a grant[51], and also at the stage of final development of a product developed through utilisation[52]

and consequently the utilisation falls under the scope of the EU Regulation

Members of CETAF are unlikely to be reporting under Article 7(2) of the EU Regulation but may well under Article 7(1)[53].

The declaration at the stage of research funding must be made after the first instalment of funding has been received and all the GR and TKaGR that are utilised in the funded research have been obtained, but no later than at the time of the final project report (or if there is no such report, at the project end) (Implementing Act article 5). Further information is given in the CETAF Practical Advice document (**Annex 5**). For utilisation that happens inside the EU, the time of submission of such declaration may be further specified by national authorities. Reports must be made to the Checkpoint in the EU Member State where the user is based (in the EU these are the Competent Authorities in individual EU Member States, who are responsible for implementation of the EU Regulation). If the research project is funded from more than one source or involves more than one recipient, a single declaration may be made on behalf of the users, which should be made by the project co-ordinator to the Competent Authority of the Member State in which the project coordinator is based[54]. If the project co-ordinator is not based in the EU, the declaration should be made to the Competent Authority of one of the Member States in which the research is carried out.

4. Supply to Third Parties

Any restrictions or requirements arising from the conditions under which the specimens were obtained or arising from institutional policy should be communicated to the Third Party. This may require paper or electronic copies of relevant Mutually Agreed Terms, collecting permits and Material Transfer Agreements in some cases (especially where the specimen, sample or (processed) subsample is being permanently supplied).

The EU Regulation, Article 4, paragraph 3, sets out requirements for retention and transfer of relevant information. These are based on the information that users in any Party to the Nagoya Protocol (that has established compliance measures) will have to provide to their respective Checkpoints on utilisation. CETAF members are well advised to understand the provisions of the EU Regulation not only as necessary for material accessed after October 2014, but also as general best practice to be applied to all material, not only as required for GR specifically acquired for utilisation and accessed after October 2014. The relevant paragraph reads:

51) EU Regulation article 7(1)

52 EU Regulation article 7(2)

53) Switzerland, which has very similar regulations, does not have a checkpoint at the stage of research funding.

54 Implementing Act Art 5(3). If the Project Co-Ordinator is based outside the EU a project member in the EU could take on the role, or all users make separate declarations. If the project does not have a Co-ordinator, then one could be identified in the research agreement between collaborators for this purpose.

"For the purposes of paragraph 1, users shall seek, keep and transfer to subsequent users:

(a) the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or

(b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:

(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;

(ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;

(iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

(iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;

(v) access permits, where applicable;

(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable."

Some of the information listed above is required by the EU Regulation to be submitted to Checkpoints in reports of utilisation of GR (i.e. when reporting due diligence under the EU Regulation and the Implementing Act). Note that point (iii) above implies that this information includes records of users. It may, therefore, be appropriate to inform Third Parties (and in particular those utilising genetic resources) that information on their utilisation will be retained for reporting purposes.

4.1. Temporary supply (e.g. loans/sharing of tissues/DNA subsamples)

This section deals with temporary supply of biological material to a Third Party without change in ownership, i.e. material that is under temporary custodianship by a researcher in an institution that was not involved in the original Access. This can only take place if not prohibited by the original PIC and MAT.

Third Parties borrowing biological material should be made aware of terms and conditions governing use of that material, including both restrictions and requirements.

Institutions should use CETAF MTAs[55] to establish a new agreement to cover temporary Third Party transfers. These may be adapted to meet institutional requirements.

Institutions should have procedures setting out how to respond to a request from a Third Party for a change of use of material sourced from the Institution from that allowed by the original PIC and MAT or other conditions set out in the relevant MTA (loan agreement). Institutions should have clear and robust policies for how they handle inappropriate utilisation of such material (which may occur either inadvertently or purposefully) by Third Parties.

[55] See MTA templates, here specifically MTA 1 (Annex 6.1)

Records should be maintained of specimens or samples borrowed by Third Parties, including utilisation of GR if it takes place.

4.2. Permanent supply to Third Parties

Biological material or associated Traditional Knowledge should not be permanently transferred to another institution if prohibited under the original PIC and MAT. If transfer is not prohibited under the original PIC and MAT, biological material may be transferred to Third Parties under an appropriate MTA, at least as restrictive as the MTA signed with the Provider. By this MTA the Third Party would undertake to use the biological material only in a manner compliant with the original PIC and MAT[56]. Details of PIC and MAT should be transferred with the material (see also EU Regulation text above), and records should be maintained of specimens or samples transferred permanently to Third Parties.

If an Institution is approached by a Third Party wishing to utilise the biological material or TKaGR in a manner different from the conditions as set out in the original PIC and MAT or MTA, possible responses may include denial of the request, requirement that the Third Party obtains PIC and MAT from the Provider, or partnership with the Third Party in seeking such permission.

Any commercial facility to which samples are sent as a part of research (e.g. for DNA sequencing) should be required to return or destroy residues following completion of the work.

5. Benefit-sharing

Institutions should implement procedures to share benefits arising from their utilisation of GR or TKaGR fairly and equitably with the Providing Country and other appropriate stakeholders as agreed in Prior Informed Consent and Mutually Agreed Terms at the time of access, or as renegotiated with a subsequent change of use. These procedures will include maintaining appropriate records of benefits agreed in the PIC and MAT (see Section 2 on data management). Institutions are advised to keep a record of benefits shared.

Wherever possible benefit-sharing agreements should be negotiated in such a way that allows for directing the benefits towards the conservation of biological diversity and the sustainable use of its components, in agreement with Article 9 of the Nagoya Protocol. Benefits agreed with the Providing Country are likely to include any of those listed in the Annex to the Nagoya Protocol (see **Annex 4** to this document). Because of the not-for-profit nature of the work of institutions, benefits are most likely to be non-monetary, *inter alia*: scientific training, education, capacity building, transfer of technologies, collaboration on scientific work programmes, mutual sharing of research results and of associated publications, as well as acknowledgment of the Provider when publishing data or research results. Management of benefit delivery will be facilitated if a standard list is used with the

[56] Where sequence or other analytical data are retained by the Third Party as a part of the log file of the sequencer or other datasets, a contract should be agreed prior to analysis that excludes utilisation not in compliance with the terms and conditions under which the biological resources were acquired

Providing Country as a basis for agreement (see Annex 4), since this will support record management by use of a standard vocabulary.

Publications resulting from the utilisation of Genetic Resources, and other use of biological material, should acknowledge the Providing Country. Ideally, publications should also include an identifier such as a document number referring to respective documents (permits or equivalent) on file at the Institution. Such permits or similar agreements, where these exist[57], should cover the collecting (access to) and use of the specimens, and should list references to specimens or samples studied. "Publication" includes paper and electronic publications, as well as online databases in the public domain, such as GenBank.

Institutions should strive to implement procedures to share any benefits arising from the new utilisation of GR or TKaGR accessed or otherwise acquired prior to the entry into force of the Nagoya Protocol, as far as reasonably possible, in the same manner as for those acquired thereafter.

6. Institutional Policies and Procedures

Clear policy statements will assist institutions in managing compliance with provisions arising from the Nagoya Protocol, the EU Regulation and Implementing Act, and other applicable national ABS regulations and legislation. They need to govern activities or points in workflows, where decisions have to be taken – which have an ABS implication, which are governed by ABS legislation, or where ABS concerns have to be managed.

Any policies on GR and TKaGR should make explicit who is obliged to follow them (e.g. staff, whether onsite or elsewhere, including when working as a visitor in another institution; students attached to the Institution; associates (e.g. Research Associates, Honorary Associates, emeritus posts); volunteers; visitors working in the Institution, etc.). Special consideration may need to be given to individuals or groups working across more than one institution.

The Institution (and/or other appropriate entity) should have an overall Access and Benefit-Sharing policy (this can be an "umbrella" policy covering all aspects of ABS and be used as a reference in other policies[58]). Harmonised policies and procedures will help the Institution and its staff to manage compliance with national and international ABS legislation. Where possible, policies should echo wording in accepted legal frameworks, including the EU Regulation, Implementing Act and any national implementing regulation. Aspects that may be considered for separate policy statements include those listed below. There should be means either in policies or procedures to ensure compliance in each of these areas (as discussed in this document).

57) This would not be required for genetic resources collected from countries that at the time of collection were not Party to the Nagoya Protocol or had no requirements for access permits or issuance of PIC; it should be good practice to reference and document these conditions, as access laws could change.

58) It is advisable to develop policies and clear procedures for utilisation of pre-NP specimens (collected *in-situ* or acquired *ex-situ* prior to 12 Oct 2014) and pre-CBD specimens (collected *in-situ* or acquired *ex-situ* prior to 29 Dec 1993)

On developing the policies institutions should also ensure that practices are developed to ensure the policies are sufficient.

6.1. Acquiring new specimens

1. Field Collecting – to cover all aspects of collecting, including the requirement to obtain appropriate documents including permits, PIC and MAT. Should also identify responsibility for signing permits / PIC and MAT.
2. Object Entry – governing what legal documentation is required by the Institution when biological material enters the Institution prior to accession, how this is assessed and recorded, and how both entry and documentation are managed by the Institution.
3. Accession – governing the conditions required for specimens to be added to the collections and pass under the ownership or custodianship of the Institution, including long-term loans and material held in trust. The policy may need to address:
    a. Documents required (e.g. PIC, MAT, MTA, donation letter, Transfer of Title document[59]), and how these are managed;
    b. Identification of the individual (e.g. Director, Head of collections etc.) within the Institution responsible for authorising accession.

6.2. Managing the collection

4. Means of managing compliance with MAT – This includes accommodating continuing obligations within the legal framework governing the collections (e.g. that specimens be returned to the Providing Country). Also addresses intended change of use from that agreed in PIC and MAT.
5. Incoming loans, including DNA and tissues – Documents required (e.g. copies of PIC and MAT, MTA, loan form), and how these are managed.
6. Special or newly-developing collections within the Institution – e.g. frozen tissue and DNA collections conferred to dried or spirit collections. Should develop harmonisation of policies and record keeping.
7. Destructive and invasive sampling – covers any form of subsampling intended for DNA extraction. Management of restrictions and requirements agreed with the Providing Country (MAT).
8. Living collections – Utilisation of cultures and other bred and propagated organisms in collections; living material sourced from commercial suppliers[60]; agreements required for supply to Third Parties.
9. Traditional Knowledge associated with Genetic Resources – covering all aspects of the Institution's acquisition, documenting, digitisation, achieving of Traditional Knowledge associated with genetic resources. Should include how it is stored, who can access it, conditions under which it can be made public.
10. Incoming and outgoing exhibition loans/acquisition – although not utilised for scientific research such loans may require ABS permits (including for TKaGR).[61]

[59] Legal document managing the formal change of ownership of an object from one person or organisation to another.

[60] If a change of use is involved, e.g. from pet trade to utilisation of genetic resources.

11. Outgoing loans – conditions under which users in other institutions can borrow biological material, in compliance with terms under which material was acquired, including:
    a. list of analytical processes (e.g. using tick boxes) loan recipients are permitted to carry out on material received and, if appropriate, what is prohibited; anything that is not stipulated in the loan form is prohibited;
    b. requirements for documentation to be provided with loans (e.g. copies of original PIC and MAT or summary thereof);
    c. action should commercialisation be requested by the Third Party;
    d. action should the Third Party undertake inappropriate utilisation.
12. Outgoing DNA and tissues – or products of other destructive sampling techniques (see also 6.3 below); these may include the elements from 11 above, and:
    a. return or disposal of any residual samples/aliquots/derivatives that have not been consumed for analysis;
    b. any subsequent utilisation by a borrower;
    c. Loans are considered personal and are not transferable by the borrower.
13. Research and ABS – governs access to GR, utilisation of GR and use and publication of results during research activities by the Institution.
14. Data management and documentation – all data management that includes ABS-related documentation or information, including:
    a. storage and access to ABS-related documents and associated information;
    b. mechanism to cross reference intended use with PIC and MAT;
    c. sharing content of ABS documents with Third Parties, including through reporting and compliance mechanism;
    d. special treatment of sensitive information (e.g. Traditional Knowledge associated with genetic resources, information restricted under PIC and MAT);
    e. means of keeping records of tissue and DNA subsamples congruent when physically separate, e.g. if samples (tissues, DNAs and voucher specimens) are physically stored and/or managed by different departments or entities in the Institution;
    f. protocols for publishing additional information (e.g. Provider, permit number, restrictions on use) associated with sequence data (e.g. publication through GenBank);
    g. record-keeping.
15. Internal Collections Audit – Monitoring or audit system in order to determine if the Institution is managing its ABS documentation effectively, compliance with agreements and associated processes, and whether improvements are required or possible.

6.3. Removal of specimens from the collection, including consumption during analysis

16. Dispatch and object exit – covering all items leaving the Institution temporarily or permanently, including:
    a. documentation required internally, with special regard to consumption of (sub) samples and derivatives thereof;
    b. documentation required by recipient if transferred to a Third Party;

[61] They also may be required to comply with additional requirements such as CITES compliance.

c. documentation required by the Providing Country.

17. Loss or complete consumption – the course of action to be taken with regard to ABS requirements (e.g. under MAT), including documentation, should specimens no longer be available in the collections for internal (e.g. complete consumption for DNA analysis) or external (e.g. loss of loaned specimens) reason.
18. Deaccessioning and disposals[62] (including exchanges and transfers) – governing how specimens leave the ownership/custodianship of the Institution, which may be governed by Mutually Agreed Terms or a Material Transfer Agreement.

7. Staff training and awareness-raising

CETAF members should appoint a member of staff as institutional Focal Point on ABS, to liaise with the CETAF Legislation and Regulations group. This will be the main conduit for information between the Institution and the expert group, and with other CETAF members.

All staff whose work involves collecting, managing and researching on specimens, including those undertaking laboratory work and managing loans to other institutions, should receive training in implementing the ABS policy and ABS aspects of other policies. An identified staff member should be responsible for coordinating delivery of training and keeping records of training being delivered. Institutions should ensure at least one member of staff should have sufficient expertise to deliver such training. It would be advantageous if institutions would identify a small number of staff for detailed training, e.g. to allow holiday replacement. These colleagues could act as local "super-users" able to advise their peers.

A handbook to the Institution's policies and processes regarding ABS should be made available digitally or in hard copy. RBG Kew has made their policy available on the web at https://www.kew.org/science/who-we-are-and-what-we-do/policy-work/cbd-and-nagoya-protocol.

Developing an institutional web-site may be helpful. The Natural History Museum, RBG Kew and RBG Edinburgh have collaborated to develop a web-based resource centre at http://nagoyaprotocol.myspecies.info/. The German Natural History Collections united under the DNFS consortium acknowledged the CETAF Code of Conduct for the implementation of internal ABS procedures on 27 March 2017. The ABS group of the DNFS is tasked to support DNFS members during in their implementation and to offer guidance, first members like the SNSB (Bavarian Natural History Collections) offer web-based tools at http://www.snsb.mwn.de/index.php/de/allgemeines-zu-abs. NHM has put some of its training material on this site as well as providing links to other sites (http://nagoyaprotocol.myspecies.info/node/12).

Kew has an intranet area focussed on ABS and available only to staff.

A regular (e.g. annual) audit of the Institution's ABS skills and procedures should be undertaken.

62) e.g. PCR and cycle sequencing products

Consortium of European Taxonomic Facilities (CETAF)

ANNEX 2 to the Code of Conduct on ABS

Statement of Use of Biological Material

The document below is intended for use in discussions with Providers of biological material when seeking access. It might also be used in donations or exchanges of material, or when material is provided unsolicited such as for identification. By its use ambiguities or uncertainties of how material may be used can be avoided. It should be provided to Competent Authorities in Providing Countries and may be annexed to an agreement. If Providers do not wish their material to be treated in this way or wish to place any specific restrictions, staff should ensure that this is expressly set out in writing in the agreement or permit, and the relevant elements of the document deleted or struck out. Written restrictions and conditions in a permit or equivalent will always take precedence over the text of the use statement.

***

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 utilised. 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 material under [the attached permit / agreement] [permit/agreement number] is not to be treated in a manner described, or there are any specific restrictions, these should be indicated on the agreement or this document. Written restrictions and conditions in a permit or equivalent will always take precedence over the text of the use statement. If the Provider does not place any express written restrictions, then the material will be accessioned and used under the conditions set out below.

[**Optional text**: [*Institution*] is a member of the Consortium of European Taxonomic Facilities (CETAF) and subscribes to the CETAF Code of Conduct on Access and Benefit Sharing and Best Practice.]

Use of Biological Material

Research at [*Institution*]: Any biological material at [*Institution*] may be made available to its staff and authorised visitors for non-commercial research such as systematics, ecology, conservation, genetics, morphology, physiology, molecular biology, evolutionary biology, biodiversity, genomics,

environmental genomics and science supporting sustainable use. Such work may involve making anatomical and cytological preparations, carrying out isotope and chemical analysis. DNA, RNA, proteins or other biomolecules may be sequenced or otherwise analysed. Such analyses may result in complete destruction of the material. Associated organisms such as pollen, spores, parasites and symbionts or the metagenome[63] of complete organisms may be examined in similar ways.

Research results: Results of research will be made available through publication in printed or online form (such as books, scientific journals, publicly-available databases, published images or internet sites). DNA sequence data will be deposited in publicly-available databases such as GenBank and, where possible, referenced to the respective biological material and/or subsamples thereof stored at [*Institution*].

Information and images: As a scientific institution involved in research of the diversity and conservation of biological life, 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 digital representation (e.g., images or 3D models) of samples and of associated data, and publication of such representations and information to be freely available on the internet. Images and data may also be presented in research publications and on public display.

Loans: [*Institution*] may lend biological material (specimens) to Third Parties [**Optional text to specify "Third Party" sector(s), e.g.**: *in other scientific research institutions*] for identification, scientific research or for educational purposes subject to the Loan Conditions of the [*Institution*] [**Optional text**: *URL if Loan Conditions are available on the internet*] and consistent with the terms and conditions under which the material was acquired from the Provider.

Permanent Supply to Third Parties: [*Institution*] may supply biological material to other scientific research institutions and/or to individual scientists for scientific research or for educational purposes, including through donation and exchange for other specimens or samples or parts thereof, subject to the terms and conditions under which the material was originally acquired from the Provider. Transfer will be effected when the recipient institution or individual has signed a "Material Transfer Agreement" with [*Institution*].

Propagation and public display: Living specimens may be [**Optional alternatives:** *propagated*[64] */ bred*[65]] at the Institution. Any specimens grown from such [**Optional alternatives:** *propagation / breeding*], or otherwise acquired, may be put on public display at [*Institution*]. [*Institution*] will maintain data records on any specimens grown from such [*propagation / breeding*] to enable its origin and associated records such as PIC and MAT to be retrieved. In addition to living specimens dead preserved specimens may also be placed on public display.

[63] Metagenomics is the molecular study of freshly collected in-situ samples, also called environmental genomics, ecogenomics or community genomics, aiming to reveal the hidden diversity of organisms and associated organisms and microbes in their natural biome. Through genomic sequencing, metagenomics aims to understand the microbial and organismal interactions and ecology in the living world.

[64] For botanical collections

[65] For zoological collections

Traditional Knowledge associated with Genetic Resources

If there is Traditional Knowledge associated with the Genetic Resources when accessed by the [*Institution*], it will be managed and used according to the terms and conditions originally agreed with the Provider.

Commercialisation

[*Institution*] is a not-for-profit institution and is [**Optional alternatives**: *not / only rarely*] involved in commercialisation of collection-based genetic resources. However, as part of its mission, [*Institution*] investigates [**Optional alternatives**: *animals / plants / microorganisms / fungi / genomic samples*] and their constituents for taxonomic and other scientific research. This research may lead to the discovery of potential commercial uses of certain genetic resources. In such cases, if commercialisation is not already approved in the terms and conditions agreed with the Provider, [*Institution*] will initiate renegotiation of the terms and conditions.

Benefit-sharing

[*Institution*] will share benefits arising from its utilisation of genetic resources fairly and equitably with the Providing Country and other appropriate stakeholders[66]. It will strive to share benefits arising from the new utilisation of genetic resources accessed or otherwise acquired prior to the entry into force of the Nagoya Protocol, as far as reasonably possible, in the same manner as for those acquired thereafter[67].

Benefits may include any of those listed in the Annex to the Nagoya Protocol, although because of the not-for-profit nature of the work of the Participating institutions are most likely to be non-monetary, *inter alia*: scientific training, education, capacity building, transfer of technologies, collaboration on scientific work programmes, and the mutual sharing of research results and of associated publications.

***

66) As agreed in Prior Informed Consent and Mutually Agreed Terms at the time of Access, or as renegotiated following a subsequent change of use.

67) While reasonable efforts will be made, no responsibility is accepted for any retroactive claims, such as benefit-sharing.

ANNEXE 3 to the Code of Conduct on ABS

GLOSSARY

Access – The acquisition of Genetic Resources or of Traditional Knowledge associated with Genetic Resources from a Providing Country. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organisations. The EU Regulation defines access as "the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol".

Access and Benefit Sharing Clearing House – Information sharing mechanism developed under the Convention on Biological Diversity to make information available on national contacts, national legislation and other matters relevant to Access and Benefits-Sharing generally and the Nagoya Protocol in particular. It is on the internet at https://absch.cbd.int/.

Accession – The addition of specimens and samples to a collection, by which process they pass under the ownership or custodianship of the Institution, including long-term loans and material held in trust. See also *Object Entry*.

Benefits arising from the use of genetic resources – Benefits may be monetary or non-monetary. They may include: (1) Monetary benefits when research and developments leads to a commercial product (e.g. royalties, milestone payments, licensing fees); (2) Non-monetary benefits (e.g. technology transfer, enhancement of research skills, sharing research results, research partnerships, Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies, etc.). Examples are given in the Annex to the Nagoya Protocol (attached in Annex 4 to this document).

Biological material – All specimens and samples of or subsamples from living or dead organisms, regardless if they contain 'functional units of heredity' or not. See also 'Genetic material' and 'specimen'.

Biorepository – A repository that collects, processes, stores, and distributes biological specimens to support future scientific investigation. See also *Collection.*

Biotechnology – Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Collection – A group of specimens or samples that can be seen, studied, and kept together. They are generally associated through sharing some feature, e.g. being of the same taxon (e.g. mammals, insects, sharks), from the same general locality or ecosystem, or collected by the same collector or on the same expedition. Collections are maintained by collection-holding institutions. The term *biorepository* or *biobank* may also be used, to include specimens which are not necessarily of whole organisms.

Commercialisation and *Commercialise* – Applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner, commencement of product development, conducting market research, and seeking pre-market approval and/or the sale of any resulting product based on utilisation of the original genetic resource. Handling fees (e.g. for providing DNA samples), entrance charges etc., fall under the scope of management and/or administration of public research facilities, do not involve the utilisation of Genetic Resources, and are not considered as a commercialization of research activity on Genetic Resources.

Competent National Authority – The body or individual in a country authorised to sign ABS agreements.

Data – Unless otherwise stated, information, including locality and other collecting information, permits and other agreements, and any other information provided by the supplier with the material.

EU Regulation – Where used in this document, this refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, which entered into force for Europe on 6 Jun 2014.

Exchange – Also '*Transfer*', and '*Permanent supply*'. Permanent transfer of specimens to a Third Party to the original agreement; note that 'exchange' implies a receipt of items in return for providing or transferring items. This is somewhat different from a straight transfer.

Genetic material – Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Genetic Resources (GR) – Genetic material of actual or potential value (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Implementing Act – Where used in this document, this refers to Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.

Internationally Recognised Certificate of Compliance – A record generated when the Competent National Authority of a Providing Country publishes a permit or equivalent (e.g. PIC and MAT) on the ABS Clearing House. This is given a unique identifier by the Clearing House and provides legal surety of the genetic resources covered. It may also be used to simplify reporting.

Material Transfer Agreement (MTA) – An agreement between two institutions stipulating the terms and conditions for transferring specimens or samples, including genetic material.

Memorandum of Cooperation (MoC) – An agreement between two or more institutions to cooperate. In the context of the CETAF Code of Conduct and Best Practice this will include reference to ABS.

Mutually Agreed Terms (MAT) – An agreement reached between the Providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

Object Entry – The point at which a specimen, sample or collection enters the institution, whether temporarily as a loan or being carried by a visitor for study, or with the intention of it coming into ownership or custodianship of the institution. At this point decisions based on ABS compliance and responsibilities may be taken. See also *Accession*.

Participating Institution – A member of CETAF which has signed the CETAF Code of Conduct and agreed to follow CETAF Best Practice.

Prior Informed Consent (PIC) – The permission given by the Competent National Authority of a Providing Country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework; i.e. what a user can and cannot do with the material.

Providing Country – The country supplying genetic resources collected from *in situ* sources, including populations of both wild and domesticated species, or taken from *ex situ* sources, which may or may not have originated in that country (definition from Article 2 of the Convention on Biological Diversity).

Research – The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions[68] (OED). This does not include any development of commercial applications.

[68] Definition from Oxford English Dictionary

Specimen – This includes any type of biological material.

Traditional Knowledge (TK) – There is currently no generally accepted definition of TK at an international level. WIPO defines it as "knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity." It also notes that "TK in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations."[69] The Nagoya Protocol and EU Regulation cover TK associated with Genetic Resources (TKaGR), not TK as a separate element.

Use – The purposes to which samples and specimens (biological and genetic material) are put, including but not limited to 'utilisation' in the sense of the Nagoya Protocol (See Annex 2 "Statement of Use").

User – Person or institution that uses or mandates uses of samples, specimens and MATERIAL including but not limited to 'utilisation' in the sense of the Nagoya Protocol.

Utilisation (of GR) – 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 (definition from the Nagoya Protocol).

[69] http://www.wipo.int/tk/en/tk/

ANNEX 4 to the Code of Conduct on ABS

MONETARY AND NON-MONETARY BENEFITS

As listed in the Annex to the NAGOYA PROTOCOL (NP) of 29 October 2010, on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization, to the CONVENTION ON BIOLOGICAL DIVERSITY (CBD).

1. **Monetary benefits** may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.

2. **Non-monetary benefits** may include, but not be limited to:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
   (c) Participation in product development;
   (d) Collaboration, cooperation and contribution in education and training;
   (e) Admittance to ex situ facilities of genetic resources and to databases;
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilisation of biological diversity;
   (g) Strengthening capacities for technology transfer;
   (h) Institutional capacity-building;
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

Consortium of European Taxonomic Facilities (CETAF)

ANNEXE 5 to the CETAF Code of Conduct on ABS

CETAF Practical Advice for ABS management in Museums, Herbaria and Botanic Gardens

Introduction

This document is designed to be used with the CETAF Code of Conduct (CoC) and Best Practices (BP) for ABS. While the latter of these documents suggest policy and procedural elements to put in place at institutional level to deliver the desired outcomes, the Practical Advice attempts to focus on step by step guidance and examples of tools, for application both at institutional and individual levels.

Getting Started

While many organisations and their staff are aware of Access and Benefit-Sharing (ABS) and the Nagoya Protocol they can find it difficult to know how to respond to situations where there is an ABS aspect.

A good start is to use some of the resources on the web as a 'primer' to help understand.

Organisation	Resource type	URL
ABS Capacity Development Initiative	Explanatory film	https://tinyurl.com/l2srv4u
Convention on Biological Diversity	ABS Information Kit and factsheets	https://www.cbd.int/abs/awareness-raising/default.shtml#the ABS information kit
Swiss Academy of Sciences:	*Good practice Guide for Access and Benefit Sharing*	https://naturwissenschaften.ch/organisations/biodiversity/abs

NHMUK, RBG Kew, RBG Edinburgh	Information, tools, links to many resources	http://nagoyaprotocol.myspecies.info/
SNSB	Information, tools, links to many resources	http://www.snsb.mwn.de/index.php/en/abs-english
CETAF	Comprehensive information including training modules on ABS	http://www.cetaf.org/taxonomy/publications
The Society For The Preservation of Natural History Collections (SPHNC)	WIKI on Access and Benefit-Sharing	http://spnhc.biowikifarm.net/wiki/Access_and_Benefit-Sharing_(Nagoya_Protocol_and_the_CBD)
Linnean Society	briefing document on the Nagoya Protocol	https://www.linnean.org/the-society/news/2017/04/07/7th-april-2017-summary-briefing-document-on-the-nagoya-protocol-access-and-benefit-sharing
Botanic Gardens Conservation International (BGCI)	ABS policy	https://www.bgci.org/policy/abs/
	useful links	http://www.bgci.org/policy/abs_links/.
	BGCI ABS learning tool	https://www.bgci.org/policy/abs_learning/
Williams & Lyal, 2017	Self-assessment tool for ABS Compliance by organizations	http://nagoyaprotocol.myspecies.info/content/self-assessment-tool-abs-compliance-organizations
EU	Relevant contacts and information on ABS in the EU	http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

In addition to these resources the following should be examined:

- Regulation 511/2014 of the European Parliament and Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and

Equitable Sharing of Benefits Arising from their Utilisation in the Union (hereafter the 'EU Regulation')

- Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices (hereafter the 'Implementing Act')
- National ABS legislation and websites – look on the ABS Clearing House for your national profile.
- Guidance document on the scope of the application and core obligations of the (EU) Regulation No 511/2014[70]

Some of the terms used below and in other documents about ABS are explained in the Glossary (**Annex 3**) to the CETAF Code of Conduct.

[70] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

Institutional Management of Access and Benefit-Sharing

This PRACTICAL GUIDE gives information on planning ABS negotiations, what to consider during field work and how to manage ABS compliance in your institution. Institutions and users might find it useful to stick to the basic schemes and procedures here, including for acquisition of specimens, utilisation of genetic resources and associated traditional knowledge, sending specimens to third parties, disposing of material, publishing information held and the results of research, managing data and information, and changing agreed uses of material held.

6 basic ABS steps institutions should employ for ABS management:

1. Designate ABS-responsible staff: These persons should support and manage ABS activities as detailed below. Depending on the size of the institution some tasks and responsibilities might be delegated. Some CETAF institutions have a Registrar post.
2. Determine and establish which activities require managing for ABS and the Nagoya Protocol: define the responsibilities of the Institution for each of these activities (see Best Practice section 6).
3. Determine whether the current policies and procedures of the institution are sufficient to deliver the appropriate outcomes for these activities, or if modification or replacement is required for compliance with National Regulations and, for utilisation in the EU, with the EU Regulation and Implementing Act[71].
4. Provide resources[72] and training[73]: Staff need to understand the rationale of ABS, so that responsible individuals can meet the institutional policies and procedures as well as the requirements for ABS compliance[74].
5. Develop record-keeping systems to manage all relevant information (see Best Practice Section 2.1), and make available to all staff managing or using Genetic Resources in the Institution.
6. Extend existing procedures to record activities and manage documents at five internal monitoring points:

    (a) Field work: Field work may trigger ABS responsibilities. The institution and individuals need to know what requirements in the Providing and User Countries apply and who is responsible to handle these.
    (b) Object entry: The institution needs to establish mechanisms to record and document information that is linked with specimens within the institution independent of specific individuals. This will ensure appropriate ABS record keeping and management. These include the conditions on the Permit / PIC and MAT.
    (c) DNA Extraction: Responsible staff of the DNA facilities (either DNA lab or Biorepository) are of major importance to record the use of GR inside the institution, especially of externally funded project groups. Thus institutional procedures should support staff in the DNA Facilities to collect relevant information at the point of DNA Extraction, not only because of ABS obligations, but also to support proper management of used tissues and DNA[75].
    (d) Delivery of agreed benefits to Providing Country. As part of contract management it is important to know what was agreed, when it has been delivered, and when all contractual obligations are fulfilled.
    (e) Disposal and/or transfer of the object, including destruction, consumption in analysis, return to origin and exchange to third parties.

    The sections below give specific practical advice on different parts of the workflow of CETAF members.

71) See CETAF Best Practices section 6 for policy advice; the detailed suggestions and examples in this Practical Advice below will assist in informing and implementing these.
72) For example web pages on an intranet that offer guidance, templates for MTAs, draft letters for contacting NFPs, etc.
73) See Best Practices section 7. CETAF is planning annual training and information exchange for members' representatives.
74) See links under "getting started"; external resources such as the ABS Web Pages by CETAF, SPNHC, Linnean Society, Botanic Gardens International and the ABS clearing house [https://absch.cbd.int/] are continuously updated.
75) For extraction and lab routines, standardised sample sheets are widely used; these can easily be expanded to collect ABS-relevant information to support compliance and to record use and consumption of GR inside the institution obligations

Acquiring GR from in-situ or ex-situ sources in Providing Countries (including field collecting)

Even though not all specimens or samples collected might be 'utilised', agreements, permits or other relevant documents should allow later utilisation. This approach helps your Institution to reduce risks and uncertainties linked with collection objects, to facilitate overall legal compliance and to minimise later queries to clarify the status of the material.

This section includes both field collecting of specimens and acquisitions from *ex situ* collections in the Providing Country. This is because some countries include access to specimens from the country already held in national *ex situ* collections, and many of the same conditions apply (See CETAF Best Practices section 1.1).

1. Planning a project & Grant Proposal

- **The institution might:**
  - ✓ Develop templates for grant applications to ensure the institution's ABS compliance using its implementation of the CETAF Code of Conduct and Best Practices.
  - ✓ Develop overseeing functions applied during the project workflow (e.g. checking permits are being sought when travel applications for fieldwork are made or in applications for project funding). Relevant information that the responsible national authorities in the respective Providing Country have been contacted should be recorded with successful travel applications[76].
  - ✓ Guide staff members seeking information about legal requirements of Providing Countries.
- **An individual planning fieldwork should:**
  - ✓ Check if your research is utilising genetic resources (GR) or Traditional Knowledge associated with Genetic Resources (TKaGR) and is thus potentially subject to Access and Benefit Sharing requirements.
  - ✓ Use the ABS Clearing House website (https://absch.cbd.int/countries) to discover if the country in which field work will be conducted has ratified the NP or not. This is relevant for future reporting requirements under the EU and national reporting requirements. Even if the country is not Party to the NP national access laws may apply in this country.
  - ✓ Use the ABS Clearing House and other sources (e.g. contacting the National ABS Focal Point – as detailed on the ABSCH website) to discover if the country restricts or grants free access to its GR occurring inside national boundaries (be aware that some EU countries do or will regulate access)[77].
  - ✓ If access is regulated, discover the requirements for permits in the country by using the ABS Clearing House and web searches, e.g. of the Providing Country government websites, and by getting into contact with the respective National ABS Focal Point. The Competent National Authority of the Country may also to be contacted (add appropriate wording in your application for research funding, that contact will be / is established).
  - ✓ Note that there may be permits required additional to those for ABS, and these might be issued by different government departments.
  - ✓ Consider additional travel funding for necessary meetings inside Providing Countries for ABS negotiations.
  - ✓ Allocate sufficient time for negotiations before the project starts (could involve more than one meeting).
- **An individual planning to acquire material from *ex situ* collections:**

76) For example, the Royal Botanic Gardens Kew has a cross-departmental 'Overseas Fieldwork Committee' responsible for monitoring all overseas collecting trips by Kew staff (approximately 60 – 80 trips per year). The team has an advisory function, to help to ensure that local, national and international ABS laws are understood and followed by Kew staff.

77) Some institutions like the Natural History Museum London (NHMUK) or the Bavarian Natural History Collections (SNSB) offer informal information on specific web sites (http://nagoyaprotocol.myspecies.info/node/16; http://www.snsb.mwn.de/index.php/en/abs-english)

- ✓ Check if your research is utilising genetic resources (GR) or Traditional Knowledge associated with Genetic Resources (TKaGR) and is thus potentially subject to Access and Benefit Sharing requirements
- ✓ Check, if the collections are in the country of origin of the specimens to be studied, whether the country has access legislation that includes *ex situ* material accessioned in its collections. If yes, contact the collection holders for advice, or proceed as above for fieldwork.
- ✓ Check that material is available without conditions that would compromise your research.
- ✓ File all documents that may accompany the material that is acquired from this institution; this may include that the receiving institution has to agree to specific responsibilities linked with this the transferred material.

2. *Before starting negotiations with Competent National Authority*

- **The Institution should:**
  - ✓ Designate one or more individuals or offices (e.g. director, conservator or appropriate technical staff member) to be responsible for agreeing to terms and sign MAT and PIC agreements on behalf of the Institution[78].
  - ✓ Where necessary (e.g. for permits issued within a country), delegate responsibility to negotiate and sign agreements (in some institutions individual researchers or curators are not entitled to do this or need specific permission for this).
  - ✓ Make clear to all employees limits to what can and cannot be agreed in negotiations or on permits, such as restrictions on sequencing, subsequent loan of the material or its transfer to third parties. Agreed terms must be able to be met and should not conflict with the institutions policies and activities.
  - ✓ Adopt the CETAF *Use of Biological Material* document (Code of Conduct, Annex 2) for use by its employees.

- **The researcher should:**
  - ✓ Be clear what specimens or samples are to be collected and what research or other activities will be carried out on them. This includes any (oral or other) traditional knowledge associated (TKaGR) with the GR; if TKaGR is to be accessed, this should be reflected during negotiations and addressed in agreements, since TKaGR is also covered by ABS requirements and the Nagoya Protocol.
  - ✓ When entering into negotiations for research agreements with partner institutions in Providing Countries, it is advisable to refer to the CETAF Code of Conduct, including the Best Practices (Annex 1). and the Statement of Use (Annex 2) where appropriate. The CETAF Glossary of terms (Annex 5) can be helpful to establish a common understanding of terms in bilateral contracts between both research institutions. Established research collaborations and a signed Memorandum of Understanding (MoU) often are a prerequisite before the start of official negotiations with Competent Authorities of Providing Countries.
  - ✓ Before negotiating MoUs or access conditions with Competent Authorities, be clear what general conditions are required by your institution, and ensure that agreements meet them. If such conditions cannot be met (e.g. sequencing, loans or transfers to third parties not permitted), be prepared to work in a different country.
  - ✓ Use the CETAF "*Use of Biological Material"* document (Code of Conduct, Annex 2) for providing to the local authorities for information.
  - ✓ Where necessary identify the activities of subcontractors (e.g. for external barcoding) and partners based outside your institution, and include these in all final agreements where relevant.

78) For example, NHMUK requires Memoranda of Cooperation to be signed by the Director of Science, but individual staff may be permitted to sign collecting permits (PIC and MAT) in Providing Countries. They also have a Registrar with the responsibility of overseeing all legal agreements and providing advice to staff.

3. *During negotiations with National Competent Authority*

- **The individual should:**
  - ✓ Make use of the CETAF "*Use of Biological Material*" document to cover possible uses of material. If possible make this part of the PIC. Recall that the Providing Country can delete any uses to which they do not agree.
  - ✓ If the *Use of Biological Material* document is not accepted, or there is a need to specify particular uses:
    - Be clear for what purposes the accessed biological material will be or could be used and how genetic resources will be or could be utilised (within current technical understanding including possible internal future uses of colleagues, based on the scientific scope of your institution[79]).
    - Include – as far as foreseeable and possible – any potential future uses (e.g. Genome Sequencing) beyond current research interests.
    - Consider any external sequencing, external DNA analysis (especially NextGen Sequencing / Genomic Sequencing), sharing of raw data (e.g. cloud based DNA analysis), sharing of analysis results with external colleagues or third parties (contracted sequencing), publication of DNA sequence information and other information resulting from your utilisation of GR (e.g. Traditional Knowledge on the use of specific GR accessed).
  - ✓ Be clear if GR resources are exclusively accessed for non-commercial purpose or if later commercial requests (of Third Parties) need to be included in the agreement; if commercial aspects are to be included, delivery of benefits resulting from this (Third Party) commercialisation should be set out.
  - ✓ Establish understanding of ownership of GR that are to be accessed; PIC and MAT should allow legal acquisition of accessed biological material (some countries might wish to grant only change of custodianship but not change in ownership).
  - ✓ Establish whether change in ownership includes transfer of intellectual property rights on products and derivatives resulting from utilisation of GR (especially in case of intended commercialisation – explicit exclusion of gaining intellectual property rights or patentability on accessed GR might help to smooth negotiations.
  - ✓ Agree only to benefits that can realistically be delivered, both during field work and/or at any later point e.g. as part of collaborative research projects.[80]
  - ✓ Seek agreement on benefits that support conservation of biodiversity and sustainable use of its components;
  - ✓ Consider that collected objects might carry GR, irrespective of the original purpose or intention under which the material was collected (e.g. soil samples, archaeological objects, drill cores); if there is a possibility that the GR will be utilised subsequently, ensure that appropriate agreements are reached with the Providing Country.
  - ✓ Consider GR associated with the samples collected which are outside of the focus of the proposed research project or scope of the home institution (gut contents, associated viruses or microbes), and ensure there is clarity on what can be done with them.

79) Ideally stressing any non-commercial biodiversity research, monitoring or conservation of global biodiversity, identification of invasive and potential pest species

80) see Annex 4 for reference

- ✓ Be clear whether or not any freelancers/amateurs / hobbyists associated with your institutions working in the field with you are included and covered in permit agreement with the Providing Country; this can be advisable if external expertise of third parties outside your institution is necessary or wanted.
- ✓ Check that the terms agreed fit with practices in your home institution, including conditions on existing MTAs / loan forms for transfer of biological material. It is important to read the conditions – do not agree something that has not been read!

- **<u>If the agreement being negotiated is for a long-term association with the country</u>:**
  - ✓ Consider if it is appropriate to extend the agreement to cover material from this country already available in your institution, for example from earlier field work, donations or bequests, or unsolicited samples which might be sent in to your institution for identification at a later date.
  - ✓ Check if Providing Country requires agreements to be made on different administrative levels and with different government departments, institutions or communities, for example depending where and how material is sourced (e.g. *in-situ* or *ex-situ*), in which areas the research is planned or which organisms are targeted for the planned research.
  - ✓ Consider if it is appropriate to extend the agreement to cover existing specimens inside your collection (GR that are currently not utilised but might be utilised at some point in the future).
  - ✓ Once agreement is reached or, if required by home institution policies, prior to that, submit all relevant documents to the Central Administration of your home institution.

4. Prior Informed Consent & Mutually Agreed Terms

- **<u>The Institution might:</u>**
  - ✓ Develop framework agreements with the Competent National Authorities of respective countries – ideally representing all disciplines of your institution covering organismal life - as broad as possible instead of restricting agreements to specific species or samples.

- **<u>The individual should:</u>**
  - ✓ Where possible annex the CETAF "*Use of Biological Material*" document (Code of Conduct, Annex 2) to any written agreement with the Providing Country, in a form agreed with the Providing Country, to be clear what uses are allowed, and what not.
  - ✓ Be aware that MAT & PIC ***do not necessarily include*** Collecting Permits, and Collecting Permits ***do not necessarily replace*** MAT & PIC (so discover which additional authorities you need to contact).
  - ✓ MAT should clearly list all benefits that are to be delivered by your institution (which helps to ensure that all benefits being delivered are recorded) – refer to lists of non-monetary and monetary benefits[81].

5. Before you start your field work

- **<u>The individual should:</u>**
  - ✓ Check if all research and/or collecting permits are in place;
    i. Valid PIC & MAT agreements must be in place if the Providing Country has regulations governing access to GR naturally occurring inside its national boundaries.

81) See Annex 4

ii. If the country does not have access legislation or regulations, (i.e. does not require PIC and MAT), document that the country grants free access at time of access.[82]

- ✓ Check the status of Nagoya Protocol ratification and respective national laws immediately before starting field work to ensure there has been no change since starting planning and negotiations.
- ✓ If *ex-situ* collections inside the Providing Country are to be approached for access to GR, check with the body governing the *ex situ* collection if the terms agree with intended acquisition and use (ownership should be clear).

6. *During field work / when accessing GR under in-situ conditions in a Providing Country*

- **The Institution should:**
  - ✓ Ensure that staff members are aware of the permissions and legal documentation required.
  - ✓ Make sure that staff members do not start any fieldwork until the required permits are agreed and finalised.
  - ✓ Make sure that fieldwork in a Providing Country is conducted in accordance with all laws and regulations of that country.
  - ✓ Make sure the staff member collects and subsequently submits all necessary documentation, for example local permissions or authorisations where relevant, in order to establish legal certainty on access and enable compliance with laws and regulations in the Providing Country and the EU Regulation. Additional permits and documents may be required for the issuing of export permits, and for example may include relevant information or terms of access, benefit sharing or subsequent use of the material. On return to the home institution these documents are to be stored securely, ideally with all other relevant ABS documents of respective field trips, and be made readily retrievable by anyone who requires them for due diligence and benefit-sharing purposes.

- **The individual should:**
  - ✓ Record all benefits resulting from joint collecting as collaborative venture with research organisations based in the Providing Country, especially if part of benefit sharing arrangements. [83]
  - ✓ Record all payments (including direct and indirect such as coverage of accommodation costs, fees for permits, etc.) if part of benefit sharing arrangements.
  - ✓ Not carry out any additional collecting, sampling or other acquisition of biological material for private or other use, including on behalf of or for sale to Third Parties, if not explicitly included in existing PIC & MAT.

82) The Competent National Authority may not issue documentation to this effect; in this case it might be advisable to record the date and any relevant country information provided on ABS Clearing House website https://absch.cbd.int/countries Keep any communication from the CNA or National Focal Point stating there are no requirements. Be aware that colleagues in the country may be unaware of national requirements.

83) Includes any practical, taxonomic, scientific or other training, education, capacity building technology transfer, collaborative scientific work

- ✓ Retain and pass on to your institution as appropriate the following information[84].
    i. Number of the Internationally Recognised Certificate of Compliance, if generated by the Providing Country;
    ii. Permit number(s) / unique identifier(s);
    iii. Person or entity who granted PIC;
    iv. The Mutually Agreed Terms / permit conditions;
    v. Date of access of the GR;
    vi. Source of the GR/TKaGR when directly obtained (may be an indigenous community or even an individual).

[84] If utilisation of the collected material is to be reported subsequently to a Checkpoint in the EU as a due diligence declaration, this information will be required.

GR entering the institution

Not all specimens or samples entering the institution might be 'utilised'. However, if the specimens are to be retained by the institution it is helpful to operate as if everything will be utilised. This approach also facilitates overall legal compliance, reduces risks and uncertainties that might be associated with collection objects and simplifies the management of the collections. GR may enter the institution in a number of ways; these are considered separately below.

- **The institution should:**
  - ✓ Put in place an object entry system, to ensure that there is a record of GR entering (and where appropriate leaving) the institution, and the appropriate data and documents are processed and stored. Where appropriate this can link with a quarantine and pest control system. This could apply to some or all of the various types of entry discussed below.
  - ✓ Check for any documenting and reporting or other obligations stemming from contractual agreements linked to arriving samples and record these on object entry. These conditions and obligations must remain linked to individual samples during all stages of storage and proposed utilisation.
  - ✓ Consider labelling all samples/specimens with something that indicates any restrictions or requirements on their use (e.g. by using document numbers or similar identifiers such as QR codes linking to conditions filed in the institution, or a simple 'flag' that indicates that there are conditions and the original documents must be consulted).

Different types of entry may require different responses:

A. GR is a donation or purchase and the institution expects to gain ownership (See CETAF Best Practices Section 1.3)

- **The Institution should:**
  - ✓ Ensure that any contracts or documents describing the means of this transfer clarify the legal status of the material and that the biological material was acquired in accordance with applicable law.
  - ✓ Consider using the CETAF MTA 3, for receipt of material with change in ownership (See CETAF Code of Conduct).
  - ✓ Set conditions for staff members on what documents and information are sought with received GR, noting the information that might be required for transmission or reporting under national requirements, including due diligence declarations under the EU Regulation.
- **The individual receiving the GR should:**
  - ✓ Comply with institutional policies and practices and check and record available documentation; the information gathered by individual researchers must be sufficient to fulfil reporting obligations under European law [EU Regulation Art 4(3)] as below, or other national laws (for non-EU countries):

    3. Staff "shall seek, keep and transfer to subsequent users:

    (a) the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or

    (b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:

    (i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;

    (ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;

(iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

(iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;

(v) access permits, where applicable;

(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable."

- ✓ Check if documentation of incoming material is missing or incomplete. This could risk a breach of terms under which genetic resources were accessed.
- ✓ Check the provenance and legal status if biological material is acquired from a commercial supplier (including laboratory suppliers, vets, plant breeders, shops etc.); utilising such material could constitute a change of use which could require PIC and MAT from the original provider.

B. GR are on temporary transfer to a member of staff (including for utilisation), sometimes as part of joint research (See CETAF Best Practices Section 1.2)

- **The Institution should:**
  - ✓ develop procedures for establishing who is responsible for making a due diligence declaration (if required) for a joint project and ensure this is agreed with all parties to the project and recorded.

- **The Individual receiving the GR should:**
  - ✓ be aware whose responsibility it is to make any due diligence declaration (e.g. in a joint research project with staff in another institution it might be agreed that this is the responsibility of the project coordinator or project leader for all GR utilised, even if that person is in a different institution or country). This should be stated in the project agreements.

C. GR is on long-term deposit in trust, while the ownership rests elsewhere (including sometimes with the Providing Country)

- **The Institution should:**
  - ✓ negotiate clarity on how material can be used, with the most favourable being in the same manner as the rest of the collection.
  - ✓ have a standardised labelling system to alert collection users to the special status of collections held in trust.
  - ✓ Set conditions for staff members on what documents and information are sought with received GR, noting the information that might be required for transmission or reporting under national requirements, including due diligence declarations under the EU Regulation.

- **The Individual receiving the biological material should:**
  - ✓ Comply with institutional policies and practices and check and record available documentation; the information gathered must be sufficient to fulfil any subsequent due diligence reporting obligations under European law [EU Regulation Art 4(3)], or other national law (for non-EU countries), should utilisation be permitted under the terms on which the material is held.
  - ✓ ensure it matches institutional requirements.
  - ✓ ensure the collection is appropriately labelled.

D. GR are sent for identification (which may involve utilisation) from the Providing Country or elsewhere (See CETAF Best Practices Section 1.4)

- **The Individual should:**
  - ✓ check documentation of arriving unsolicited objects; unsolicited donations need to include appropriate documentation or a supported statement explaining why such documentation was not required;
    a. If identification requires genetic analysis, strictly speaking this should not be done without appropriate PIC and MAT from the Providing Country, if these are required[85].
  - ✓ return GR to the sender after identification.
  - ✓ not bring sequence information developed during identification into a research project without conducting due diligence on the need for PIC and MAT.
  - ✓ not publish sequence or other data from objects submitted for identification without clarity on whether this is legally appropriate.

E. GR is sent for identification and holding (quarantine / CITES / customs / police interception)

- **The Institution should:**
  - ✓ have a procedure for receipt of illegal material of this nature, including:
    (a) Specialised version of CETAF MTA3 for material arriving without all necessary permits or documents.
    (b) Addition of explicit labelling stating its origins and limitations on its use.
    (c) Policy not to use such material for utilisation.

F. GR is brought in by a visitor for examination or sequencing as a part of their research (See CETAF Best Practices Sections 1.3 and 1.4)

- **The Institution should:**
  - ✓ have a clear policy and procedure on agreeing responsibility for undertaking and reporting due diligence in such cases, and make a written agreement with the visitor specifying who should be responsible for due diligence and submitting a due diligence declaration, if required[86].
  - ✓ Make and retain a record of the utilisation carried out by the visitor using the institution's resources, to facilitate response to any subsequent requests for clarification by the Regulator or Providing Country.
  - ✓ Use CETAF MTA 4 to document the conditions under which GR can be utilised, and send it for signature by the visitor prior to their visit.
- **The Individual should:**

85) Identification alone does not constitute R&D under the EU Regulation and is consequently out of its scope. Failure to provide identifications could have a negative effect on the Providing Country, for example if the material is a pathogen, pest or invasive species. However, Providing Country legislation may not exclude identification from its concept of utilisation and might require PIC and MAT to be sought.

86 As discussed in the Best Practice Section 1.3, if the Institution is not involved in the research, has no interest in the research materials, and has not received research funding for the research, the responsibility is likely to rest with the visitor. Nevertheless, a written agreement should be made to clarify responsibility for all concerned.

- ✓ check if any objects, derivatives, data or anything else associated with the GR are left after departure of guests or visitors from your home institution.
- ✓ return material left by visitors to them; if the visitor does not want it, exercise due diligence as for unsolicited donations and seek clarity on its legal provenance before taking a decision on whether it can be retained.
- ✓ not utilise or publish sequence or other data from objects brought into the institution by visitors or guests without clarity on whether this is legally appropriate.

G. Under contract for sequencing, the institution acting as a subcontractor.

If the institution is acting for others[87] a contract between the submitter and the institution should set out that the entity contracting the task is responsible for due diligence obligations under the EU Regulation, including any submitting of declarations or reports if this utilisation falls under the scope of the EU Regulation. This contract should also specify the return, subsequent curation or destruction of the submitted material once the contracted work is completed.

Utilisation of GR, documentation and record keeping

See CETAF Best Practices Section 3 and Section 6.

- **The institution should:**
  - ✓ Put in place a system to make clear who in the Institution is responsible for due diligence obligations, for example under Article 4 of the EU Regulation, and for preparation of reports, such as submitting due diligence declarations under Art 7 of the EU Regulation[88]. These may be different individuals. Reporting and making declarations may be centralised to one office, or be the responsibility of individual scientists.
  - ✓ Put in place a system that alerts the relevant individual(s) when there is a necessity for reporting or submitting a due diligence declaration (i.e. when utilisation of a GR in scope is supported by a grant[89])
  - ✓ Ensure that documents (including permits) that cover GRs held in the institution are stored securely, can be accessed rapidly, and databased where appropriate.
  - ✓ If different parts of the collection are on separate databases ensure that information necessary for ABS compliance (document numbers of PIC and MAT etc.) are available to all. Ensure that any unique identifiers are present in both databases.
  - ✓ Establish clear workflows to support its staff in exercising due diligence and to ascertain that GR and TKaGR have been accessed in accordance with applicable ABS legislation or regulatory requirements.
  - ✓ Keep records, including [obligations of users under the EU Regulation Art 4(3)]:

    (a) the number of the Internationally Recognised Certificate of Compliance,

[87] Including formal subcontracting
[88] The cited Articles are relevant for institutions based in the EU; CETAF members and others outside the EU will have their own relevant regulations, and should make themselves aware of these.
[89] Under EU Regulation No. 511/2014 both public and private funding are included

(b) where no Internationally Recognised Certificate of Compliance is available, information and relevant documents on:

i. access permits, where applicable;

ii. the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;

iii. the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;

iv. the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

v. the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;

vi. mutually agreed terms, including benefit-sharing arrangements, where applicable .

- ✓ Be aware that any utilisation of GR within institutional facilities (e.g. by staff, guests or external materials that are utilised in their labs) may trigger reporting responsibilities, Including the duty to submit a due diligence declaration under the EU Regulation[90] . Accordingly, it should establish procedures in each case to:

  (a) Decide where the responsibility should lie;

  (b) Make it clear to all parties who is responsible. This should be done as a clause in a Research Partnership Agreement, Visitor Agreement Form or contract (see above and Best Practice Section 1.3 where special conditions on visiting researchers and subcontracting are discussed).

  (c) Keep records documenting who is responsible.[91]

  (d) When a declaration is to be made by a project coordinator in another institution ensure that individual is provided with all of the required information for relevant GR utilised within your own institution.

- ✓ Ensure that records are kept of due diligence declarations if not submitted by the online DECLARE system of the EU.[92].

- ✓ Put in place clear and robust policies and processes to handle any internal inappropriate utilisation of genetic resources or use of biological material. This might include seeking retroactive approval from the Providing Country.

[91)] Use CETAF MTA 3 or 4 to clarify the status of any external materials and responsibilities.

[92] DECLARE is the online system for making due diligence declarations in most countries of the EU, and provides a means for users to compile and submit their declarations to their national competent authorities. Information can be found at https://content.govdelivery.com/attachments/UKNMO/2017/10/23/file_attachments/900529/DECLARE_ABS_QA.docx

- ✓ Implement appropriate data management systems[93] that allow tracking and reporting the utilisation of GR inside the institution; this will help to comply with national and international reporting obligations resulting from utilisation of GR accessed or acquired after entering into force of the Nagoya Protocol and the European ABS law.
- ✓ Collect and keep records of shared benefits; this includes direct or indirect benefits granted during field work, monetary or non-monetary benefits as agreed in PIC and MAT at the time of Access, or as renegotiated with a subsequent change of use at any later point with the original Providing Country; ideally, management of benefit delivery uses a standard list with standard vocabulary.

Reporting Due Diligence

This refers particularly to reporting obligations within the EU; countries elsewhere will, if they are Parties to the Nagoya Protocol, have their own reporting obligations and will need to adapt this advice accordingly.

- **The Institution should:**
  - ✓ Make it clear to its staff:
    - who is responsible for carrying out due diligence and submitting due diligence declarations to the National Authority in EU Member States if GR are utilised in the EU or are shared or pooled by researchers for EU-wide projects;
    - under what circumstances these declarations should be made;
    - how declarations should be made (the EU Commission has developed a web-based submission tool, DECLARE[94], which may be used in almost all Member States[95].
  - ✓ Train relevant staff in when and how to make declarations.
  - ✓ Facilitate triggering declarations by providing all necessary information in a single place and in a timely manner for the relevant staff to use. Note that declarations at the stage of research funding under Art 7(1) of the EU Regulation are only necessary if the utilisation is funded by a grant, so establishing methods of linking grant information with utilisation information should be considered.
- **Making a Declaration:**
  - ✓ If using DECLARE (all EU MS other than Spain and France) the person tasked with making them should:
    - Review the information document produced by the Commission at http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/questions-and-answers-for-declare-users.docx
    - Create an EU Account at https://webgate.ec.europa.eu/declare/
    - Register on DECLARE at https://webgate.ec.europa.eu/declare/

93) See Point 2.1 in Annex 1 (CETAF Best Practice) of the CETAF ABS document package

94 DECLARE is available at https://webgate.ec.europa.eu/declare/

95 Except for Spain and France for a declaration at the stage of research funding – which require use of their national reporting IT systems;

- Follow the instructions to make a declaration

✓ In countries where DECLARE is not used, contact your Checkpoint for advice.

Transfer of GR to third parties

- **The Institution should:**
  - ✓ Use Material Transfer Agreements (MTAs) to carry documentation and provide legal certainty when transferring GR either temporarily or permanently. The template MTAs developed by CETAF (MTAs 1 and 2 annexed to the Code of Conduct) are designed for this purpose (for non-commercial research only);
  - ✓ Use MTAs that distinguish non-commercial and commercial as well as permanent and non-permanent transfers (change in ownership) and should address ownership issues and intellectual property rights of any product or derivate resulting from utilisation of the original samples or specimen;
  - ✓ Keep and maintain records of specimens or samples borrowed by or supplied to Third Parties, including utilisation of GR if it takes place;
  - ✓ Put in place clear and robust policies[96] and procedures to handle inappropriate utilisation of Third Parties (which may occur either inadvertently or purposefully.

[96] Ideally, institutions adopt policies identified in the CETAF ABS document Package as closely as feasible

Consortium of European Taxonomic Facilities (CETAF)

ANNEX 6.1 to the CETAF CoC for ABS

MTA 1

Material Transfer Agreement for PROVISION OF MATERIAL, with no change in ownership

Preamble

a) This AGREEMENT covers the **temporary transfer** of MATERIAL containing GENETIC RESOURCES for non-commercial UTILISATION[97] with no change in ownership / permanent custodianship.

b) The activities of our institution are guided by the Convention on Biological Diversity (CBD)[98] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their UTILISATION (ABS)[99]. MATERIAL is transferred between both parties to this AGREEMENT on the condition that users agree to use MATERIALS and DATA in compliance with international laws and conventions. This AGREEMENT is designed to promote and facilitate non-commercial scientific research and transfer of GENETIC RESOURCES by research institutions and researchers that are associated to such institutions.

c) The conditions and clauses set out in MUTUALLY AGREED TERMS with the PROVIDING COUNTRY for the access of the GENETIC RESOURCES transferred under this AGREEMENT remain valid for the RECIPIENT and the subsequent UTILISATION of this MATERIAL. The SUPPLIER reserves the right not to supply any MATERIAL if such supply would be contrary to any terms attached to the MATERIAL and/or is not consistent with provisions of the CBD.

d) This MTA is exclusively designed to cover non-commercial uses of GENETIC RESOURCES. Any other uses with the intention of probable or potential commercial UTILISATION or application by the recipient or researchers associated to or mandated by the recipient institutions is not the subject matter of this AGREEMENT and is not authorised.

97) This MTA is an advanced version of the Material Transfer Agreement that was developed jointly with the Global Genome Biodiversity Network (GGBN)

98) http://www.cbd.int/convention/text/

99) http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

e) Definitions of terms are provided in the **Annex (a)** to this AGREEMENT.

Parties to AGREEMENT

SUPPLIER:

RECIPIENT (receiving Institution):

USER of transferred GENETIC RESOURCES:

RESPONSIBLE PROJECT LEADER [4]:

The SUPPLIER will supply the MATERIALS listed on the List A attached to this AGREEMENT ("MATERIAL") under the following terms and conditions:

Ownership of MATERIAL and relevant information

1. The SUPPLIER warrants that it is not aware of third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this AGREEMENT.

2. The MATERIAL and DATA do not enter into ownership of the RECIPIENT, but the RECIPIENT is free to use the MATERIAL under the terms of this AGREEMENT.

3. Nothing in this AGREEMENT shall or may be construed as granting the RECIPIENT any right or license to the MATERIAL for any use other than the purpose described herein.

4. The SUPPLIER shall be free, at its sole discretion, to distribute the MATERIAL to others for any USE and to USE the MATERIAL for its own purposes.

[100)] To be filled in if applicable or needed

5. The RECIPIENT shall acknowledge the SUPPLIER as the source of the MATERIAL in all written and electronic publications and reports, including repository data, such as unique sample IDs or voucher numbers where available.

6. The RECIPIENT shall make associated genetic information resulting from his UTILISATION publicly available.

7. The RECIPIENT must submit sequence data to an International Nucleotide Sequence Database Collaboration (INSDC) data repository (GenBank, EMBL or DDBJ) or the Barcode of Life Database (BOLD) with assigned unique tissue or DNA identifiers provided by the SUPPLIER and provide the SUPPLIER with a list of such deposits including the database Accession numbers. Any additional data sent to these databases must remain linked to the original specimen and accession number provided by the SUPPLIER.

8. In any publication, or with submission to a public database, the RECIPIENT should include the following data USE statement: "[Data on genetic material contained in this paper / These data] are published for non-commercial use only. Use for purposes other than non-commercial scientific RESEARCH may infringe the conditions under which the genetic resources were originally accessed, and should not be undertaken without seeking permission from [corresponding author of the paper / depositor of the sequence data] and/or the original provider of the genetic material."

9. The RECIPIENT agrees to acknowledge the PROVIDING COUNTRY as the source of the MATERIAL in any and all publications arising from its UTILISATION.

10. The RECIPIENT will provide the SUPPLIER with copies of the publications resulting from the UTILISATION.

11. Unless otherwise indicated, no proprietary claims (e.g. copyright, patent rights, trade secrets) or ownership can be claimed by the RECIPIENT on the MATERIAL, its encoded properties or on the DATA supplied with the MATERIAL. The RECIPIENT may use these DATA on condition that they are used solely for scholarly, education or not-for-profit research purposes; that they are not used for commercial purposes.

12. In general, DATA / METADATA shall not be modified in publications without permission from the SUPPLIER. If substantive modification is proposed this should be agreed with the SUPPLIER prior to publication.

13. The MATERIAL may not be transferred wholly or partially by the RECIPIENT to third parties, without prior written authorization from the SUPPLIER.

14. The RECIPIENT retains ownership of:
    i. MODIFICATIONS (excluding rights to the MATERIAL included therein), and
    ii. those substances created through the use of the MATERIAL or
    iii. MODIFICATIONS without UNMODIFIED DERIVATIVES or
    iv. MODIFICATIONS without ORIGINAL MATERIAL.

    Note: If i) - iv) results from the collaborative efforts of the SUPPLIER and RECIPIENT the joint ownership may be negotiated under a separate agreement.

15. Copies of relevant documentation[101], as indicated below, is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT.

- ☐ Collecting Permit _____
- ☐ Mutually-Agreed terms _____
- ☐ Prior Informed Consent _____
- ☐ Export permit _____
- ☐ Import permit _____
- ☐ Letter informing Providing Country of third-Party Transfer _____
- ☐ CITES Registry code of SUPPLIER _____
- ☐ Other (please specify) _____
- ☐ The Internationally-Recognized Certificate of Compliance number(s) is/are: _____
- ☐ No such documentation is attached because the GENETIC RESOURCES were accessed
  - ☐ Prior to the entering into force of the CBD[102]
  - ☐ Prior to the entering into force of the NP[6]
  - ☐ Original access to the GENETIC RESOURCES was free (no documents have been issued)[103]

16. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying DATA provided by the SUPPLIER.

Use of MATERIAL

17. The RECIPIENT may only use the MATERIAL and resulting derivatives for non-commercial, not-for-profit purposes in scientific research, education, and conservation; the RECIPIENT shall not sell, distribute or use for profit or any other commercial application the MATERIAL, related derivatives or any direct or indirect results obtained from analysis or use of the MATERIAL.

[101] Where there is more than one document of a single type attached please make it clear to which specimens each refers

[102] This condition does not invalidate ABS obligations of the USER or the RECIPIENT

[103] i.e. not restricted under national access laws at the date of original in-situ access

Benefit-sharing

18. The RECIPIENT shall share fairly and equitably the benefits arising from their UTILISATION of the MATERIAL, its progeny or derivatives in accordance with the CBD with original PROVIDING COUNTRIES. A non-exhaustive list of non-monetary and monetary benefits is given at Appendix II to the Annex to the Nagoya Protocol[104] (**Annex 4** to the CETAF CoC on ABS).

19. If, at any time, any product or process derived from MATERIALS shipped under the terms of this AGREEMENT, whether or not such product or process is subject to any proprietary protection claims, is identified as having potential commercial use not previously discussed with the SUPPLIER, the RECIPIENT shall immediately cease all further research and activity undertaken in connection with the Materials and shall promptly notify the SUPPLIER. The RECIPIENT shall be prohibited from continuing to engage in the activity for which the commercial potential was identified until it has entered into a written agreement with the SUPPLIER and a bilateral agreement with the PROVIDING COUNTRY has been reached.

Risks and Warranties

20. The RECIPIENT is solely responsible for safe receipt, use, storage and disposal of MATERIALS and DERIVATIVES.

21. The RECIPIENT indemnifies the SUPPLIER, its officers, employees and agents ('those indemnified') against all expenses, losses, damages and costs (including legal costs on a full indemnity basis) incurred by or awarded against those indemnified arising out of a claim by any person in relation to:

(a) the RECIPIENT's use of the MATERIAL and its derivatives, and any other exercise of rights under this AGREEMENT; and
(b) breach of this AGREEMENT by the RECIPIENT.

22. The SUPPLIER makes no representation or warranty of any kind, either express or implied, as to the identity, safety or fitness for any particular purpose of the MATERIAL, its progeny or derivatives, or as to the accuracy or reliability of any DATA supplied.

23. The SUPPLIER is not liable for failures in any molecular analysis (DNA extraction, PCR product, sequencing reaction, etc.).

Transport of MATERIAL

24. The RECIPIENT shall take all appropriate and necessary measures that the importation, storage and USE of the MATERIAL complies with all applicable laws and regulations.

25. The RECIPIENT is responsible for ensuring that it can provide all required permits to the SUPPLIER if requested.

104) http://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37

26. Neither party may assign or otherwise transfer this AGREEMENT and the rights acquired hereunder without the written consent of the other party. Any permitted assignee must agree in writing to be bound by the terms of this AGREEMENT.

27. Each party will ensure that its officers, employees and agents comply with the obligations imposed on it by this AGREEMENT as if personally bound by those obligations.

28. This AGREEMENT will terminate on the earliest of the following occasions[105]:

- ☐ on completion of RECIPIENT's current research with the MATERIAL
- ☐ on the termination of the USERS's research project or project funding
- ☐ on a thirty (30) days written notice by either party to the other
- ☐ on the predetermined closure date of this AGREEMENT [date: DD/MM/YYYY].

29. This AGREEMENT terminates immediately if the RECIPIENT willingly or unwillingly violates the clauses and conditions of this AGREEMENT, especially paragraphs 1-4, 6-20, 22-29 and 32-33 (breach of this AGREEMENT) or violates the prior MUTUALLY AGREED TERMS that pertains to the transferred MATERIAL that were established with the original PROVIDER OF THE MATERIAL.

30. If termination occurs under 28 or 29, the RECIPIENT shall discontinue its use of the MATERIAL, which is no longer valid under this AGREEMENT, and

- ☐ return any unconsumed MATERIAL and related derivatives
- ☐ destroy any unconsumed MATERIAL and all DERIVATIVES
- ☐ notify the SUPPLIER in written form about the disposal of unconsumed MATERIAL and all related DERIVATIVES, such as of PCR products, cycle-sequencing products or similar by-products.

31. In the event that the SUPPLIER terminates this AGREEMENT, other than for breach of this AGREEMENT or conflict with prior MUTUALLY AGREED TERMS, upon written request from the RECIPIENT the effective date of termination may be prolonged for a period of up to one year, to permit completion of RESEARCH in progress.

Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the SUPPLIER, return or destroy any unconsumed MATERIAL and related DERIVATIVES.

32. The expiration or termination of this AGREEMENT, shall not affect the legal obligations of the RECIPIENT contained in this AGREEMENT.

[105] Multiple selections possible

33. This AGREEMENT is governed by and shall be construed in accordance with the law of the home country of the SUPPLIER.

Signatures of Parties to the AGREEMENT

Authorized signatory for the SUPPLIER:	Authorized signatory for the RECIPIENT:
…….	……
Name in block letters:	Name in block letters:
.....	.....
Date:	Date:
Place:	Place:

ANNEX (a) to MTA 1. DEFINITION OF TERMS

ACCESS: Acquisition of GENETIC RESOURCES with permission as granted by the country that has sovereign right over those resources (PROVIDING COUNTRY), or other relevant entity. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations. An agreed definition should be included in all legal documents. The EU Regulation defines ACCESS as 'the acquisition of GENETIC RESOURCES or of traditional knowledge associated with GENETIC RESOURCES in a Party to the Nagoya Protocol'.

AGREEMENT: this document.

BIODIVERSITY BIOBANK: A facility for preservation and storage of typically non-human, GENETIC MATERIAL and associated DATA, which follows standard operating procedures and supplies material for scientific USE. Examples include culture collections, DNA banks and tissue collections.

COLLECTION: A group of SPECIMENs or SAMPLEs that are managed for the purpose of preservation and study. They are generally associated through sharing some feature, e.g. being of the same taxon (e.g. mammals, insects, sharks), from the same general locality or ecosystem, or collected by the same collector or on the same expedition. COLLECTIONs are maintained by COLLECTION-holding institutions, for example natural history museums, herbaria, botanical gardens, seed banks or BIODIVERSITY BIOBANKs.

COMMERCIALISATION,COMMERCIALISE, COMMERCIAL PURPOSES: Applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license or in any other manner, commencement of product development, conducting market assessments, and seeking pre-market approval and/or the sale of any resulting product based on UTILISATION of the original GENETIC RESOURCE or screening of compound libraries. Also the sale, lease, or license of MATERIAL, PROGENY, or DERIVATIVES; or USEs of MATERIAL, PROGENY, or DERIVATIVES by any organization, including the RECIPIENT, to screen compound libraries in order to produce or manufacture products for general sale. Handling fees (e.g. for providing DNA samples), analytical cost recovery, entrance charges etc., fall under the scope of management and/or administration of public facilities, do not involve the UTILISATION of GENETIC RESOURCES, and are not considered as a commercialization of RESEARCH activity on GENETIC RESOURCES.

DATA: Any information associated with a specimen and/or collection which are provided to the RECIPIENT by the SUPPLIER, including but not limited to: provenance information, biological information, taxonomic information, chain of custody information, and images.

DERIVATIVE: Means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or GENETIC RESOURCES, even if it does not contain functional units of heredity (definition from Nagoya Protocol Art 2).

EU REGULATION – Where used in this document, this refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, which entered into force for Europe on 6 Jun 2014.

EVALUATION: means both the formulation of the MATERIAL and the testing of the MATERIAL.

GENETIC MATERIAL: Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Article 2 of the Convention on Biological Diversity).

GENETIC RESOURCES: GENETIC MATERIAL of actual or potential value (definition from Article 2 of the Convention on Biological Diversity)

GLOBAL GENOME BIODIVERSITY NETWORK (GGBN): A global network of well-managed COLLECTIONs of genomic tissue samples from across the Tree of Life, benefiting society through biodiversity RESEARCH, and long-term conservation of the archived materials. This network will foster collaborations among BIODIVERSITY BIOBANKS in order to ensure quality standards, improve best practices, secure interoperability, and harmonize transfer of GENETIC RESOURCES, of material in accordance with national laws and best practices.

MATERIAL: Refers to the items listed on the reverse of this AGREEMENT.

MATERIAL TRANSFER AGREEMENT (MTA): An agreement between two institutions stipulating the terms and conditions for transferring SPECIMENs or samples, including GENETIC MATERIAL.

METADATA: Any data associated with the MATERIAL that describes the origin or identifies the original provenience of the MATERIAL.

MODIFICATIONS: Substances created by the RECIPIENT by using the MATERIAL which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.

MUTUALLY AGREED TERMS (MAT): An agreement reached between the PROVIDING COUNTRY of GENETIC RESOURCES and users on the conditions of ACCESS and USE and the benefits to be shared between both parties.

ORIGINAL MATERIAL: That which was originally supplied to the SUPPLIER by the depositor.

OWNERSHIP: Property of a person or institution including all legal rights associated with that property; in some countries also indicated by Transfer of Title or similar documents confirming legal transfer.

PRIOR INFORMED CONSENT (PIC): The permission given by the Competent National Authority of a PROVIDING COUNTRY to a user prior to accessing GENETIC RESOURCES, in line with an

appropriate national legal and institutional framework, i.e. what a user can and cannot do with the material.

PROGENY: Unmodified descendant (e.g. subculture or replicate) from the MATERIAL.

PROVIDING COUNTRY / PROVIDER OF MATERIAL: (or "Country providing GENETIC RESOURCES") Means the country supplying GENETIC RESOURCES collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country (Definition from CBD Art 2). The PROVIDER is an entity providing access to the GENETIC RESOURCES within the PROVIDING COUNTRY.

RECIPIENT: The organization to whom the SUPPLIER sends the MATERIAL.

RESEARCH: The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. This does not include any development of commercial or non-commercial applications.

RESPONSIBLE PROJECT LEADER: This is the person that has the obligation to carry out due diligence and any reporting on the UTILISATION including under the EU regulation.

SAMPLE: See also SPECIMEN.

SPECIMEN: This includes any type of biological material. The term “SPECIMEN” is usually synonymous with “material” or “samples” or “subsamples” in this context. The concept can include associated SPECIMENs or materials such as but not limited to parasites and gut content.

SUPPLIER: The party supplying the MATERIAL.

TRANSFER: To convey MATERIAL temporarily or permanently from one person or institution to another.

UNMODIFIED DERIVATIVES: Replicates or substances which constitute an unmodified functional subunit or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA.

USE: The purposes to which samples and SPECIMENs (biological and genetic material) are put, including but not limited to ‘UTILISATION’ in the sense of the Nagoya Protocol.

USER: Person or institution that uses or mandates uses of samples, specimens and MATERIAL including but not limited to ‘UTILISATION’ in the sense of the Nagoya Protocol.

UTILISATION (OF GENETIC RESOURCES): 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 (definition from the Nagoya Protocol).

Consortium of European Taxonomic Facilities (CETAF)

ANNEX 6.2 to the CETAF CoC for ABS

MTA 2

Material Transfer Agreement for PROVISION OF MATERIAL, with change in ownership

Preamble

2. This AGREEMENT covers the **permanent transfer** of MATERIAL containing GENETIC RESOURCES for non-commercial UTILISATION[106] with change in ownership / permanent custodianship.

3. The activities of our institution are guided by the Convention on Biological Diversity (CBD)[107] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their UTILISATION (ABS)[108]. MATERIAL is transferred between both contractual parties on the condition that users agree to use MATERIAL and DATA in compliance with international laws and conventions. This AGREEMENT is designed to promote and facilitate non-commercial scientific research and transfer of GENETIC RESOURCES by research institutions and researchers that are associated to said institutions.

4. The conditions and clauses set out in MUTUALLY AGREED TERMS with the PROVIDING COUNTRY for the access of the GENETIC RESOURCES transferred under this contract remain valid for the RECIPIENT and the subsequent UTILISATION of this MATERIAL. The SUPPLIER reserves the right not to supply any MATERIAL if such supply would be contrary to any terms attached to the MATERIAL and/or is not consistent with provisions of the CBD.

5. This MTA is exclusively designed to cover non-commercial uses of GENETIC RESOURCES. Any other uses with the intention of probable or potential commercial UTILISATION or application by the recipient or researchers associated to or mandated by the recipient institutions is not the subject matter of this contract and is not authorised.

6. Definitions of terms are provided in the **Annex (a)** to this AGREEMENT.

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[106] This MTA is an advanced version of the Material Transfer Agreement that was developed jointly with the Global Genome Biodiversity Network (GGBN), used for transfer with a change in ownership / permanent custodianship.

[107] http://www.cbd.int/convention/text/

[108] http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

Parties to AGREEMENT

SUPPLIER:

RECIPIENT (receiving institution):

USER of transferred GENETIC RESOURCES

and/or RESPONSIBLE PROJECT LEADER:

The SUPPLIER supplies the specimens or samples listed on the annex attached to this AGREEMENT ("MATERIAL") under the following terms and conditions:

Ownership of MATERIAL and relevant information

1. The SUPPLIER warrants that it is not aware of third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this AGREEMENT.

2. The SUPPLIER hereby transfers ownership in the MATERIAL to the RECIPIENT.

3. The SUPPLIER makes no representation or warranty that the use of the MATERIAL will not infringe any third party patent or other proprietary right directly or indirectly linked with the provided MATERIAL. The RECIPIENT acknowledges his responsibility to verify if the MATERIAL is or may be the subject of a patent or patent application.

4. Copies of relevant documentation[109], as indicated below, is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT.

☐ Collecting Permit

☐ Mutually-Agreed terms

☐ Prior Informed Consent

☐ Export permit

☐ Import permit

☐ Letter informing Providing Country of third-Party Transfer

☐ CITES Registry code of SUPPLIER

☐ Other (please specify)

☐ The Internationally-Recognized Certificate of Compliance number(s) is/are:

No such documentation is attached because the GENETIC RESOURCES were accessed

☐ Prior to the entering into force of the CBD[110]

☐ Prior to the entering into force of the NP[5]

☐ Original access to the GENETIC RESOURCES was free (no documents have been issued)[111]

5. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying DATA provided by the SUPPLIER;

6. The RECIPIENT shall make associated genetic information resulting from his UTILISATION publicly available

[109] Where there is more than one document of a single type attached please make it clear to which specimens each refers

[110] this condition does not invalidate ABS obligations of the USER or the RECIPIENT

[111] i.e. not restricted under national access laws at the date of original in-situ access

7. The RECIPIENT must submit sequence data to an International Nucleotide Sequence Database Collaboration (INSDC) data repository (GenBank, EMBL or DDBJ) or the Barcode of Life Database (BOLD) with assigned unique tissue or DNA identifiers provided by the SUPPLIER and provide the SUPPLIER with a list of such deposits including the database Accession numbers. Any additional data sent to these databases must remain linked to the original specimen, unique sample IDs, voucher numbers and/or accession number provided by the SUPPLIER.

Benefit-sharing related to acquisition and utilisation of the material detailed in the annex to this contract

8. The RECIPIENT agrees to abide by the PRIOR INFORMED CONSENT (PIC) and MUTUALLY AGREED TERMS (MAT) and any other conditions under which the MATERIAL was originally acquired, providing this is made available, and will contact the PROVIDING COUNTRY prior to any activities that might conflict with the existing PIC and MAT or any other conditions.

9. If, at any time, any product or process derived from MATERIALS shipped under the terms of this AGREEMENT, whether or not such product or process is subject to any proprietary protection claims, is identified as having potential commercial use, new bilateral contracts between the RECIPIENT and PROVIDING COUNTR must be sought covering the intended UTILISATION or product development.

10. The RECIPIENT shall, according on the original access conditions, share fairly and equitably the benefits arising from their UTILISATION of the MATERIAL, its progeny or DERIVATIVES in accordance with the CBD and Nagoya Protocol. A non-exhaustive list of non-monetary and monetary benefits is given at Appendix II and the Annex to the Nagoya Protocol[112].

11. The SUPPLIER will forward information on the MATERIAL supplied on request to the relevant national authority in PROVIDING COUNTRY.

Risks and Warranties

12. The RECIPIENT is solely responsible for safe receipt, use, storage and disposal of MATERIAL and DERIVATIVES.

13. The RECIPIENT acknowledges that the risks represented by any MATERIAL received from the SUPPLIER should be assessed on the basis of intended use.

14. The RECIPIENT acknowledges that it uses the MATERIAL and its derivatives and exercises its rights under this AGREEMENT at its own risk.

15. The RECIPIENT indemnifies the SUPPLIER, its officers, employees and agents ("those indemnified") against all expenses, losses, damages and costs (including legal costs on a full indemnity basis) incurred by or awarded against those indemnified arising out of a claim by any person in relation to:

a. the RECIPIENT's use of the MATERIAL, and its derivatives , and any other exercise of rights under this AGREEMENT; and

b. breach of this AGREEMENT by the RECIPIENT.

[112)] http://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37

Transport of MATERIAL

16. The RECIPIENT shall take all appropriate and necessary measures that the import, storage and UTILISATION of the MATERIAL complies with all applicable laws and regulations.

17. The RECIPIENT is responsible for ensuring that it can provide all required permits to the SUPPLIER if requested.

Agreement

18. TRANSFER or MATERIAL by the RECIPIENT to third parties is only permissible provided the third party agrees with the RECIPIENT in writing to be bound by the terms of this AGREEMENT, specifically to clauses 8-11 and 21.

19. Each party will ensure that its officers, employees and agents comply with the obligations imposed on it by this AGREEMENT as if personally bound by those obligations.

20. This AGREEMENT is governed by and shall be construed in accordance with the law of [country of SUPPLIER]

21. This AGREEMENT terminates immediately if the RECIPIENT willingly or unwillingly violates the clauses and conditions of this contract, especially paragraphs 1-4, 6-24 (breach of this AGREEMENT) or violates the prior MUTUALLY AGREED TERMS that pertains to the transferred MATERIAL that were established with the original PROVIDER OF THE MATERIAL.

22. If termination occurs under 21, the RECIPIENT I is obliged to discontinue the use of the MATERIAL, which is no longer valid under this contract, and destroy any unconsumed MATERIAL and all DERIVATIVES.

Signatures of Parties to the AGREEMENT

Authorized signatory for the SUPPLIER:

Date:

Place:

…….

Name in block letters:

…….

Authorized signatory for the RECIPIENT:

…….

Date:

……

Name in block letters:

Place:

ANNEX (a) to MTA 2. DEFINITION OF TERMS

ACCESS: Acquisition of GENETIC RESOURCES with permission as granted by the country that has sovereign right over those resources (PROVIDING COUNTRY), or other relevant entity. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations. An agreed definition should be included in all legal documents. The EU Regulation defines ACCESS as "the acquisition of GENETIC RESOURCES or of traditional knowledge associated with GENETIC RESOURCES in a Party to the Nagoya Protocol".

AGREEMENT: this document.

BIODIVERSITY BIOBANK: A facility for preservation and storage of typically non-human, GENETIC RESOURCES and associated DATA, which follows standard operating procedures and supplies material for scientific USE. Examples include culture collections, DNA banks and tissue collections.

COLLECTION: A group of SPECIMENs or SAMPLEs that are managed for the purpose of preservation and study. They are generally associated through sharing some feature, e.g. being of the same taxon (e.g. mammals, insects, sharks), from the same general locality or ecosystem, or collected by the same collector or on the same expedition. COLLECTIONs are maintained by COLLECTION-holding institutions, for example natural history museums, herbaria, botanical gardens, seed banks or BIODIVERSITY BIOBANKs.

COMMERCIALISATION,COMMERCIALISE, COMMERCIAL PURPOSES: Applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license or in any other manner, commencement of product development, conducting market assessments, and seeking pre-market approval and/or the sale of any resulting product based on UTILISATION of the original GENETIC RESOURCE or screening of compound libraries. Also the sale, lease, or license of MATERIAL, PROGENY, or DERIVATIVES; or USEs of MATERIAL, PROGENY, or DERIVATIVES by any organization, including the RECIPIENT, to screen compound libraries in order to produce or manufacture products for general sale. Handling fees (e.g. for providing DNA samples), analytical cost recovery, entrance charges etc., fall under the scope of management and/or administration of public facilities, do not involve the UTILISATION of GENETIC RESOURCES, and are not considered as a commercialization of RESEARCH activity on GENETIC RESOURCES.

DATA: Any information associated with a specimen and/or collection which are provided to the RECIPIENT by the SUPPLIER, including but not limited to: provenance information, biological information, taxonomic information, chain of custody information, and images.

DERIVATIVE: Means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or GENETIC RESOURCES, even if it does not contain functional units of heredity (definition from Nagoya Protocol Art 2).

EU REGULATION – Where used in this document, this refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their UTILISATION in the Union, which entered into force for Europe on 6 Jun 2014.

EVALUATION: means both the formulation of the MATERIAL and the testing of the MATERIAL.

GENETIC MATERIAL: Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Article 2 of the Convention on Biological Diversity).

GENETIC RESOURCES: GENETIC MATERIAL of actual or potential value (definition from Article 2 of the Convention on Biological Diversity).

GLOBAL GENOME BIODIVERSITY NETWORK (GGBN): A global network of well-managed COLLECTIONs of genomic tissue samples from across the Tree of Life, benefiting society through biodiversity RESEARCH, and long-term conservation of the archived materials. This network will foster collaborations among BIODIVERSITY BIOBANKS in order to ensure quality standards, improve best practices, secure interoperability, and harmonize transfer of GENETIC RESOURCES, of material in accordance with national laws and best practices.

MATERIAL: Refers to the items listed on the reverse of this AGREEMENT.

MATERIAL TRANSFER AGREEMENT (MTA): An agreement between two institutions stipulating the terms and conditions for transferring SPECIMENs or samples, including GENETIC MATERIAL.

MUTUALLY AGREED TERMS (MAT): An agreement reached between the PROVIDING COUNTRY of GENETIC RESOURCES and users on the conditions of ACCESS and USE and the benefits to be shared between both parties.

OWNERSHIP: Property of a person or institution including all legal rights associated with that property; in some countries also indicated by Transfer of Title or similar documents confirming legal transfer.

PRIOR INFORMED CONSENT (PIC): The permission given by the Competent National Authority of a PROVIDING COUNTRY to a user prior to accessing GENETIC RESOURCES, in line with an appropriate national legal and institutional framework, i.e. what a user can and cannot do with the material.

PROGENY: Unmodified descendant (e.g. subculture or replicate) from the MATERIAL.

PROVIDING COUNTRY / PROVIDER OF MATERIAL: (or "Country providing GENETIC RESOURCES") Means the country supplying GENETIC RESOURCES collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country (Definition from CBD Art 2).

RECIPIENT: The organization to whom the SUPPLIER sends the MATERIAL.

RESEARCH: The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. This does not include any development of commercial or non-commercial applications.

RESPONSIBLE PROJECT LEADER: This is the person that has the obligation to carry out due diligence and any reporting on the UTILISATION including under the EU regulation.

SAMPLE: See also SPECIMEN.

SPECIMEN: This includes any type of biological material. The term “SPECIMEN” is usually synonymous with “material” or “samples” or “subsamples” in this context. The concept can include associated SPECIMENs or materials such as but not limited to parasites and gut content.

SUPPLIER: The party supplying the MATERIAL.

TRANSFER: To convey MATERIAL temporarily or permanently from one person or institution to another.

UNMODIFIED DERIVATIVES: Replicates or substances which constitute an unmodified functional subunit or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA.

USE: The purposes to which samples and SPECIMENs (biological and genetic material) are put, including but not limited to "UTILISATION" in the sense of the Nagoya Protocol.

USER: Person or institution that uses or mandates uses of samples, specimens and MATERIAL including but not limited to "UTILISATION" in the sense of the Nagoya Protocol.

UTILISATION (OF GENETIC RESOURCES): 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 (definition from the Nagoya Protocol).

MTA 3

Material Transfer Agreement for RECEIPT OF MATERIAL, with change in ownership

Preamble

7. This AGREEMENT covers the permanent transfer of MATERIAL containing GENETIC RESOURCES for non-commercial UTILISATION [113] with change in ownership / permanent custodianship.

8. CETAF's activities are guided by the Convention on Biological Diversity (CBD)[114] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)[115]. MATERIAL is transferred between both parties to this AGREEMENT on the condition that users agree to use MATERIAL and DATA in compliance with international laws and conventions. This AGREEMENT is designed to promote and facilitate non-commercial scientific research and transfer of GENETIC RESOURCES, whilst recognising the terms on which the SUPPLIER acquired the MATERIAL.

9. The conditions and clauses set out in MUTUALLY AGREED TERMS with the PROVIDING COUNTRY for the access of the GENETIC RESOURCES transferred under this AGREEMENT remain valid for the RECIPIENT and the subsequent UTILISATION of this MATERIAL. The SUPPLIER reserves the right not to supply any MATERIAL if such supply would be contrary to any terms attached to the MATERIAL and/or is not consistent with provisions of the CBD.

10. This MTA is exclusively designed to cover non-commercial uses of GENETIC RESOURCES. Any other uses with the intention of probable or potential commercial UTILISATION or application by the recipient or researchers associated to or mandated by the recipient institutions is not the subject matter of this AGREEMENT and is not authorised.

11. Definitions of terms are provided in the **Annex (a)** to this AGREEMENT.

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113) This MTA is an advanced version of the Material Transfer Agreement that was developed jointly with the Global Genome Biodiversity Network (GGBN)

114) http://www.cbd.int/convention/text/

115) http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

Parties to AGREEMENT

SUPPLIER:

RECIPIENT (receiving Institution):

USER of transferred GENETIC RESOURCES:

RESPONSIBLE PROJECT LEADER[4]:

The SUPPLIER will supply the MATERIALS listed on the List attached to this AGREEMENT ("MATERIAL") under the following terms and conditions:

Ownership of MATERIAL and relevant information

1. The SUPPLIER warrants that it is not aware of third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this AGREEMENT.
2. The SUPPLIER hereby transfers ownership in the MATERIAL to the RECIPIENT.
3. The SUPPLIER makes no representation or warranty that the use of the MATERIAL will not infringe any third party patent or other proprietary right directly or indirectly linked with the provided MATERIAL. The RECIPIENT acknowledges his responsibility to verify if the MATERIAL is or may be the subject of a patent or patent application.
4. The SUPPLIER acknowledges the ownership of the RECIPIENT in the MATERIAL and shall indicate and disclose information on the original PROVIDING COUNTRY of the GENETIC RESOURCES, the

[116] To be filled in if applicable or needed

date of ACCESS and the source of the transferred MATERIAL and any associated DATA upon request.

5. Copies of relevant documentation[117], as indicated below, is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT.

☐ Collecting Permit

☐ Mutually-Agreed terms

☐ Prior Informed Consent

☐ Export permit

☐ Import permit

☐ Letter informing Providing Country of third-Party Transfer

☐ CITES Registry code of SUPPLIER

☐ Other (please specify)

☐ The Internationally-Recognized Certificate of Compliance number(s) is/are:

☐ No such documentation is attached because the GENETIC RESOURCES were accessed

- ☐ Prior to the entering into force of the CBD[118]
- ☐ Prior to the entering into force of the NP[6]
- ☐ Original access to the GENETIC RESOURCES was free (no documents have been issued)[119]

6. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying DATA or METADATA provided by the SUPPLIER.

7. To the extent that the SUPPLIER owns the copyright or any other intellectual property rights in the Items, the SUPPLIER hereby assigns such rights to the RECIPIENT

[117] Where there is more than one document of a single type attached, or the attached document covers nly some of the specimens, please make it clear to which specimens each refers

[118] This condition does not invalidate ABS obligations of the USER or the RECIPIENT

[119] i.e. not restricted under national access laws at the date of original in-situ access

8. Unless otherwise agreed in writing between the parties, the SUPPLIER hereby assigns to the RECIPIENT the copyright and any other intellectual property rights in the MATRIAL, DATA and METADATA.

9. The RECIPIENT is allowed to use the DATA or METADATA without restrictions for PUBLIC DOMAIN USES (provided General Data Protection Regulation-GDPR- requirements are met) and to disseminate research results, DATA or, METADATA resulting from research activities conducted on the MATERIAL transferred under this AGREEMENT, for example through online media, or print media, and to make it publicly available at no more than the incremental costs of dissemination.

Benefit-sharing related to acquisition and UTILISATION of the material detailed in the annex to this AGREEMENT

10. The RECIPIENT agrees to abide by the PRIOR INFORMED CONSENT (PIC) and MUTUALLY AGREED TERMS (MAT) and any other conditions under which the MATERIAL was originally acquired, providing this is made available, agrees to acknowledge the PROVIDING COUNTRY as the source of the MATERIAL in any and all publications arising from its UTILISATION and will contact the PROVINDING COUNTRY prior to any activities that might conflict with the PIC and MAT and any other conditions.

11. The RECIPIENT shall, if applicable, share fairly and equitably the benefits arising from their UTILISATION of the MATERIAL, its progeny or derivatives in accordance with the CBD. A non-exhaustive list of non-monetary and monetary benefits is given at Appendix II and the Annex to the Nagoya Protocol[120].

12. *The SUPPLIER will forward information on the MATERIAL supplied on request to the relevant national authority in the PROVIDING COUNTRY.*

Risks and Warranties

13. The SUPPLIER warrants that the MATERIAL has not been:
    a. stolen or looted from their rightful owners or country of origin;
    b. obtained by violent means (including during an armed conflict in the country of origin);
    c. obtained in violation of the legislation of their country of origin (i.e. obtained without the necessary permits);
    d. exported illegally or illicitly from their country of origin; or
    e. imported illegally or illicitly into the country of the RECIPIENT.

120) http://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37

14. The SUPPLIER warrants that it will make no subsequent claim to ownership of the MATERIAL following the execution of this Agreement.

15. The RECIPIENT is solely responsible for safe receipt, use, storage and disposal of MATERIAL and DERIVATIVES.

16. The RECIPIENT acknowledges that the risks represented by any MATERIAL received from the SUPPLIER should be assessed on the basis of intended USE.

17. The RECIPIENT acknowledges that it uses the MATERIAL and its DERIVATIVES and exercises its rights under this AGREEMENT at its own risk.

18. The RECIPIENT indemnifies the SUPPLIER, its officers, employees and agents ('those indemnified') against all expenses, losses, damages and costs (including legal costs on a full indemnity basis) incurred by or awarded against those indemnified arising out of a claim by any person in relation to:

c. the RECIPIENT's USE of the MATERIAL, and its DERIVATIVES , and any other exercise of rights under this AGREEMENT; and

d. breach of this AGREEMENT by the RECIPIENT.

Transport of MATERIAL

19. The RECIPIENT and SUPPLIER shall take all appropriate and necessary measures that the importation, storage and UTILISATION of the MATERIAL complies with all applicable laws and regulations;

20. The RECIPIENT is responsible for ensuring that it can provide all required import permits to the SUPPLIER if requested.

Agreement

21. TRANSFER of MATERIAL by the RECIPIENT to third parties is only permissible provided the third party agrees with the RECIPIENT in writing to be bound by the terms of this AGREEMENT, specifically to clauses 10-12.

22. Each party will ensure that its officers, employees and agents comply with the obligations imposed on it by this AGREEMENT as if personally bound by those obligations.

This AGREEMENT is governed by and shall be construed in accordance with the law of the home country of the RECIPIENT (please specify)

_____.

Signatures of Parties to the AGREEMENT

Authorized signatory for the SUPPLIER:	Authorized signatory for the RECIPIENT:
…….	……
Name in block letters:	Name in block letters:
…….	…….
Date:	Date:
Place:	Place

ANNEX (a) to MTA 3. DEFINITION OF TERMS

ACCESS: Acquisition of GENETIC RESOURCES with permission as granted by the country that has sovereign right over those resources (PROVIDING COUNTRY), or other relevant entity. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations. An agreed definition should be included in all legal documents. The EU Regulation defines ACCESS as 'the acquisition of GENETIC RESOURCES or of traditional knowledge associated with GENETIC RESOURCES in a Party to the Nagoya Protocol'.

AGREEMENT: this document.

BIODIVERSITY BIOBANK: A facility for preservation and storage of typically non-human, GENETIC RESOURCES and associated DATA, which follows standard operating procedures and supplies material for scientific USE. Examples include culture collections, DNA banks and tissue collections.

COLLECTION: A group of SPECIMENs or SAMPLEs that are managed for the purpose of preservation and study. They are generally associated through sharing some feature, e.g. being of the same taxon (e.g. mammals, insects, sharks), from the same general locality or ecosystem, or collected by the same collector or on the same expedition. COLLECTIONs are maintained by COLLECTION-holding

institutions, for example natural history museums, herbaria, botanical gardens, seed banks or BIODIVERSITY BIOBANKs.

COMMERCIALISATION,COMMERCIALISE, COMMERCIAL PURPOSES: Applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license or in any other manner, commencement of product development, conducting market assessments, and seeking pre-market approval and/or the sale of any resulting product based on UTILISATION of the original GENETIC RESOURCE or screening of compound libraries. Also the sale, lease, or license of MATERIAL, PROGENY, or DERIVATIVES; or USEs of MATERIAL, PROGENY, or DERIVATIVES by any organization, including the RECIPIENT, to screen compound libraries in order to produce or manufacture products for general sale. Handling fees (e.g. for providing DNA samples), analytical cost recovery, entrance charges etc., fall under the scope of management and/or administration of public facilities, do not involve the UTILISATION of GENETIC RESOURCES, and are not considered as a commercialization of RESEARCH activity on GENETIC RESOURCES.

DATA: Any information associated with a specimen and/or collection which are provided to the RECIPIENT by the SUPPLIER, including but not limited to: provenance information, biological information, taxonomic information, chain of custody information, and images.

DERIVATIVE: Means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or GENETIC RESOURCES, even if it does not contain functional units of heredity (definition from Nagoya Protocol Art 2).

EU REGULATION – Where used in this document, this refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, which entered into force for Europe on 6 Jun 2014.

GDPR-General Data Protection Regulation: the EU regulation (EU) 2016/679 enforced on 25 May 2018 to harmonize data privacy laws across Europe, and protect citizens from privacy and data breaches across Europe.

GENETIC MATERIAL: Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Article 2 of the Convention on Biological Diversity).

GENETIC RESOURCES: GENETIC MATERIAL of actual or potential value (definition from Article 2 of the Convention on Biological Diversity).

GLOBAL GENOME BIODIVERSITY NETWORK (GGBN): A global network of well-managed COLLECTIONs of genomic tissue samples from across the Tree of Life, benefiting society through biodiversity RESEARCH, and long-term conservation of the archived materials. This network will foster collaborations among BIODIVERSITY BIOBANKS in order to ensure quality standards, improve best practices, secure interoperability, and harmonize transfer of GENETIC RESOURCES, of material in accordance with national laws and best practices.

MATERIAL: Refers to the items listed on the reverse of this AGREEMENT.

MATERIAL TRANSFER AGREEMENT (MTA): An agreement between two institutions stipulating the terms and conditions for transferring SPECIMENs or samples, including GENETIC MATERIAL.

METADATA: Any data associated with the MATERIAL that describes the origin or identifies the original provenience of the MATERIAL.

MODIFICATIONS: Substances created by the RECIPIENT by using the MATERIAL which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.

MUTUALLY AGREED TERMS (MAT): An agreement reached between the PROVIDING COUNTRY of GENETIC RESOURCES and users on the conditions of ACCESS and USE and the benefits to be shared between both parties.

ORIGINAL MATERIAL: That which was originally supplied to the SUPPLIER by the depositor.

OWNERSHIP: Property of a person or institution including all legal rights associated with that property; in some countries also indicated by Transfer of Title or similar documents confirming legal transfer.

PRIOR INFORMED CONSENT (PIC): The permission given by the Competent National Authority of a PROVIDING COUNTRY to a user prior to accessing GENETIC RESOURCES, in line with an appropriate national legal and institutional framework, i.e. what a user can and cannot do with the material.

PROGENY: Unmodified descendant (e.g. subculture or replicate) from the MATERIAL.

PROVIDING COUNTRY / PROVIDER OF MATERIAL: (or "Country providing GENETIC RESOURCES") Means the country supplying GENETIC RESOURCES collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country (Definition from CBD Art 2).

PUBLIC DOMAIN USE: means scientific research that aims at making analytic results and knowledge publicly available at no more than incremental costs for dissemination, and without protecting or aiming to protect such results under patent, intellectual property or similar rights.

RECIPIENT: The organization to whom the SUPPLIER sends the MATERIAL.

RESEARCH: The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. This does not include any development of commercial or non-commercial applications.

RESPONSIBLE PROJECT LEADER: This is the person that has the obligation to carry out due diligence and any reporting on the UTILISATION including under the EU regulation.

SAMPLE: See also SPECIMEN.

SPECIMEN: This includes any type of biological material. The term “SPECIMEN” is usually synonymous with “material” or “samples” or “subsamples” in this context. The concept can include associated SPECIMENs or materials such as but not limited to parasites and gut content.

SUPPLIER: The party supplying the MATERIAL.

TRANSFER: To convey MATERIAL temporarily or permanently from one person or institution to another.

UNMODIFIED DERIVATIVES: Replicates or substances which constitute an unmodified functional subunit or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA.

USE: The purposes to which samples and SPECIMENs (biological and genetic material) are put, including but not limited to 'UTILISATION' in the sense of the Nagoya Protocol.

USER: Person or institution that uses or mandates uses of samples, specimens and MATERIAL including but not limited to 'UTILISATION' in the sense of the Nagoya Protocol.

UTILISATION (OF GENETIC RESOURCES): 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 (definition from the Nagoya Protocol).

Consortium of European Taxonomic Facilities (CETAF)

ANNEX 6.4 to the CETAF CoC for ABS

MATERIAL TRANSFER AGREEMENT - MTA 4

Agreement for guest researchers BRINGING BIOLOGICAL MATERIAL to facilitate their own research at hosting institutions

Preamble

1. This AGREEMENT is between [Institution] (the HOSTING INSTITUTION) and an external researcher[121] not employed by or otherwise working for [*Institution*] and using RESEARCH MATERIALs containing GENETIC RESOURCES

☐ for research that does not include UTILISATION in the sense of the Nagoya Protocol[122]

☐ **for UTILISATION in the sense of the Nagoya Protocol**[123]

It grants permission to conduct RESEARCH in the labs of the HOSTING INSTITUTION.

2. The Activities of the HOSTING INSTITUTION are guided by the *Convention on Biological Diversity* (CBD)[124] and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their utilization* (ABS)[125] and *the CETAF Code of Conduct*, the *CETAF Use Statement* and *CETAF Best Practice on use and utilisation of objects containing GENETIC RESOURCES*. Researchers bringing and using any MATERIAL must be compliant with international laws and conventions as well with established internal procedures and policies when using our facilities. The HOSTING INSTITUTION reserves the right not to grant allowance to bring MATERIAL into the institution if its use would be contrary to our institutional ABS policies and/or is not consistent with provisions of the CBD, the NP or other relevant laws.

3. Definitions of terms are provided in the Annex to this AGREEMENT.

[121] Including students from institutions other than the HOSTING INSTITUTION
[122] such as morphological investigation, stable isotope analysis, ct-scanning, 3-d reconstructions, etc.
[123] such as DNA-extractions and any sequencing activities or investigations on the genomes of biological materials
[124] http://www.cbd.int/convention/text/
[125] http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

Parties to AGREEMENT

GUEST RESEARCHER (*name and institution*):

HOSTING INSTITUTION (*name and Department*):

For the purposes of this AGREEMENT RESEARCH MATERIALs and/or DERIVATIVES would include tissues, samples, subsamples, and GENETIC RESOURCES such as, inter alia, DNA and/or PCR products. The MATERIAL/DERIVATIVES I am transporting into [enter name of research facility]

The MATERIAL/DERIVATIVES (SPECIMENS) I am transporting into [*Institution*] (the HOSTING INSTITUTION) as stated on the attached list (attached as **List A** and hereinafter referred to as "RESEARCH MATERIAL") are for the specific and limited purpose of study and analysis.

[126] person that may have or is appointed with ABS-reporting obligations

Warranty for bringing external research materials for analytical purposes to the facilities of the HOSTING INSTITUTION

In consideration of the opportunity to study and analyse these RESEARCH MATERIALs in this research institution, **I make, on behalf of myself and my institution, the following representations and warranties**:

I am ☐ / I am not ☐ bringing in unregistered BIOLOGICAL MATERIAL[127]

I am ☐ / I am not ☐ bringing in registered BIOLOGICAL MATERIAL[128]

I am ☐ / I am not ☐ authorized to have custody of and to conduct RESEARCH upon the RESEARCH MATERIALs in my possession

I am ☐ / I am not ☐ using BIOLOGICAL MATERIAL of the HOSTING INSTITUTION

I am ☐ / I am not ☐ bringing in MATERIAL/DERIVATIVES for UTILISATION in the sense of the NP.

I am ☐ / **I am not** ☐ not bringing in sequence / genomic data.

AND,

To my knowledge, all applicable laws and regulations regarding the collection, possession, transportation, exportation and importation of these research specimens have been observed and fully satisfied in all relevant jurisdictions; I acknowledge that I have full responsibility ensuring that this has been done.

I take the responsibility for submitting, as a result of my research activities, any due diligence declaration or other report under Nagoya Protocol / ABS compliance laws or regulations, including Regulation 511/2014 of the European Parliament and Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their UTILISATION in the Union.

Agreement

I understand that I am expected to take any external RESEARCH MATERIALs (original and/or newly generated) with me when I leave the facilities of the HOSTING INSTITUTION.

If any external RESEARCH MATERIALs remain at the HOSTING INSTITUTION with permission of the HOSTING INSTITUTION, I understand that I am ceding authority for acquiring or disposing of the RESEARCH MATERIALs at the institution's discretion, according to terms of the applicable Collections Management and ABS Policies. I further represent and warrant that I am fully authorized to make these decisions regarding use or disposal of these MATERIALs.

☐ I agree to abide by institutional policies including ABS policies and procedures of the HOSTING INSTITUTION.

[127] e.g. field samples not registered in any institutional collection
[128] e.g. material accessioned into or registered by an institutional collection

☐ I agree to forward information on the MATERIAL on request of the HOSTING INSTITUTION and relevant national authorities.

Duration of the Agreement and applicable law

1. Neither party may assign or otherwise transfer this AGREEMENT and the rights acquired hereunder without the written consent of the other party. Any permitted assignee must agree in writing to be bound by the terms of this AGREEMENT.
2. Each party will ensure that its officers, employees and agents comply with the obligations imposed on it by this AGREEMENT as if personally bound by those obligations.
3. This AGREEMENT will terminate on the earliest of the following occasions[129]:

☐ On completion of the GUEST RESEARCHER'S current research at the HOSTING INSTITUTION

☐ On the departure of the GUEST RESEARCHER from the HOSTING INSTITUTION

☐ On a thirty (30) day written notice by either party to the other

☐ On the predetermined closure date of this AGREEMENT [date: DD/MM/YYYY].

The expiration or termination of this AGREEMENT, shall not affect other legal obligations of the GUEST RESEARCHERS entered into with the HOSTING INSTITUTION. This AGREEMENT is governed by and shall be construed in accordance with the law of the home country of the HOSTING INSTITUTION.

Name (in block letters) signature Guest Researcher:

…… ……

The following signatures grant permission to utilise genetic resources and conduct research at:

Name of HOSTING INSTITUTION

……

Confirmed by:

[129] multiple selections possible

…….

Date:

Place:

ANNEX A to MTA 3. DEFINITION OF TERMS

ACCESS: Acquisition of GENETIC RESOURCES with permission as granted by the country that has sovereign right over those resources (PROVIDING COUNTRY), or other relevant entity. Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organizations. An agreed definition should be included in all legal documents.

The EU Regulation defines ACCESS as 'the acquisition of GENETIC RESOURCES or of traditional knowledge associated with GENETIC RESOURCES in a Party to the Nagoya Protocol'.

AGREEMENT: this document.

BIOLOGICAL MATERIAL – All specimens and samples of or subsamples from living or dead organisms, regardless if they contain 'functional units of heredity' or not.

COMMERCIALISATION,COMMERCIALISE, COMMERCIAL PURPOSES: Applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license or in any other manner, commencement of product development, conducting market assessments, and seeking pre-market approval and/or the sale of any resulting product based on UTILISATION of the original GENETIC RESOURCE or screening of compound libraries. Also the sale, lease, or license of MATERIAL, PROGENY, or DERIVATIVES; or USEs of MATERIAL, PROGENY, or DERIVATIVES by any organization, including the RECIPIENT, to screen compound libraries in order to produce or manufacture products for general sale. Handling fees (e.g. for providing DNA samples), analytical cost recovery, entrance charges etc., fall under the scope of management and/or administration of public facilities, do not involve the UTILISATION of GENETIC RESOURCES, and are not considered as a commercialization of RESEARCH activity on GENETIC RESOURCES.

DERIVATIVE: Means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or GENETIC RESOURCES, even if it does not contain functional units of heredity (definition from Nagoya Protocol Art 2).

EU REGULATION – Where used in this document, this refers to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, which entered into force for Europe on 6 Jun 2014.

GENETIC MATERIAL: Any material of plant, animal, microbial or other origin containing functional units of heredity (definition from Article 2 of the Convention on Biological Diversity).

GENETIC RESOURCES: GENETIC MATERIAL of actual or potential value (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

GLOBAL GENOME BIODIVERSITY NETWORK (GGBN): A global network of well-managed COLLECTIONs of genomic tissue samples from across the Tree of Life, benefiting society through biodiversity RESEARCH, and long-term conservation of the archived materials. This network will foster collaborations among BIODIVERSITY BIOBANKS in order to ensure quality standards, improve best practices, secure interoperability, and harmonize transfer of GENETIC RESOURCES, of material in accordance with national laws and best practices.

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MODIFICATIONS: Substances created by the RECIPIENT by using the MATERIAL which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.

MUTUALLY AGREED TERMS (MAT): An agreement reached between the PROVIDING COUNTRY of GENETIC RESOURCES and users on the conditions of ACCESS and USE and the benefits to be shared between both parties.

ORIGINAL MATERIAL: That which was originally supplied to the SUPPLIER by the depositor.

OWNERSHIP: Property of a person or institution including all legal rights associated with that property; in some countries also indicated by Transfer of Title or similar documents confirming legal transfer.

PRIOR INFORMED CONSENT (PIC): The permission given by the Competent National Authority of a PROVIDING COUNTRY to a user prior to accessing GENETIC RESOURCES, in line with an appropriate national legal and institutional framework, i.e. what a user can and cannot do with the material.

PROGENY: Unmodified descendant (e.g. subculture or replicate) from the MATERIAL.

PROVIDING COUNTRY / PROVIDER OF MATERIAL: (or "Country providing GENETIC RESOURCES") Means the country supplying GENETIC RESOURCES collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country (Definition from CBD Art 2).

RECIPIENT: The organization to whom the SUPPLIER sends the MATERIAL.

RESEARCH: The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. This does not include any development of commercial or non-commercial applications.

RESPONSIBLE PROJECT LEADER: The person that has the obligation to carry out due diligence and any reporting on the UTILISATION including under the EU ABS regulation.

SAMPLE: See SPECIMEN.

SPECIMEN: This includes any type of biological material. The term “SPECIMEN” is usually synonymous with “material” or “sample” or “subsample” in this context. The concept can include associated SPECIMENs or materials such as but not limited to parasites and gut content.

SUPPLIER: The party supplying the MATERIAL.

TRANSFER: To convey MATERIAL temporarily or permanently from one person or institution to another.

UNMODIFIED DERIVATIVES: Replicates or substances which constitute an unmodified functional subunit or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA.

USE: The purposes to which samples and SPECIMENs (biological and genetic material) are put, including but not limited to 'UTILISATION' in the sense of the Nagoya Protocol.

USER: Person or institution that uses (including through subcontracting) of samples, specimens and MATERIAL including but not limited to 'UTILISATION' in the sense of the Nagoya Protocol.

UTILISATION (OF GENETIC RESOURCES): 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 (definition from the Nagoya Protocol).

ANNEX 7 to the CETAF CoC for ABS

DATA USE STATEMENT

This text may be added in the introduction or elsewhere in scientific papers. It may also be appended to uploaded digital records such as DNA sequences, molecular composition etc.

Data on genetic material contained in this paper / in this database are published for non-commercial use only. Use by third parties for purposes other than non-commercial scientific research may infringe the conditions under which the genetic resources were originally accessed, and should not be undertaken without obtaining consent from the corresponding author of the paper and/or obtaining permission from the original provider of the genetic material.