Global Genome Biodiversity Network (GGBN) Guidance:

Best Practice for Access and Benefit-Sharing

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Introduction

The Global Genome Biodiversity Network (GGBN) is 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 exchange of material in accordance with national laws and best practices.

Consistent with Article 20 in the Nagoya Protocol, GGBN has developed and adopted these Best Practices for Access and Benefit-Sharing. They complement two other guidance documents, the GGBN *Code of Conduct* and a *Statement of Use of Genomic Material* to provide clarity on how GGBN members use and treat samples of genomic material.

The principles and practices stated in these three guidance documents are designed to support fully GGBN members' operations as biodiversity biobanks, providing genome-quality samples from across the Tree of Life for research, and training, thereby contributing to the conservation of global genetic diversity for generations to come.

The guidance documents (i) outline governing principles under which collections are managed and collection-based research conducted in GGBN member institutions (the Code of Conduct); (ii) provide details of best practices to implement those principles; (iii) explain to both providers and users how specimens are used by GGBN institutions. Together, this information provides a clear basis for participants to have clarity and transparency in the permitting, research, and maintenance of the collected materials consistent with the national obligations of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) with Providing Countries.

GGBN Best Practice on Access and Benefit-sharing

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

I. Preamble

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

- it can understand its rights and responsibilities under the national laws implementing appropriate treaties and relationships with Providing Countries of biological material;
- its staff, authorised visitors and associates abide by appropriate laws and regulations when working in or on behalf of the institution;
- biological material entering the collections is obtained with appropriate legal certainty and can legally be retained; and that
- it manages effectively obligations and legal contracts entered into with Providers.

Not all parts of this practice may be relevant or applicable for all institutions to implement.

In order to comply with ABS regulations and function effectively, institutions should:

- 1. Acquire only biological material that has been legally accessed (whether from *in situ* or *ex situ* sources such as museum collections or botanical gardens);
- 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. Use¹ of biological material is only in a way consistent with the terms and conditions under which the material was acquired;
- 4. **Supply biological material** to Third Parties for their use only as consistent with the terms and conditions under which the original material was acquired from the Providing Country;
- 5. Share benefits with the Providing Country;
- 6. Develop institutional ABS policies; and
- 7. Train their staff and inform authorized visitors and associates.

These aspects of work are discussed in detail below.

This Best Practice guidance applies in particular to biological material accessed after 1993 and thus covered by the Articles of the CBD and, after October 2014, the provisions of the Nagoya Protocol.

II. Acquisition of Biological Material

There are different ways of acquiring biological material: collecting in the field or from collections in a Providing Country (*in situ*), and permanent (e.g., exchange, donations, sharing of tissue or DNA samples) or temporary transfer (e.g., loans,) from other *ex situ* sources. Institutions should make sure that their internal policies and procedures cover the aspects where there may be an ABS aspect, as described below.

Overall, internal policies on acquisition may need to address:

a. Field collecting (see section II.1.)

¹ See 'Statement of Use of Biological Material' for a description of the spectrum of 'use'.

- b. Specimen (and associated specimens/materials) entry, governing what legal documentation is required by the institution when biological material enters the Institution prior to accession or as incoming loans, including, but not restricted to, DNA and tissues, including how both entry and required documentation are managed by the institution².
- c. Accession, governing the conditions required for specimens to be added to the collections and pass under the ownership or custodianship of the Institution, and including:
 - i. Documents required (e.g. PIC, MAT, MTA, donation letter, document confirming transfer of title to the material);
 - ii. Designation of individual(s) within institution that is/are authorized to sign agreements or to accept any material in the name of the institution (e.g., Director, Head of Collections).

1. Acquisition from in situ sources (fieldwork)

Permission from the Providing Country to undertake fieldwork will typically include Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), sometimes combined in a permit. Staff may have to negotiate and agree these with the Providing Country. Institutions should require staff members, prior to undertaking fieldwork, to make themselves aware of the required permissions and legal documentation required, and seek to obtain the relevant documentation from the appropriate National Competent Authority/ies within the Providing Country^{3,4}. Institutions and staff should be aware, when contacting the National Competent Authority that other offices might need to be contacted as well, depending on the Providing Country's legislation.

Fieldwork to be covered by the permit should not be undertaken by anyone associated with the requesting institution 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.

Staff should only sign MAT (e.g. conditions in permits) if the institution is able to meet the terms agreed, and if they are consistent with the Code of Conduct. When negotiating PIC and MAT, the institution or its staff should be clear and explicit about the purposes for which the material will be used at the institution and the conditions for Third Party use. Institutions and their staff are encouraged to refer to the GGBN 'Statement of Use of Biological Material', because it sets out the typical ways in which biological material may be used, and might help in the negotiation process. Institutions should draw up guidelines to assist staff in this formal process, including clear rules on who is authorized to sign any agreements.

Where possible and appropriate, 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. This can be included in the MAT as a benefit arising from the work.

² Specimens can contain or be associated with other specimens that are relevant for PIC and MAT agreement. Such associated specimens may include, but are not limited to, gut contents and parasites. Some countries prohibit utilization of genetic resources from such associates unless stated in PIC and MAT.

³ In cases where an institution conducts long-term or repeated project in certain Providing Countries, it might be beneficial to develop framework agreements between the National Competent Authorities of the involved countries

⁴ Relevant information on national ABS legislation and Competent Authorities can be obtained from the ABS clearing house website (https://absch.cbd.int/).

Activities involving collecting specimens or samples 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 institution⁵.

MAT terms should be renegotiated if a change in use is anticipated at any time in the life of the project.

2. Permanent acquisition from ex situ sources

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

Institutions should exercise due diligence 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, except with the express consent of an appropriate outside authority. 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 MAT.

If biological material is acquired from a commercial supplier, the institution should be aware that this could constitute a change of use which could require PIC and MAT from the original provider. Institutions are advised to check the provenance and legal status of this material before acquiring it.

Shipments of unsolicited biological material that are not accompanied by appropriate documentation that demonstrates compliance with laws and regulations should be held in a quarantined status until the recipient institution can be assured that legal requirements are met and any PIC or MAT terms are formalized. The material should not be used until its status is acceptable.

Recipients of biological material where there is a change in ownership should take responsibility for being aware of any MAT or other permit terms that accompany the material; such information should be recorded and available to appropriate personnel.

3. 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 collection. This might include incoming loans of material for research or exhibition use or material brought in by guest scientists for analysis in the DNA lab of the institution or any specimens brought in by visitors for examination in the institution.

A policy may be helpful that sets out conditions under which loans received by staff or other associates of the institution can be accepted in the context of ABS.

⁵ Institutions are advised to develop or revise procedures to train and inform freelancers and associated scientists prior to doing fieldwork for and in the name of that institution.

III. Curation and Data management

As with other aspects of work, Institutions should make sure that their internal policies and procedures cover the aspects where there may be an ABS aspect. Overall, internal policies on acquisition may need to address:

- a. Harmonisation of policies, management and record keeping protocols across all collections in the institution. Separate or newly-developing collections (e.g. Frozen tissue and DNA collections) should have protocols and policies congruent with those applying to the more traditional collections, if the institution holds these.
- Living collections. Special conditions may apply to living collections, including utilization of cultures and other bred and propagated organisms in collections. Consideration should be given to protocols on sourcing living material from commercial suppliers (and repurposing it for scientific study) or gifts, including, if appropriate, the triggering of new PIC and MAT.
- c. Research and ABS. Policies may be needed to govern access to and utilisation of genetic resources, 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, depending on how closely researchers' and collection managers' various processes and record keeping systems are integrated, whether there is regular and thorough communication across the institution, and whether any institutional systems for accountability are active.
- d. Destructive and invasive sampling covers any form of subsampling intended for genomic or other studies from specimens held in other parts of the collection. Management of restrictions and requirements agreed with the Providing Country (MAT).
- e. Traditional Knowledge associated with genetic resources covering all aspects of the institution's collecting, documenting, storing and release 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.
- f. Data management and documentation (see section III.1).
- g. Internal Collections Audit Monitoring or audit system in order to determine if the institution is managing effectively its ABS documentation, compliance with agreements and associated processes, and whether improvements are required or possible.

1. Record-keeping and data management

Institutions should manage their collections and associated information so that biological material is used only in a way consistent with the terms and conditions under which the material was acquired from the Providing Country.

For that purpose, institutions should **keep records** – preferably with the Registrar or an equivalent central office in the institution – on

- acquisition of biological material, including core metadata associated with genetic resources such as
 - \circ a description of the genetic resources⁶ (at appropriate taxonomic level),
 - *the date and place of access of genetic resources* and any associated traditional knowledge,
 - \circ the source from which the resources or the knowledge were directly obtained,
 - associated legal documentation and any unique references to it (*permits, number of Internationally Recognized Certificate of Compliance, PIC, MAT*, etc.), including the

⁶ In this list the items in italics are those that may be required for reporting to a Checkpoint, as and when the Nagoya Protocol comes into force, for institutions in countries party to the Nagoya Protocol

authority responsible for granting PIC and the person or entity to whom PIC was granted and

- conditions and obligations entailed in the PIC and MAT agreements;
- any transfer to Third Parties, whether on loan or permanent transfer (see also Section IV);
- deaccessioning, disposal and loss, including consumption of samples in connection with its use.

and implement appropriate data management systems that allow the institution to

- a) <u>track</u> the origin of any sample or specimen of biological material that is in the institution's collections, and provide staff or authorized visitors with information on terms and conditions of use.
- b) <u>trace</u> the biological material that entered the collections (including utilization or transfer to Third Parties).

To accomplish this, the data management system ideally will cover the following elements:

- Means to discover rapidly what legal requirements and restrictions are associated with a specimen (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 acquisition, use or transfer of specimens or samples; this might include the establishment of unique identifiers 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 (for example, under the EU Regulation this period is at least 20 years after utilization has ended for information relevant to access and benefit sharing). Retention of records on an indefinite basis is desirable.

2. Deaccession and Disposal of collections

As with other aspects of collection management, one or more policies may be helpful here (see Section VI). Disposal should only take place if it is in accord with the conditions agreed with the Providing Country.

MAT 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. Institutions should have a process in place to manage such destruction of genetic resources in line with the original PIC, MAT or MTA, if required, and confirming this with the Providing Country.

IV. Utilization

Institutions should not sample biological material for utilization of genetic resources if this is prohibited by MAT, where these exist. Institutions should therefore develop means to associate any data indicating restrictions on the use of biological material (including utilization of genetic resources) with each individual (sub) sample of this material. They should also put mechanisms in place so that

staff members and other users, such as partners in collaborative projects can inform themselves or are informed about and abide by terms and conditions regarding GR and TKaGR.

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

Publications resulting from the utilization of genetic resources, and other use of biological material, should acknowledge the Providing Country. Ideally publications should also include an identifier of the permit or other agreement covering the collecting (access to) and use of the specimens, and list references to specimens or samples studied. 'Publication' includes paper and electronic publications, including databases such as GenBank.

1. Supply to Third Parties for their utilization

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 Third party user. This may require paper or electronic copies of relevant MAT, collecting permits and Material Transfer Agreements in some cases (especially where the specimen, sample or (processed) subsample is being permanently transferred).

Under some countries' implementation of the Nagoya Protocol collections are required to keep records of users of their material (e.g. EU Regulation 511/2014 on ABS). In such cases it may, therefore, be appropriate to inform Third Parties (and in particular those utilizing genetic resources) that information on their utilization will be retained for reporting purposes. This would form part of a standard MTA.

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

This section deals with temporary transfer of biological material to and use by a Third Party. This can only take place if permitted by the original PIC and MAT.

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

Institutions should develop procedures to respond to a request from a Third Party for a change of use from that agreed in the MTA (loan document). Records should be maintained of specimens or samples borrowed by Third Parties, including utilization of Genetic Resources if it takes place.

3. Permanent transfer to Third Parties

Biological material 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 to Third Parties on their signature of an appropriate Material Transfer Agreement (MTA). By this MTA they would undertake to utilize the material only in a manner compliant with the original PIC and MAT.

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 sampled transferred permanently to Third Parties.

If material is required by the Third Par for uses not compliant with the original PIC and MAT, the Third Party user should negotiate with the Providing Country.

V. Benefit-sharing

Institutions should implement procedures to share any benefits generated from their utilization of genetic resources fairly and equitably with the Providing Country and other appropriate stakeholders as agreed in PIC and MAT at the time of Access, or as renegotiated with a subsequent change of use. Benefits agreed with the Providing Country are likely to include any of those listed in the Annex to the Nagoya Protocol (see Annex 2 to this document). Because of the not-for-profit nature of the work of the Institutions, benefits are most likely to be non-monetary, inter alia: scientific training, education, capacity building, collaboration on scientific work programmes, mutual sharing of research results and of associated publications, acknowledgment of the Providing Country when publishing data or research results. Management of delivery will be facilitated if a standard list is used with the Providing Country as a basis for agreement (see Section II), since this will support record management by use of a standard vocabulary.

VI. Institutional Policies

Clear policy statements will assist institutions in managing compliance with legal provisions arising from ABS regulations and legislation that apply. 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 considerations, or where ABS concerns have to be managed.

Any policies on Genetic Resources should be made explicit that all persons associated with the institution are bound by the policy. This means that 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., are all responsible for compliance with policy. 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 <u>Access and Benefit-Sharing</u> policy (this can be an 'umbrella' policy covering all aspects of <u>Access and Benefit-Sharing</u> and be used as a reference in other policies). Aspects that may be considered for separate policy statements include:

1. Acquiring new specimen

- a) Field Collecting to cover all aspects of collecting, including the requirement to obtain appropriate documents, including permits, PIC and MAT.
- b) Specimen / sample Entry governing what legal documentation is required by the institution when specimens enter the Institution prior to accession including how both entry and documentation are managed by the institution.
- 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:
 - i. Documents required (e.g. PIC, MAT. MTA, donation letter, Transfer of Title document⁷) and
 - ii. Identification of the individual (e.g., Director, Head of Collections) within the institution responsible for authorising accession.

2. Managing the collection

- d) 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 actions on proposed change of use from that agreed in PIC and MAT.
- e) Incoming loans, including DNA and tissues Documents required (e.g. copies of PIC and MAT, MTA, loan form), and how these are managed.
- f) Separate or newly-developing collections within the Institution (e.g. frozen tissue and DNA collections cf. dried or spirit collections). - Should develop harmonisation of policies and record keeping.
- g) Destructive and invasive sampling covers use of frozen and other collections for extraction of DNA and other genetic and cellular contents, and consequently requirements to observe restrictions and requirements agreed with the Providing Country or other provider of genetic resources.
- h) Living collections –Utilization of cultures and other bred and propagated organisms in collections; living material sourced from commercial suppliers; agreements required for supply to Third Parties.
- 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.

⁷Legal document managing the formal change of ownership of an object from one person or organisation to another.

- j) Outgoing material for research- conditions under which users in other institutions can borrow Biological Resources, including:
 - i. what analytical processes loan recipients are permitted to carry out on material received and what is prohibited;
 - ii. return or disposal of any residual samples / aliquots that have not been consumed for analysis;
 - iii. any subsequent utilization by a borrower;
 - iv. requirements for documentation to be provided with loans (e.g. copies of original PIC and MAT or summary thereof);
 - v. action should commercialisation be requested by the Third Party;
 - vi. action should the Third Party undertake inappropriate utilization.
- k) Research and ABS –governing access to, utilisation and publication of results during research activities involving the use of Genetic Resources by the institution.
- 1) Data management and documentation all data management that includes ABS related documentation or information, including:
 - i. storage and access to ABS-related documents and associated information;
 - ii. mechanism to cross reference intended use with PIC and MAT;
 - iii. sharing content of ABS documents with Third Parties, including through reporting;
 - special treatment of sensitive information (e.g. Traditional Knowledge associated with genetic resources, information restricted under PIC and MAT);
 - v. Means of keeping records of tissue and DNA subsamples congruent when items are physically separate;
 - vi. Protocols for publishing metadata associated with the sequence data (e.g. through GenBank) and
 - vii. Record-keeping.
- m) Internal Collections Audit Regular audit of a sample of genetic resources to determine if the institution is managing effectively its ABS documentation, compliance with agreements and associated processes and whether improvements are required or possible.

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

- n) Dispatch and object exit –covering all items leaving the institution temporarily or permanently, including:
 - i. documentation required internally, with special regard to consumption of (sub)samples and derivatives thereof;
 - ii. documentation required by recipient if transferred to a Third Party and
 - iii. documentation required by the Providing Country.
- <u>Loss or complete consumption –</u> the course of action to be taken with regard to ABS requirements (e.g. under MAT), including documentation, in the event of loss or consumption of specimens from the collections.
- p) <u>Disposals (including exchanges and transfers) governing how specimens leave the</u> ownership of the Institution, which may be governed by MAT or a MTA.

Additional advice: Institutional policies

Institutions may find it helpful to manage all required infra-national, national and international legal documentation under the same policy umbrella. By doing this they will be able to harmonise both policies and the processes they emplace to manage compliance, including information management, and provide more effective staff training. Such legal 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
- Further relevant permissions negotiated at local, national or international level
- Process for resolving disputes regarding disposition, use or other matters.

Each of these policy elements, once agreed, should be accompanied by a procedures document to set out what actions staff members have to take in various situations in order that they and the institution are compliant. Workflow diagrams can be helpful.

VII. Staff training

All staff whose work involves collecting, managing and researching on specimens, including those that undertake 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.

Annex 1: Glossary

- Access The acquisition of Genetic Resources or of Traditional Knowledge associated with Genetic Resources from 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 relevant 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'.
- 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 <u>https://absch.cbd.int/</u>.
- 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.
- *Benefits arising from the use of genetic resources* Not defined, but 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.)
- *Biodiversity Biobank* a facility for collection, preservation, storage and supply of typically nonhuman, biological samples and associated data, which follows standardized operating procedures and provides material for scientific use. Examples include natural history museums, herbaria, botanical gardens, culture collections, seed banks, and gene banks.
- *Biological material* all specimens and samples of or subsampled from living or dead organisms in GGBN member collections, regardless if it contains 'functional units of heredity' or not. See also 'Genetic material' and 'specimen'.
- *Biorepository* A general term biological for any material repository that collects, processes, stores, and distributes biological, **including human**, 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 *biodiversity 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 utilization 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 utilization 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.
- *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).
- *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 form Nagoya Protocol, repeated 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)
- Genome-quality High-molecular weight DNA or RNA ideally including the whole genome.
- 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.
- Material refers to the items listed on the reverse of the Material Transfer Agreement.
- *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.
- Memorandum of Cooperation (MoC) an agreement between two or more institutions to cooperate. In the context of the GGBN Code of Conduct and Best practice this will include reference to ABS.

- *Participating Institution* A member of GGBN which has signed the GGBN Code of Conduct and agreed to follow GGBN 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).
- Recipient the organisation 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 applications.
- 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.
- 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." (http://www.wipo.int/tk/en/tk/). 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 'utilization' in the sense of the Nagoya Protocol.
- *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 are not 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 Providing Country 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.