CETAF

CONSORTIUM OF EUROPEAN TAXONOMIC FACILITIES

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

THE PACKAGE OF DOCUMENTS

In order to fully support the operations of taxonomic collection-holding and non-commercial biological research institutions in complying with the Nagoya Protocol of the Convention on Biological Diversity (CBD), and the pending European Access and Benefit-Sharing (ABS) Regulation, a package of documents is needed. The function of these documents is to explain to both providers and users how biological specimens are used by these institutions. This will support the negotiation of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), outline the principles under which collections are operated, and provide details of the practices undertaken to ensure those principles are followed. Such documents are already in use by a number of networks, but few thus far have been broadened across botanical and zoological collection holders, or updated to include the Nagoya Protocol requirements.

The Consortium of European Taxonomic Facilities, aware of this need, is developing a single package of documents, in order to provide guidance on means for such organisations to successfully implement the Nagoya Protocol. This will be available for CETAF Members and, equally, to any other institution that, while not being a member of the Consortium, wishes to implement the principles and the content of the documents included in this package.

The 'package' of documents contains several elements:

1) Use statement. This outlines the uses to which the biological resources (specimens) may be put, including details of utilization of genetic resources. This will support obtaining Prior Informed Consent and provides a useful reference for text in the other documents.
2) Code of Conduct. This provides the overview of the way in which the signatory institutions operate, through baseline standards for use of biological resources.
3) Best Practice. This provides detail of how the Code of Conduct should be implemented, including recommendations for policies and processes.

In addition to the documents listed above, which are provided below, CETAF is developing two more:

4) Material Transfer Agreement (MTA). This sets out the terms under which specimens are transferred from one party to another. A standard MTA will provide consistency when

transferring specimens from one collection to another. MAT, where they have been negotiated, will underpin the clauses used in MTAs

5) Draft templates for MAT & PIC as guidance for ABS negotiations in countries of origin.

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USE STATEMENT

This document sets out the typical/usual ways in which biological resources[1] accessioned into the collections of [*institution name*] ("[*institution acronym*]"), will be used. This includes use both in facilities managed or owned by the legal body and in facilities owned or managed by others but used for specific purposes under the direct responsibility of the institution (for example temporary use of external labs such as for DNA sequencing). If suppliers of biological resources do not wish their material to be treated in this way or wish to place any specific restrictions on use, this needs to be expressly set out in writing when granting access, or when donating or exchanging the resources with [*institution*]. If the supplier does not place any express written restrictions on these uses, then the material will be accessioned and used by [*institution*] under the conditions set out below.

[*institution*] is a member of [*network name*] and subscribes to the [*network name*] Code of Conduct and Best Practice.

CETAF USE OF BIOLOGICAL MATERIAL

Research at [*institution*]: Any biological resources at [*institution*] will be made available to its staff and authorised visitors for non-commercial scientific research on systematics, ecology, conservation, genetics, horticulture, morphology, physiology, molecular biology, genomics, environmental genomics and sustainable use. Such work may involve making anatomical and cytological preparations, carrying out isotope analysis, and sampling for pollen, spores, and/or chemicals. DNA and RNA may be sequenced.

Research results: Results of research will be made available through publication in printed form (books, scientific journals), publically-available databases, published images or internet sites. DNA sequence data will be deposited in publicly-available databases such as GenBank and referenced to the respective biological specimens stored at [*institution*]. It is usual practice for [*institution*] to provide a copy of published research results to its local counterpart(s) and to acknowledge its counterpart(s) in any such publications.

Information and images: As a scientific institution it is important that [*institution*] makes its collections as accessible as possible to its direct scientific counterparts and to the wider scientific and conservation community. This may involve the digital imaging of specimens and of associated data, and publication of such images and information to be freely available on the internet. Images and data may also be presented in research publications. [*Institution*] will maintain data records on the biological resources stored in its collections to enable its origin and associated records such as PIC and MAT to be retrieved.

[1] In the definitions provided by the CBD 'biological resources' include 'genetic resources'. Because some of the uses to which biological specimens are put in research do not include utilization of genetic resources the more inclusive term is used in this document where appropriate.

Loans: [*institution*] may lend biological resources (specimens) to third parties in other scientific research institutions for identification, further scientific research or for educational purposes subject to the standard Loan Conditions of the [*institution*] [**Optional text**: *URL if Loan Conditions are available on the internet*]. The terms of these Conditions include that the specimens may only be used [**Optional text, but some description is required here**: *for non-commercial purposes / in a way consistent with the Mutually Agreed Terms under which the material was obtained from the Providing Country /in a way consistent with this Use Statement and the CETAF Code of Conduct on Access and Benefit Sharing*] unless there is specific permission from [*institution*]. Such permission would only be given [**Optional text**: *if the third party agrees MAT with the Providing Country / with permission from the Providing Country / or, for material acquired prior to the entry into force of the CBD (29th December 1993), in a way consistent with this Use Statement and the borrower is from an institution that is signatory to the CETAF Code of Conduct on Access and Benefit Sharing*].

Permanent Supply to third parties: [*institution*] may supply biological resources permanently 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, unless this is excluded by the Providing Country in the respective MAT. Transfer will be effected when the recipient institution or individual has signed a "Material Transfer Agreement" with [institution] [**Optional text**: *excluding any commercialisation or other utilization of genetic resources not in accordance with the original MAT (if appropriate) arising from utilization of any genetic resources supplied and has signed the CETAF Code of Conduct on Access and Benefit Sharing / has agreed MAT with the Providing Country*].

Propagation and public display: Live specimens will be made available to [*institution*] staff and authorised visitors for [**Optional alternatives:** *propagation*[2] */ breeding*[3]]. 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.

Traditional Knowledge

Traditional Knowledge (TK) in the public domain may be used in research and may be published in paper or electronic formats. The [*institution*] will, as far as is practicable and reasonable, for TK known to be in its collections, store it in such a way that it is not made available to third parties or released into the public domain without PIC and MAT, if the holder is known.

Commercialisation

[*institution*] is a not-for-profit institution and is [**Optional alternatives**: *not / only rarely*] involved in commercialisation of its 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, and this research may lead to the discovery of potential commercial uses of certain genetic resources.

[*institution*] will not Commercialise any [**Optional alternatives:** *biological / genetic*] resources collected after the Convention on Biological Diversity came into force (29th December 1993) and prior to the coming into force of the Nagoya Protocol without the prior informed consent of the

[2] For botanical collections
[3] For zoological collections

Providing Country and any bodies within that country as required, including local communities. [*Institution*] also undertakes to share any benefits arising from such Commercialisation fairly and equitably, as far as is possible.

Should [*institution*] wish to Commercialise any genetic resources collected before the Convention on Biological Diversity came into force (29th December 1993), [*institution*] will, as far as is possible, share benefits fairly and equitably.

Benefit-sharing

At all times, and regardless of when biological resources were acquired by [*institution*], [*institution*] will use its best efforts to share fairly and equitably with the Providing Country, or appropriate stakeholders[4], any benefits arising from the utilisation of genetic resources obtained from that country. Non-monetary benefits may involve, *inter alia*: scientific training, education and capacity building; collaboration on relevant scientific work programmes; and the mutual sharing of research results and of associated publications (Nagoya Protocol Annex: non-monetary benefits; see also Annex 2 to this document).

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CETAF CODE OF CONDUCT ON ACCESS AND BENEFIT-SHARING

CETAF 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 Member Institutions commit themselves to the following Code of Conduct on access to genetic resources and benefit-sharing. This is to be read in the context of the "Use of Biological material" document.

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 CBD, The Nagoya Protocol to the CBD, The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and other relevant international agreements.
- Abide by international and national laws and regulations relating to Access and Benefit-sharing, including those relating to Traditional Knowledge.
- Comply with PIC, MAT and other agreements entered into with and within the Providing Country (and also the provider if from ex situ source).

Acquisition of genetic resources

CETAF Member institutions will:

[4] Using the Global Multilateral Benefit Sharing Mechanism where necessary and appropriate, once this is in place.

- In order to obtain Prior Informed Consent, provide a full explanation of the purposes for which the biological resources will be acquired and used and how genetic resources will be utilized (within current technical understanding).
- When accessing genetic resources from *in situ* conditions, (i) obtain information on the Providing Country's access laws and the procedures for obtaining Prior Informed Consent and relevant permits, and for agreeing Mutually Agreed Terms, and (ii) obtain Prior Informed Consent and relevant permits from the Government of the Providing Country and any other relevant stakeholders, and (iii) agree terms, according to applicable law and best practice.
- When acquiring genetic resources from *ex situ* collections, agree terms under which the material can be utilized with the body governing the *ex situ* collection.
- When acquiring genetic resources from *ex situ* sources, whether from scientific collections, commercial sources or individuals, evaluate available documentation and, where necessary, take appropriate steps to ensure, as far as is reasonably possible, that the genetic resources were acquired in accordance with applicable law and best practice.

Use and supply of genetic resources

CETAF Member institutions will:

- Utilize genetic resources and their derivatives on terms and conditions consistent with those under which they were accessed or otherwise acquired.
- Use Traditional Knowledge only on the terms and conditions under which it was acquired.
- Request new PIC and MAT agreements if a new use is proposed that triggers the need for additional agreements, and not change the use without such agreements.
- Supply biological resources and their derivatives to third parties on loan only on terms and conditions consistent with those under which they were acquired. Should a third party seek to utilize genetic resources in a way not covered by the original agreements or that triggers the need for additional agreements, the GR will not be supplied until the third party has approached the Providing Country and secured appropriate PIC and MAT.
- Transfer genetic resources and their derivatives permanently to third parties only with copies of the documentation showing agreements with the Providing Country, where applicable, including PIC, MAT or other relevant permits. Should a third party seek to utilize genetic resources in a way not covered by the original agreements, the GR will not be supplied until the third party has approached the Providing Country and secured appropriate PIC and MAT.

Use of written agreements

CETAF Member institutions will:

- Access or otherwise acquire genetic resources and Traditional Knowledge using written agreements, where required by applicable law and best practice, ensuring there is a record of Prior Informed Consent (PIC) by the appropriate national bodies and any relevant bodies within the Providing country, and setting out the terms and conditions under which the genetic resources may be acquired, used and supplied and resulting benefits shared (Mutually Agreed Terms). These documents may be separate as outlined, take the form of a permit where appropriate under national legislation, or any other required form.
- Supply genetic resources and derivatives, and Traditional Knowledge to Third Parties using written Material Transfer Agreements (MTA), where required by applicable law and best practice, setting out the terms and conditions under which the genetic resources may be acquired, used and supplied and resulting benefits shared (MAT).

Traditional Knowledge

CETAF Member institutions will:

- As far as practicable maintain a permanent record of any Traditional Knowledge (TK) known to be in its collections, including in its library, archives or associated with specimens, in order to ensure appropriate management.
- As far as is practicable and reasonable safeguard TK information and store it in such a way that it is not made available to third parties or released into the public domain without PIC and MAT, if the holder is known.

Benefit-sharing

CETAF Member institutions will:

- Share benefits arising from their utilization of genetic resources and their derivatives fairly and equitably with the Providing Country and other appropriate stakeholders.
- Strive to share benefits arising from the use of genetic resources accessed or otherwise acquired prior to the entry into force of the CBD, as far as possible, in the same manner as for those acquired thereafter.

Curation[5]

In order to comply with these Principles, CETAF Member institutions will maintain records and mechanisms to:

- record the terms and conditions under which genetic resources and traditional knowledge are accessed or otherwise acquired;
- track their utilization of GR, and benefits arising from that utilization;
- record supply to third parties, including the terms and conditions of supply; and
- record when and how genetic resources and traditional knowledge records pass out of custodianship, including complete consumption of samples or disposal.

Custodianship

CETAF Member Institutions will retain genetic resources and TK permanently and manage them as it manages other resources within the collections it cares for unless otherwise stipulated by MAT or MTA.

Policies

CETAF Member institutions will:

- Prepare, adopt and communicate institutional policies setting out how the Participating Institution will implement these Principles.
- Prepare a transparent policy on utilization of genetic resources and their derivatives.

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[5] It has been suggested that this also include the duration of custodianship, the default being permanent, but of course dependant on the conditions of the MAT/MTA

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CETAF BEST PRACTICE ON ACCESS AND BENEFIT-SHARING

CETAF Member Institutions endorse the following Best Practice on access to genetic resources and benefit-sharing.

Preamble

These Best Practice components are designed to indicate routes to implement the CETAF Code of Conduct on Access and Benefit-sharing, and cover uses of biological specimens, including genetic resources, as set out in the *Use Of Biological Material* statement.

The Best Practice on Access and Benefit-sharing outlines the requirements that should be considered when conducting day-to-day work at the institution. Not all parts of this practice may be relevant or applicable for all institutions to implement.

The following components are covered:

- Policies
- Data management / curation
- Staff training
- Fieldwork
- Utilization
- Utilization by third parties
- Benefit-sharing
- Disposal of collections

Policies

The policies and associated processes should ensure:

- The institution understands its rights and responsibilities under the appropriate treaties and relationships with Providers;
- Its staff, authorised visitors and associates abide by appropriate national, infranational and international laws and regulations when working in or on behalf of the institution;
- biological resources entering the repository are obtained with appropriate legal certainty;
- biological resources deposited in the repository can legally be retained;
- terms and conditions (PIC[6], MAT[7], MTAs[8], Permit(s) and MoC[9]s) governing samples are complied with by the repository, including staff of the repository and third parties using the repository, and that renegotiation takes place in the case of proposed change in utilization from that previously agreed ;
- terms and conditions (PIC, MAT, MTAs, Permit(s) and MoCs) governing biological resources are recorded and can be accessed effectively to manage use of those resources, including third-party transfer and disposal. This should include incorporation within a records management system and data management system;

[6] PIC – Prior Informed Consent – see glossary
[7] MAT – Mutually Agreed terms – see glossary
[8] MTA – Material transfer Agreement – see glossary
[9] MoC – Memorandum of Cooperation – see glossary

- the institution can address benefit-sharing issues regarding Genetic Resources held that were accessed prior to the requirement for PIC, MAT or Permit, or from countries where such requirements do not exist, or which have not signed and ratified the Nagoya Protocol.

Any policies on GRs should be explicit about who is obliged to follow them (e.g. staff, whether on-site 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 etc).

Clear policies should be adopted to cover the institution's work in all areas where relevant, e.g. provisions arising from the Nagoya Protocol and other ABS regulations and legislation might apply. They need to govern activities or points in workflows where decisions have to be taken which have an ABS implication or are governed by ABS considerations ABS concerns have to be managed.

The institution should have an overall Access and Benefit-Sharing policy (this can be an 'umbrella' policy covering all aspects of Access and Benefit-Sharing and be used as a reference in other policies). Aspects that may be considered for separate policy statements include:

Acquiring new specimens:

1. Field Collecting – to cover all aspects of collecting, including the requirement to obtain appropriate permits, PIC and MAT.
2. Object Entry – governing what legal documentation is required by the institution when specimens enter the Institution, including, 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 of the Institution. The policy may need to address:
    a. Documents required (e.g. PIC, MAT. MTA, Transfer of Title document);
    b. Authorising individual within institution;
    c. Means of managing compliance with MAT;
    d. Issues associated with the legal framework governing the collections and how this can accommodate persistent obligations (e.g. the fairly common inclusion in MAT that newly-described holotypes be returned to the Country of Origin).
4. Incoming research loans – setting out conditions under which loans received by staff or other associates of the institution can be accepted in the context of ABS. This is important since staff in this circumstance risk being in breach of terms under which genetic resources were accessed if they are unaware of those terms, or of illegally utilizing genetic resources if they were illegally collected.

Managing the collection

5. Frozen tissue / DNA collections – where these are separate. Since such collections are comparatively novel for many institutions, they may have separate policies; these should include reference to ABS requirements.
6. Living collections – Utilization of cultures and other bred and propagated organisms in collections, including agreements required for supply to third parties.
7. Traditional Knowledge – covering all aspects of the institution's collecting, documenting, storing and release of Traditional Knowledge. Should include how it is stored, who can access it, conditions under which it can be made public.

8. Long-term loans and material held in trust for provider countries. Should include documentation required, MAT.
9. Destructive and invasive sampling – covers use of frozen and other collections for DNA extraction, and consequently requirements to observe restrictions and requirements agreed with the Providing Country or other provider of genetic resources. May also cover utilization of genetic resources by third parties (e.g. recipients of loans, visitors), and protocols for publicising sequence data (e.g. through GenBank).
10. Incoming and outgoing exhibition loans / acquisition – although not utilized for scientific research such loans may require ABS permits (including for Traditional Knowledge). They also may be required to comply with additional requirements such as CITES compliance.
11. Outgoing research loans – conditions under which users in other institutions can borrow Biological resources, including:
    a. what analytical processes loan recipients are permitted to carry out on material received, including compliance with terms under which material was acquired;
    b. return or disposal of any residual samples / aliquots / derivatives that have not been consumed for analysis;
    c. any subsequent utilization by a borrower;
    d. requirements for documentation to be provided with loans (e.g. copies of original PIC and MAT or summary thereof);
    e. action should commercialisation be requested by the third party (e.g. requirement for renegotiation of PIC, MAT or MTA by borrower with the Providing Country);
    f. action should the third party undertake inappropriate utilization.
12. Research – governing access to GR, utilisation of GR and publication of results during research activities by the institution. This may be covered by other ABS policy elements, or a separate policy may be required.
13. 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. sharing content of ABS documents with third parties, including through reporting;
    c. special treatment of sensitive information (e.g. TK, information restricted under PIC and MAT).
    d. Record-keeping (see Annex 3).
14. Internal Collections Audit – Regular audit of a sample of genetic resources to determine if the institution is managing its ABS documentation, compliance with agreements and associated processes effectively and whether improvements are required or possible.

Removal of specimens from the collection

15. 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 derivates thereof;
    b. documentation required by recipient;
    c. situation under which renegotiation of PIC/MAT or MTA is required;
    d. documentation required by the Country of Origin or Provider Country.

    Some of the above is covered under 'Outgoing research loans'.
16. Loss – the course of action to be taken with regard to ABS requirements (e.g. under MAT), including documentation, in the event of loss of specimens from the collections.

17. Disposals (including exchanges and transfers) - governing how specimens leave the ownership of the Institution, which may be governed by Mutually Agreed terms or a Material Transfer Agreement.

Institutions may find it helpful to manage all required infranational, national and international legal documentation under the same policy umbrella; by doing this they will be able to use common database solutions and provide more effective staff training. Such documentation may include:

- Collecting permits
- Research permits
- Prior Informed Consent documents
- Mutually Agreed Terms
- Material Transfer Agreements
- Export permits
- Import permits
- Memoranda of Cooperation
- National / international laws regulating ownership of specimens, such as CITES permits
- Nagoya Protocol International Certificate of Compliance
- Further relevant permissions negotiated at local, national or international level

Where possible policies should echo wording in accepted legal frameworks, including, when agreed, the EU Regulation on Access and Benefit-Sharing; this has been done in the example in Annex 3.

Each of these policies should be accompanied by a process document to set out what actions staff have to take in various situations in order that they and the institution are compliant. Workflow diagrams can be helpful.

Data management / Curation

Best Practice will require the following elements:

a. Data management system to support the policies outlined above;
b. Period of retention of all legal documentation covering Genetic Resources (to comply with the draft on European ABS Regulation this is 20 years; CITES requires permanent documentation; for Best Practice documentation should be retained permanently];
c. Means to track where a GR was originally collected or originated from (core data);
d. Means to trace where a GR under its responsibility is at any given time;
e. Means to track where a GR has been while under its responsibility (including incoming loans) and what processes (including utilization) have been carried out on it;
f. Means to discover rapidly what legal requirements and restrictions are associated with a specimen 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;
g. Means to discover rapidly if and how commitments linked to genetic resources (i.e. as set out in Mutually Agreed Terms, Material Transfer Agreements, or other relevant permits or legal obligations linked with the sample) have been met, and manage their delivery;
h. Apply, as far as possible (or required by the EU Regulation), unique Identifiers to appropriate data items allowing tracking of specimens (especially for processed DNA samples);
i. Record entry, accession, loans, identification, processes carried out (including consumption of tissues and DNA aliquots), and deaccession of material;

j. Record core data associated with GR, including:
    a. the date and place of access of genetic resources and traditional knowledge associated with such resources;
    b. the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources;
    c. associated legal documentation.

The institutional data management system should provide staff with information on permits required for countries where fieldwork is carried out, MoCs with relevant organisations and governments, current projects, etc.

Permits, MATs, PIC and other documents, or information that certain specific documents are not needed (exemptions), should be deposited as original signed copies with the Registrar or equivalent office in the Institution, and a mechanism developed to ensure that the provisions within them are associated with the specimens or samples to which they apply.

Staff training

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. A handbook to the Institution's policies and processes regarding ABS should be made available digitally or in hard copy.

Fieldwork

Prior to undertaking fieldwork staff should be aware of the required permissions and legal documentation that are required to carry out fieldwork, and seek to obtain the relevant documentation. In cases where the permits cannot be obtained outside the Providing Country staff should not undertake any fieldwork in that country until the requisite permits are agreed and finalised, or appropriate written guarantees received. Staff should carry out fieldwork only in accordance with the laws and regulations of the sovereign nation in whose territory they are working.

Staff should only sign Mutually Agreed Terms if the institution is able to meet the terms agreed, and if they are consistent with the Code of Conduct. Institutions should draw up guidelines to assist staff in this process.

Activities involving collecting specimens or samples while on fieldwork should be carried out only for and in the name of the Institution responsible for the fieldwork; additional acquisition of genetic resources for private or other use, including on behalf of or for sale to third parties, should be prohibited.

Where possible, fieldwork in countries other than that of the institution should be conducted as part of a collaborative venture with a museum, botanic garden, university, or other recognized scientific research organization in the Providing Country.

Utilization

Institutions should ensure that data indicating all restrictions on the use of individual samples or parts thereof follow each sample and that a mechanism is in place which ensures that staff and users are informed about the restrictions.

Use that is not congruent with the conditions agreed for Access, where these exist, should not be undertaken.

Records should be kept of utilization. An institution should have clear and robust policies for how it handles inappropriate utilisation (which may occur either inadvertently or purposefully) by staff and third parties.

Publications resulting from the utilization of genetic resources, and other use of biological resources, should in most if not all cases cite the Providing Country of the specimens, and ideally include an identifier of the permit or other agreement covering the collecting (access to) and use of the specimens. This includes paper and electronic publications, including databases such as GenBank.

Utilization by third parties

The paragraphs below apply to specimens accessed after 1993 and thus covered by the Articles of the CBD and, after 2014, the provisions of the NP. For specimens accessed before that date the Institution should develop its own policy, recalling the Code of Conduct and Best Practice sections on Benefit Sharing.

Any restrictions or requirements arising from the conditions under which the specimens were obtained, or others arising from institutional policy should, if relevant, be communicated to the user. 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 transferred).

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

Third party use that is consistent with the conditions under which the specimens were obtained should be permitted where the custodianship of the specimen does not pass out of the institution, (unless constrained by the agreement covering acquisition by the Institution). This includes temporary use as a loan from the institution or within the institution (e.g. research cooperation).

Processes should be developed to ensure that if a temporary Third Party user requests a change of utilisation (including those potentially leading to commercialisation), appropriate action can be taken, which may include renegotiation with the Providing Country. An institution should have clear and robust policies for how it handles inappropriate utilisation (which may occur either inadvertently or purposefully) by Third Parties.

Any commercial sequencing 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.

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

Permanent transfer to Third Parties

Specimens 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, specimens may be freely transferred between signatories to the CETAF Code of Conduct and who have adopted this Best Practice. Both institutions should retain records of the transfer. If transfer is not prohibited under the original PIC and MAT, specimens may be transferred to third parties who have not signed the CETAF Code of Conduct or adopted this Best Practice, either on their signature of an appropriate Material Transfer Agreement by which they undertake to utilize the specimens only in a manner compliant with the original PIC and MAT or if planning a different utilization, with evidence that they have agreed PIC and MAT with the Providing Country.

Records should be maintained of specimens or sampled transferred permanently to Third Parties.

Benefit-sharing

Genetic Resources should be treated uniformly regarding benefit-sharing irrespective of whether they were accessed before or after the Nagoya Protocol comes into force.

Processes should be developed to ensure that any benefits generated from utilization of genetic resources accessed prior to the coming into force of the Nagoya Protocol are shared fairly and equitably.

Institutions should keep a record of benefits shared.

An indicative list of non-monetary benefits likely to be delivered as a result of non-commercial biodiversity research is provided in the Annex to the Nagoya Protocol (Annex 2 to this document).

Deaccession and Disposal of collections

Disposal should only take place if it is in accord with the conditions agreed with the Providing Country.

Records should be kept of any consumption of samples or disposal, including to a third party for permanent deposit.

Mutually Agreed terms may require that specimens be destroyed following use (e.g. DNA sent for sequencing to a third-party laboratory) or returned to the Providing Country. Destruction should only be carried out if congruent with any restrictions or requirements. Broadly, other than under MAT requirements or through consumption of samples as a necessary part of application of molecular techniques, specimens should not be destroyed unless they cannot be used to provide further scientific information. Institutions should have a process in place to ensure genetic resources have been destroyed in line with the original PIC, MAT or MTA and confirming this with the provider Country.

Annex 1: Glossary

Access - Permission to collect / sample genetic resources as granted by the country that has sovereign right over those resources (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. An agreed definition should be included in all legal documents.

Benefits arising from the use of genetic resources – Not defined, but may include: (1) Monetary when research and developments leads to a commercial product (e.g. royalties, milestone payments, licensing fees); (2) Non-monetary (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)

Biological resources - includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity (definition from Article 2 of the Convention on Biological Diversity). Biological collections refer to 'specimens; (often discrete individuals of one or more species), 'samples' (generally unsorted collections of many individuals from individual locations) and 'material' (term covering specimens and samples in a collection, or part of a collection).

Biorepository - A biological materials repository that collects, processes, stores, and distributes biospecimens 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 may also be used, to include specimens which are not necessarily of whole organisms, and even include human specimens.

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 utilization of the original genetic resource or derivatives thereof. 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 utilization of GR, and are not considered as a commercialization of research activity on GR.

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

Country of origin of genetic resources - the country which possesses those genetic resources in in-situ conditions (definition from Article 2 of the Convention on Biological Diversity). See also 'Country providing genetic resources'.

Country providing genetic resources - 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). – see also '*Providing Country'*

Derivative - 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).

Exchange – also '*Transfer*', and '*Permanent supply*'. Permanent transfer of specimens to a third party to the original agreement.

Genetic resources - genetic material of actual or potential value (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity)

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).

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

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.

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

Participating Institution – A member of CETAF who 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 provider 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 providing genetic resources; this may be the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention on Biological Diversity (see *'Country of origin'* and *'Country providing genetic resources'*).

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 applications.

Use – The purposes to which samples and specimens (biological and genetic material) are put, including but not limited to 'utilization' in the sense of the NP.

Utilization (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 2: Non-monetary benefits

The indicative list of non-monetary benefits below is that given in the Annex to the Nagoya Protocol. 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
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to ex situ facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(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.

Annex 3: Retention of records.

Institutional policies on data management should include clarity of what information will be held and a statement of how long documents will be kept. For example:

> "The [*institution*] will seek, keep and transfer to subsequent users as appropriate information on:
>
> a. the date and place of access of genetic resources and traditional knowledge associated with such resources;
> b. the description of genetic resources or traditional knowledge associated with such resources used, including available unique identifiers;
> c. the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources;
> d. the presence or absence of rights and obligations related to access and benefit-sharing;
> e. access decisions and mutually agreed terms, where applicable;
>
> Information relevant for access and benefit-sharing, including originals of relevant permits and other documents, will be retained for at least twenty years after the period of utilization of Genetic resources" [NB this is taken from the draft text of the European Regulation on ABS; institutions will wish to retain the information permanently]. This will allow agreements about use or utilization to be honoured indefinitely, as may be required. In many cases even if information is removed from the system (for example if the specimen or sample is consumed, destroyed or deaccessioned) it is helpful or necessary to keep a record of what was removed.