The Nagoya Protocol – Checklist for Researchers

This checklist should be used in conjunction with the Nagoya Protocol webpage, which has further information, prior to starting research.

1. **Determine whether the Nagoya Protocol will apply to the material.** Tick the statements that apply. If all, proceed with checklist[1].

- ❑ The material is a genetic resource (i.e. any material containing functional units of heredity [e.g. genes or DNA]) or their derivatives (e.g. proteins, lipids, enzymes);
- ❑ The genetic resource is non-human (human material is exempt);
- ❑ It is *not* already covered by an existing legal agreement i.e. the International Treaty on Plant Genetic Resources for Food and Agriculture or WHO's Pandemic Influenza Preparedness Framework);
- ❑ It is found within an area of national jurisdiction (areas outside national jurisdiction, e.g. the high seas, are exempt);
- ❑ The genetic resource will be 'utilised'[2] by you or a third party, and/or the genetic resource will be held in a museum collection or registered collection[3] and made available for research.
- ❑ The genetic resource was accessed directly i.e. obtained from its country of origin by you or a third party after 12th October 2014.

2**. Identify information on the provider country.** Use the Access and Benefit Sharing (ABS) Clearing House website and/or the country's named ABS National Focal Point (see guide). Tick the statements that apply. If all, proceed with checklist[1].

- ❑ The country has ratified the Nagoya Protocol;
- ❑ The country has established measures relating to ABS for the genetic resource you intend to use (or it is unclear to you whether or not there are access measures).

3. If you tick all the boxes, your work will be within the scope of the Nagoya Protocol and you must **undertake due diligence**.

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[1] If you determine that your work is not within the scope of the Nagoya Protocol, please keep a record of your actions as a 'due diligence' record. No further action is required to ensure compliance with the Protocol.
[2] Utilization means 'to conduct research and development on the genetic and/or biochemical composition of genetic resources'. Further guidance on what constitutes research and research development here.
[3] A 'registered collection' is a verified collection of ABS-compliant genetic resources that meets the criteria set out in the EU ABS Regulation (Article 5) e.g. DSMZ. The register of collections is available here".

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3. Undertake due diligence. The steps required will vary depending on how you will access the genetic resource (GR).

3a. Direct Access – the GR will be obtained directly from the provider country

- ❑ Determine what access measures the country has established for the GR;
- ❑ If unsure, contact that country's National Focal Point to confirm;
- ❑ If required, apply for '**P**rior **I**nformed **C**onsent' (PIC);
- ❑ If required, the University will negotiate '**M**utually **A**greed **T**erms' (MAT) with the Competent National Authority;
- ❑ Check if you will need other permits (e.g. for access to protected areas);
- ❑ The Competent National Authority provides the researcher with a national permit;
- ❑ The ABS Clearing House generates an **I**nternationally **R**ecognised **C**ertificate of **C**ompliance (IRCC);
- ❑ Comply with the terms of the PIC & MAT throughout research.

3b. Indirect Access – the GR will be accessed from a third party.

Liaise with the third party (e.g. registered collection, collaborator etc.) to complete the following steps:

- ❑ Determine the best way to obtain the GR for your project;
- ❑ Confirm if PIC and MAT were established when the resources were originally accessed;
- ❑ Obtain PIC and MAT from the third party or records confirming they were not required;
- ❑ Confirm that the transfer and your utilization will be covered by PIC and MAT conditions;
- ❑ If not, or if PIC and MAT are required and not established, apply for a new or modified PIC and MAT from the provider county;
- ❑ Comply with the terms of PIC & MAT throughout research.

4. **Submit a Due Diligence Declaration** (see the Nagoya Protocol webpage for further information).

Due diligence declarations will be required at one of two checkpoints. If your project reaches either checkpoint, you must submit a due diligence declaration.

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

On reaching either checkpoint:

- ❑ Complete the relevant due diligence declaration template;
- ❑ Contact the research office who will assist in submitting the declaration to the Office of Product Safety and Standards using the European web-portal DECLARE.

5. Record Keeping & Transfer. Due diligence records (i.e. IRCC or equivalent information) must be stored for 20 years after the end of utilisation. If transferring the GR to a third party, you must provide the IRCC or equivalent information.

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.

Mutually Agreed Terms (MAT): An agreement between the provider and user of genetic resources that governs the use of genetic resources and benefit-sharing conditions.

Internationally recognised certificate of compliance (IRCC): A domestic access permit that has been made available to the ABS Clearing-House.

Prior Informed Consent (PIC): Approval by the authorities of the providing country of access to and utilization of genetic resources