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 that document gives outcomes and suggests policy and procedural elements to put in place at institutional level to deliver the 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.

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

Explanatory film produced by the ABS Capacity Development Initiative: https://tinyurl.com/l2srv4u

ABS Information Kit and factsheets on the website of the Convention on Biological Diversity: https://www.cbd.int/abs/awareness-raising/default.shtml#the ABS information kit

Good practice *Guide for Access and Benefit Sharing* of the Swiss Academy of Sciences: https://naturwissenschaften.ch/organisations/biodiversity/abs

Comprehensive information including training modules on ABS can also be found on the CETAF website: cetaf.org/natural-science-collections-and-access-and-benefit-sharing

BGCI ABS learning tool: https://www.bgci.org/policy/abs_learning/

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

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 acquisition of specimens, 'utilization' 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).

5 basic ABS management tools for proper ABS management institutions should consider:

- Designation of 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.
- 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).
- 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 the EU Regulations on ABS[1].
- Provide resources[2] and training[3]: Staff needs 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[4].
- Expand existing procedures to record activities and manage documents at three internal due diligence monitoring points[5]:
    (a) Field work: Field work may trigger ABS responsibilities. The institution and individuals need to know which requirements in the provider and user country 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 to ensure appropriate ABS record keeping and management.
    (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].

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

[1] CETAF Best Practices section 6 for policy advice and the detailed suggestions and examples in this Practical Advice below will assist in developing these.
[2] for example web pages on an intranet that offer guidance, templates for MTAs, draft letters for contacting NFPs, etc.
[3] see Best Practices section 7
[4] 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.
[5] this is distinct from the responsibility to report due diligence under EU Regulation Art 7
[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 provider countries (including field collecting)

Even though not all specimens or samples collected might be 'utilized', agreements, permits or other relevant documents should allow later utilisation. This approach helps your Institution to facilitate overall legal compliance and to minimise later queries to clarify the status of the material. Provider countries are likely to take this approach also.

This section includes both field collecting of specimens, as well as acquisitions from *ex situ* collections in the provider country. This is because some countries extend their concept of access to specimens from the country to specimens already held in *ex situ* collections, so 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 addressing the institution's ABS compliance and implementation of the CETAF Code of Conduct and Best Practices.
  - ✓ Develop overseeing functions (e.g. travel applications for fieldwork or for proposals for applications for project funding). Relevant information that the responsible national authorities in the respective providing country have been contacted should be recorded together 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 using (analysing) genetic resources (GR) or Traditional Knowledge associated with Genetic Resources (aTK) and is thus 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 Regulation on ABS. Even if the country is not Party to the NP national access laws may apply in this country.
  - ✓ Use 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 restrict access).
  - ✓ If access is restricted, 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.

- An individual planning to acquire material from *ex situ* collections:

  - ✓ Check if your research is using (analysing) genetic resources (GR) or Traditional Knowledge associated with Genetic Resources (aTK) and is thus 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 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 any other technical staff) to be responsible for agreeing to terms and sign MAT and PIC agreements on behalf of the Institution.

  ✓ 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 loan or 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 Section 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 (aTK) with the GR; if aTK is to be accessed, this should be reflected during negotiations and addressed in agreements, since aTK is also covered by ABS requirements and the Nagoya Protocol.

  ✓ Be clear what general conditions are required by your institution, and ensure that agreements meet them. If such conditions cannot be met (e.g. loans or transfers to third parties not permitted) be prepared to work in a different country.

  ✓ Where necessary identify the activities of subcontractors (e.g. for external barcoding) and partners based outside your institution that should be identified in the final agreement.

  ✓ Ideally, use CETAF templates and refer to the CETAF Code of Conduct, including the Statement of Use and Best Practices.

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 delate 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 utilized (within current technical understanding including possible internal future uses of colleagues, based on the scientific scope of your institution[8]).
    - 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).
  - ✓ Check that the terms agreed fit with practices in your home institution, including conditions on existing MTAs / loan forms for transfer of biological material.
  - ✓ 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 or at any later point e.g. as part of collaborative research projects.[9]
  - ✓ consider that collected objects might carry GR, irrespective of the original purpose or intention under which the material was collected (e.g. soil samples, archaeological objects, drill cores); if there is a possibility that the GR will be utilised subsequently, ensure that appropriate agreements are reached with the provider 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.

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

[9] see bullet point 4 & % under point 6 below and compare Annex 4 of the CETAF ABS Doc package for reference

- ✓ Be clear whether or not any freelancers/amateurs / hobbyists associated with your institutions working in the field with you and 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.

- <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 any material of *ex-situ* sources such as unsolicited samples which might be sent in to your institution for identification at a later point from any person or party inside or outside of the Providing country.
  - ✓ 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 utilized 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

- The Institution might:

  ✓ 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.

- The individual should:

  ✓ Where possible annex the CETAF Use of Biological Materials Statement (CoC Annex 2), as agreed with the Providing Country, in any written agreement 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[10].

  ✓ Document what documenting and reporting obligations for use of accessed GR are in place (or not).

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.[11]

  ✓ 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 if terms with the body governing the *ex situ* collection agree with intended acquisition and use (ownership should be clear).

[10] Compare Annex 4 of the CETAF ABS Doc package

[11] 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

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

- <u>The Institution should:</u>

  - ✓ Ensure that staff are aware of the permissions and legal documentation required.
  - ✓ Make sure that staff 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.

- <u>The individual should:</u>

  - ✓ 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. [12]
  - ✓ Record all payments (including direct and indirect such as coverage of accommodation costs, fees for permits, etc.) if part of benefit sharing arrangements.
  - ✓ Do 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. (If utilization of the collected material is to be reported subsequently to your national checkpoint (EU) this information will be required).
    i. Number of the Internationally Recognised Certificate of Compliance, if generated by the provider country;
    ii. Document number of permits
    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/aTK when directly obtained (may be an indigenous community or even an individual)

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

GR entering the institution

Not all specimens or samples entering the institution might be 'utilized'. However, if the specimens are to be retained by the institution it is helpful to operate as if everything will be utilized. This approach also facilitates overall legal compliance 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.
  - ✓ Consider labelling all samples/specimens with something that indicates any restrictions or requirements on their use (e.g. a QR code linking to conditions as stored on the institutional database, or a simple 'flag' indicating that there are conditions and the database should 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 was material 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 on what documents and information are sought with received GR, noting the information that might be required under the EU Regulation on ABS.

- The individual receiving the GR should:
  - ✓ Subject to institutional policy and practice, check and record available documentation; so that the available documentation sufficient to fulfil reporting obligations under national and European law Art 4(3):

    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 missing or incomplete documentation of incoming material could risk a breach of terms under which genetic resources were accessed or evoke charge of illegally utilizing genetic resources.
- ✓ 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 utilization), sometimes as part of joint research (See CETAF Best Practices Section 1.2);*

- The Institution could:
  - ✓ develop procedures for establishing who is responsible for making a Declaration of Due Diligence (if required) for a joint project.
- The Individual receiving the GR should
  - ✓ be aware whose responsibility it is to make any declaration of due diligence (e.g. if the project Principle Investigator is in a different institution the Principle Investigator may have the responsibility).

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.
- The Individual receiving the biological material should
  - ✓ ensure it matches institutional requirements.
  - ✓ ensure the collection is appropriately labelled.

D. *GR are sent for identification (which may involve utilization) from the provider 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 (utilization), strictly speaking this should not be done without appropriate PIC and MAT from the providing country[13].
  - ✓ return GR to the sender after identification.
  - ✓ not bring information derived from identification (sequencing) results into a research project without conducting due diligence on its origin.
  - ✓ not publish sequence or other data from objects submitted for identification without clarity on whether this is legally appropriate.

[13] However, the currently prevailing view (April 2017) in the draft sectorial guidance documents is that identification does not constitute R&D and is consequently out of scope of the EU Regulation. 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.

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 illegal material.
  (b) Addition of explicit labelling stating its origins and limitations on its use.
  (c) Policy not to use such material for utilization.

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

- The Institution should:

✓ have a clear policy on responsibility for reporting due diligence, and a written agreement with the visitor (almost certainly the institution in which the GR are utilized has a legal responsibility to carry out due diligence).

✓ develop a procedure for carrying out due diligence on the origin of the GR and for preventing sequencing if no evidence is provided by the visitor to show the legality of this. The information required would be:
  (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:
  (c) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
  (d) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;
  (e) 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;
  (f) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;
  (g) access permits, where applicable;
  (h) mutually agreed terms, including benefit-sharing arrangements, where applicable.

✓ Use CETAF MTA 4 to document the conditions under which GR can be utilized, 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 should to the visitors or clarity on its legal provenance sought as for unsolicited donations.

✓ not utilise or publish sequence or other data from objects submitted left by visitors or guests without clarity on whether this is legally appropriate.

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

The legal responsibilities under the EU Regulation are currently unresolved and further information will be provided when available. In the interim, a contract between the submitter and the institution should set out who is responsible for due diligence obligations under the Regulation, including any declarations.

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 is responsible for due diligence obligations under the Regulation, including making Declarations of Due Diligence under Art 7 of the EU Regulation on ABS.
- ✓ Put in place a system that flags the necessity for making a Declaration (i.e. when utilization of a GR in scope is supported by a grant[14])
- ✓ Ensure that documents (including permits) that cover GR 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.
- ✓ Establish clear workflows to support its staff in exercising due diligence and to ascertain that GR and aTK have been accessed in accordance with applicable ABS legislation or regulatory requirements; this is ideally done when the material is acquired.
- ✓ Keep records, including:
  (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:
  (c) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
  (d) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;
  (e) 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;
  (f) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;
  (g) access permits, where applicable;
  (h) mutually agreed terms, including benefit-sharing arrangements, where applicable.
- ✓ be aware that any utilization of GR within institutional facilities (e.g. by staff, guests or external materials that are utilised in their labs) may trigger reporting responsibilities. Accordingly, it should establish procedures in each case to record who is responsible, and to ensure reporting is done. [15]
- ✓ put in place clear and robust policies and processes to handle any internal inappropriate utilization of biological material. This might include seeking retroactive approval from the providing country.
- ✓ implement appropriate data management systems[16] 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.

[14] Under EU No. 511/2014 both public and private funding are included and governed under the ABS Implementing Act of the EU Commission

[15] See Nagoya Protocol, Article 15 & EU ABS regulation Art. 5(3); use CETAF MTA 3 or 4 to clarify the status of any external materials

[16] See Point 2.1 in Annex 2 (CETAF Best Practice) of the CETAF ABS document package

- ✓ 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:
    i. who is responsible for carrying out due diligence under the Regulation, including making Declarations of Due Diligence to the National Competent Authority;
    ii. under what circumstances these declarations should be made;
    iii. how declarations should be made (the Commission is developing a web-based submission tool, DECLARE, which may be used in some Member States – national authorities will provide links)
  - ✓ 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 under Art 7(1) of the EU Regulation are only necessary if the utilization is funded by a grant, so there needs to be a method of linking grant information with utilization information.

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;
  - ✓ 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 Third Parties, including utilization of GR if it takes place;
  - ✓ Put in place clear and robust policies[17] and procedures to handle inappropriate utilization of Third Parties (which may occur either inadvertently or purposefully); this might include notification of the Checkpoint or National Focal Point of the user's country.

[17] Ideally, institutions adopt policies laid down in the CETAF ABS doc Package as closely as feasible