# Nagoya Protocol (Use of Non-Human Genetic Material)

The Nagoya Protocol is an international legal framework covering the use of non-human genetic material - specifically plant, animal and microbial material.

Researchers who source or use such material are required to 'exercise diligence' to ensure that genetic resources and traditional knowledge associated with those resources have been accessed/ acquired in accordance with applicable access and benefit sharing laws implemented by the source country.

The Protocol recognises that every country has rights over the genetic resources that exist within its borders and is intended to ensure that genetic resources, and local knowledge about them, are not exploited without reference to the country or community in which it originated. Researchers have a legal obligation to comply with the Nagoya Protocol.

## Does the Nagoya Protocol Apply to my Research?

The Protocol and related due diligence requirements will apply if:

1. The research involves a genetic resource that is in scope of the Protocol:
    - Genetic resources - any material of plant, animal, microbial or other origin (excluding human) containing functional units of heredity (e.g. genes and DNA) which is of actual or potential value; or their derivatives, e.g. proteins, lipids, enzymes or RNA
    - Traditional knowledge - knowledge, know-how and practice of indigenous and local communities relevant for the utilisation of the genetic resource;

2. The utilisation of the generic resources is in scope of the protocol. For the purposes of the Protocol, 'utilisation' means to conduct research on the genetic and/or biochemical composition of genetic resources, including through application of biotechnology. This includes basic and applied research;

3. The country from which the genetic resources originated has ratified the Protocol and established applicable access measures (https://www.cbd.int/abs/nagoya-protocol/signatories/). Note that the Protocol may apply whether the genetic resource is accessed directly from the country of origin, or via a third party; and

4. The genetic resources were originally accessed from the country of origin after 12 October 2014. This includes access from an ex-situ collection in the country of origin, regardless of when the resources entered the collection.

## What to Do if the Protocol Applies?

Undertake due diligence regarding access to the genetic resource and comply with relevant access measures, specifically:

1. Use the Access and Benefit-Sharing Clearing-House (https://absch.cbd.int/) to identify the relevant national laws, procedures and contact points in the country(ies) from which you wish to source the material;

2. Make all reasonable efforts to gain prior, explicit informed consent and agree the terms and conditions of access. There is no mandated legal template for the informed consent and access agreements - researchers are expected to act in good faith and keep records of relevant discussions and agreements. Agreements should deal with the dissemination of research results, the publication or other sharing of research data, and any potential exploitation;

3. Submit details of the date and place of acquisition, description of material, source obtained from, and any access permits/mutually agreed terms, to ethicssupport@shu.ac.uk;

4. You will also be required to submit a formal Due Diligence Declaration to the UK Office for Product Safety and Standards if your project reaches one of two checkpoints: when in receipt of a research grant to support the utilisation of the genetic resource, or during the final stages of product development (i.e. commercialisation) as a result of utilising of the genetic resource. Templates for these are Annexes 2 and 3 of the Commission Implementing Regulation (EU) 2015/1866 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN);

5. Keep related records for 20 years - these may be inspected by a regulator; and

6. Provide copies of relevant information if you are transferring the genetic resource to another user.