**The Nagoya Protocol – Checklist for Researchers**

**This checklist should be used in conjunction with the Nagoya Protocol** [**webpage**](https://www.abdn.ac.uk/staffnet/research/nagoya-protocol-10646.php)

**prior to starting research. In any case, keep this checklist as a record[[1]](#footnote-1) of your due diligence.** This process is complementary to obtaining [ethical approval](https://www.abdn.ac.uk/staffnet/research/ethical-review-10645.php) for your research. Apply for ethical approval at the earliest opportunity, you will only need to have completed the steps of the first page for that.

1. **Determine whether the Nagoya Protocol will apply to the material.** Tick the statements that apply.

The material is a non-human genetic resource (i.e. any material containing DNA) or a derivative (e.g. proteins, lipids, enzymes)

[It is not already covered by an existing access and benefit-sharing instrument (i.e. the](http://www.fao.org/plant-treaty/overview/texts-treaty/en/) [International Treaty on Plant Genetic Resources for Food and Agriculture](https://www.fao.org/plant-treaty/en/) [or the](http://www.who.int/influenza/resources/pip_framework/en/) [PIP Framework](https://www.who.int/initiatives/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]](#footnote-2) by you or a third party (= ‘user’2), and/or the genetic resource will be held in a museum collection or registered collectionand made available for research.

You accessed the genetic resource or associated traditional knowledge3 directly (i.e. obtained from its country of origin) or through a third party on or after 12th October 2014

1. **Identify information on the provider country.** Use the Access and Benefit Sharing

(ABS) Clearing House [website](https://absch.cbd.int/) and/or contact the country’s named ABS National Focal Point. Tick the statements that apply.

The country has ratified/is party to 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 there are access measures)

If you ticked all the boxes above, your work is likely in the scope of the Nagoya Protocol, and **you must** **undertake further due diligence to comply**. At this time, also apply for ethical approval for your research. Proceed with checklist and [ask for advice.](mailto:nagoyaprotocol@abdn.ac.uk)

|  |  |
| --- | --- |
| Principal Investigator (if PhD student, add supervisor) |  |
| Project title |  |
| Country material is originating from |  |
| In scope (if no, explain why not) |  |

**3. Undertake due diligence to comply with the regulations of the Nagoya Protocol.** The steps required will vary depending on how you will access the genetic resource (GR)

**3b. Indirect Access**:

The GR will be obtained from a third party

**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) – ! depending on country, you might need [ethical approval](https://www.abdn.ac.uk/staffnet/research/ethical-review-10645.php) for your research first

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

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 utilisation 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 country

Comply with the terms of PIC & MAT throughout research.

1. **Submit a Due Diligence Declaration** (see the [UK Guidance](https://www.gov.uk/guidance/abs#making-a-due-diligence-declaration) 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 utilisation of the GR – the declaration is required after the receipt of the first instalment of funding but before the final project report

Reaching final stages of product development (i.e. commercialisation) as a result of utilising GR

**On reaching either checkpoint,** [**contact us**](mailto:nagoyaprotocol@abdn.ac.uk) **and we will assist in submitting the declaration to the Office of Product Safety and Standards using the European web-portal DECLARE:**

Complete and submit the [due diligence declaration](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fassets.publishing.service.gov.uk%2Fgovernment%2Fuploads%2Fsystem%2Fuploads%2Fattachment_data%2Ffile%2F974976%2Fnayoga-protocol-form-due-diligence-declaration-2.odt&wdOrigin=BROWSELINK)  – Checkpoint 1  Checkpoint 2

**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.

**Utilisation:** Research that leads to the discovery of specific genetic and/or biochemical properties – [more guidance](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075912/abs-guidance-defra-2022.pdf)

**User:** a natural or legal person that utilises GR or traditional knowledge associated with GR. Exempt are subcontractors that strictly provide agreed service to a user and no other R&D activities.

**Internationally Recognised Certificate of Compliance (IRCC):** A domestic access permit that has been made available to the ABS Clearing-House.

**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.

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

1. Whether or not your research is in scope of the Nagoya Protocol, please keep a record of your actions as a ‘due diligence’ record. If it is not in scope, no further action is required to ensure compliance with the Protocol. [↑](#footnote-ref-1)
2. Further guidance on what constitutes ‘utilisation’ and who is considered a ‘user’ is available [here](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075912/abs-guidance-defra-2022.pdf).

   3 Associated traditional knowledge is that of indigenous and local communities that result from the close interaction with their natural environment and may provide information for discoveries on properties of genetic resources. [↑](#footnote-ref-2)