**Nagoya Protocol – record of due diligence checks**

**For ALL projects involving the use of non-human genetic material at St Andrews, or at another location by a service provider engaged by St Andrews, you MUST complete and keep this record indefinitely.**

**This record is just the first step in a process of determining whether the Nagoya Protocol might apply to your planned research**.

|  |  |
| --- | --- |
| **Researcher Name** |  |
| **Project Name** |  |
| **University email address/username** |  |
| **School/Unit:** |  |

**Does this project involve any activity that corresponds to BOTH of the criteria below?**

**Criterion one** – non-human genetic material, originally obtained from the wild within a non-UK national jurisdiction during or after October 2014, will be received by St Andrews

*Definitions and guidance*

* ‘non-human genetic material’ means any physical material of plant, animal, microbial or other non-human origin, whether whole organisms or microorganisms, or samples or extracts thereof, containing functional units of heredity (e.g. DNA or RNA).
* ‘originally obtained from the wild…during or after October 2014’ means that genetic material does not count if it does not contain material obtained from the wild during or after this point. This may be the case for many cell lines, plasmids and other genetically modified organisms shared between researchers and available from commercial suppliers.
* ‘within a non-UK national jurisdiction’ means that areas outside national jurisdiction are exempt, e.g. the high seas.
* ‘received by St Andrews’ means received by any facility owned or operated by St Andrews, or engaged by St Andrews as a service provider, located outwith the national jurisdiction in which the genetic material was originally obtained. This receipt of material can be direct (collected by St Andrews researchers from the wild) or indirect (received via a collaborator or museum/collection). If the material is solely received by a research collaborator outwith St Andrews, this does not count.

**Criterion two –** the material referred to in criterion one will be used for either of these purposes:

**Purpose one** - 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.

**Purpose two** - holding the genetic material or its derivatives in a museum collection or registered collection to be made available for the type of research and development described in purpose one.

*Definitions and guidance*

* ‘Derivatives’ means naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources (e.g. proteins, lipids, micro RNA)
* The meaning, and limits, of ‘in which investigation of the genetic or biochemical composition of the material (or derivatives) is the object of the research, including through application of biotechnology’ are outlined below using indicative examples:
* *Example one -* undertaking research that only involves measurements of physical characteristics (i.e. ascertaining the physical size) of the sample*.*
	+ This criterion does not apply because the research does not involve ‘investigation of the genetic or biochemical composition of the material (or derivatives)’, just physical measurements. For example, measuring tree rings, ascertaining the sizes and numbers of different types of cells under a microscope, or comparing the sizes of animal or insect body parts.
* *Example two -* undertaking research that involves only identifying the presence or quantity of genetic material or its derivatives without generating new knowledge on the genetic material itself*.*
	+ This criterion does not apply because the ‘genetic or biochemical composition of the material (or derivatives)’ is not the ‘object of the research’, they are only used as a tool to determine something else. This is still the case even if morphological, molecular or genetic information is used. For example, simply determining the sex, age, or strain/species of the material, or the presence of and relative quantities of different microorganisms in a sample.
* *Example three* – undertaking research that involves determining the sequence/structure/function of the genetic material or its derivatives in order to generate new knowledge on those aspects of the material or its derivatives (including through application of biotechnology)
	+ This criterion applies. For example, undertaking lab work to sequence the genome (or RNA, e.g. micro RNAs) of a microorganism, or investigate the sequence, structure or function of a protein or other derivative arising from a microorganism.
* ‘Biotechnology’ means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

| **DATE OF COMPLETION OF THIS DOCUMENT** | Click or tap to enter a date. |
| --- | --- |
| **ANSWER:** | **Click to select****---IF YOU ANSWERED ‘YES’ OR ‘MAYBE’, EMAIL** **researchgovernance@st-andrews.ac.uk** **as soon as possible---****---IF YOU ANSWERED ‘NO’, write in the NOTES section below why it is that you answered NO, and then store this document with your project files and keep it indefinitely---** |
| **NOTES** |  |