

The Nagoya Protocol – Guidance for Researchers (EHU)

Key terms

Genetic resources (GR): any material of plant, animal, microbial or other origin containing functional units of heredity, which is of actual or potential value, or derivatives. GR can also include any relevant traditional knowledge associated (aTK) with their use. aTK is traditional knowledge held by an indigenous/local community that is relevant for the utilisation of GR.

Internationally recognised certificate of compliance (IRCC): a domestic access permit that has been made available to the Protocol's Clearing-House. All parties with users in their jurisdiction must recognise such certificates as evidence of acquisition in accordance with the applicable rule of the GR covered.

Mutually agreed terms (MAT): a legal agreement between two private parties; defining the conditions governing the use of GR and benefit-sharing. The mechanism usually used is a Material Transfer Agreement (MTA).

Prior Informed Consent (PIC): approval by the authorities of the providing country of access to and utilisation of GR.

Utilisation of GR: to conduct research and development (R&D) on the genetic and/or biochemical composition of GR, including through application of biotechnology.

Introduction

The Nagoya Protocol on Access to GR and the Fair and Equitable Sharing of Benefits Arising from their utilisation to the Convention on Biological Diversity (CBD) ("the Protocol") is an international agreement to ensure the fair and equitable access and benefit sharing (ABS) in using GR. The aims of the CBD are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of GR, including by appropriate access to GR and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. The Protocol was adopted by European legislation through Regulation (EU) No. 511/2014 and came into force on 12th October 2014 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511>. It was implemented into UK law through Statutory Instrument No. 821 "The Nagoya Protocol (Compliance) Regulations 2015." The legislation is implemented and enforced in the UK by the Office for Product Safety and Standards (OPS&S) <https://www.gov.uk/government/organisations/office-for-product-safety-and-standards%20>

There is a legal obligation for researchers to comply with the Protocol. Researchers planning projects that may involve the collection of GR for research and development purposes must; consider this guidance, fill out the Nagoya Protocol checklist and discuss with the RO when deciding whether the Protocol applies.

Researchers who use GR are required to follow several steps to ensure that GR (and any aTK with those resources) have been accessed in accordance with applicable access and benefit sharing laws implemented by the provider country. These steps are detailed below. The RO will work with you to complete these steps.

Researchers should refer to the Access and Benefit-sharing Clearing House (ABS Clearing House) website <https://absch.cbd.int/> which is an international web-based tool that facilitates the implementation of the Nagoya Protocol. ABS Clearing House shares relevant information about ABS and supports the monitoring of utilisation of GR.

Steps to take

1. Determine whether the Nagoya Protocol applies to the GR by using the Checklist. If the Protocol does not apply, skip to step 7.
2. Identify information on the provider country using the Checklist and referring to the ABS Clearing House website to determine whether the provider country has ratified the Protocol and established measures to regulate the GR. However, please note that information on the ABS Clearing House website may not always be up to date in some developing countries. Therefore, it is always a good idea to contact the National Focal Point (NFP)/Competent National Authority (CNA) to ensure you have got the most up to date information.
3. Undertake Due Diligence. The Due Diligence steps required will vary depending on how the GR was accessed:

Direct Access (i.e. using GR obtained directly from the country of origin by the researcher):

- Using the ABS Clearing House, determine whether the access measures include requirements to obtain the PIC and the MAT (or equivalent) for the GR.
- If unsure, contact that country's named ABS NFP or CNA designated under the Protocol to confirm.
- If required, apply for the PIC. This involves submitting the required information (which will vary) to the identified entry points and stakeholders of the provider country e.g. the CNA, local communities and different levels of government.
- If GR or any aTK are obtained from indigenous or local communities, it is best practice to negotiate MAT for access even if this is not required in the national legislation.
- Check whether you need other permits (e.g. export control, access to protected areas, import permits to the UK via contacting the Animal and Plant Health Agency (APHA)).
- After the PIC is obtained, the RO will negotiate the MAT with the CNA.
- The CNA in the provider country issues a national permit or its equivalent to the user.

- In countries with access legislation, the provider country may upload the PIC and MAT they have negotiated with a user to the ABS clearing house, at which point it becomes an IRCC. While not a compulsory action, it can be a useful way to keep ABS related documentation associated with a GR together and in one place. For the user, it's a document that can be referenced to demonstrate Due Diligence in a declaration, or easily transferred to any new users of the GR.

For Indirect Access (i.e. the GR is accessed from a third party e.g. collaborator):

- Inquire about the best way to obtain the GR for your project from the intermediary (this may vary depending on if the intermediary is a registered collection, collaborator, ex situ facility etc.).
 - Confirm whether the PIC and MAT were established by the intermediary when the resources were originally accessed or seek records confirming that the PIC and MAT were not required. Please note that it may be that the original use was out of scope of the EU regulation and the provider country access measures, however the new use requires a PIC & MAT. In this case, the new user will need the information detailed under Article 4:3(b) in order to determine whether they need to contact the provider country.
 - Obtain the PIC and MAT from the intermediary. This will likely be in the form of an IRCC but may alternatively be in the form of equivalent information.
 - Confirm that the transfer and your intended utilisation are covered by the PIC and MAT conditions.
 - If not apply for a new or modified MAT from the provider country.
4. Submit a Due Diligence declaration if either of the checkpoints are triggered (see below).
 5. Keep appropriate records (see below). Due Diligence records must be stored for a minimum of 20 years after the end of utilisation.
 6. Transfer:
 - Transferring GR must be in accordance with the requirements set out in the PIC and MAT.
 - The transfer should include: the PIC and MAT (or the equivalent).
 - The transferred information must be kept by the new holder and included in any subsequent transfers.
 7. If you determine that your work is not within the scope of the Nagoya Protocol:
 - Please keep a record of your rationale that determined this decision as a Due Diligence record. The RO will also keep a record of this.
 - Some nations may have their own ABS legislation unrelated to the Nagoya Protocol and this legislation would still need to be followed.

Submitting a Due Diligence Declaration

There are two checkpoints that trigger the requirement for a Due Diligence Declaration:

1. Receipt of research grants to support the utilisation of GR – the declaration is required after the receipt of the first instalment of funding and after obtaining all GR but before the final project report;
2. Reaching the final stages of product development (i.e. commercialisation) as a result of utilising the GR;

On reaching either checkpoint:

- Contact the RO who will assist in submitting the declaration to the Office of Product Safety and Standards using the European web-portal DECLARE. (An alternative DECLARE system will be put in place for EU Exit.) <https://www.gov.uk/guidance/abs>

Record Keeping & Transfer

Due Diligence records must be stored for 20 years after the end of utilisation.

What information do we need to keep?

- Description of the GR;
- Details of any aTK;
- Name and registration code of the relevant EU Registered Collection (if applicable);
- Due Diligence completed e.g. any correspondence or evidence done to determine whether the GR is within the scope of the Protocol and what further requirements are necessary;
- A copy of the IRCC (if provided);
- Alternative compliance information:
 - Date of access of GR or aTK;
 - Place of access of GR or aTK;
 - Source of access – providing names and addresses where applicable;
 - Whether material rights and obligations exist relating to ABS, including for subsequent applications and commercialisation (including copies of PICs and MATs);
 - Details of person who granted PIC and person to whom prior informed consent was granted (if not given directly to EHU).