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 | http://www.cetaf.org/taxonomy/publications |

| | | |
|---|---|---|
| | including training modules on ABS | |
| 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[1]

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.

[1] 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[2].
4. Provide resources[3] and training[4]: 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[5].
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[6].
    (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.

2) 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.
3) For example web pages on an intranet that offer guidance, templates for MTAs, draft letters for contacting NFPs, etc.
4) See Best Practices section 7. CETAF is planning annual training and information exchange for members' representatives.
5) 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.
6) 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[7].
  - ✓ 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)[8].
  - ✓ 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).

7) 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.

8) 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)

- **An individual planning to acquire material from *ex situ* collections:**
  - ✓ 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[9].
  - ✓ 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.

9) 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.

- ✓ 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.

## 3. During negotiations with National Competent Authority

- **<u>The individual should:</u>**
  - ✓ 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[10]).
    - 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.[11]
  - ✓ 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

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

11) see Annex 4 for reference

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.
- ✓ 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[12].

12) See Annex 4

## 5. Before you start your field work

- **The individual should:**
  - ✓ 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.
    - 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.[13]
  - ✓ 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. [14]

[13] 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.

- ✓ 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.
- ✓ Retain and pass on to your institution as appropriate the following information[15].

    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).

[14] Includes any practical, taxonomic, scientific or other training, education, capacity building technology transfer, collaborative scientific work

[15] 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[16].
  - ✓ 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[17].
  - ✓ 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.

16) 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.

17 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.

- ✓ 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:**
  - ✓ 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[18] 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[19]. 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[20])
  - ✓ 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.

[18] Including formal subcontracting

[19] 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.

[20)] Under EU Regulation No. 511/2014 both public and private funding are included

- ✓ 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,
    (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[21] . 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.[22]
    (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.[23].

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

[23] 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.

- ✓ 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.
- ✓ Implement appropriate data management systems[24] 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[25], which may be used in almost all Member States[26].
  - ✓ 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.

Information can be found at https://content.govdelivery.com/attachments/UKNMO/2017/10/23/file_attachments/900529/DECLARE_ABS_QA.docx

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

[25] DECLARE is available at https://webgate.ec.europa.eu/declare/

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

- **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/
    - 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[27] and procedures to handle inappropriate utilisation of Third Parties (which may occur either inadvertently or purposefully.

27) Ideally, institutions adopt policies identified in the CETAF ABS document Package as closely as feasible