Nagoya Protocol and the use of non-human genetic material - Checklist for researchers

Please complete this checklist after reading the information on the Nagoya Protocol webpage and before commencing research.

Please retain a copy of the completed checklist for due diligence purposes and also provide a copy to zoe.deacy-clarke@york.ac.uk and phil.wiles@york.ac.uk of the *Policy, Integrity and Performance Team* for central record keeping.

The purpose of this checklist is to enable researchers to understand and meet compliance needs. Although the Policy, Integrity and Performance team is able to advise and assist, this process should be led by researchers.

Please add a description of the non-human genetic material in question, the country of origin and the project title and Worktribe ID/Code (if applicable). Please complete a separate checklist for different genetic materials or if the same material originates from a different country.			
Genetic material	**Country of origin**	**Project title**	**Project ID/R Code/ contract ID**

Please answer the following questions and follow the guidance provided.

1.	**Is my research in scope of the Nagoya Protocol and related Regulations?**	**Yes/no/don't know**
a.	You intend to use a non-human genetic resource (i.e. any material of plant, animal, microbial or other origin [excluding human]) containing functional units of heredity [i.e. genes and DNA] and/or associated traditional knowledge ("**Genetic Resource**").	
b.	The Genetic Resource is not already covered by an international specialised instrument which has already established access and benefit sharing conditions e.g. ITPGRFA or the PIP Framework.	
c.	The Genetic Resource is found within an area of national jurisdiction e.g. over which a sovereign state exercises rights (areas outside of national jurisdiction include the high seas or areas covered by the Antarctic Treaty System).	
d.	The Genetic Resource was, or will be, accessed from the country of origin on or after 12 October 2014.	
e.	The Genetic Resource will be utilised in the UK. "Utilised" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. See the Nagoya Protocol webpage for further guidance on what does and does not constitute research and development for these purposes.	

If you have answered "yes" to all of the statements above **your research is potentially in scope**. **Please continue with the checklist.**

If you have answered "no" to any of the statements your research may not be in scope but **please continue with the checklist to determine if any access measures apply**.

If you have answered "don't know" to any of the statements please contact zoe.deacy-clarke@york.ac.uk and phil.wiles@york.ac.uk of the *Policy, Integrity and Performance Team* for assistance.

2.	**What is the status of the provider country (the country from which the Genetic Resource originates even if it is now in another country)? Please refer to the Nagoya Protocol webpage for guidance on how to use the ABS Clearing House and/or contact the country's National Focal Point.**	**Yes/No/Don't know**
a.	Is the country a party to the Nagoya Protocol?	
b.	Has the country established access measures that cover the Genetic Resource or is it not clear?	

If you have answered "yes" to both questions above your research is in scope and **you must continue to undertake due diligence**. **Please continue with the checklist.**

If you have answered "no" to both questions or you have answered "yes" to question 2(a) but "no" to question 2(b) your research is not in scope. **Please keep a record of your actions as a due diligence record. Go to question 5 below.**

If you have answered "no" to question 2(a) but "yes" to question 2(b) your research is not in scope but you must still **comply with the relevant country's access measures. Please keep a record of your actions as a due diligence record. Go to question 5 below.**

If you have answered "don't know" to either of the questions please contact zoe.deacy-clarke@york.ac.uk and phil.wiles@york.ac.uk of the *Policy, Integrity and Performance Team* for assistance.

3.	**If my research is in scope how do I undertake due diligence?**
a.	Notify the *Policy, Integrity and Performance Team* at an early stage if you think your research is in scope.
b.	Understand that the due diligence process can be time consuming. Consider the additional time and administration that may be required to comply with the access requirements when planning your project.
c.	Determine if the Genetic Resource will be provided directly from the country of origin or if it will be provided by a third party.
d.	Once determined, follow the relevant guidance on the university's Nagoya Protocol webpage under the heading "**3. If my research is in scope how do I undertake due diligence?"**
e.	If required, apply for Prior Informed Consent ("PIC") and contact the Research and Knowledge Exchange Contracts team to negotiate Mutually Agreed Terms ("MAT") as determined by the relevant access measures before research commences.

f.	Comply with any PIC, MAT or other permits throughout the research. Retain copies for your records and provide copies to the *Policy, Integrity and Performance Team*.

If you require any advice please contact zoe.deacy-clarke@york.ac.uk and phil.wiles@york.ac.uk of the *Policy, Integrity and Performance Team* for assistance.

Please continue with the checklist.

4.	**Is a due diligence declaration required?**	**Yes/No/Don't know**
a.	Have you received a research grant for work involving utilisation of the Genetic Resource?	
b.	Have you reached the final stages of development of a product developed via the utilisation of the Genetic Resource?	

If you have answered "yes" to either question and your research is in scope **a due diligence declaration is required**. In the case of 4(a) a due diligence declaration must be submitted after the first instalment of funding has been received and all the Genetic Resources that are utilised in the funded project have been obtained, and no later than at the time of the final report or project end. In the case of 4(b) a due diligence declaration must be submitted at the first event from a list of product development stages. See the Nagoya Protocol webpage for more detail.

If you determine a due diligence declaration is required you should complete a due diligence declaration form and provide the completed form to Zoe Deacy-Clarke and Phil Wiles in the the *Policy, Integrity and Performance Team* who will assist you with the submission of the form to Defra on behalf of the university. See the Nagoya Protocol webpage for more detail.

Please continue with the checklist.

5.	**What records do I need to keep? Due diligence records must be kept for 20 years after the end of utilisation. Examples include:**	**Provided to PIP? Yes/No/Not applicable**
a.	This completed Checklist for researchers.	
b.	Evidence the Genetic Resource is not in scope e.g. it was accessed before 12 October 2014, it is already covered by other international specialised instruments etc. See question 1 above.	
c.	Screen shots from the ABS Clearing House for the relevant provider country.	
d.	Communications with the provider country's National Focal Point.	
e.	Communications with any third party providers e.g. collaborators, collections.	
f.	Any IRCC or equivalent information (the date and place of access of the Genetic Resource, a description of the Genetic Resource including unique identifiers where available, the source from which the Genetic Resource was directly obtained, any existing rights and obligations relating to access and benefit sharing, any permits or MATS (see below)). **PLEASE NOTE THIS INFORMATION MUST BE MAINTAINED WHERE APPLICABLE.**	

g.	Any PICs, MATs or other permits, including any application paperwork.		
h.	Any records from third parties confirming why PICs, MATs or permits were not required.		
i.	Any completed due diligence declaration form.		
j.	Other: [INSERT]		

Please retain due diligence records for your own records and also provide copies, preferably in one folder, to zoe.deacy-clarke@york.ac.uk and phil.wiles@york.ac.uk of the *Policy, Integrity and Performance Team* for central record keeping.

6.	**Can I transfer the Genetic Resource to a third party?**
Do not transfer the Genetic Resource to any third party unless your PIC and MAT give you permission to do so. To demonstrate compliance, users are required to seek, keep and transfer to subsequent users key information either by: (a) referring to an Internationally Recognised Certificate of Compliance (IRCC) associated with their access to the Genetic Resource; or (b) seeking and acquiring the necessary equivalent information. See the Nagoya Protocol web page for more information.	