Wellcome Sanger Institute

Best Practice – the Nagoya Protocol and Access and Benefit Sharing (ABS)

wellcome sanger institute

Contents

Introduction

Wellcome Sanger Institute and Access and Benefit Sharing (ABS)

This document has been produced in order to provide assurance to Nagoya Protocol member states, regulators, researchers, collaborators and peers, that the Wellcome Sanger Institute has initiated and carries out appropriate processes and procedures to enable compliance with global Access and Benefit Sharing (hereafter; ABS) measures and compliance with the UK ABS legislation[5] implementing the Nagoya Protocol[1] for scientific research undertaken. Within this document are the tools, processes and procedures, comprising Institute policy, that when employed correctly staff and associates of the Wellcome Sanger Institute can be confident that they are conducting their research in accordance with the UK ABS legislation and in turn, ABS legislation in force globally.

The Wellcome Sanger Institute is one of the premier centres of genomic discovery and understanding in the world. It leads ambitious collaborations across the globe to provide the foundations for further research and transformative healthcare innovations. Its success is founded on the expertise and knowledge of its people and the Institute seeks to share its discoveries and techniques with the next generation of genomics scientists and researchers worldwide. Pertinent areas of work include global-scale surveillance programmes with vital aims of providing centres of disease control within endemic countries with real-time, implementable, genetic information to combat the spread of disease, and global efforts to sequence the biodiversity of the Earth with a view to aid conservation efforts to protect biodiversity.

Due to the nature of the work carried out, worldwide collaboration is instrumental to the success of the Institute's goal of improving human health. The associated legal, ethical and moral responsibilities are of the greatest importance in order to promote the highest standard of regulatory compliance associated with scientific research, and a unified, cohesive scientific community.

In response to the third objective of the Convention on Biological Diversity (CBD)[2] as set out in 1993, Article 20 of the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation*, and the subsequent UK ABS legislation[5]*, the Wellcome Sanger Institute has created this Best Practice guidance based upon its current implemented practices.

This document aims to set out a framework to address, support and promote the legal requirements for compliance with ABS practices, namely the access measures within providing countries for the utilisation of Genetic Resources (and associated Traditional Knowledge) (hereafter; GR(aTK)). It does so by providing a combination of tools and

*Collectively, the UK ABS legislation consists of: retained direct EU law (Regulation (EU) No. 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and Commission Implementing Regulation (EU) No. 2015/1866 laying down detailed rules for the implementation of Regulation (EU) No 511/2014), as amended by The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (SI 2018/1393) and The Environment and Wildlife (Legislative Functions) (EU Exit) Regulations 2019 (SI 2019/473); and The Nagoya Protocol (Compliance) Regulations 2015 (SI 2015/821)."

methods that when effectively implemented enables the 'user' to comply with the obligations as set out in Articles 4 and 7 of the retained EU Regulation 511/2014[4]. In addition, this document provides guidance on the practical interpretation of the Nagoya Protocol, and practical implementation to enable compliance within an academic environment, emphasises the significance of diligent monitoring and record keeping, and sets out the expectations of 'users' of GR(aTK) within scientific research.

The policies and practices described within this document outline our approach to the access, management and utilisation in the research setting of materials considered to be GR(aTK), of countries worldwide. All methodologies are under-pinned by the principles and standards upheld by the Institute, and are in place to guarantee the successful application of ABS governing legislation and ensure all staff on Sanger-led projects are well informed of their obligations under the Nagoya Protocol, and associated UK ABS legislation.

How to use this document

The content of this document is formatted according to its purposes as set out above, this is denoted as below:

Information on the subject area that provides the background and context for the remainder of the content, and completes the document as a comprehensive knowledge base

Practical guidance in addition to the information above, that may be applicable within the sector (and wider) as informed by legal obligations and experience to date

Wellcome Sanger Institute internal procedure, processes and instruction for its staff

Internal staff please note: If you are working with GR(aTK), it is your responsibility as the 'user' to ensure that you are working within, and according to, all applicable national and international laws and regulations as well as the Sanger internal processes detailed within this document in place to support this.

Contact information

Internal and external enquires: nagoya@sanger.ac.uk

Wellcome Sanger Institute - External webpage; - Intranet (internal only)

UK Competent National Authority (CNA) and regulator (Dept. for Business, Energy & Industrial Strategy (Office for Product Safety & Standards)), and policy holder (Department for Environment, Food & Rural Affairs) - abs@defra.gov.uk

The Nagoya Protocol

The Earth's biological diversity is vast, and vital to life. It was once widely considered to be the "common heritage" of humanity, yet the 1962 United Nations General Assembly declared Permanent Sovereignty over Natural Resources found under National Jurisdiction for the promotion of economic development in under-developed countries and the right of indigenous peoples; this is a founding principle of ABS.

The term 'biodiversity' was introduced in 1985 and the environment has since gained exponential recognition of its tremendous value and growing fragility. Both key turning points together instigated the creation of the CBD, a multilateral treaty that entered into force on 29th December 1993, of which the United Kingdom of Great Britain and Northern Ireland is one of 196 Parties. The Convention is focussed upon three main objectives:

1. The conservation of biological diversity
2. The sustainable use of the components of biological diversity
3. The fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

The Nagoya Protocol on access and benefit sharing is a supplementary agreement to the Convention[2] for the effective implementation of its third objective; to enable the fair and equitable sharing of the benefits arising out of the utilisation of GR(aTK). The Protocol[1] entered into force on 12th October 2014 and was implemented in the EU by Regulation (EU) No 511/2014 and Commission Implementing Regulation (EU) No 2015/1866[6], which have been retained and amended in UK law (see 'Introduction; Wellcome Sanger Institute and Access and Benefit Sharing (ABS). It aims to raise awareness of ABS legislation worldwide, and secondly ensures a global, legal framework setting out a more predictable process for access to GR(aTK) from its Parties. In addition, it obliges the *monitoring* of such access to GR(aTK) by its Parties (as required), and the *enforcement of compliance* with global access measures by users within each Party. Please note that the countries that have ratified and become Party to the Protocol continues to expand and therefore cannot be considered a static list.

UK ABS user obligations

The UK ABS legislation (see 'Introduction; Wellcome Sanger Institute and Access and Benefit Sharing (ABS) enforces the user obligations set out in Articles 4 and 7 of the retained EU Regulation 511/2014 on compliance measures for users[4]. The following obligations apply to the access and utilisation of GR(aTK) that fall within the parameters set out in the succeeding section:

1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agree terms, in accordance with any applicable legislation or regulatory requirements.

2. Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements

3. For the purposes of paragraph 1, users shall seek, keep and transfer to subsequent users:
   (a) The internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or
   (b) Where no internally-recognised certificate of compliance is available, information on:
      (i) The date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
      (ii) The description of the genetic resources or of traditional knowledge associated with genetic resources utilised;
      (iii) The source from which the genetic resource or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;
      (iv) The presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;
      (v) Access permits, where applicable;
      (vi) Mutually agreed terms, including benefit sharing arrangements, where applicable.

4. Users acquiring Plant Genetic Resources for Food and Agriculture (PGRFA) in a country that is Party to the Nagoya Protocol which has determined that PGRFA under its management and control and in the public domain, contained in Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), will also be subject to the terms and conditions of the standards material transfer agreement for the purposes set out under the ITPGRFA, shall be considered to have exercised due diligence in accordance with paragraph 3 of this Article.

5. When the information in their possession is insufficient of uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation.

6. Users shall keep the information relevant to access and benefit sharing for 20 years after the end of the period of utilisation.

7. Users obtaining a genetic resource from a collection included in the register of collections within the United Kingdom, referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information listed in paragraph 3 of this Article.

8. User acquiring a genetic resources that is determined to be, or is determined likely to be, the causing pathogen of a present or imminent public health emergency of international concern, within the meaning of the International Health Regulations (2005), or of a serious cross border threat to heath, for the purpose of public health emergency preparedness in not yet affected countries and response in affected countries, shall fulfil the obligations listed in paragraph 3 or 5 of this Article at the latest:
    (a) One month after the imminent or present threat to public health is terminated; or
    (b) Three months after commencement of utilisation of the genetic resource; whichever is the earlier.

    Should the obligations listed in paragraph 3 or 5 of this Article not be fulfilled by the deadlines laid down in points (a) and (b) of the first subparagraph of this paragraph utilisation shall be discontinued.

Lastly, users are obliged to declare to the CNA '(Office for Product Safety and Standards, Department for Business, Energy & Industrial Strategy') that the above user obligations have been fulfilled and shall submit due diligence declarations (addressed in 'Data Management; Due diligence declaration').

Scope of the Nagoya Protocol and UK ABS legislation

The Nagoya Protocol addresses the process whereby a user is able to access GR(aTK) from a Party country for the purpose of utilisation, and facilitates the return of benefits to the provider country.

The applicability of the Nagoya Protocol, and subsequently the UK ABS legislation, with regards to a GR(aTK), is determined by the *in-situ* geographical location of its origin (geographical scope), the date of access (in this context, access is defined as 'the acquisition of GR(aTK) originating from a country Party to the Nagoya Protocol) (temporal scope), the nature of the genetic resource (GR) (material scope) and the proposed 'user' of the resource, a natural or legal person carrying out utilisation (personal scope).

The UK ABS legislation applies to those resources that meet these conditions; described further below, and that are to be utilised for research and development purposes (addressed in 'Definition: utilisation').

Geographical scope

Geographical scope defines the origin of the GR(aTK) considered to fall within scope of the UK ABS legislation. There are a number of aspects to this arm of scope, firstly, the regulation applies only to GR(aTK) over which a State exercises sovereign rights.

This affords the relevant competent authorities the dispensation to grant and monitor access as they find appropriate, under their obligations as set out by the Protocol.

Secondly, the provider country in question must be Party to, and have enforced the Protocol by establishing applicable access measures.

> There are instances where provider countries may regulate only certain types of GR(aTK), from certain locations within the country only, or the use of GR(aTK) for specific purposes only e.g. commercial intent. Therefore a thorough understanding of the provider country legislation is essential.

If one or both of the above criteria are not met, the UK ABS legislation does not apply (addressed in 'Scope of the Nagoya Protocol; Out of scope of the Nagoya Protocol and UK ABS legislation').

Temporal scope

Temporal scope defines the time period for which the access to GR(aTK) falls into scope of the UK ABS legislation. The Nagoya Protocol entered into force on 12th October 2014 and therefore GR(aTK) accessed on or after this date only, are subject to the obligations set out by the Protocol and associated UK ABS legislation.

> Individual countries became signatories, ratified the Protocol, and became Party to the Protocol at varying points in time since its inception. It is therefore the *'enforcement date'* of the provider country in question, to which the date of *access* of your GR(aTK) is to be compared.

GR(aTK) removed from *in-situ* conditions and/or from the provider country itself i.e. *'accessed'* prior to that country's enforcement date, fall out of scope of the Protocol and UK ABS legislation (addressed in 'Scope of the Nagoya Protocol; Out of scope of the Nagoya Protocol and UK ABS legislation').

Material scope

Material scope defines the type of resource intended for utilisation that may be considered a GR by the provider country according to the below:

Genetic resources are defined by the CBD as 'genetic material of actual or potential value', where 'genetic' is described by the presence of 'functional units of heredity'.

These include, but are not exclusively, plants, animals* and microorganisms, and in addition, 'derivatives' defined as '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 include proteins, lipids, enzymes, RNA'. The UK ABS legislation recognises the requirement for there to be continuity between a derivative and the GR for it to fall within scope.

The GR is to be the *focus* of the utilisation (research and development) for the UK

* The above definitions use the term 'animal' to refer to 'non-human animal'.

ABS legislation to apply. There are instances where additional material may be present within, or form part of, the GR that you wish to access for utilisation. This additional material may act as a vector e.g. human blood harbouring a parasite, or be present within the material as a bi-product e.g. unintended bacteria present. At the point that there is intent to utilise any non-human material considered to be a GR, this falls into scope of the UK ABS legislation. Due diligence activities to facilitate compliance with applicable ABS measures are to be carried out for this material according to the provider country ABS legislation.

> Each country has differing criteria for which material is considered a GR of that country, and therefore this must not be assumed equivalent to that of the UK ABS legislation e.g. microorganisms are considered GR and are regulated by some countries, but not all (addressed in 'Scope of the Nagoya Protocol; Out of scope of the Nagoya Protocol and UK ABS legislation').
>
> Any naturally occurring GR that can be found in *in-situ* conditions may be considered to fall under sovereign rights.

Associated traditional knowledge (aTK) to genetic resources, similarly to the physical material it is associated with, falls within the scope of the Protocol and is better locally defined within provider countries. However, for the purposes of practical implementation the UK ABS legislation applies to 'traditional knowledge associated with genetic resources held by an indigenous or local community that is described as such in mutually agreed terms/benefit sharing agreement applying to the utilisation of traditional knowledge'[5].

Personal scope

Under the UK ABS legislation, the obligation to carry out due diligence on any GR(aTK) obtained for the purpose of utilisation, falls to *all* users wishing to carry out utilisation within the UK. This obligation of due diligence exists irrespective of any prior use or utilisation of the GR(aTK), i.e. all those who wish to physically receive and utilise the genetic resource irrespective of whether obtaining directly from the provider country or via a third party (for clarity; including through commercial purchase). This could be an individual researcher, a representative on behalf of a project, collaboration or consortia, or legal entity. In practice, this requires each user to ensure that prior to access and utilisation, the GR(aTK) which they intend to utilise has been accessed in accordance with all applicable ABS legislation and associated regulatory requirements evidenced by Prior Informed Consent (PIC). And that where applicable, benefits are to be fairly and equitably shared upon Mutually Agreed Terms (MAT), in accordance with the applicable ABS legislation. In addition, evidence of this due diligence must be appropriately recorded and maintained.

> The status of a country with respect to the CBD and/or the Nagoya Protocol does not pre-determine its user's capacity to comply with the access measures and ABS legislation in place within provider countries. It is the

status of the providing country *only* that determines the ABS requirements in order to access and utilise GR(aTK). In principle, those who wish to directly access a GR(aTK) from the provider country are obliged to do so in compliance with the national ABS legislation in place within that country at that time. For any additional/further (including third party) utilisation of this GR(aTK), the permitting documentation (including terms and conditions of use, where present) must precede the transfer of the GR(aTK) and/or derivatives, to any downstream users in order to ensure that their applicability can be assessed, renegotiation can be completed where required, and therefore the GR(aTK) can be utilised in accordance with the permitting documentation and user obligations under the UK ABS legislation are met.

Out of scope of the Nagoya Protocol and UK ABS legislation

There are a number of reasons, related to the above criteria, why the access to and utilisation of a GR(aTK) may be determined to fall out of scope of the Nagoya Protocol and by extension, the UK ABS legislation. However, the legal obligation to comply with all applicable legislation and regulation of a country within which an individual wishes to work, including by accessing GR(aTK) of, remains in place for all individuals. This applies to national ABS legislation, therefore irrespective of the country's position to the Nagoya Protocol.

As within each of the areas of scope above, the same principles apply to assessing the conditions under which any given country's national ABS legislation will apply to proposed access and utilisation of GR(aTK). Variations in geographical, temporal and material scope are present in the same way as within the ABS legislation of Party countries, and are to be equally observed. In addition, in our experience 'temporary procedures' ahead of formalised legislation within a country are not uncommon.

At the Wellcome Sanger Institute we both approach and record the use of GR(aTK) that fall out of scope of the Nagoya Protocol and the UK ABS legislation in the same way, and is addressed within this document. This works to both raise awareness to ABS and related legislation more broadly, yet crucially, ensure legal certainty around the access to and utilisation of all material considered to be GR(aTK). For clarity, cases of 'temporary procedure/process' as above, fall within the remit of this statement.

Exemptions to the Protocol are 'human genetic resources', GR traded and used as commodities *only* (not to be subject to R&D), as well as those covered by specialised international instruments e.g. Pandemic Influenza Preparedness (PIP) framework, yet within countries Party to these frameworks and where duly recognised only.

The Nagoya Protocol requires each Party to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. However in such scenarios, a GR determined to be, or determined likely to be a causative pathogen remains within scope and the access measures in place within the provider country will ultimately set out the requirements for access and utilisation.

The UK ABS due diligence obligations on the user in order to access such resources for the purpose of emergency preparedness purposes are adapted, and are required to be carried out according to the earliest of the below opportunities:

1. One month after the imminent or present threat to public health is terminated; *or*
2. Three months after commencement of utilisation of the genetic resource;

Utilisation of Genetic Resources

Definition: utilisation

The utilisation of GR(aTK) forms the basis of the Protocol, national ABS legislation, and applicability of the UK ABS legislation. By the CBD, it is defined as:

'Utilisation of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (Article 3(5) of the Regulation; Article 2(c) of the Protocol),[3,4]*.* (Please see 'Annexes; Glossary')

> The Oxford Dictionary definition of 'research'*: 'the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions'.*

When interpreted in line with the principles of ABS, 'utilisation' is widely encompassing of purposes for access and is generally agreed upon whilst acknowledging that the breadth of the definition is conscious, so as not to pre-empt changes in the rapidly evolving knowledge and technology of the sectors. In order to help distinguish whether the proposed purpose of use constitutes utilisation under the Protocol and in turn the UK ABS legislation in the academic research setting, the helpful statements below can to be applied in the first instance:

- Is the *purpose* of access for the taxonomic identification of the GR only? – **'***Identification of organisms is the process of providing a name for a sample, i.e. assigning it to a taxon, hence 'taxonomic'. The name may be at strain, species, genus or other rank depending on the precision of the identification, but in all cases will assign it to a taxon.'* [6]
- Is the GR to be used as a 'testing or reference tool'? – *'The material is not the object of the research in itself and serves to confirm or verify the desired features of other products developed or under development.'* [6]

The above represent two categories of intent that do not constitute 'utilisation'. The below is a statement that if met, equals 'utilisation' under the UK ABS legislation.

- Is there *potential* for the generation of new insights, knowledge or discovery of information on the functionality on the genetic or biochemical properties of the GR as part of the research?

Whilst largely aligned, provider countries may have established conditions within access procedures that differ from those set out in the UK ABS legislation regarding 'utilisation'. This may be in the form of further exclusions or conversely the inclusion of activities excluded under the UK ABS legislation and therefore compliance with the provider country national ABS legislation will be required wherever this is applicable. Where uncertainty arises, advice may be sought from the NFP/CNA of the providing country in the first instance and the UK regulator if uncertainty persists.

The Wellcome Sanger Institute approaches and procedures set out within this document enable the most up to date and accurate information, by provider country as well as provided by the UK regulator, to be available throughout the internal process so that staff are advised accordingly (addressed in 'Access to genetic resources – at the Wellcome Sanger Institute; Internal procedure, and Institutional Policies and Procedures').

Any change in purpose of utilisation must be done so in accordance with the national ABS legislation of the provider country and where already present the PIC and/or MAT under which the GR(aTK) was accessed. This may require a new access application or renegotiation of current PIC and/or MAT, and is to be completed prior to this change.

Inappropriate utilisation

Inappropriate utilisation consists of any and all use that is not set out in the access request, and subsequently granted permission for, in the issued compliance documents that constitute PIC and/or MAT, as well as any utilisation that proceeds without appropriate due diligence exercised.

Policies and procedures established within institutes are encouraged and required to work to prevent the inappropriate access to and utilisation of GR(aTK). Appropriate foresight, planning and notification processes provide the user and their establishment the means and time to carry out thorough due diligence to enable compliance with the applicable ABS legislation, thereby minimising as much as possible the possibility of acquiring illegally accessed material (whether inadvertent or otherwise).

In all cases, where uncertainty arises in the event of accessed GR(aTK), the Research Governance office will work with staff, individuals acting on behalf of the Institute, collaborators and the provider country to clarify the legality and permitted use of the GR(aTK) under inquiry. After a thorough review of the information and documentation available, should it transpire that the GR(aTK) has been accessed and utilised outside of applicable ABS legislation or permitting in place, PIC and/or MAT will be actively sought or amended (as required) at the earliest opportunity or utilisation will be discontinued. ABS activities will be completed ahead of project milestones such as publication and/or data release.

In all cases where an 'incident' is considered to have occurred, the Research Governance office will conduct an investigation which may, under certain conditions, comprise of a 'root cause analysis' as part of the internal 'incident management' workflow. This process aims to result in the identification and implementation of measures to prevent the recurrence of such situations in the future.

Supply to third-party users

The supply of GR(aTK) and/or derivatives of, to third-party users is legalised only by the current, corresponding compliance documentation satisfying PIC and/or MAT as provided by the provider country, where it is applicable. If it is not explicitly permitted, third party transfer is not implicit and must not take place. Where supply is explicitly permitted, in order to fulfil obligations under the UK ABS legislation regarding the transfer of GR(aTK), the providing establishment must ensure that the corresponding compliance documentation: electronic copies of the IRCC (where issued), PIC, MAT and supporting evidence (where applicable), is sent prior to the sending of samples in order for the recipient to review and accept (or not as the case may be) the content of the documentation with respect to the purpose of transfer.

Please note that should third-party transfer be permitted, the purpose of utilisation, period of licence, benefit-sharing (if stated), and additional terms and conditions of use must correspond with the *proposed* use and be fully accepted by the recipient. In the case of differing intent, or the inability to comply with aspects of the documentation, renegotiation must take place with the provider country prior to release of the material from the providing establishment.

There may be further obligations for the provider set out within the PIC and/or MAT and/or the applicable ABS legislation of the provider country more generally. For example, the requirement for any third party transfer to take place under an MTA or similar terms, or the requirement to notify the applicable CNA of such a transfer.

Prior to the transfer of material considered to be a GR(aTK) and/or derivatives of (please see 'Annexes; Glossary') **by Institute staff, contact (and advice if required) is to be made with the Research Governance office (nagoya@sanger.ac.uk) for the purposes of ensuring adherence to PIC and/or MAT where in place, for maintaining accurate Institute records and in turn ensuring we fulfil our obligations under the UK ABS legislation** (addressed in 'Access to genetic resources – at the Wellcome Sanger Institute; Internal procedure').

In addition to the above, the Wellcome Sanger Institute advises all staff to ensure that the transfer of material from the Institute is supported by the relevant legal document (MTA, RCA) to facilitate the transfer and that it is consistent with the PIC and/or MAT, where applicable. The Institute's Legal team is responsible for the negotiation and execution of these documents and contact should be made appropriately.

Should the supply to a third-party user be for the purpose of procuring a service only, the responsibility for adhering to the PIC and/or MAT associated with the GR(aTK) continues to lie with the procurer of that service i.e. the user (addressed in 'Access to Genetic Resources; Acquisition as a 'service'').

Digital Sequence Information (DSI)

At the time of writing, the access to and utilisation of Digital Sequence Information (DSI) falls outside of the scope of the Nagoya Protocol and CBD. The implications of, and benefit sharing from, the utilisation of data (as derived from GR(aTK)) is under consideration by the CBD and the Parties to the Protocol.

Please note that there are examples of provider countries that do have in place provisions for the treatment and use of genetic data ahead of a CBD level decision, and these must be complied with where applicable. In addition, the user of the GR(aTK) from which sequence data may be obtained must in all cases, respect and comply with the terms under which access was granted, including those that extend to the data.

As a leading scientific research institution, the Wellcome Sanger Institute is founded upon principles of openness and the sharing of scientific data; the Data Sharing policy requires that researchers share their data as widely and effectively as possible in line with a number of considerations. Data should be deposited in readily accessible repositories for the public and/or research community.

To date, access requests have explicitly detailed the intended use and dissemination of the anticipated data and this has been permitted by provider countries.

Access to Genetic Resources

For users both within the provider country as well as overseas, *access* can be defined as the acquisition of GR(aTK) from *in-situ* or *ex-situ* conditions for the purpose of research and development, the obligations under the Nagoya Protocol in order to access and utilise GR(aTK) remain the same. Please note that the definition of access within national ABS legislation in place within some countries may differ or extend beyond this definition, and in turn beyond the scope of the UK ABS legislation (addressed in 'Scope of the Nagoya Protocol ; Out of scope of the Nagoya Protocol and UK ABS legislation').

Under the UK ABS legislation, users are obliged to always determine and record the status and legality of the GR(aTK) to be accessed, with respect to the Nagoya Protocol and applicable ABS legislation.

> In addition, users should be aware that further national and international laws and regulations may exist outside the scope of ABS, that similarly relate to the collection, research and transfer activities for which applicability will be dependent upon the nature of the material and activities to be carried out.

In order to proceed to access and utilise GR(aTK), the Protocol defines a high-level process whereby Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) are to be obtained prior to receipt of GR(aTK). As evidence of obtaining PIC, MAT (or a combination of) and therefore completion of the process, an Internationally Recognised Certificate of Compliance (IRCC) may also be issued and is uploaded to the Access and Benefit Sharing Clearing House (ABSCH) by the provider country.

Access measures

Under the Protocol, each country has the opportunity to establish methods and tools (access measures) in order to manage and monitor their GR(aTK) and by doing so, provides a route for users to obtain PIC and/or MAT as appropriate.

> These access measures differ between countries, however there are consistent themes: assurance relating to the research proposed concerning the use of the GR(aTK) to be accessed, assurance relating to the establishment under which the research is to be carried out, and for some countries; personal identification.
>
> The ABSCH was formed to create a central information point for Protocol member states and users alike, and provides direct access to current, related legislation and information for each country. This is the first port of call to establish the status of the provider country, contact details for the designated National Focal Point (NFP), the established Competent National Authority(ies) (CNA), as well as the access procedure and legislative (access) measures in place, where available. It is therefore essential to being able to determine whether your material falls into scope of the national ABS legislation. If the provider country has populated the 'legislative

measures' and/or 'ABS procedure' on the ABSCH then this is the best place to begin. If this is not the case, the NFP is best placed to advise on the relevant access measures based upon an informative request.

Access requests

Requesting access according to the access measures is the first step to obtaining the permitting documentation; PIC and/or MAT, in order to proceed to access and utilise a GR(aTK). Access requests are typically made to the NFP (unless otherwise specified e.g. to the CNA) of the provider country of the GR(aTK) to be accessed and utilised. The NFP is the designated point of contact for the country and is best placed to respond to and advise on access requests.

There is no defined process for access set out by the Nagoya Protocol, nor one set of access measures to comply with, therefore here lies the difficulty in setting out a consistent approach to requesting access. Procedures typically range from an 'application form', to a dosier. Universally however, access requests are to be inclusive of all known information regarding the GR(aTK) to be accessed, proposed use and the project/collaboration under which it is to be utilised, for the purpose of gaining PIC for the declared work.

Where a defined access procedure is not in place, the Wellcome Sanger Institute has, formalised the initial contact with the NFP in as much, the type and content, consisting of an 'Access request letter' (please see 'Annexes: Supporting Documentation') **which is provided to staff for completion during contact with nagoya@sanger.ac.uk where use is applicable. Within this, the following is outlined to the best of the user's knowledge at the point of writing:**

- **Description of the GR(aTK) and associated material (if any) to be accessed in as much detail as possible**
- **Original sourcing of the GR(aTK)**
- **Provider of the GR(aTK) and proposed recipients**
- **Brief description of the proposed research and activities to be undertaken**
- **Proposed use of the data, results, information and images obtained through utilisation**
- **Intent to supply to third parties (if any)**
- **Intent to propagate (if any)**
- **Institute position regarding, and intent for (if any) commercialisation (if any)**

Staff and individuals acting on behalf of the Wellcome Sanger Institute are strongly encouraged to consider the future directions of the proposed research and the project and whether the use of the GR(aTK) may change course

accordingly. It is recommended to stipulate details of the expected course of action for samples for the duration of the project, i.e. will multiple shipments be required (for surveillance studies, for example) and will any movement of the GR(aTK) or derivatives take place between known collaborators. These considerations can work towards obtaining PIC and/or MAT that is applicable for all activities under the proposed research and minimises the potential requirement for amendment or renegotiation.

In the Institute's experience, the above 'Access request letter' is typically inclusive of all required information and has been successful in providing the provider country with the information necessary where there may be no template document/application form available in order to progress the request and issue the appropriate permission and or documents. Yet in some cases, as referenced above, additional documentation outside of the project and GR(aTK) specifics, are requested in addition.

Prior Informed Consent (PIC)

PIC constitutes the acknowledgement, consent and in some cases, be in the form of, a permit or licence required in order to access and utilise GR(aTK) from a country in compliance with the national ABS legislation and therefore the UK ABS legislation.

PIC (and MAT) are defined by the CBD (please see: 'Annexes: Glossary') and in practice take the form of a variety of written forms. Beyond their definitions, the format under which PIC and/or MAT may be issued can be expected to differ between each country.

In order to maintain appropriate records and to ensure that any documentation obtained does indeed satisfy PIC, it is advised to ensure that there is sufficient evidence describing the documentation that constitutes PIC within the provider country in question, as this widely differs, as does the requirement for MAT in addition to PIC. Furthermore, if the NFP or CNA provides information resulting in there being no requirement for PIC and/or MAT this must also be documented as evidence of the result of due diligence and decision making (addressed in 'Data Management; Evidence').

Crucially, users are obliged to acquire and record PIC and/or MAT documentation prior to the access to and utilisation of any GR(aTK) (addressed in 'Data Management; Evidence').

For GR(aTK) to be accessed and utilised by staff and individuals acting on behalf of the Wellcome Sanger Institute, final PIC (and MAT) documentation is to be centrally reviewed and recorded by the Research Governance office prior to the commencement of access and utilisation as part of the internal workflows outlined within this document.

Mutually Agreed Terms (MAT) - Terms and conditions of use

MAT constitute the terms and conditions, specifically noting the benefit-sharing requirements, in order to access and utilise GR(aTK) from a country in compliance with the national ABS legislation, and therefore the UK ABS legislation.

To date, the requirement for MAT in addition to the documentation provided to satisfy PIC is increasing. In some cases, the documentation provided as PIC also details, or can be provided alongside, standard terms and conditions of use and therefore fulfils MAT.

There are however instances where MAT are more common, typically in response to access requests outlining the intent to commercially benefit from the access to and utilisation of GR(aTK), or perhaps where GR(aTK) are recognised as indigenous biological resources, or where the provider country in question has taken the approach to formally issue contract documents to constitute both PIC and MAT.

Where the negotiation of MAT is required, the Wellcome Sanger Institutes Legal team are responsible for overseeing the negotiation and completion of any document, and provide the subsequent signing of any agreement made with provider countries in order to ensure responsible, accurate and manageable declarations/obligations in keeping with Wellcome Sanger Institute policies. Engagement with the Legal team will be sought through the Research Governance office as part of the internal workflows outlined within this document.

Crucially, users are obliged to acquire and record PIC and/or MAT documentation prior to the access to and utilisation of any GR(aTK) (addressed in 'Data Management; Evidence').

For GR(aTK) to be accessed and utilised by staff and individuals acting on behalf of the Wellcome Sanger Institute, final (PIC and) MAT documentation is to be centrally reviewed and recorded by the Research Governance office prior to the commencement of access and utilisation as part of the internal workflows outlined within this document.

Benefit-sharing

The Nagoya Protocol was created for the purposes of ensuring benefit-sharing; to uphold the rights of the provider country and its indigenous and local communities, ensuring that they secure fair and equitable benefits arising from the utilisation of their GR(aTK), and possible subsequent applications. Therefore, in order to uphold the intentions of the Protocol, benefit-sharing is a key aspect of the negotiations of access and utilisation, and is to be addressed within the MAT.

The Protocol itself, in accordance with the CBD, refers to examples of monetary and non-monetary benefits that may be agreed upon.

The Wellcome Sanger Institute recognises this as the driving force for the implementation of the Protocol and strives to ensure that where appropriate, and whilst remaining in keeping with the Institute's and Wellcome's mission statements, fair and equitable benefits will be attributed to the provider country with an emphasis on the indigenous and local communities from where GR(aTK) may be accessed, where applicable. Typical examples of benefit-sharing to date have taken the form of knowledge, data and information transfer, training opportunities and publication related designations.

Legal documentation; ABS clauses

Within the scientific sector and beyond, legal documentation e.g. Material Transfer Agreement (MTA), Research Collaboration Agreement (RCA), facilitates the movement of material of any kind between collaborators, establishments and by extension therefor between countries. Furthermore, some provider countries require such documentation as part of their access measures in order to grant PIC and negotiate MAT and/or as part of the MAT. Therefore, it is advisable to ensure that when importing/exporting or transferring GR(aTK), there be the appropriate legal documentation to reflect this.

Within all legal documentation entered into by the Legal team on behalf of the Wellcome Sanger Institute that addresses material that may be considered a GR(aTK) in the context of the CBD, and where any level of due diligence may be required in order to establish the legal status of the GR(aTK) with respect to ABS, a specific clause detailing the circumstances under which we look to accept or transfer the GR(aTK), and the obligations of each Party in order to do so is present by standard approach. (Please see 'Annexes: Supporting documentation').

Access to Genetic Resources - at the Wellcome Sanger Institute

A reminder, if you are working with genetic resources it is your responsibility as the user to ensure that you are working within, and according to, all applicable national and international laws and regulations as well as the Sanger internal processes detailed below and within this document in place to enable and support this.

For clarity, the following procedures in this section are applicable to all materials considered to be a GR(aTK), to enable compliance with the UK ABS user obligations (addressed in: 'The Nagoya Protocol; UK ABS legislation user obligations') and the ABS legislation in place in any given provider country, at any given point in time.

The Wellcome Sanger Institute has centralised 'ABS compliance' within its Legal and Governance structure as to be able to better support its staff and maintain detailed records of all GR(aTK) on site as set out within the UK ABS legislation, for eventualities such as, internal and external audits.

All staff are required to inform the Research Governance office through nagoya@sanger.ac.uk and/or through the related internal processes referenced in this document, of prospective plans to receive any non-human material (due to the potential to be considered GR(aTK)) onto site along with any appropriate documentation held at this point (please see 'Annexes: Training and implementation'), **and are advised to do so at the earliest opportunity. This works to mitigate as much as possible, the time/resource that ABS compliance activities may take. The process to compliance will then consequently progress with the benefit of the Institute's Legal and Governance support. The Legal and Governance office can facilitate the access procedure, provide legal advice regarding accepting terms and conditions associated with permitted access; particularly essential for MAT negotiations, as well as ensure the provision of accurate and up-to-date knowledge and experience of specific provider country legislation and processes applicable to the GR(aTK) and proposed work.**

Legal and Governance staff and programme Research Administration will work with researchers and collaborators of providing organisations to plan the receipt of material, and in doing so enable compliance with access procedures. In practice, the Research Governance office will contribute to and carry out the due diligence required with the prospective user(s). This involves determining whether the GR(aTK) to be accessed or acquired is in scope of the UK ABS legislation and/or national ABS legislation of the provider country, the access procedure in place, and carrying out and completing the activities required to permit access and utilisation in order to proceed. Following these activities, the Research Governance office will review the final permitting documentation and provide approval at this stage.

Access and utilisation of GR(aTK) by Wellcome Sanger Institute staff, and individuals acting on behalf of the Institute, is not permitted without a prior review of and evidencing of PIC and/or MAT or legally-satisfying documentation where applicable, and due diligence undertaken in all cases.

The responsibility to ensure that the utilisation of the GR(aTK) remains within the remit of PIC and/or MAT issued (where applicable) and therefore the permitted activities sits with the user for the duration of the project/PIC and/or MAT/terms and conditions of use, as applicable to each GR(aTK).

The Research Governance office will submit all due diligence declarations for research carried out on site on behalf of its users according to the requirements set out within the UK ABS legislation.

Staff and individuals representing the Institute, are made aware (addressed in 'Training; Staff and associates') **of the legality and obligations as set out by the UK ABS legislation in response to the Nagoya Protocol, the presence of ABS legislation globally and the requirement for due diligence to be complete prior to any action taken towards receiving such material. Please contact nagoya@sanger.ac.uk to discuss further training requirements.**

A high-level course to ensuring compliance for non-commercial scientific research can be simply defined as below.

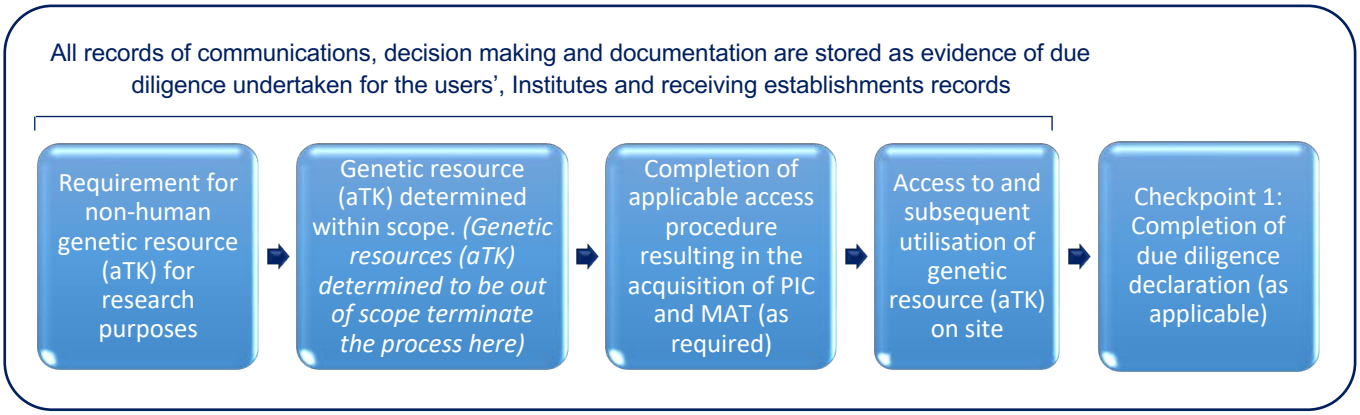

Figure 1: High-level workflow for carrying out ABS compliance for access to GR(aTK) for non-commercial utilisation.

There are a number of overarching 'circumstances of acquisition' under which GR(aTK) may be accessed for the purposes of non-commercial scientific research that encompasses the nature of the engagements that we as a scientific organisation experience. They are set out below along with the Wellcome Sanger Institute's approach and important considerations for its staff within each, to ensure legal acquisition according to Institute standards.

The processes within the table below and described thereafter are to be carried out by the researcher and the Research Governance office as described above (addressed in 'Access to Genetic Resources – at the Wellcome Sanger Institute; Internal procedure')**.**
Please ensure that you have read and understood this document in full in order to complement the use of the Institute workflows that follow.

Circumstance of acquisition		Description		Figure
Provider country is Party to the Nagoya Protocol	Provider country	*(In-situ)* field collection	Applicable for the proposed direct access to and utilisation of GR(aTK) found, and collected from in *in-situ* conditions	**2**
		Collaborating establishment	Applicable for the proposed access to and utilisation of GR(aTK) found in *ex-situ* conditions	**3**
	Outside of provider country		Applicable for the proposed access to and utilisation of GR(aTK) found in *ex-situ* conditions	**4**
Provider country is not Party to the Nagoya Protocol	Provider country	*(In-situ)* field collection *or* collaborating establishment	Applicable for the proposed access to and utilisation of GR(aTK) found, and collected from either *in-situ* or *ex-situ* conditions	**5**
	Outside of provider country	Collaborating establishment	Applicable for the proposed access to and utilisation of GR(aTK) found in *ex-situ* conditions	**6**
Description				**Page**
Applicable for the proposed access to and utilisation of genetic resources acquired from non-collaborating establishments and/or in circumstances not already addressed.				**34**

Table 1: A quick access 'figure guide' pertaining to typical high-level access scenarios as set out within this section.

Acquisition from countries Party to the Nagoya Protocol

Provider country: *(In-situ)* field collection

The below is applicable for proposed direct access to and utilisation of, GR(aTK) found *in-situ*.

For a country to be considered the provider country and therefore the country of origin, the GR in question must be able to be found in *in-situ* conditions within that country and have therefore established a viable population.

In all instances, the primary proposed user of the GR(aTK) is in the best and most informed position to be able to take the lead in carrying out due diligence, and ensuring compliance with all applicable ABS legislation in place at the time of access, collection and export in and from the country . As part of the access request (addressed in 'Access to Genetic Resources: Access requests'), future known transfer to establishments or scope of utilisation and/or research purpose is to be described to ensure that the full extent of the proposed utilisation is clear.

Special considerations, collaboration or consortia: In the case of collaboration or consortia, a single project lead is best placed to carry out access negotiations with the relevant provider country on behalf of, and with the support of, all involved - they are to be able to answer any questions pertaining to the project, GR(aTK) to be accessed, the proposed utilisation as well as any downstream events.

Special considerations, national and international requirements: There are likely to be additional permissions and/or permits required for the *in-situ* collection and export of indigenous species and more broadly materials, including but not exclusively, land owner/community permissions, national and internationally prescribed species and/or habitat specific permits, research permits, export permits, and these must be sought in addition to ABS PIC and/or MAT. It is to be assumed that the process for obtaining ABS PIC and/or MAT sits alongside other processes for sample collection, research, export etc. Compliance with the national ABS legislation is *in addition* to, and does not supersede any active legislation or procedure in force at the point of activity.

In addition the Wellcome Sanger Institute will endeavour to ensure that indigenous and local customary laws and procedures are abided by and where possible form part of the MAT/benefit sharing agreement.

An overview of the process for direct access to and utilisation of GR(aTK) found *in-situ* is outlined below, with the addition of the corresponding necessary actions with the Research Governance office (orange) and necessary additional considerations (grey) complementary to the ABS compliance process within the provider country:

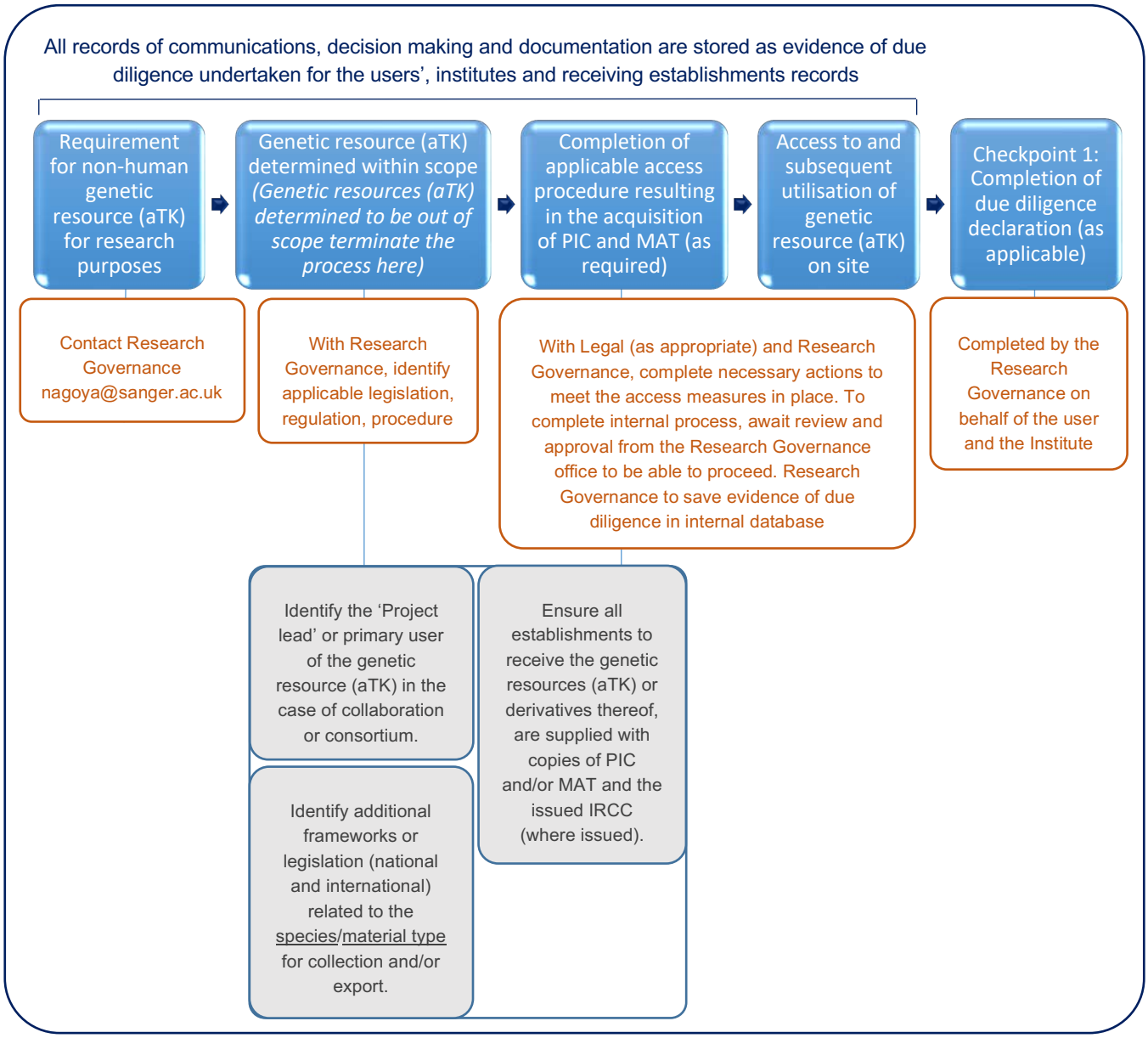

Figure 2: High-level workflow for directly accessing a genetic resource (aTK) for non-commercial utilisation.

Provider country: Collaborating establishment *(Ex-situ)*

The below is applicable for proposed access to and utilisation of GR(aTK) found in *ex-situ* conditions within a collaborating establishment within the provider country.

When the access to and utilisation of GR(aTK) is undertaken as part of collaboration, it is important to note that the principles set out by the Nagoya Protocol applies to all users of GR(aTK) irrespective of their geographical position; i.e. it is possible that users may reside within the provider country of the GR(aTK) they wish to access. It is to be assumed that the national ABS legislation and access measures in place within a country is applicable to those users within the country in a similar way to those outside of the country, unless stated otherwise. It is important to note the distinction between the 'providing collaborator', who

may also constitute a ‘user’, and the ‘provider country’. ABS compliance activities take place between the user and the provider country by way of the CNA. However a reminder, that the UK ABS user obligations apply only when utilisation takes place within the UK and where the circumstances of access meet the conditions set out earlier in this document (addressed in ‘The Nagoya Protocol; Scope of the Nagoya Protocol (and UK ABS legislation)’).

In circumstances such as these the GR(aTK) has been removed from *in situ* conditions either historically or perhaps for the purposes of related projects, yet they remain within the provider country. User obligations require the prospective user to enquire after the status of compliance of the GR(aTK) with the applicable ABS legislation. If the current use of the GR(aTK) by the providing collaborator constitutes utilisation and the material has been accessed in accordance with applicable ABS legislation, the prospective user will need to ensure that their proposed purpose of utilisation and transfer/export is permitted by the documentation in place i.e. PIC and/or MAT. Therefore, prior to access, the prospective user must request electronic copies of the PIC and/or MAT and IRCC for review and assessment, and for their records. If the proposed utilisation and transfer/export is not currently permitted, an amendment to the PIC and/or MAT, or new PIC and/or MAT is required prior to access and should be sought by the prospective user according to the figure below. The material cannot be accessed and utilised until the appropriate PIC and/or MAT is obtained.

If on the other hand, the current use does *not* constitute utilisation or if the current utilisation is *not* permitted under the applicable ABS legislation, the process proceeds as below in conjunction with the collaborating researcher, with a view to incorporating a request for the current utilisation where related and where possible.

> Special considerations, collaboration or consortia: In the case of collaboration or consortia, a single project lead is best placed to carry out access negotiations with the relevant provider country on behalf of, and with the support of, all involved - they are to be able to answer any questions pertaining to the project, GR(aTK) to be accessed, the proposed utilisation as well as any downstream events.
>
> Special considerations, in-country collaborators: In the Institute’s experience, when the access request has been made from within the provider country, local understanding of regulations and processes has facilitated access being granted.
>
> Special considerations, national and international requirements: There are likely to be additional permissions and/or permits required for the *in-situ* collection and export of indigenous species and more broadly materials, including but not exclusively, land owner/community permissions, national and internationally prescribed species and/or habitat specific permits, research permits, export permits, and these must be sought in addition to ABS PIC and/or MAT. It is to be assumed that the process for obtaining ABS PIC and/or MAT sits alongside other processes for sample collection, research, export etc. Compliance with the national ABS legislation is *in addition* to, and does not supersede any active legislation or procedure in force at the point of activity.

An overview of the process for access to, and utilisation of, GR(aTK) found in *ex-situ* conditions in a collaborating establishment within the provider country is outlined below, with

the addition of the corresponding necessary actions with the Research Governance office (orange) and key additional considerations (yellow) complementary to the ABS compliance process within the provider country.

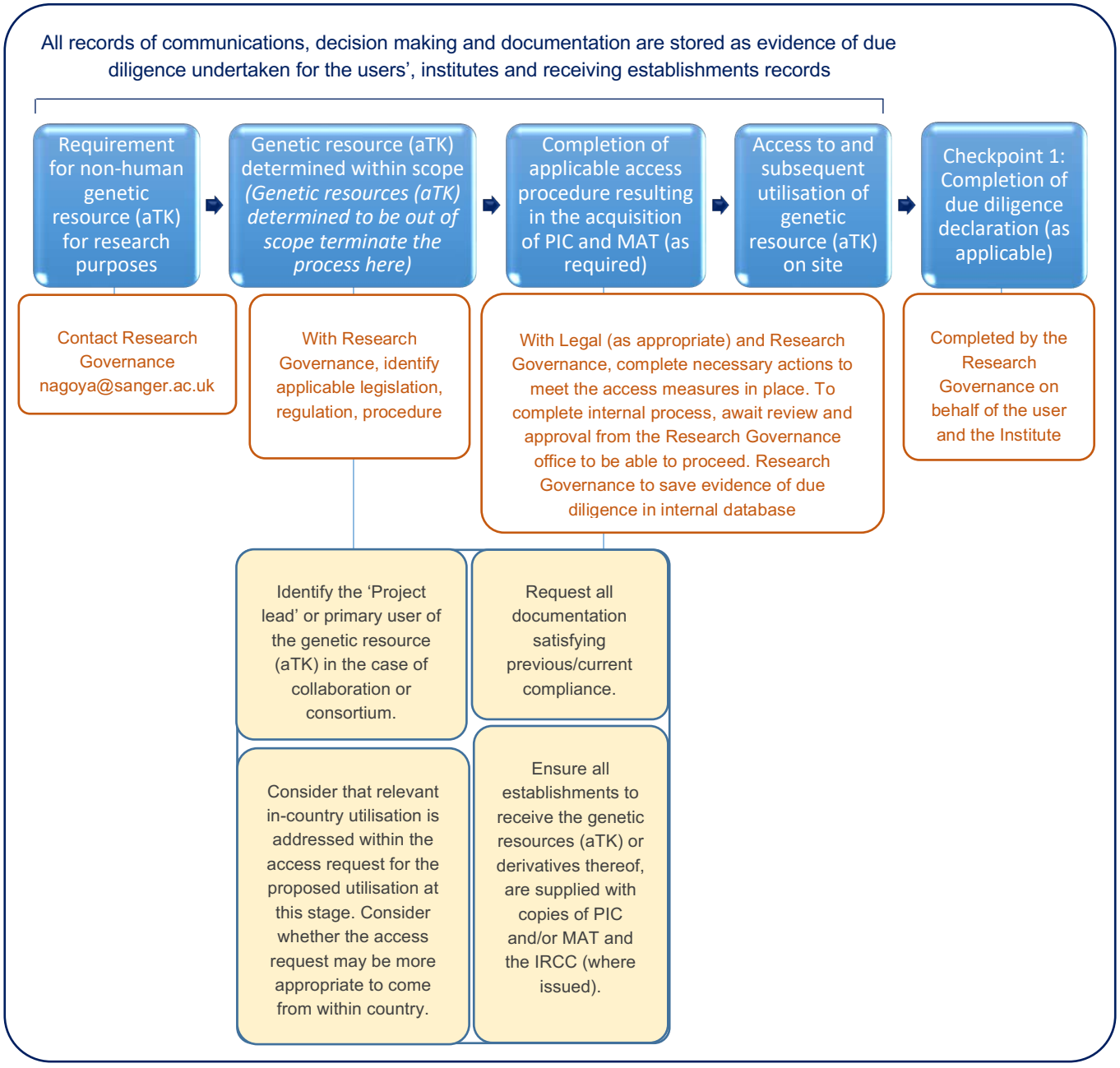

Figure 3: High-level workflow for accessing a genetic resource (aTK) from a collaborating establishment within the provider country (Party to the Nagoya Protocol) for non-commercial utilisation.

Outside of provider country: Collaborating establishment *(Ex-situ)*

The below is applicable for proposed acquisition and utilisation of, GR(aTK) found in *ex-situ* conditions within a collaborating establishment outside of the provider country.

In circumstances such as these, the GR(aTK) has already been accessed from the provider country by a third party. This may have been by the collaborating establishment themselves, or the material may have changed hands multiple times since its original access.

User obligations require the prospective user to enquire after the status of compliance with the applicable ABS legislation with respect to the material. If the current use of the GR(aTK) by the providing collaborator constitutes utilisation and the material has been accessed in accordance with applicable ABS legislation, the prospective user will need to ensure that their proposed purpose of utilisation and transfer/export is permitted by the documentation in place i.e. PIC and/or MAT. Therefore, prior to access, the prospective user must request electronic copies of the PIC and/or MAT and IRCC for review and assessment, and for their records. If the proposed utilisation and transfer/export is not currently permitted, an amendment to the PIC and/or MAT, or new PIC and/or MAT is required prior to access and should be sought by the prospective user according to the figure below. The material cannot be accessed and utilised until the appropriate PIC and/or MAT is obtained.

If on the other hand, the current use does not constitute utilisation or if the current utilisation is not permitted under the applicable ABS legislation, the process proceeds as below in conjunction with the collaborating researcher, with a view to incorporating a request for the current utilisation where related and where possible.

> Special considerations, collaboration or consortia: In the case of collaboration or consortia, a single project lead is best placed to carry out access negotiations with the relevant provider country on behalf of, and with the support of, all involved - they are to be able to answer any questions pertaining to the project, GR(aTK) to be accessed, the proposed utilisation as well as any downstream events.
>
> Special considerations, national and international requirements: There are likely to be additional permissions and/or permits required for the *in-situ* collection and export of indigenous species and more broadly materials, including but not exclusively, land owner/community permissions, national and internationally prescribed species and/or habitat specific permits, research permits, export permits, and these must be sought in addition to ABS PIC and/or MAT. It is to be assumed that the process for obtaining ABS PIC and/or MAT sits alongside other processes for sample collection, research, export etc. Compliance with the national ABS legislation is *in addition* to, and does not supersede any active legislation or procedure in force at the point of activity.

An overview of the process for acquisition and utilisation of, GR(aTK) found in *ex-situ* conditions within a collaborating establishment outside of the provider country is outlined below, with the addition of the corresponding necessary actions with the Research Governance office (orange) and key additional considerations (green) complementary to the ABS compliance process within the provider country:

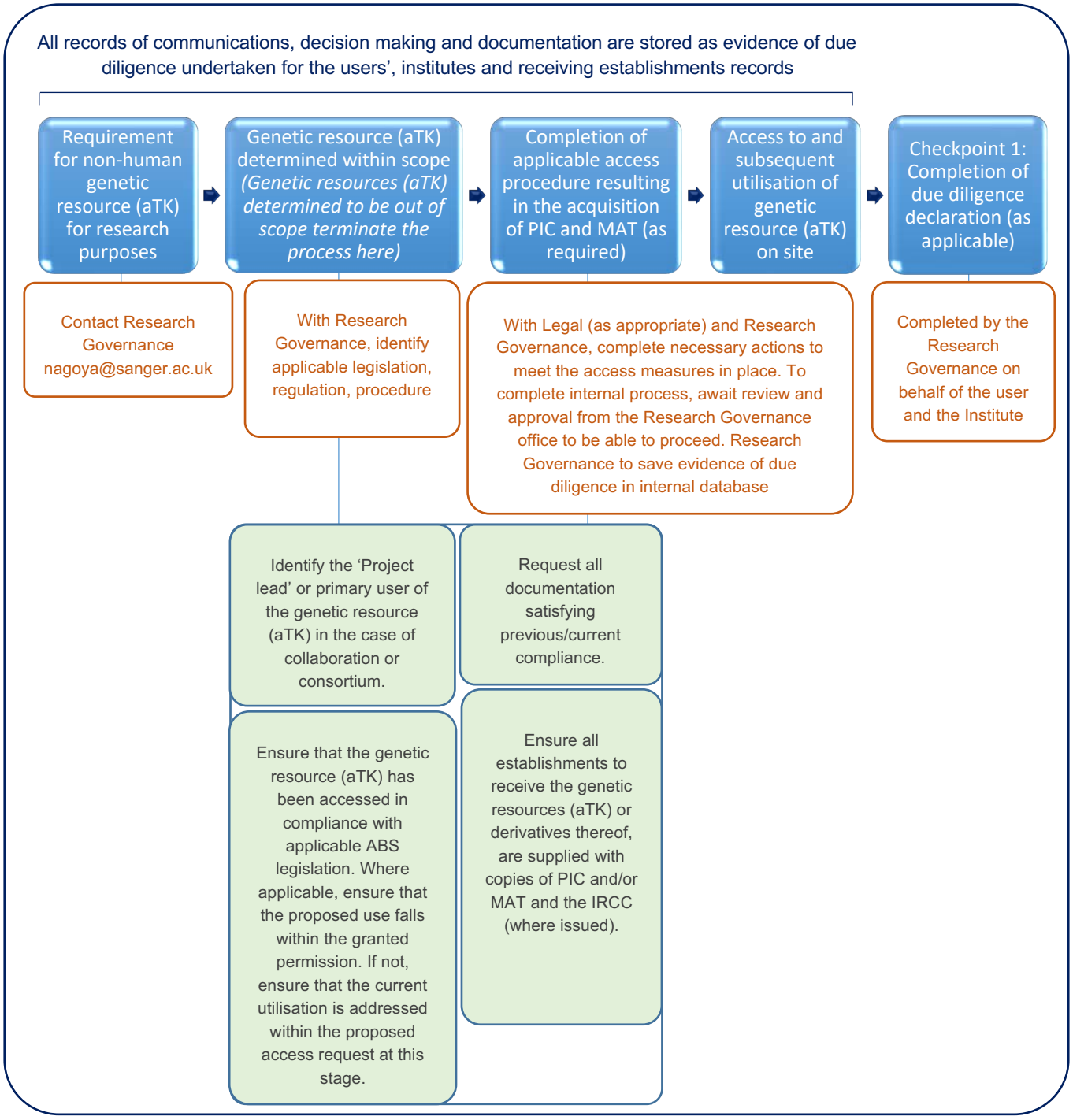

Figure 4: High-level workflow for accessing a genetic resource (aTK) from a collaborating establishment outside of the provider country (Party to the Nagoya Protocol) for non-commercial utilisation.

Acquisition from Countries not Party to the Nagoya Protocol

Provider country: *(In-situ)* field collection / Collaborating establishment *(Ex-situ)*

The below is applicable for proposed access to GR(aTK) either found *in-situ* or *ex-situ* from within a country that is not Party to the Nagoya Protocol.

There are a number of countries who are not Party to the Nagoya Protocol and therefore access to GR(aTK) originating in these countries may or may not follow the more predictable course of the framework that the Protocol sets out. It however cannot be assumed that there is no national ABS legislation in place, or related legislation that in some capacity addresses the access to and utilisation of GR(aTK) (addressed in 'Scope of the Nagoya Protocol ; Out of scope of the Nagoya Protocol and UK ABS legislation').

However, access to genetic resources from countries not Party to the Nagoya Protocol falls out of scope of the UK ABS legislation and therefore outside of the obligations associated (addressed in 'The Nagoya Protocol; UK ABS legislation user obligations).

In-situ: Prior to the commencement of field collection, due diligence is to be exercised in the same way as set out in 'Provider country: (*In-situ*) field collection' (pg.23) to enquire after the permissions and/or permits namely, but not solely, those relating to ABS, required for such activities with the appropriate departments or ministries within the provider country.

Ex-situ: Prior to the receipt of samples due diligence is to be exercised in the same way as set out in: 'Provider country: Collaborating establishment (*Ex-situ*) (pg.24) to enquire after the permissions and/or permits namely, but not solely, those relating to ABS, required for such activities with the appropriate departments or ministries within the provider country.

An overview of the process for acquisition and utilisation of GR(aTK) that falls outside of the UK obligations, yet remains in scope of the national ABS legislation of the provider country is outlined below, with the addition of the corresponding necessary actions with the Research Governance office (orange) and key additional considerations (purple) complementary to the ABS compliance process within the provider country:

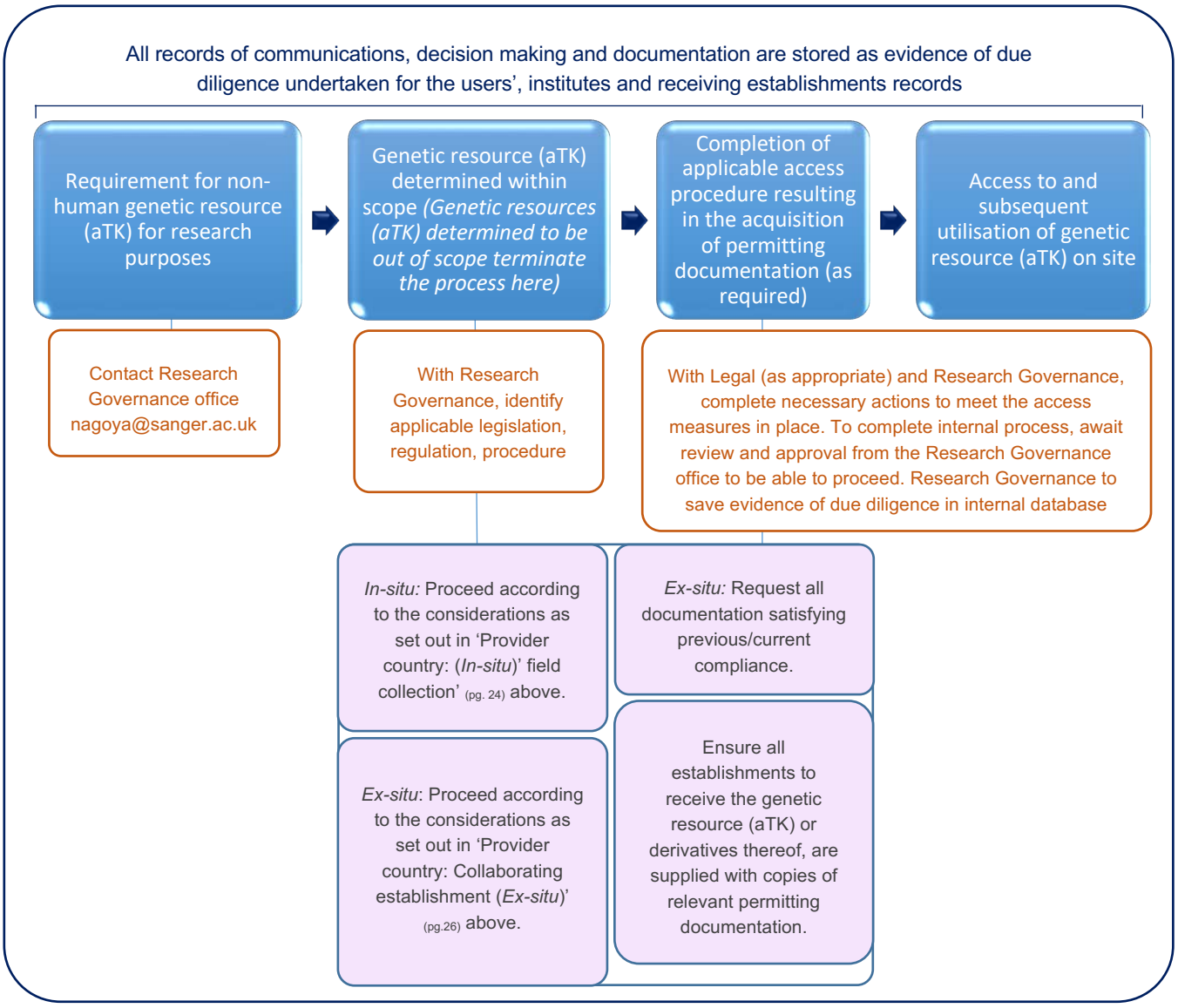

Figure 5: High-level workflow for accessing a genetic resource (aTK) from the provider country (not Party to the Nagoya Protocol) for non-commercial utilisation.

Outside of Provider country: Collaborating establishment *(Ex-situ)*

The below is applicable for proposed access to GR(aTK) from within a country that is not the provider country, and not Party to the Nagoya Protocol.

Similarly to 'Acquisition from countries Party to the Nagoya Protocol: Outside of Provider country: Collaborating establishment *(Ex-situ)'* in circumstances such as these, the GR(aTK) has already been accessed from the provider country by a third party. This may have been by the collaborating establishment themselves, or the material may have changed hands multiple times since its original access.

As previously mentioned, the status of a country with respect to the Nagoya Protocol does not determine its users' obligation to comply with the access measures in place and the national ABS legislation in force within other countries. Therefore, current (not the proposed)

and/or previous users within third-party countries, which may or may not be Party to the Protocol, who accessed the GR(aTK) from the provider country must have done so in accordance with the national ABS legislation in place at the time of access, where applicable.

Prior to the receipt of samples due diligence is to be exercised in the same way as set out in: 'Outside of Provider country: Collaborating establishment (Ex-situ) (pg.26) to enquire after the permissions and/or permits including, but not solely, those relating to ABS, required for such activities with the appropriate departments or ministries within the provider country.

An overview of the process for access that falls outside of the UK obligations, yet remains in scope of the national ABS legislation of the provider country is outlined below, with the addition of the corresponding necessary actions with the Research Governance office (orange) and key additional considerations (blue) complementary to the ABS compliance process within the applicable provider country.

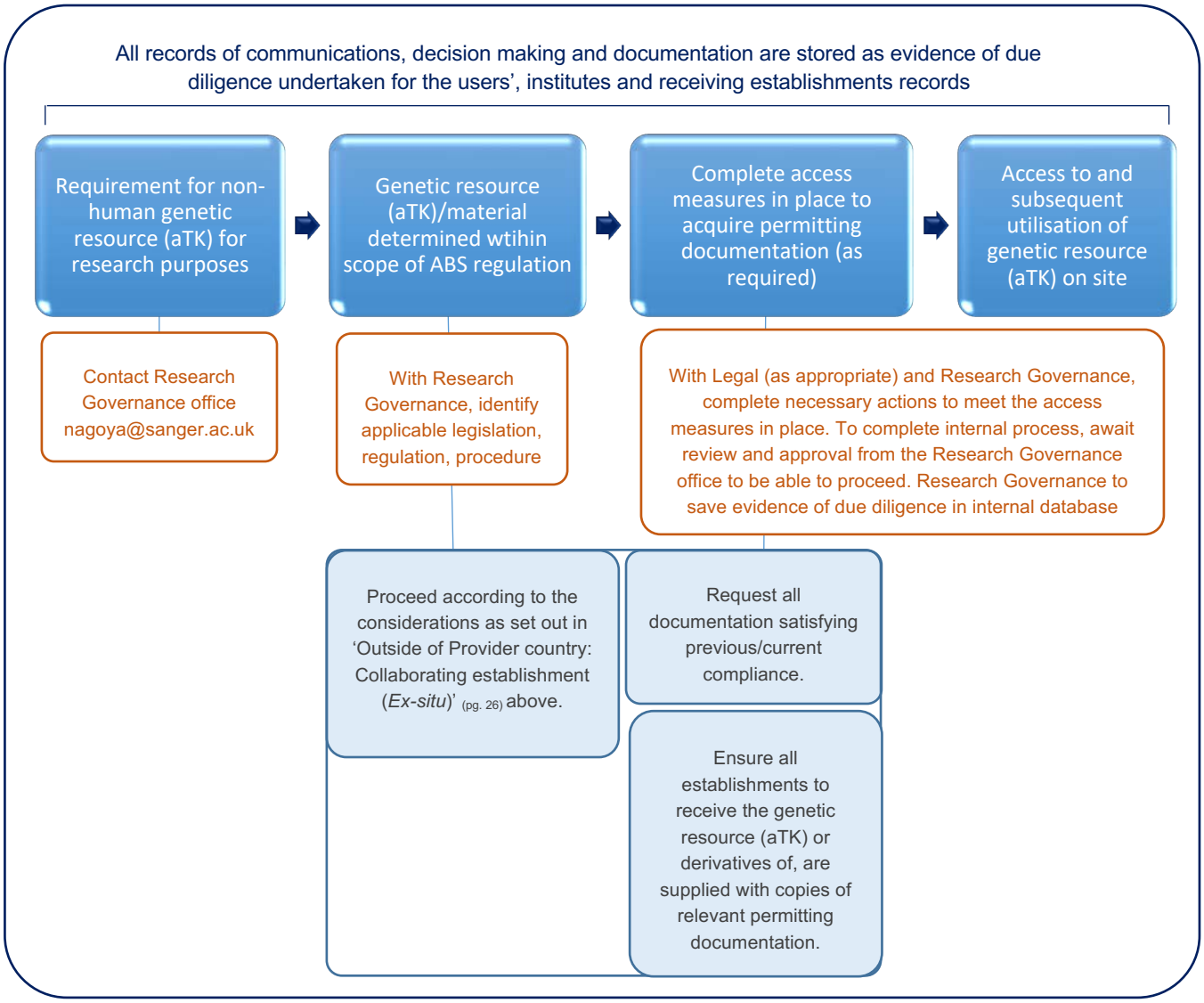

Figure 6: High-level workflow for accessing a genetic resource (aTK) from outside of the provider country (not Party to the Nagoya Protocol) for non-commercial utilisation.

Examples of acquisition from non-collaborating establishments

There are a number of instances where GR(aTK) may be acquired from non-collaborating establishments for the purposes of research within the academic scientific sector. Examples of such GR(aTK) and non-collaborating establishments are described below along with additional information and the Institute's approach to each. Please note: in the case that applicable ABS legislation is in place and the proposed access to and utilisation of the GR(aTK) requires steps to be taken to comply with this legislation, the internal process will proceed according to the appropriate set of circumstances set out in the preceding section.

- **Laboratory strains from research laboratories/breeding facilities/commercially obtained**: Laboratory strains to be accessed i.e. strains or model organisms distinct from the original material isolated from in *in-situ* conditions, do not fall into scope of the UK ABS legislation due to the intentional breeding/selection strategies altering the genetics of the species away from that that can be found *in-situ*. Please note: unintentional mutation or genetic deviation, due to a period of time or similar, does not fall within this category of 'laboratory strain' and the process would proceed according to the applicable scenario as described in the preceding section.
  User obligations do however require the prospective user to enquire after the *original* sampling carried out in order to generate the strain, to determine the circumstances of this acquisition and whether the proposed access to and utilisation of the GR(aTK) would fall into scope based upon the circumstances of original sampling and the provider country's ABS legislation.
- **GR(aTK) from collection establishments**: The work undertaken by collections typically falls out of scope of the UK ABS legislation based upon the type of activities carried out, therefore it is likely that compliance with national ABS legislation was not required in order for the collection to access the GR(aTK) from the provider country for its activities. As a prospective user, due diligence is required to determine whether the proposed access to and utilisation of the GR(aTK) would fall into scope of the UK ABS legislation and/or national ABS legislation of the provider country based upon the circumstances of original sampling and the provider country's ABS legislation.
  - ❖ **Registered Collections**: When accessing GR(aTK) from a collection registered (entirely or partly) under Article 5 of the Regulation[4], by doing so the prospective user is considered to have undertaken their due diligence with regards to enquiring after the information related to the origin of the material for the purposes of ABS (if the materials is to be provided from the relevant, registered part of that collection). The obligation to supply the GR(aTK) along with all relevant information and documentation lies with the registered collection. However the obligation to hold and maintain the record of the GR(aTK), and submit a due diligence declaration (where applicable) remains with the user and therefore internal procedure applies to GR(aTK) sourced in this way (addressed in 'Data Management: Document storage').

  GR from industry: The Nagoya Protocol and associated regulations are applicable to GR(aTK) over which a country is able to exercise sovereign rights and are typically

described as ‘naturally occurring resources’. Broadly, this excludes commercially obtained material that has been *generated* by industry e.g. cell lines. However, similarly to accessing laboratory strains, where this material has been generated from original material defined as GR(aTK), user obligations require the prospective user to enquire after the *original* sampling carried out in order to generate the material, to determine the circumstances of this acquisition and whether the proposed access to and utilisation of the GR(aTK) would fall into scope based upon the circumstances of original sampling and the provider country’s ABS legislation.

- **GR bought as a commodity**: GR(aTK) purchased as a commodity fall out of scope *only* where the intent does not constitute utilisation (addressed in ‘Utilisation of Genetic Resources; Definition: Utilisation’). If purchased with the intent to carry out research and development or if a change in intent occurs after the act of purchasing the GR(aTK), the GR(aTK) and the proposed utilisation may fall under the UK ABS legislation. Due diligence is to be exercised to determine the provider country and whether the proposed access to and utilisation of the GR(aTK) would fall into scope based upon the provider country’s ABS legislation.

Acquisition as a ‘service’

When an institution or organisation is the recipient of GR for the purposes of solely providing a service, the procuring researcher or institution remains the defined user and therefore retains the ownership and responsibility of ensuring compliance with the applicable national ABS legislation for the acquisition and utilisation of the GR. Such roles and responsibilities and subsequent due diligence declaration duties (where applicable) are to ideally be outlined in the appropriate accompanying legal documentation. The use of remaining material and terms of disposal are also to be considered in such documentation, and must reflect the terms and conditions of use as set out in the PIC and/or MAT where they are present.

The Wellcome Sanger Institute on occasion, may receive requests to provide a sequencing service due to its long-standing reputation and expertise in the field. The Wellcome Sanger Institute may on occasion procure services of entities in the same way. On such occasions, the reviewing and negotiating of the appropriate legal documentation constituting a service agreement is carried out by the Institutes Legal team, within which the responsibilities relating to GR(aTK) are defined. In the case of the Wellcome Sanger Institute being the service provider, electronic copies of PIC and/or MAT *may* be requested for the purposes of clarity and to prevent any breach of conditions as set out upon original access, only.

Troubleshooting

- **Obtaining confirmation of access measures in place within a provider country:** There are a number of routes that can be taken to help determine the access

measures in place applicable to the GR(aTK) in question. Following the relevant workflow(s) set out in the preceding section will ensure that the appropriate point of contact (NFP or CNA where specified) within a country are engaged with (either via email, telephone) and this is always the most accurate and up to date source of information. However, the ABSCH, internet searches, government websites and legislative and guidance documentation are also a valuable resource and can in some cases provide the clarity that may not be able to be achieved through contact. Access to and utilisation of a GR(aTK) should not be proceeded with until the national ABS legislation is complied with, or the absence of or inapplicability of ABS legislation can be evidenced.

Every effort is to be made in order to confirm the presence or absence of applicable access measures as part of the workflows in the preceding section, using the supporting information and resources provided in this document. However in cases where this is not possible, and on a case-by-case basis, a risk-based review by the Research Governance office of the level of due diligence undertaken, and evidence available may be considered, with a view to leading to a decision in order to proceed (addressed in 'Institutional Policies and Procedures; Compliance and fast-moving academia').

- **Determining the provider country:** The provider country may also be determined through the employment of a number of routes: previous users, providing collections or establishments, on-line resources e.g. publications, databases, records, or through knowledge of the nature and patterns of the species itself.

Every effort is to be made in order to identify the provider country and evidence provenance of GR(aTK). In cases where this is not possible, and on a case-by-case basis, a risk-based review by the Research Governance office of the level of due diligence undertaken and evidence available may be considered, with a view to leading to a decision in order to proceed (addressed in 'Institutional Policies and Procedures; Compliance and fast-moving academia').

Data Management

Data tracking and record keeping is arguably one of the most essential aspects of ensuring compliance with the UK ABS legislation. Users, and naturally by extension institutions, are urged to accurately and comprehensively record all evidence of due diligence in all cases where GR(aTK) have been accessed and utilised. Therefore, also encompassing those cases that are ultimately determined as out of scope.

Process tracking

The initiation of compliance with a national ABS legislation may take the form of correspondence with the NFP, the review of evidence already held within an institute, the providing institute or individual, or information found on the ABSCH and/or government websites and documentation. Therefore, the diverse starting points alone prompts the need for an efficient method of following numerous cases at any one time.

The method of doing so is to be cohesive and simply incorporated into all related processes within an institute; for an academic institution, these are likely to include programme (or similar) management and administration, legal consultation, and sample management, among others. The diverse nature of research collaborations, and the reactivity of scientific goals to global circumstances, requires the process in place to be inclusive of this and proactive in its approach to both obtaining and recording the information required to progress access cases effectively.

The Wellcome Sanger Institute has established a manual, approach that tracks the movement and milestones of, and provides an up to date summary of each case initiated with the Research Governance office. This precedes and crosses over with the internal database system in place to complete the process of maintaining central records of all GR(aTK) that arrive onto site, from initiation through to due diligence declaration.

To enable the operation of these systems as part of internal process, staff should:

- **Initiate their requirement for non-human material with nagoya@sanger.ac.uk, this along with other methods in place as part of internal procedures ensure that we capture and record all GR(aTK), and;**
- **Maintain communication until the process is completed and approval has been provided, and;**
- **Maintain appropriate communication throughout the duration of utilisation to enable the recording of actions such as third party transfer, change in utilisation and project completion and/or end of utilisation.**

Upon completion of the ABS compliance procedure, the acquisition of samples and the recording of all evidence, a 'summary' is provided to the primary staff member (user), and applicable programme administration confirming the permitted use, key terms and conditions and obligations and/or restrictions associated. The responsibility for adherence to these lies with the user who accessed and is to utilise the GR(aTK), all the while supported by the Institute, Research Governance office and the procedures in place within this document.

Document storage

Users, and by extension institutions, are obliged [(*)] and encouraged [(+)] to maintain records on the below for each GR(aTK) accessed to comply with the UK ABS legislation, and these shall be kept for at least 20 years following the "end of utilisation":

1. [*]Description of the GR(aTK) (at the appropriate level of specification)
2. [*]Date and location of access of the GR(aTK)
3. [*]Country of origin (provider country) ([+]to include provenance and details of sourcing)
4. [*]Direct provider of the GR(aTK) (if different to the country of origin)
5. [*]Documentation to satisfy compliance; electronic copies of the IRCC (where issued), PIC, MAT and supporting evidence (where required)
6. [*]Rights, obligations, term and conditions of use (if applicable)
7. [*]Description of the utilisation of the GR(aTK) carried out under PIC/MAT at the Institution (particularly relevant for service requests), as well as the utilisation carried out under renegotiated terms (if applicable)
8. [*]Subsequent supply to third parties (if applicable)
9. [*]Benefit sharing (if applicable)
10. [+]Funding status.

The quantity and detail of information required, and the likelihood for numerous access requests, demands a sophisticated system for the accurate recording, storage and reporting of associated evidence within an institution. To ensure efficiency, a central system that can easily be incorporated into all relevant internal processes and practices, e.g. legal review, activities relating to the import, utilisation and export of GR(aTK), is advisable.

The Wellcome Sanger Institute has adopted an internal database approach to maintain consistent record keeping according to the UK ABS legislation requirements above.

Centralised storage of the necessary information is carried out by the Research Governance office during, and once due diligence is complete for the utilisation of all GR(aTK) . This is facilitated by the accurate supply of information from the user

(staff) regarding the GR(aTK) and project under which it is to be utilised. In doing so, this ensures:

- **Accurate record keeping of the use of GR(aTK) on site**
- **Document and evidence storage and management**
- **Provisions for long-term accessible storage and maintenance of cases allowing for the recording of renegotiation, transfer, terms and conditions and benefit-sharing**
- **Ease of use for staff, Research Governance staff, and programme management alike**
- **Internal and external audit reporting.**

The Wellcome Sanger Institute encourages all users (staff) to maintain additional records in line with the requirements of the UK ABS legislation to facilitate users to carry out utilisation within and in accordance with any and all PIC and/or MAT obtained for the GR(aTK) accessed.

Due diligence declaration

Due diligence declarations defined within the UK ABS legislation is a response to Article 17 of the Nagoya Protocol outlining the obligation to monitor the utilisation of GR(aTK), requires users to report on the utilisation that occurs within the UK, at two 'checkpoints' within the research and development process:

1. Once in receipt of public or private grant funding; between the first instalment and the project end or final report, but critically once all GR(aTK) for utilisation under the funding have been obtained.

Or

2. At the stage of final development of a product where utilisation of a GR(aTK) has contributed.

The purpose of the above checkpoints is to enable the collating of information regarding GR(aTK) utilisation by users within the UK, and the recording and reporting of the means by which the access were made possible. This information will be used to inform the ABSCH, and in turn the CNAs of provider countries.

In practice, due diligence declarations take the form of a submission of information from that of which is set out above (addressed in 'Document storage'). The mechanism by which this is achieved in the UK is set out by DEFRA and requires the completion of a form: Submitting a

Due Diligence Declaration (please see 'Annexes: Supporting documentation; Submitting a Due Diligence Declaration'). Users may be required to provide further evidence upon request.

Due to the Wellcome Sanger Institute centralising the process of users obtaining and recording compliance with ABS legislations for the access to and utilisation of GR(aTK) as part of research on site, due diligence declarations for all applicable work carried out are submitted by the Research Governance office.

To enable the completion of the 'checkpoint' requirement for grant-funded research undertaken at the Institute, we are able to utilise the internal system for the submission and approval of all externally grant funded projects. This system and the surrounding workflow enables the Institute's supporting functions, including but not limited to, Research Governance, to carry out the necessary actions in order to approve and proceed the work. Relevant to this document, for the use of non-human materials in research projects submitted through this system, the selection of the applicable type of materials to be used initiates notifications to the Research Governance office to begin the due diligence process. For the use of GR(aTK) this email address is nagoya@sanger.ac.uk. As part of the system, each project is assigned a unique identifier, this identifier is recorded within the internal database for the storage of information on the utilisation of GR(aTK), (addressed in 'Data Management; Document storage') **and in turn this contributes to determining the requirement for a due diligence declaration. Leading up to the 'grant end-date' the internal system provides notification to the Research Governance office (among others) of this at various intervals, and this is used to trigger the completion of the due diligence declaration.**

Special considerations, collaboration/consortia: In the case of more than one recipient of the same grant, or multiple sources of funding for the same project, only one due diligence declaration is required for the GR(aTK) utilised, and may to be submitted by the 'lead' party for the project or collaboration. This obligation is to be allocated within the relevant legal agreements associated with the GR(aTK) for clarity.

Internal audit

A regular internal audit cycle is essential for the consistency and maintenance of accurate records, as well as the effectiveness of the controls and workflows in place that enable the generation of those records. In addition to this, the internal audit process allows for a smooth, efficient external audit scenario where an institution, and/or users can be confident in the evidence obtained and decisions made based upon that evidence.

The Wellcome Sanger Institute Research Governance office employs a risk-based audit strategy across all compliance areas; each area is assessed using a

risk management framework on an annual basis to generate an audit and monitoring plan which is proportionate to the risk posed by each area. This audit plan is also designed to allow resources for emerging risk or incidents which need immediate or unforeseen attention. Corrective Actions / Preventative Action plans (CAPAs) are the result of the audit process and are utilised as a way of maintaining a constant internal cycle of review and improvement.

Institutional Policies and Procedures

In order to effectively implement compliance with the UK ABS legislation with minimal interruption, the establishment of and adherence to internal policies, procedures and workflows are mandatory to ensure all relevant proposed access is captured at the appropriate opportunity, all evidence of due diligence is obtained and recorded within the institute and research progresses in a timely manner whilst in compliance with all applicable ABS laws and regulation. Workflows should interact with key points in the research process, that inform decision making, and in turn, work to prevent the unlawful acquisition and utilisation of GR(aTK).

Policies should at the minimum conform to the accepted legal frameworks regarding ABS and ensure clear working standards for all those operating within them (addressed in 'Access to Genetic Resources – at the Wellcome Sanger Institute; Internal procedure').

Evidence

Written evidence of due diligence, decision making and compliance (where necessary) is essential for all GR(aTK) where access and utilisation are proposed to be undertaken at the Institute. This evidence is crucial to being able to determine and understand the circumstances under which GR(aTK) have been accessed and utilised.

For direct access, where compliance with national ABS legislation is required, the Wellcome Sanger Institute seeks and records electronic copies of all documentation that satisfies PIC and/or MAT (as applicable), the IRCC if available, correspondence with the NFP detailing the access measures and their completion if this took place, and where required the appropriate references to the legislative measures and or information as detailed on the ABSCH, or government websites/documentation to support this. With a view to ensure absolute confidence in the actions that were carried out to comply.

For third-party access, at a minimum and where available, the IRCC of original access, complemented by the MAT (as applicable) is sufficient. In cases where this is not available or there remains an element of doubt, all documentation required for direct access to the GR(aTK) in line with the above, where compliance was necessary is sought.

For direct access from countries not Party to the Protocol and/or with no established national ABS legislation or access measures, the Wellcome Sanger Institute seeks written evidence from the NFP or CNA to this effect. If this is not possible, information from the ABSCH or government websites/documentation evidencing this is recorded along with additional due diligence carried out. Evidencing that genetic resources fall out of scope form part of the due diligence obligation under the UK ABS legislation.

Anticipating the future

Up to date knowledge on the status of all countries and their relevant laws and regulations governing ABS is essential for ensuring the correct level of due diligence required for each case at the time of proposed access. Building an institutional knowledge base facilitates the transfer of 'learnings' to new projects, researchers and collaborators, this is cumulatively generated through working with each country yet pre-emptively carrying out an element of due diligence can work to enable a smooth process.

In order to generate an internal knowledge bank of provider country ABS legislation, access measures and procedures, we at the Wellcome Sanger Institute as much as possible proactively contact the NFPs to request the status of ABS legislation and access measures in place, and subsequently save this along with any relevant documentation for later use. This has built a level of provider country knowledge worldwide and works towards being able to provide timely information regarding the applicable compliance procedure to a user at the point of contact, and has the potential to work to minimise unnecessary delays for future projects.

At the point a project is determined to involve the access to and utilisation of GR(aTK) within scope of a national ABS legislation, the Research Governance office will work with the user in order to utilise this information source along with the information available elsewhere to be able to initiate the up to date and correct processes essential in order to proceed.

There are occasions where at the point of contact with the NFP, the provider country is either in the process of generating formalised access measures, currently do not regulate their GR(aTK) but this is anticipated, do not regulate their GR(aTK) yet the political landscape is subject to change and therefore as are the access measures and/or ABS legislation, or the interpretation of the in-country ABS legislation evolves. Each of these situations requires monitoring if access and utilisation of GR(aTK) is anticipated to ensure the correct and current understanding/status of ABS procedures.

In order to mediate the risk of a fluid landscape to research at the Wellcome Sanger Institute, the below actions and processes have been initiated:

- **ABSCH 'new-record' notifications**
- **A periodic time-frame for reviewing and re-confirming provider country access measures for situations such as those described above with the NFP within country.**

Compliance and fast-moving academia

Time efficiency is of high importance in academic research, in particular when such research is in response to global health concerns or where there is intent to inform provider country disease control programmes in response to surveillance. As such, the ABS compliance process needs to occur early on in the planning stage in order to facilitate the desired collection and import time-frame, and subsequent work.

To this end, there are a number of steps *within* the workflow established at the Wellcome Sanger Institute to work towards this goal.

1. **It is advised to begin the process *at least* 3 months prior to the expected collection or date of receipt, yet ultimately at the earliest opportunity**
2. **Week 1-4: Using the ABSCH all forms of communication are used in the process of obtaining information regarding the access measures in place if not already known, or explicitly clear for the presence or absence of these.**
3. **Week 4-6: If after the above, a response from the NFP/CNA is not received, or the above results in ambiguity or doubt, utilise other means and contacts to obtain the necessary information required in order to rule materials in or out of scope.**

In the majority of cases, progress is made through steps 1-3 and the process continues through to completion.

4. **Week 6-8: If uncertainty remains over the existence of access measures in place, or the steps to take in order to comply, a review by the Research Governance office of the due diligence undertaken, and evidence available in line with the current circumstances will be carried out with a view to leading to a decision in order to proceed. In doing so, remaining up to date with changes to regulations and in the knowledge that we would retrospectively seek compliance if and when access measures are learnt of, and are found to be applicable.**

Training

Staff and associates

Awareness and understanding of the Nagoya Protocol and ABS is essential for all staff within institutions that contribute to the research project trajectory, sample acquisition, and sample management.

Regular up to date communications and readily accessible resources are essential to ensure that ABS considerations are incorporated into the planning of research concerning the use of GR(aTK). Due to the length of time that seeking PIC and/or MAT have the potential to take, planning and initiation of the process ahead of time is key, and is critical to the receptiveness and positive response of researchers and academic collaborations to the ABS legislations and the UK compliance obligations.

Within the Wellcome Sanger Institute, there are a number of key stages that have been identified within related, critical pathways for ensuring that staff are provided with and gain an understanding of ABS, the Nagoya Protocol, the UK ABS legislation, and the associated internal procedures put in place by the Research Governance office. All to enable the successful implementation of, and continued compliance with all (please see 'Annexes; Training and implementation').

Concluding statement

The Nagoya Protocol was developed to promote and raise awareness to Access and Benefit Sharing, to enforce compliance to national legislations in this area, and works to both legalise and endorse ethical access to the world's genetic resources and associated traditional knowledge. Whilst widespread implementation remains in its infancy, strides have already been made to ensure that these principles are upheld and that working relationships between users and provider countries are fostered.

A collaborative approach to the process is essential in order for the Protocol's full potential to be realised and, given time, cohesive working will undoubtedly take the place of any operational issues that can be perceived here and now.

The long-term benefits of global trust, collaboration, transparency and combined efforts towards realising valuable benefit sharing will certainly work towards enabling a unified effort to tackle worldwide scientific and biodiversity harms that are so very pertinent at this time.

Wider sector awareness building

Worldwide collaboration within the academic research field is extremely common and lends itself to the sharing and mutual benefit of scientific knowledge and resources. As such, awareness raising of the Nagoya Protocol and ABS and its association to the work carried out within these collaborations is vital to the successful continuation of the research and the feedback of benefits to the global population and the provider country in particular.

Suppliers of, and recipients of GR(aTK) must be aware of the status of the GR(aTK) with regards to the applicable ABS legislation, and in doing so, must ensure and be of the same understanding of what therefore constitutes legal utilisation in this context. This mutual understanding and interpretation, the obligations on each party and what is required in practice is crucial to the co-operative working of researchers worldwide and the positive interaction with the access measures of provider countries.

Relationship building with counterparts in establishments from both within and outside of the academic scientific sectors will help to ensure that mirrored levels of due diligence are undertaken when looking to receive GR(aTK). This is essential for multi-party collaboration and consortia, and will result in similar guidance being worked to and create a shared expectation of what is to be undertaken.

References and notable documentation

[1]. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf)

[2]. Convention on Biological Diversity (https://www.cbd.int/doc/legal/cbd-en.pdf)

[3]. Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (EUR-Lex - 52021XC0112(02) - EN - EUR-Lex (europa.eu))

[4]. Regulation (EU) No 511/2014 of European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511)

[5]. The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (https://www.legislation.gov.uk/uksi/2018/1393/made)

[6]. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices (EUR-Lex - 32015R1866 - EN - EUR-Lex (europa.eu))

Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practice for Access and Benefit-Sharing.
(https://cetaf.org/sites/default/files/documents/cetaf_abs_code_of_conduct_all_annexes.pdf)

Microbial Resource Research Infrastructure - Best Practice Manual on Access and Benefit Sharing

(https://absch.cbd.int/api/v2013/documents/F1C80F1C-1EB7-F02A-CEED-E7D523F17079/attachments/MIRRI%20ABS%20Manual_web.pdf)

Annexes

Glossary

Access: The acquisition of genetic resources or of associated traditional knowledge associated with genetic resources

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[1]. (https://absch.cbd.int/).

Benefit-sharing: The process by which the providing country of the genetic resource benefits from the access to, and utilisation of, a genetic resource through either monetary or non-monetary means.

(Biological) material: Material from which genetic information may be obtained.

Biotechnology: as defined in Article 2 of the Convention[2] means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Collection: A set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities, with the potential to distribute to the academic community.

Collaboration: The process by which two or more persons or organisations work together to complete a piece of work or project.

Commercialisation: The process of introducing a new product or production method into commerce - making it available on the market.

Competent National Authority (CNA): The issuing authority within the provider country.

Consortium: An association of two or more individuals, organizations or governments with the objective of participating in a common activity (project) or pooling their resources to achieve a common goal.

Convention on Biological Diversity (Convention) (CBD): A legally-binding multilateral treaty. The response of the United Nations Environment Programme (UNEP) to the recognition for the need of the sustainability of the Earth's biological resources.

Country of origin: A country which possesses those genetic resources and (associated traditional knowledge) in *in-situ* conditions. Please also see 'Provider country'.

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.

Digital Sequence Information (DSI): Whilst used in CBD[2] discussions, it is at the time of writing, undefined and interpreted differently. Although not an exhaustive list, DSI could potentially include nucleic acid sequence reads and information on sequence assembly, annotation, genetic mapping, gene expression, macromolecules, ecological relationships, taxonomy structure and function.

EU (ABS) Regulation: Regulation (EU) No 511/2014 of European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

Ex-situ: Off site of, or away from the natural or original location.

Genetic material: Any, and all, material of plant, *animal, microbial or other origin containing functional units of heredity.

Genetic Resource(s) (GR): The genetic material of plant, *animal, microbial or other origin deemed to be of actual or potential value.

In-situ: In the natural or original location.

Internationally Recognised Certificate of Compliance (IRCC): Evidence published by the providing country on the Access and Benefit Sharing Clearing House that the genetic resource that it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the providing Party.

Material Transfer Agreement (MTA): A contract that governs the transfer of tangible research materials.

Mutually Agreed Terms (MAT): The legal obligations of provider and users of genetic resources and associated traditional knowledge, and the terms and conditions of access and utilisation of that genetic resource and associated traditional knowledge.

Party to the Protocol: A state that has ratified the Nagoya Protocol in a formal legal proceeding.

Prior Informed Consent (PIC): The prior approval or consent to the access and utilisation of the genetic resource and associated traditional knowledge as issued by the provider country.

Protocol: The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

Provider country: The country (of origin) supplying genetic resources (and associated traditional knowledge) collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, that have originated in that country.

* The above definitions use the term ‘animal’ to refer to ‘non-human animal’.

Registered collection: A collection that effectively applies measures restricting the supply of samples of genetic resources to third persons with documentation providing evidence of legal access, and ensuring the establishment of mutually agreed terms, where required.

Research (and Development) (R&D): The activities and processes involved in the creation or improvement of products and processes. In the context of the Protocol, this encompasses all research with a purpose that falls within the scope of 'utilisation'.

Research Collaboration Agreement (RCA): A contract that governs one-to-one or multi-party projects.

(Associated) Traditional Knowledge (atK): Traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources.

UK (ABS) Legislation: The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018

User: A natural or legal person who utilises a genetic resource or associated traditional knowledge of a genetic resource.

Utilisation: To conduct research and development on the genetic and/or biochemical composition of Genetic Resources, including through the application of biotechnology as defined in Article 2 of the Convention of Biological Diversity (CBD)[2].

Training and implementation

Widespread communications in written guideline format, practical information and interactive meetings are provided and disseminated through the programme structures by the Research Governance office. This is achieved through the implementation and use of the training aids and measures below:

1. 'Wellcome Sanger Institute Best Practice - the Nagoya Protocol and Access and Benefit Sharing (ABS)'
    - Circulated to all research programmes for dissemination to all research teams. Any amendment to the content will result in the document being re-circulated
    - Available through the Sanger Institute external website
    - Available through the Wellcome Genome Campus internal intranet ('Fred')
    - Provided as a first point of reference upon first contact with nagoya@sanger.ac.uk

2. Wellcome Genome Campus internal intranet ('Fred') page. Focussed upon *'Who is this policy for', 'Why do we do this', 'What do I need to do'* and an overview of the process, internal contact details, up to date useful resources (both internal and external e.g. links to ABSCH, recent applicable webinars/tools).

3. One clear, dedicated point of contact for initiating enquiries and providing support regarding the use of GR(aTK) within research: nagoya@sanger.ac.uk

4. Team meeting presentations given by the Research Governance office available at any time and carried out as part of initial implementation on site, and continued through staff inductions

5. Tailored 1:1 meeting once the requirement for the use of GR(aTK) is foreseen within a project

6. Nagoya Protocol information/'check' incorporated into the project on boarding processes: as part of the internal system for the submission and approval of projects, and as part of the 'Study set-up' within our core sequencing facility workflow

7. Regular communications with the programmes' administrative teams (outside of and in addition to 'case' work) who support and coordinate the research projects (and associated requirements) within the programmes to ensure continued close working and support structure.

Supporting documentation

Access request template (provided with associated notes for completion)

Full Name
Address line 1
Address line 2
County/country
Post/Zip code

T: +44 (0)1223 000000

W: www.sanger.ac.uk

To, the National Focal Point (as appointed for the purpose of the Nagoya Protocol on Access and Benefit Sharing)

Please accept this letter as a request of Prior Informed Consent (PIC) for [Institution e.g. Genome Research Limited operating as Wellcome Sanger Institute] to access [description of samples] from [collaborating partner] in [region, country] for the purpose and utilisation set out below only.

[For multiple 'users'/recipients of the genetic resources, please duplicate this paragraph for each, and outline the activities to be carried out at each]

Research to be undertaken at [institution]: any genetic resource and/or associated traditional knowledge obtained will be made available to staff and authorised visitors of [institution] only and used for non-commercial academic research including but not limited to molecular biology, genomics and environmental analysis [please add in additional areas if appropriate]. [Please also give a brief description of the purpose of the research and use of the material where possible].

Research results/data: [If the data is to be used for a specific purpose, please describe e.g. list known databases to be used. Please also consider the ownership of data if applicable to the provider country]. Results of research may be made available to the public domain through publication either in print or online. This may be in the form of scientific papers, publicly-available databases, images or internet sites but not excluding other forms.

Information and images, public display: As a leading scientific research institution, [institution] is founded upon principles of openness and the sharing of scientific data and readily participates in public engagement and educational activities where information and images relating to research undertaken using the genetic resource and/or associated traditional knowledge may be used. This will be for research purposes only and not with a view to further commercial gain.

Supply to third parties: [Institution] may supply the genetic resource and/or associated traditional knowledge, and/or derivatives to collaborating institutions and/or individual scientists only, [list if possible] for the purpose of research limited to that outlined above.

Propagation: *(NB. Relevant for live material only).* For the purposes of the research outlined above it may be necessary to propagate living material. Any derived material will be used as outlined above only and records kept as such in order to enable them to be attributed to the relevant PIC and MAT.

Commercialisation: Any genetic resource obtained as part of this request for PIC will be for the purpose of basic research and will not be utilised for commercial gain. However, as part of its mission, the Wellcome Sanger Institute aims 'to use information from genome sequences to advance understanding of biology and improve health'. This in turn may lead to the discovery of potential commercial uses of certain genetic resources. However where possible, this will be addressed in the Mutually Agreed Terms (MAT). Where not possible, the [Institution] will initiate the renegotiation of the MAT.

[Duplicate as appropriate]

Signed: _____

Print name: _____

Date: _____

Legal wording (example of) – Ref. Additional legal documentation clauses

‘To the extent that any of the [Materials] are either (i) considered to be genetic resources for the purposes of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (“Nagoya Protocol”) or (ii) covered by any other applicable laws or regulations on biodiversity and the access and utilisation of genetic resources in the country from which the [Materials] are sourced (“Other ABS Laws”), the [Provider Institution] will provide [Sanger] with all assistance, documentation and other information as may be required by [Sanger] to (a) enable [Sanger] to verify that its use of the [Materials] will be in compliance with the Nagoya Protocol or, as the case may be, any Other ABS Laws; and (b) meet [Sanger’s] obligations under the laws and regulations that implement the Nagoya Protocol in the UK. [Sanger] shall be responsible for reporting to the UK authorities and for making any declarations of due diligence required by the UK authorities in respect of its use of such genetic resources.’

Department for Environment Food & Rural Affairs

Submitting a Due Diligence Declaration

PART A

Information to be transmitted to the ABS Clearing House in accordance with Access and Benefit Sharing (ABS) legislation[1]

If the information provided is confidential tick the respective box and provide the justification for confidentiality at the end of this form; this material will not be submitted to the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

Please send any questions relating to due diligence declarations, or the completed application form to Defra at abs@defra.gov.uk.

If the utilisation has involved more than one genetic resource or any traditional knowledge associated with genetic resources, please provide relevant information for each genetic resource or any traditional knowledge utilised.

Please tick or complete the appropriate box(es) below.

1. Person or entity responsible for utilisation of the genetic resources and making information available to the checkpoint[2]	
Name	
Address	

[1] 'ABS legislation' means legislation implementing the requirements of the Nagoya Protocol (on Access and Benefit Sharing (ABS)) in the UK, comprising The Nagoya Protocol (Compliance) (Amendment) Regulations 2015 (1691) and retained EU direct legislation (Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015), as amended by the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (SI 2018/1393) and the Environment and Wildlife (Legislative Function) (EU Exit) Regulations 2019 (SI 2019/473)).

[2] This information allows the provider of the genetic resource to check whether the person or entity to whom the Prior Informed Consent (PIC) was granted is the same person or entity providing evidence of PIC and Mutually Agreed Terms (MAT) at the checkpoint. For the purposes of the ABS Clearing House this information can be confidential.

Email	
Telephone	
Website (where available)	
Confidential	
2. I am making this declaration for the utilisation of (Please check one or both if appropriate)	
Genetic resources	
Traditional knowledge associated with genetic resources	
Confidential	
3. Title of Due Diligence Declaration[3]	
4. Source of the genetic resource[4]	
Confidential	
5. Subject matter or genetic resources collected or received[5]	
Confidential	

[3] This field serves as the title of the record, therefore it should be distinct and help to easily identify the record in the ABS Clearing House.

[4] Select the country/ies which is /are the source of the genetic resource. The country/ies selected will be the ones receiving the Check Point Communique issued from the information registered. If marked as confidential the information will not be made public on the clearing house but the National Focal Point of the provider country will be notified.

[5] Please provide details on the subject-matter or genetic resources relevant to the information collected or received by the checkpoint. This could include biota at any taxonomic rank, which may carry a taxonomic name. It may also include a locality of collection of the material. It may also be possible to identify the genetic resource through reference to a voucher specimen or field notes held in an identified archive or collection.

6. Short description of the information relevant to the utilization of genetic resources, including the type of use[6].			
Confidential			
7. I am making this declaration			
At the stage of research funding: please complete **column A** only			
At the stage of final development of a product: please complete **column B** only			
Column A		**Column B**	
The research grant is funded by the following sources (please check one or both if appropriate).		I have previously submitted a due diligence declaration at the stage of research funding.	
Private		Yes	
Public		No	
Confidential		Not applicable	
		Confidential	
		This Declaration is being made at the following stage	
		Market approval or authorisation sought for a product developed as a result of utilisation of a genetic resource.	

[6] This could include information on utilization of genetic resources at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization. The information provided will allow the provider of the genetic resource to check whether the use of the genetic resource is in conformity with PIC and MAT and that benefits are shared in accordance with MAT.

	A notification required prior to placing a product, developed as a result of genetic resource utilisation, on the market for the first time.	
	Placing a product, developed as a result of utilisation, on the market for the first time, for which no market approval, authorisation or notification is required.	
	The result of utilisation is sold or transferred in any other way to a natural or legal person within the UK in order for that person to carry out one of the activities referred to above)	
	The utilisation has ended in the UK and its outcome is sold or transferred in any other way to a natural or legal person outside the UK.	
	Confidential	
8. Information on exercise of due diligence		
An internationally recognised certificate of compliance was issued for the genetic resources and / or associated traditional knowledge to which I have been granted access.		
Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate(s) of compliance and proceed to Part B on Confidentiality[7]		
Confidential		
Where there is no internationally recognised certification of compliance, please submit the following information		

[7] Links to internationally recognized certificate(s) of compliance (IRCC) that relate to this communiqué.

Date of access[8]	
Confidential	
Identifier of access permit or its equivalent[9]	
Confidential	
Person or entity **that granted** prior informed consent[10]	
Confidential	
Person or entity **to whom** the prior informed consent was granted[11]	
Confidential	
Reference or evidence of establishment of mutually agreed terms including benefit sharing:[12]	
Confidential	

PART B

Confidentiality

8 Date of access means the point at which users obtain the physical genetic resource from the provider country. This is typically when researchers are in the provider country and sample / collect the material. If a genetic resource is obtained from a third party (e.g. from a collection / biobank or similar), the time of access would still be considered as the point at which the initial material was sampled / collected in the provider country.

9 This field is to provide information on PIC. This includes information on any national reference or identifiers that may aid countries to search and retrieve information related to PIC, or the permit or its equivalent in their national files.

10 Full details of person or entity plus contact telephone number, address and email.

11 Full details of person or entity plus contact telephone number, address and email.

12 This field is to provide information on MAT. This includes information on any national reference or identifiers that may aid users to search and retrieve information related to MAT, the permit or its equivalent in their national files. Please refer to and include attachments if appropriate.

If you have declared that some information is confidential please state the reasons for each piece of information for which you have declared that confidentiality applies	
Date	
Signature	
Once complete, please send this form to Defra at abs@defra.gov.uk	