# **Nagoya Protocol (NP) and Access and Benefit Sharing (ABS) Compliance Checklist**

## Introduction

If you intend to use non-human genetic material that originates from outside the UK for research, you are legally obliged to comply with the Nagoya Protocol (“NP”). Please use this checklist to help determine what actions are required.

The [Nagoya Protocol](https://www.cbd.int/abs) is an international agreement that enables equitable sharing of non-human genetic resources (and traditional knowledge associated with genetic resources). It recognizes the sovereign rights of countries/states to genetic resources within their jurisdiction.

As relevant, please read the [University Nagoya Protocol webpage](https://www.research-operations.admin.cam.ac.uk/nagoya-protocol/) for further information about the Nagoya Protocol and Access Benefit Sharing (ABS). You can also seek advice from the research governance team.

## Navigation of this Checklist

**Part 1:** Anyone intending to access a non-human genetic resource (“GR”) **that originates from outside the UK** for research should use the decision tool ([**Part 1**](#_Part_1)) to identify whether the non-human genetic resource may be subject to obligations under the NP and/or any national Access and Benefit Sharing (“ABS”) legislation.

**Part 2:** If there are no NP-related or ABS obligations, use the recordkeeping template **(**[**Part 2**](#_Part_2)**)** to record the relevant evidence as to why this decision has been reached. If accessing additional samples, you should check that the country hasn’t implemented any new measures since you first accessed these samples and submit Part 2 again to create a dated record of your latest check prior to exporting or using the new samples.

**Part 3:** If there are (or potentially are) NP-related or ABS obligations, use [**Part 3**](#_Part_3) to support the submission of an ABS application to access the genetic resource. Upon receipt of Part 3, the research governance team will contact you regarding the next steps.

If you wish to transfer (i.e. giving the genetic resource to a third party) any genetic resources that have NP-related obligations, you must complete certain compliance actions. Please read the relevant section of [Nagoya Protocol webpage](https://www.research-operations.admin.cam.ac.uk/nagoya-protocol/) and seek further advice as appropriate.

Please continue onto the decision tool in Part 1.

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| **Part 1. Determine whether the MATERIAL is a non-human genetic resource (“GR”) that originates from outside the UK that may be subject to obligations under the Nagoya Protocol[[1]](#footnote-2) (“NP”)**  |
| **Question** | **Action** |
| A. Is the material any type of **genetic resource (“GR”)?**  A GR is material that is (or compromises a sample or extract of) any of the following. Answer yes if the material is any of the following: 1. domesticated or cultivated animals
2. cultivated plants or crops
3. laboratory strains e.g., lab mice, primary cell line, plasmid containing genetic material or other genetically modified organisms
4. human microbiota
5. plant genetic resource for food and agriculture (PGRFA) (defined in [Plant Treaty](http://www.fao.org/plant-treaty/en/))
6. influenza virus with human pandemic potential
7. wild plants, fungi, fish, animals, insects, microrganisms, virus
8. soil, water, air or other environmental samples that may contain GR
9. forest reproductive material or marine samples that may contain GR
10. GR obtained from an ex *situ* collection
11. GR obtained from a registered collection
12. **derivative** of a GR (e.g. sequencing data, proteins, enzymes, formulation ingredients from a GR)
 | If no, end tool If PGRFA or influenza virus, go to question G, If GR from registered collection, go to JIf any other type of GR or unsure, go to question B.  |
| B. Does the material originate from the UK or USA? | If no, go to question CIf yes, complete [Part 2.2](#_2.2_Geographic_scope) to end tool. |
| C. Does the material originate from a country labelled dark green or light green (light green) on [this webpage](https://www.research-operations.admin.cam.ac.uk/nagoya-protocol/map)?[**Note**: requires Raven-login. If your use of the GR includes associated traditional knowledge (aTK), do **not** use this map. Go to question D. If lab strain, check the lab strain table on this webpage].  | If dark green, complete [Part 2.2](#_2.2_Geographic_scope) to end tool.If light green complete part 3.2 to end tool.Otherwise, go to question D. |
| D. Is the material one of the following: 1. human microbiota
2. lab strain (e.g lab mouse)?
 | If human microbiota, go to question E.If lab strain, go to question F.If neither, go to question H. |
| E. Refer to the [UK guidance](https://www.research-operations.admin.cam.ac.uk/sites/www.research-operations.admin.cam.ac.uk/files/policies_and_procedures/uk_abs_guidance_april_2022.pdf) to judge whether your use of the human microbiota constitutes non-human or human material.  | If non-human, go to question HIf human, go to **O.**  |
| F. Was your access (or will your access) to the lab strain be on or after 12 October 2014? | If yes, go to question I.If no, complete [Part 2.2](#_2.2_Geographic_scope) to end tool. Seek advice from RGT as appropriate.  |
| G. Is the use of the GR covered by a specialised international ABS instrument (i.e., **PGRFA** under [ITPGRFA](http://www.fao.org/plant-treaty/en/) or influenza virus with human pandemic potential under [PIP Framework](https://www.who.int/influenza/resources/pip_framework/en/))? | If yes, complete [Part 2.3](#_2.3_Material_Scope) to end tool. If no, question B. If unsure, seek advice. |
| H. Was or will your access to the material be on or after 12 October 2014? | If yes, go to question IIf no, **M**. |
| I. Check if **the provider country** is a Party (has signed up to) to the Nagoya Protocol on the ABS Clearing House [here](https://absch.cbd.int/en/countries) (Green = Party) | If yes, go to question JIf no, go to **P** |
| J. How will you obtain the GR? 1. From a registered collection that is recognised in the UK or the EU [Check [EU register](https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/929bd3de-3a8a-4a70-9835-9ce7b74b4fba/details?download=true) and the [UK register](https://www.gov.uk/guidance/abs)]
2. Non-registered collection or any other source
 | If from Registered collection, [part 3](#_Part_3)Otherwise, go to question K |
| K. Does the research activity**[[2]](#footnote-3)** constitute **utilization[[3]](#footnote-4) of the** **GR?**   | If yes, go to [Part 3](#_Part_3)If no or unsure, go to question L |
| L. Will the material be held in a museum collection or registered collection to be made available for research and development? | If yes, go to [Part 3](#_Part_3)If no, go to **N** |

Based on your answers to the questions above, you should do one of the following:

* Go to the relevant section in [Part 2](/node/18772) to complete the Nagoya Checklist.
* Complete [Part 3](/node/18782) of the Checklist to support the submission of an ABS application to access the genetic resource.
* Read the relevant box in the dropdown menu below (M, N, O and P)
* Seek advice from the Research Governance Team (RGT).

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| **M. Temporal**Your answers indicate that the provider country is a Party to the NP but that your access to the GR pre-dates the Nagoya Protocol. Read the note below about NP countries whose country-specific ABS requirements pre-date NP and complete [Part 2.1](#_2.1_Temporal_scope) to end tool.Country-specific ABS Requirements that pre-date NPA provider country might have national access regulations relating to the GR collected prior to October 2014 (e.g. Brazil and India). It is necessary to check and comply with country-specific ABS requirements. Seek advice from research governance team where necessary.**[Exception:** If using GR from mainland Spain or France (rather than their other territories, e.g. islands), it is not necessary to do any further checks. The Spanish and French requirements do NOT pre-date the Nagoya Protocol.]  |
| **N. Utilisation**Your answers indicate that your work is out-of-scope of UK ABS (Nagoya Protocol) regulation because it does not constitute utilization[[4]](#footnote-5). Read the note below about country-specific ABS requirements and complete [Part 2.4](#_2.4_Utilisation_scope) to end tool.Country-specific ABS Requirements regarding use Your use of the GR might still be in scope of the provider country’s ABS rules e.g. Taxonomy in Uganda. It is necessary to check and comply with country-specific ABS requirements. Seek advice from research governance team where necessary. [**Exception:** If using GR from mainland Spain or France (rather than their other territories, e.g. islands), is not necessary to do any further checks. There aren’t any county-specific ABS rules for the non-utilization uses of GR.]  |
| **O. human microbiota – Utilisation**Your answers indicate that your work is out-of-scope of UK Nagoya Protocol regulation because your research involving human microbiota doesn’t constitute ‘utilization’. Read the note below about checking the country-specific ABS requirements of non-NP countries and complete [Part 2.4](#_2.4_Utilisation_scope) to end tool. Country-specific ABS Requirements regarding use of human microbiota Your use of the GR might still be in scope of the provider country’s ABS rules. It is necessary to check and comply with country-specific ABS requirements. Seek advice from research governance team where necessary. [If using human microbiota GR from mainland Spain or France, your work does not fall in scope of country-specific ABS requirements in this case].  |
| **P. Not Party to Nagoya**Your answers indicate that the country is not a Party to NP. Read the note below about checking the ABS requirements of non-NP countries and complete [Part 2.2](#_2.2_Geographic_scope) to end tool.Non-NP Country-specific ABS RequirementsSeveral non-NP countries have ABS requirements (e.g. Australia, Canada etc.) It is necessary to comply with any country-specific ABS requirements. Seek advice from research governance team where necessary. |

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| Part 2. Recordkeeping template**[[5]](#footnote-6)**  |
| Based on the outcome from the decision tree in [Part 1](#_Part_1._), the MATERIAL is **NOT** subject to NP-related obligations. As a ‘due diligence record’ please complete the table below to provide evidence and reason(s) why the MATERIAL is **NOT** subject to NP-related obligations. Contact research governance team to discuss case-specific queries (research governance team). It is necessary to keep records for 20 years. This information may be requested by the UK regulator. Please provide a copy of this document to the research governance team (you can do this by email).**Please note** that further action may be required to comply with country-specific ABS requirements and also any relevant non-ABS requirements.[[6]](#footnote-7)  |
| PI Name  |  |
| Department  |  |
| Date |  |
| R(G) Number of associated grant or research contract (if known)  |  |
| **Generic scope elements** | **Reasons for samples and/or their utilisation being out of scope** | **Examples of evidence that the project is out of scope (select relevant option(s))** |
| 2.1 Temporal scope | The GR was accessed prior to 12 October 2014 | * grant/research contract
* Postal records
* Receipts/Invoices
* Letters
* Research proposal
* Published article
* Other, please specify
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| 2.2 Geographic scope | * The GR is in an area beyond national jurisdiction (e.g high seas or Antarctic Treaty System)
* The provider country of the GR is not Party to NP
* The provider country did not have applicable access measures in place at the time of access
 | * grant/research contract
* Research proposal
* Letters/correspondence with the collection/intermediary
* Link to the [ABS CH](https://absch.cbd.int/en/countries) (or [here)](https://www.research-operations.admin.cam.ac.uk/nagoya-protocol/country-specific-information)
* Correspondence with NFP
* UCAM NP ABS Map (here)
* Other, please specify
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| 2.3 Material Scope | * The material does not meet the definition of a genetic resource (GR)
* The genetic resource is human
* The GR (and its utilisation) is covered by a specialised international ABS instrument (e.g. [ITPGRFA](http://www.fao.org/plant-treaty/en/) or the [PIP framework](https://www.who.int/influenza/resources/pip_framework/en/))
 | * grant/research contract
* Research Proposal
* Patent application
* Published articles
* Links/correspondence with websites/databases
* Other, please specify
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| 2.4 Utilisation scope | * R&D is not being conducted on the genetic and/or biochemical composition of the GR
* The R&D does not create new insight into the characteristics of the GR which is of (potential or real) benefit to the further process of product development
 | * grant/research contract
* Research Proposals
* Progress reports (to funders)
* Published articles
* Other, please specify
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| **Part 3 (online version** [**here**](https://forms.office.com/e/izBWgGuimS)**)** |
| Based on the outcome from the decision tree in [Part 1](#_Part_1), it likely that the material is subject to NP-related or ABS obligations. For further guidance on county-specific ABS compliance requirements and ABS access application to the country, please contact the research governance team by emailing at researchgovernance@Admin.cam.ac.uk (please include ‘Nagoya Protocol’ or ‘ABS’ in the subject line). Include as much of the following information as possible in your [email](https://www.research-operations.admin.cam.ac.uk/file/templateemaildocx). 1. PI leading the work
2. ROO G ref if there is one;
3. The funder/s of the project
4. Confirmation that research is for non—commerical purposes
5. Country of origin[[7]](#footnote-8)
6. Brief description of the genetic resource(s) (include the species/strain name, sample type and any relevant details about the species e.g native/protected/domesticated/wild/cultivated etc. )
7. Expected date and place of access/collection of the genetic resource
8. Collection method e.g. *ex-situ* collection, purchase, gene bank or seed bank*, in situ* collection, botanical garden, access through a Third Party by contract, registered collection etc.
9. Overall objective of the project
10. Brief description of the proposed research and activities to be undertaken, including period of utilisation

There is no defined process for access set out by the Nagoya Protocol, nor one set of access measures to comply with. If an ABS application is required, the research governance team will assist in the preparation and submission of the ABS application to the national authority in that country and will identify what additional information and documents are required. Obtaining an ABS permit through a non-negotiated process may take some time. If a formal contract is required (i.e. the ABS Contract; MAT (mutually agreed terms)), the University will negotiate the formal contract with the provider nation’s government. Please be aware that the negotiation will take several months. The ABS contract will be additional to any research contract as required under normal academic practice. |

**Key Terms**

This document uses the definitions listed in the Nagoya Protocol and UK ABS Regulations.

Access: the acquisition of **genetic resource** or of **traditional knowledge** associated with genetic resources (aTK).

Access and Benefit Sharing Clearing House (ABSCH): The nominated platform for exchanging information on ABS and a key tool for facilitating the implementation of the Nagoya Protocol. (<https://absch.cbd.int/>)

Biotechnology: ‘any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use’.

Derivative(s): ‘A naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity’. Examples of derivatives include proteins, lipids, enzymes, flavonoids, essential oils and resins.

Genetic material: ‘Any material of plant, animal, microbial or other origin containing functional units of heredity’. See **genetic resource**.

Genetic Resource(s) (GR): ‘**genetic material** of actual or value’. See **derivative**.

(IT)PGRFA: [The International Treaty on Plant Genetic Resources for Food and Agriculture](http://www.fao.org/plant-treaty/en/) (ITPGRFA) is a specialised international ABS instrument. It applies to plant genetic resources for food and agriculture (PGRFA).

[Nagoya Protocol](https://www.cbd.int/abs): is an international legal framework that implements the **access** and benefit-sharing obligations of the [Convention on Biological Diversity (CBD).](https://www.cbd.int/convention)

Registered collection: a verified collection of ABS-compliant genetic resources that meets the criteria set out in the EU ABS Regulation (Article 5), as amended by Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018.

Traditional Knowledge associated with genetic resources (aTK): ‘Traditional Knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources’

UK ABS Regulations: the legislation in force in the UK to implement the requirements of the Nagoya Protocol. All users of genetic resources in the UK must comply with the UK ABS Regulations (see section 1 in [UK ABS Guidance](https://www.research-operations.admin.cam.ac.uk/sites/www.research-operations.admin.cam.ac.uk/files/policies_and_procedures/uk_abs_guidance_april_2022.pdf) for further details).

Utilisation (of genetic resources): ‘to conduct research and development (R&D) on the genetic and/or biochemical composition of genetic resources, including through application of **biotechnology’**. This includes basic and applied research**.** Refer to the [UK ABS guidance document](https://www.research-operations.admin.cam.ac.uk/sites/www.research-operations.admin.cam.ac.uk/files/policies_and_procedures/uk_abs_guidance_april_2022.pdf) for further details.

1. In addition to NP ABS requirements, there may be stricter country-specific ABS requirements. The outcomes here specifically address the NP ABS requirements. It is necessary to check and comply with country-specific ABS requirements. [↑](#footnote-ref-2)
2. For further guidance on specific research activities, please see the [UK guidance](https://www.research-operations.admin.cam.ac.uk/sites/www.research-operations.admin.cam.ac.uk/files/policies_and_procedures/uk_abs_guidance_april_2022.pdf) – the following sections will be particularly of interest to many academic research projects: taxonomic identification of a genetic resource (Section 6.4), Characterisation (section 6.5), Phylogenetic analysis (Section 6.7), Large-scale screening (section 6.8) and testing and reference tools (section 7.9) [↑](#footnote-ref-3)
3. **Utilisation** means conducting research and development in which investigation of the genetic or biochemical composition of the genetic material or its derivatives is the object of the research, including through application of **biotechnology**. Please see the [UK guidance](https://www.research-operations.admin.cam.ac.uk/sites/www.research-operations.admin.cam.ac.uk/files/policies_and_procedures/uk_abs_guidance_april_2022.pdf) (see footnote 2 to help navigate to the relevant section). [↑](#footnote-ref-4)
4. A number of countries are in the process of implementing their ABS laws. Please be aware that if the ABS law comes into force during your project, your project may then fall into scope of the UK regulation. In such cases, seek confirmation from the relevant authority whether the law has been implemented before each time you wish to collect or transfer samples as part of this project to ensure ongoing compliance. [↑](#footnote-ref-5)
5. This is adapted from table 1 on P. 28 in the Defra guidance on the [UK ABS regulations](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075912/abs-guidance-defra-2022.pdf) [↑](#footnote-ref-6)
6. This may include: 1) [Obtaining an MTA](https://www.research-operations.admin.cam.ac.uk/research-contracts/types-contracts/material-transfer-agreement-mta) (required to transfer material from another organization to the University), 2) Import license/certificates e.g., Sanitary and Phytosanitary certificates, 3) CITES permit if importing endangered animals, 4) Obtaining research permit to access certain research sites or collect samples, 5) Overseas travel approvals (e.g., travel insurance, risk assessment etc.).See the [University import export hub](https://www.importexport.admin.cam.ac.uk/) for further information. [↑](#footnote-ref-7)
7. If **Switzerland** and non-commercial research, addressing points 1-10 is sufficient to fulfil the Switzerland ABS recordkeeping requirement. If the information is detailed in the research grant or contract specified in point 2, please refer to this.

If **Belgium** and non-commercial research, please confirm in your response that you will publish in an open access publication. If so, it is not necessary for you to address points 6-10 in this template. Once you submit the form, no further ABS compliance is required to use the samples. [↑](#footnote-ref-8)