**The Nagoya Protocol**

**RESEARCH AND INNOVATION SERVICES**

Checklist for Researchers

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

If you determine your work to be within scope of the Nagoya Protocol (as per sections 1 and 2 of the checklist), or are unsure if it is in scope, please contact our Compliance and Assurance team at ris.complianceandassurance@ucl.ac.uk for support with the steps outlined in this guide and the checklist, as required.

This checklist has been adopted with permission from the [University of Cambridge](https://www.research-operations.admin.cam.ac.uk/nagoya-protocol/guide-abs-clearing-house-website).

1. **Determine whether the Nagoya Protocol will apply to the material.** Tick the statements that apply. If all apply, proceed with checklist.[[1]](#footnote-2)

[ ]  The material is a genetic resource (GR), i.e., any material containing functional units of heredity (e.g., genes or DNA) or their derivatives (e.g., proteins, lipids, enzymes); ​

[ ]  The GR is non-human;​

[ ]  It is not already covered by an existing legal agreement i.e., the [International Treaty on Plant Genetic Resources for Food and Agriculture](http://www.fao.org/plant-treaty/overview/texts-treaty/en/) or [WHO's Pandemic Influenza Preparedness 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 GR will be ‘utilised’[[2]](#footnote-3) by you or a third party, and/or the genetic resource will be held in a museum collection or registered collection[[3]](#footnote-4) and made available for research.​

[ ]  The GR was accessed directly i.e., obtained from its country of origin by you or a third party 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/en/) and/or the country’s named ABS National Focal Point (see University of Cambridge guide). Tick the statements that apply. If all apply, proceed with checklist.1

[ ]  The country has ratified the Nagoya Protocol[[4]](#footnote-5);

[ ]  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).

If you have ticked all the above statements, your work will be within the scope of the Nagoya Protocol and you must undertake **due diligence**.

1. **Undertake due diligence.** The steps required will vary depending on:
2. **Direct Access:** the GR will be obtained directly from the provider country.

☐ With support from Compliance and Assurance Team in Research and Innovation Services 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 Internationally Recognised Certificate of Compliance (IRCC);

☐ Comply with the terms of the PIC & MAT throughout research.

1. **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 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**

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 the final stages of product development (i.e., commercialisation) as a result of utilising the GR;​

On reaching either checkpoint:​

[ ]  Contact the Compliance and Assurance Team in Research and Innovation Services who will work with you to complete the due diligence declaration form and will submit this to Defra.

1. **Record keeping and 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.​

**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 utilization of genetic resources​.

1. If you did not tick all of the boxes, 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. [↑](#footnote-ref-2)
2. Utilisation means ‘to conduct research and development on the genetic and/or biochemical composition of genetic resources’. For more details, please see [Guidance on the UK Access and Benefit Sharing Regulations](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075912/abs-guidance-defra-2022.pdf) and Annex II of [EU guidance document](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&from=EN).​ [↑](#footnote-ref-3)
3. A ‘registered collection’ is a verified collection of ABS-compliant genetic resources that meets the criteria set out in the [EU ABS Regulation](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511) (Article 5) e.g., DSMZ. [↑](#footnote-ref-4)
4. Please note that countries may have national ABS measures separate from Nagoya and these national measures still need to be complied with even if your research is out of scope of Nagoya Protocol. [↑](#footnote-ref-5)