







Project Report

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Policies Handbook on Using Molecular Collections

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Abstract

The access to molecular collections worldwide greatly improves the quality of scientific research by making a growing number of data available for investigation. The efforts on digitization also aim at facilitating the exchange of material between institutions and researchers that must follow regulations in place and respect best practice. The handbook presented here proposes a workflow to follow to safely exchange materials, in accordance with international laws and legislations. We make numerous recommendations here to help the institutions and researchers to navigate the legal and administrative procedures, to manage molecular collections in the best way possible.

Keywords

Molecular collection, handbook, best practice, ABS, international regulation, sequence submission, loan

1. Introduction

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1.1 General introduction of the handbook

Molecular collections are generally understood as samples with the capacity to store genetic material, including tissues, cell cultures, environmental samples, and nucleic acids (RNA/DNA) that institutions store for research purposes. They are a rapidly growing and an indispensable tool for researchers, in a wide array of studies, ranging from biodiversity to genomics. Effective access worldwide to these resources considerably facilitates and improves the quality of investigations, highlighting the need for effective exchange of material and cooperation between institutions. Therefore, the handling of molecular collections, like any collections, should be done in the best way possible and established scientific standards and best practices must be respected. The acquisition, management, use, and loan of molecular samples and their underlying voucher specimens must comply with national and international legislation and regulations. Therefore, institutions should have guidelines, as part of the general management of the collections, that ensure that the terms and conditions of a loan are understood and mutually agreed upon prior to handling such material.

This handbook presents best practices regarding policies and workflows on the use of molecular collections. It was produced in the context of the European Commission-funded SYNTHESYS+, a 4-year project bringing European and international institutions together with the aim of unifying operations for and access to European natural history collections. This work contributes to the objective of developing, implementing, and disseminating standardised best practices to support DNA sequencing and biobanking activities. It was designed to help institutions and researchers to develop a robust workflow, which is key to a successful management of molecular collections and crucial to respecting the regulations in place. This handbook also provides guidance in allowing the traceability of the material as well as facilitating linkage of data and citations. Above all, it aims to streamline the workflows within and between institutions. Legal and administrative procedures can delay and limit research if not addressed proactively. Here, we acknowledge the need for procedures and best practices and we provide clear, simple, and

efficient guidelines to facilitate it. The objective is to clarify best management practice of molecular collections, to allow the availability of material worldwide, and to ultimately facilitate research at a global scale.

This handbook is addressed to institutions and researchers, although it must be noted this is not a code or an obligation but rather a compilation of recommendations on good scientific practice. It has been compiled by various institutions around the world to provide the best overview possible. It is divided into five chapters that are based on a series of surveys and workshops conducted within the community. We first focused on the workflow to send material to other institutions, referred to here as outgoing loans. We developed the steps to follow for preparing and shipping loans but also the steps required to track the loans. Second, we established the workflow for the case of an institution requesting samples from a third-party institution and the steps that need to be followed to ensure best practice. Third, we focused on data tracking and how to archive and manage permits associated with the use of the material (a crucial point to follow) to comply with the regulations currently in place. Fourth, we described the workflow for sequence submissions to nucleotide sequence databases, such as the European Nucleotide Archive (ENA) or NCBI-GenBank. We particularly focused on how to comply with data quality standards. Finally, we provide an overview of guidelines and principles that support compliance with Access and Benefit Sharing (ABS) regulations.

Since methods and regulations for the exchange of molecular collections may be subject to change, this publication is flanked by a wiki system in which current developments are reflected and discussed.

We hope that this handbook will serve as a basis for best practice handling molecular collections in the best way possible, therefore facilitating exchanges between institutions and researchers. Its purpose is to serve as a reference for future initiatives to improve standardization practice and exchange of knowledge.

1.2 Definition of terms and acronyms used in this text:

Checkpoint: step where an action is required by the researcher or the institution to document the steps in a request. Therefore, checkpoints in this handbook are different from checkpoints under some national ABS compliance legislation, where the term is also used to identify the authority responsible for receiving or gathering information on utilisation of genetic resources, or the points in a workflow for fulfilling the Nagoya Protocol's Article 17 when such information is required to be submitted.

Destructive/invasive sampling: we use the term destructive sampling to indicate consumption of material in the process of isolating DNA. Steps may be taken to minimize destruction, or consumption,

depending on the nature of the sample and its quantity, so that only a part of the original sample is consumed in the process. We also use the term “replaceable” in terms of tissues or DNAs, acknowledging that the original material from a given time and place is never replaceable, but that a similar sample may be obtained at a given cost.

Loan agreement: general terms and conditions on which loan requests are granted and how the material can be used. It should be agreed upon by both parties and documented in the tracking system.

Material Transfer Agreement (MTA): an agreement between two or more institutions, individuals or with a public authority (e.g., for stewardships) stipulating the terms and conditions for transferring specimens or samples, including genetic material. This may include a temporary loan, a permanent loan, a donation, or a sale (<https://www.cetaf.org/wp-content/uploads/CETAF-Code-of-Conduct-and-Best-Practice-material-transfer-agreements-2015.pdf>).

Molecular collections: any kind of samples with the capacity to store genetic material, including tissues, tissues, cell cultures, environmental samples (e.g. soil, water) and isolated nucleic acids (RNA/DNA) that institutions store for research purposes and can potentially be used for molecular studies.

Policy: principles and best practices implemented to put in place in order to initiate and facilitate actions taken by researchers or institution(s) to improve the workflow of institutions and scientific research.

Request/Loan: we consider a tissue request and a loan to be similar and use the two interchangeably, acknowledging that some institutions request that any remaining, or resulting (e.g., DNA from tissue) material be returned at a certain point of time.

Tissue/DNA: we realise that many institutions now loan DNA samples to minimise destructive sampling, and we generally refer to tissue loans and requests in a meaning that also applies to DNA and other molecular samples. Tissues may be from internal organs (e.g., heart, liver, muscle) or skin, fur, bone, insect leg, pieces of dried plant (herbarium) or fungal material, or whole organism, (any material containing DNA).

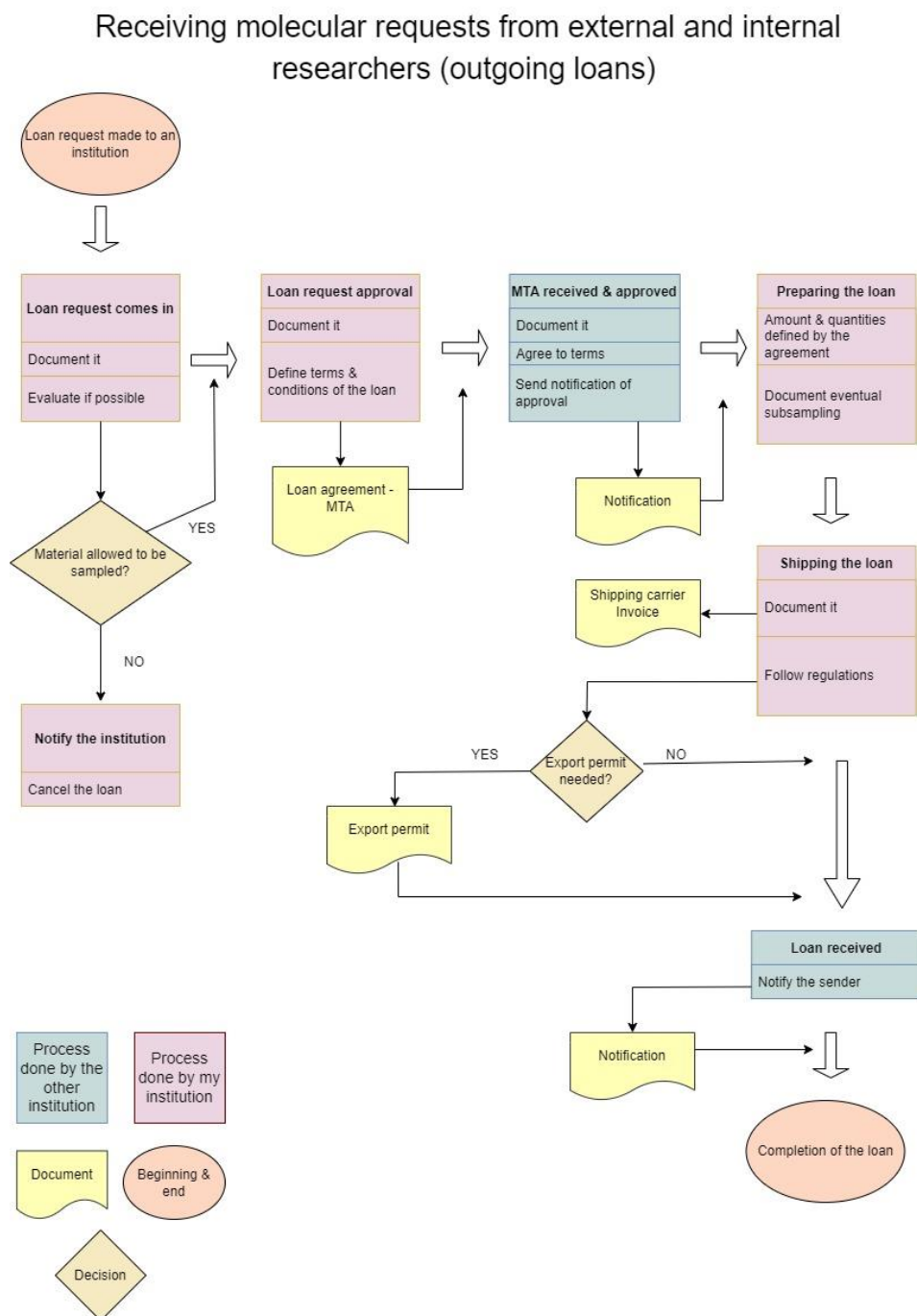
2. Receiving molecular sample requests from external and internal researchers (outgoing loans)

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This chapter is about receiving a request for DNA or tissue and wanting to ship it to a researcher. What are the things your institution must consider in order to track it? You can refer to fig. 1 for a workflow of the process.

Fig. 1: workflow and a description of the various checkpoints.



2.1 Loan Requests

Each institution should develop their own system for receiving loan requests. Regardless of how institutions plan to receive requests, they will likely come in via several channels, including ad hoc emails and institutional, or third-party data portal searches (e.g., GGBN, ELViS). It is recommended that institutional data portals are used, which are auto-directed to relevant curators and/or collection managers. All requests should be received via a standardised, auditable (e.g., ticket system) and orderly loan processing procedure supported by track-and-trace software and links to legal/regulatory documentation and checkpoint actions. Even if requests are sent directly to responsible curators and staff, they should only be accepted if they have been designated as an entry point for loans. Otherwise, the parties requesting loans should be directed to the standardised loan processing procedure, which ensures proper tracking and documentation. This will not only provide necessary tracking during the loaning process, but also helps to avoid duplication of use and records progress on research, results, and outcomes (such as publications or accession numbers in databases, etc.). Tracking information can also be used for documenting the use and demand for the collections.

Checkpoint 1: Loan request comes in — document the request.

2.2 Loan Policy

Each institution (or department) should have a formal, written loan policy to inform the borrower or user about the process, terms, and conditions of a loan. To ensure the borrower provides sufficient information, the loan policy should contain information about the institution's decision process in granting requests (see 2.3 Loan Approval below). This should also contain information about to whom loans are made. It is recommended that loans be made to professors, curators, collection managers, or other permanent staff, as opposed to students, postdoctoral fellows, and visiting researchers that change institutions more frequently. This ensures accountability of the borrowing institution accountability, and that loan conditions will be followed through to the completion of the project. Students and postdocs move around between institutions until settling on a more permanent position, and requests can be made on their behalf by their host institution collection staff. "Approved Borrower" lists can be made for institutions that regularly borrow materials to expedite loaning institution vetting processes. In any case, permission should be considered for any borrower to transfer loaned materials to them, if they should switch institutions during the course of the loan. For instance, if a student or postdoc changes institutions, loans can be transferred to the new institution's designated person in care of the nascent researcher.

Loan policies can also contain general information on how material can be used, if unused material should be returned (see below), general timelines for research, and the institution's conditions for the borrower to provide end-product information such as publications, database accession numbers,

and taxonomic revisions. Generic loan agreements can be written and made available for institutions and/or departments and specific conditions can be added or amended to the institution's general loan policy regarding the use of specific material (see 2.3 Loan Agreement below).

Loan request forms can be standardised for institutions or departments, either made available on institutional websites or incorporated into loan processing systems. They should include concise information on the nature of the study, including contribution to the field and justification for destructive sampling, who will be responsible for the loaned material (e.g., professor or Principal Investigator-PI, particularly if a student or postdoc is requesting the loan; see below), what type of data (e.g., sequence data, what loci, environmental contaminants, isotopic data) will be collected and how will it be generated (for example Sanger sequencing, next-generation sequencing, and in-house, or shipped out for processing), what and how many samples are requested (importance of number of samples justified), how much of each sample is needed, what preservative/method of storage for shipping (e.g., ambient, frozen, 95% EtOH, etc.), requester's effort to replenish genomic collections from their own fieldwork, and proper shipping information (e.g., buffers, temperatures, etc.).

2.3 Loan Approval

It is recommended that a single person, such as the 'curator-in-charge' or head of the department or collection, approve or deny loan requests in each department or collection. The decision may be made in consultation with a committee consisting of other collection staff, biorepository staff, or other scientists familiar with the nature of the request. However, the ultimate decision should be approved by the staff overseeing the collection from which materials are requested. The collection staff member in charge will generally be more familiar with the value of the material being requested, the replaceability, and can better avoid sending the same (or similar) material to different researchers conducting similar research (duplicate use). Loaning institutions can decide whether to grant access for 'duplicate use' based on informed decisions. Routine (or no special issue) loan requests (e.g., abundance of material/duplicates etc.) can be pre-approved by the local collection managers and/or escalated to senior collections management for approval, or both, if necessary. Lists of 'special issue' materials (e.g., types, last remaining material from rare or extinct species, etc.), requiring special permission/justification can be made on the institution's loan policy to streamline this process. Additionally, a 'research hold' can be placed on material, particularly if the parties involved in the collection of such material are still conducting the research for which the material was initially collected. Research holds allow for the completion of any initial research intended on the material collected. Criteria for approving loan requests should be based on the following:

- ensuring that the terms and conditions surrounding the material allow it to be sampled

- the scientific value of the proposed study
- the qualifications and abilities of the investigators
- the kind and amount of data to be generated from destructive sampling
- the rarity and reproducibility of the material
- consider whether the investigators contribute material to natural history collections through their own research (e.g., field collection).

2.4 Loan Agreement

A loan agreement should contain details about the specific loan. This may be considered a Material Transfer Agreement (MTA). However, it should be made clear whether or not it is a transfer of legal ownership, and whether or not the material may be moved or transferred to third parties, including further processing facilities. The MTA should include information regarding use of the material for the project specified in the request, whether the material may be transferred to other institutions (or labs) involved in the research, whether the material may be used for commercial use (following ABS protocols of the particular material being loaned), and what should happen to remaining product or unused material. In the case of returning unused or processed materials (e.g. DNA extraction from tissues), proper documentation should be included regarding the type of extraction, storage buffers, storage conditions, and concentrations (if available). The loan agreement should specify who is responsible for following the regulations of the receiving country (e.g., on import permissions and dangerous goods).

Loan agreements should also include information on proper citation for use of the collection and representation of the material in publications and databases, such as proper institution and collection codes. It should be clear that if any taxonomic changes are suggested in the study, recommended changes will be provided to the lending collection's staff (e.g., reprints sent, including specimen information, preferably digital format for specific specimen changes, etc.). Furthermore, any deviations from the initial loan agreement should be agreed upon, in writing between the loaning institution and the borrower.

Checkpoint 2: Loan approved, notification and MTA sent to requester — document.

2.5 Receive Acceptance of Loan Agreement

If a loan request is approved, an MTA or loan agreement should be sent to the requester for agreement. The requesting party should sign and return the MTA or loan agreement before the loan is processed. Any changes made in the loan policy by either party should be agreed upon by both parties, in writing, and documented in the tracking system. Each step should be tracked in a tracking system, such as sending of MTA, changes (if necessary), and receipt of final MTA.

Checkpoint 3: Loan Agreement received, requester agrees to terms — document.

2.6 Preparing Loans

Loans should be prepared by either biorepository staff, collection staff, or other qualified individuals. At universities, curatorial assistants or student work-study staff often may process loans if properly trained by collections staff. Amounts and quantities should be agreed upon in the loan agreement before preparing loans, and institutional restrictions indicated (e.g. maximum 1 µg genomic DNA for x number of samples). Subsampling of specimens should be recorded in a collections management database. Proper documentation of conditions before and after subsampling should be made, particularly in the case of destructive specimen sampling (e.g., feathers, skin pads, hair, insect leg, leaf tissue, bones etc.). When subsampling tissues and other genetic resources (e.g., blood, DNA), freeze/thaw cycles, thaw times, and amounts subsampled should be recorded in the collections database.

Checkpoint 4: Loan prepared — document contents.

2.7 Shipping Loans

Shipping of loans should follow all local and international regulations of the sending and receiving countries, and any anticipated intermediary countries. All people involved in the loan process should know who is responsible for observing which regulation, especially for the regulations of the receiving country. Cold chain specialist couriers are recommended for frozen samples. Dangerous goods (e.g., dry ice) should be properly handled. Transportation regulations and legislation (IATA/ADR) are regularly updated, and staff should receive training for this periodically. At present, IATA allows transport of non-infectious specimens packed with small quantities of flammable liquid on a plane, provided that IATA special provision A180 applies.

Checkpoint 5: Document e.g., shipping carrier, invoice, method shipped, import/export permits (where necessary).

2.8 Receive Acknowledgement of Loan Received

Receipt of loan notification should be obtained and recorded in the tracking system. This should include verification of the quantity and conditions (if appropriate) of the loaned material.

Checkpoint 6: Document requester received the loan.

2.9 Receive Notification of Project Completion

Loan completion should include all anticipated products, including reports, publications, public database accession numbers (e.g., INSDC, GenBank, EMBL-ENA, etc.), and any returned materials. Any changes of taxonomy should be sent to proper collection staff, including tables or appendices with

accession numbers, and specimen information. Loan completion is a very important but often overlooked or forgotten part of the loan process. With the use of standardized tracking systems, reminders can be set periodically, and loans remain “open” until these requirements are met. This may be critical for adhering to ABS compliance, to ensure that any sharing conditions are met by the borrower.

Checkpoint 7: Document e.g., completion, close loan if conditions are met, materials returned (if applicable).

2.10 Conclusion

We recommend each institution to have its own predefined system for receiving loan requests. A centralized database system, with checkpoint tracking abilities is preferred, because it will help with managing requests, aid in follow-up of loan completions, and documents collection usage.

We also recommend that each institution have its own loan policy, including general terms and conditions, types of loans available, loan granting criteria, and completion conditions. Loan approvals should be conducted by authorities of the collection being requested, or by a designated committee and if possible, loans should be made to permanent staff responsible for temporary staff (students/postdocs) and should be prepared by qualified staff members or trained technicians. Destructive sampling should be minimized. Loan agreements should include details of the specific loan, contents, allowed usage, returning conditions, and expected results (e.g., publications, accession numbers). They should be signed by both parties. The material must be shipped following all applicable laws and regulations, recipients should be notified, shipments tracked, and packaged accordingly, using specialist couriers if necessary. Recipients should be notified.

Finally, completion of loans is critical, both in terms of recording the process and ensuring all conditions were met, including providing publication citations, accession numbers, and taxonomic changes.

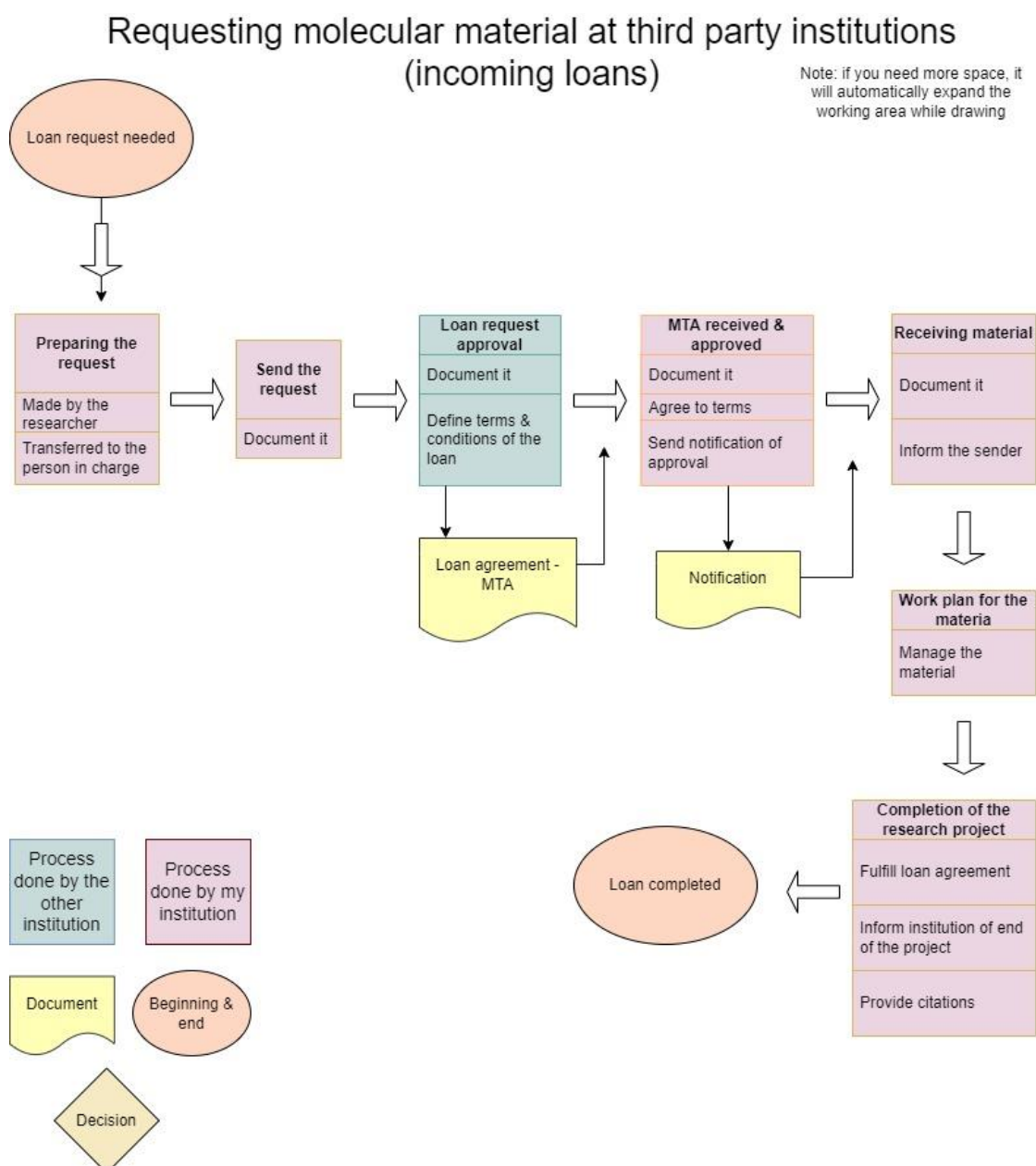
3. Requesting molecular material at third party institutions (incoming loans)

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This chapter is about wanting to request material at third party institutions for molecular research. What are the things to be considered to track it? You can refer to fig. 2 for a workflow of the process

Fig. 2: Workflow and a description of the various checkpoints.



3.1 Policy for Incoming Material (incoming loan) for molecular work

Each institution should have a formal, written policy document and inform researchers and curators about the process, terms, and conditions of incoming material requested from other institutions for molecular work at your own institution. It should contain information about your institution's management of requests and handling loans of genetic material to ensure smooth functioning of the institution's processes.

The policy document should include various information such as:

- Context of the policy
- Explanation of why the policy is necessary
- Who can make a request for material
- How incoming material is managed at the institution
- Roles and responsibilities
- Instructions on how researchers and curators should proceed with a request in the context of the policy

3.2 Preparing a request for material for molecular work (incoming loans)

A careful preparation of a request for material present various advantages. The procedure for managing the material at your institution can be centralised from the start of the process, which can ensure proper tracking and handling of genomic material in your institution's lab. Furthermore, the policy of your institution can be followed from the beginning and time can be saved for the researcher interested in making the request, as well as for both institutions (receiving and sending). The number of inappropriate requests being sent can therefore be reduced. Advice and guidance can be given to the researcher originating the request. For example, a curator who receives requests, is able to advise on what makes a useful request, see Chapter 2.3 in this document for the kind of information required in a well-planned request.

Checkpoint 1: Researcher in your institution, reads the policy and any other relevant information, prepares the request, and contacts the people in your institution in charge of managing incoming loans, such as supervisors, colleagues who have recently submitted a request or a designated person responsible for sending requests. The request may be modified at this point.

3.3 Sending the request to the other institution

It is best practice to have a central system for making and recording requests. This may be as simple as recording emails, through a range of options to a structured database. If a system is in place, the request should be logged as it is sent. This will allow the people involved (curators, researchers, supervisors etc) to track the request and reply to it. Often the replies to the request require several steps by more than one person and it will facilitate the request at both ends if there is a system in place to record communication and documentation. Furthermore, having a system in place to record loans ensures proper inventory and tracking of borrowed material in your institution. If your institution carries out an audit, for example to ensure compliance with the Nagoya Protocol, then the relevant correspondence and information is available and easily produced for verification.

Checkpoint 2: Request is sent and recorded in the system of your institution.

3.4 Completion of agreements required for the transfer of material

An agreement needs to be made between the institution sending the material and your institution specific to the material (or loan). A material transfer agreement (MTA) is a sound basis for any agreement, but institutions may have other agreements and documentation that have to be completed. A loan agreement should contain details about the specific loan. It should include information regarding use of the material for the project specified in the request, whether or not material may be transferred to other institutions involved in the research, whether or not the material may be used for commercial use (following ABS protocols), and what should happen to remaining unused material (see Chapter 2.3 for more about loan agreements). The agreement should contain a statement, that the user is only allowed to use the material as stated in the original loan request unless further written permission is granted. It should also include information on proper citation for use of the collection and representation of the material in publications and databases, such as proper institution and collection codes, and provision of accession numbers and their correspondence to vouchers specimens (or genomic-only samples) for data published in online databases such as EMBL-ENA.

Furthermore, any subsequent deviations from the initial loan agreement should be agreed upon, in writing, by both institutions (sending and receiving).

Checkpoint 3: Documentation approved by both institutions and stored centrally by your institution.

3.5 Receiving the material

Shipping of loans should follow all local and international regulations of the sending and receiving countries, as well as any anticipated intermediary countries. All people involved in the loan process should know who is responsible for observing which regulation. Cold chain specialist couriers are recommended for frozen samples. Transportation regulation and legislation IATA/ADR are regularly updated, and staff training will be needed for this periodically. At present IATA provides the possibility that non-infectious specimens packed with small quantities of flammable liquid may be transported on a plane, provided that IATA special provision A180 applies. Import permits and CITES clearance may be required.

As soon as the material is received at your institution the sender should be informed of its arrival and the institution receiving the material needs to centrally record the arrival of the material and to start processing of the material.

Checkpoint 5: Record receiving the material by informing the sender, while also recording the arrival of the material, data associated with the material and any other relevant documentation in your system.

3.6 Managing the material after receipt

One way for institutions to manage material after it has arrived is to have a work plan for the material. This can be a simple document, describing the material, referring to the agreement documentation, and explaining who is going to do what with the material, where the material will be stored and what happens to the material at the end of the project.

In addition to managing the material it is worth considering how to manage the specimen-level data in the work plan. The recording of specimen-level data will allow for the linking of the material to documentation as well as facilitating the research on the material, considering any taxonomic changes, and recording accession numbers or other relevant information for published data based on the voucher specimens.

Checkpoint 6: Creation and adherence to a work plan for the material or loan when it is in the receiving institution.

3.7 Project Completion

At the end of the research project for which the material was requested a few actions need to be completed. First, the fulfilling of any requirements in the agreements need to be checked. Second, the

sending institution need to be informed of the completion of the project. Finally, publication of information, citations, accession numbers, etc need to be provided.

Completion of loan should include all anticipated products, including reports, publications, public database accession numbers (e.g., EMBL-ENA or GenBank, BOLD system etc). Any changes of taxonomy should be sent to proper collection staff and tables or appendices with accession numbers, preferably in digital format, should be provided.

Completion of a research project or a loan is a very important but often overlooked or forgotten part of the process. With the use of standardised tracking systems, reminders can be set periodically, and loans remain “open” until these requirements are met. This may be critical for adhering to ABS compliance, to ensure any benefit sharing conditions were met.

Checkpoint 7: Check agreements and work plan, take actions to fulfil conditions and record actions, then inform the institution that sent the material.

4. Sequence Submissions

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4.1 Introduction

This chapter describes the process of submitting DNA sequences (such as those used in phylogenetic or DNA barcoding studies), to the European Nucleotide Archive (ENA; Cummins et al. 2021) and to NCBI GenBank (Sayers et al. 2021; Schoch et al. 2020), including the option of submitting selected (“curated”) metabarcoding sequence reads to these repositories. We discuss general considerations for ensuring compliance to data quality standards and for streamlining sequence submissions.

For each sequence submission, it is important to correctly annotate the loci and to provide relevant specimen metadata in sufficient detail to link sequence data to an object (usually a voucher specimen). Therefore, clear instructions, institutional guidelines, and data curation are essential. The major sequence databases and repositories occasionally change their submission pipelines, and their processing times may vary. Therefore, we focus only on general submission principles here, as the exact current procedures are specified by the repositories themselves with support available from their respective helpdesks, FAQ or tutorials.

Information on ENA submissions can be found here: <https://www.ebi.ac.uk/ena/browser/submit>

Instructions on GenBank submissions are found here: <https://www.ncbi.nlm.nih.gov/WebSub/>

There are also excellent third-party software packages with instructional tools, such as: <https://www.geneious.com/tutorials/genbank-submission/>

4.2 General considerations

Whenever possible (subject to size), and depending on journal policies, the material table with the voucher information and the sequence accession numbers should be presented as part of the main paper, rather than as supplementary material, for three reasons. First, the link between sequences and a physical specimen (or lack thereof) constitutes significant information for the study and is not just supplementary information which is normally considered useful, but not crucial. Second, the material table is the place where herbarium collections and the collectors are most visible. Third, not all journals guarantee long-term archival of supplementary materials and often such materials do not receive the same editorial care as the main body of a publication and so there is a higher probability of supplementary materials to contain errors escaping peer review.

Sequence data repositories distinguish between submitters of sequence data and authors of the corresponding paper where these data are first published, and both items are usually required upon submission. Usually, the researcher(s) involved in the study submit(s) their sequence data themselves. Alternatively, having sequences submitted by a dedicated staff member at the institution where the sequence data have been generated is an option to consider, provided that there is such dedicated staff time available.

Both approaches have their advantages and disadvantages. If researchers are responsible for their own sequence submissions, they can work independently but need to become acquainted with the submission tools and procedures, which may potentially lead to mistakes or delays if not properly supervised. A designated sequence submitter will be familiar with the tools and procedures and thus can process the submissions quickly and accurately and the researchers only need to prepare their data for submission in a given format corresponding to internal workflows. Potential drawbacks include bottlenecks when submissions are the responsibility of a single person, thus requiring researchers to consider the submitter's schedule and availability and, perhaps more importantly, a loss of knowledge if this person leaves or becomes unavailable.

Another point to consider is the geographic origin of the vouchers from which the sequence data were generated. Following the principles of the CBD and the Nagoya Protocol (Berger Filho & Maia 2022; Ambler et al. 2021; Karger & Scholz 2021; Watanabe 2019), publications of novel sequence data should generally include authors from the countries of origin involved in the project. These authors should ideally be lead- or co-authors for the sequence submission data, to avoid subsequent problems when the origin of sequence data is being scrutinised. This also ensures that regulations are followed, as these are usually better known by authors from a target country. Examples include PhD students from abroad

submitting sequence data as part of their thesis work. This does not exclude the possibility of having a dedicated institutional staff person responsible for submissions, since sequence submissions can have multiple authors and include the staff person as an additional submitter. This latter option is easily done in NCBI Genbank but in ENA, the submitting author is by default the name of the account holder (as of Oct 2022) and if a submission is to be multi-authored, each co-submitter would have to be added as account holders for the time of that particular submission.

4.3 Recommendations

We give here a few recommendations to follow to ensure an adequate sequence submission process.

1. The responsibility for sequence submissions should be specified by each institution, department, or working group, depending on their staff situation.
2. There should be protocols and specific institutional guidelines for sequence submissions.
3. If sequence submission is centralised within an institution, several people at each institution should be able to perform sequence submissions, ideally from a functional e-mail address to which those people have access.
4. The tasks of designated submitters should be clearly specified and separated from the tasks of individual researchers. The latter would be responsible for the most time-consuming steps, i.e. accurately preparing their sequence data and metadata under the guidance of the submission staff and using established workflows following the templates used by the corresponding repositories. The tasks of the submitter(s) would be registering taxon names, general data curation, quality control, data submission, communicating with the repository, and providing the accession numbers to the researcher. Once a study is published, the researcher provides the citation to the submitter, who releases the sequences and updates the citation.
5. Prior to sequence submission, it should be ensured that all regulations to obtain the sequence data have been followed and the underlying information should be documented in-house by the submitting institution, in case it is required. Note that while the United States is not a party to the Nagoya Protocol, NCBI-Genbank follow the spirit and recommendations of the protocol and it is highly recommended to take existing regulations into account when submitting sequence data to GenBank.
6. There are several submission tools that simplify preparing and submitting flat files, listed at https://ena-docs.readthedocs.io/en/latest/faq/third_party_tools.html.

Of those tools, *annonex2embl* (<https://doi.org/10.1093/bioinformatics/btaa209>) has been successfully used by one of the authors of this handbook (N. Korotkova) and its use can be recommended as it significantly speeds up the submission process. Genbank also has submission tools for particular sequence

types, such as rRNA genes, which include automated algorithms to check sequence quality and correct allocations of metadata.

4.4 Taxon names, sample metadata and vouchers

All taxon's names which are part of a sequence submission must be included in the NCBI Taxonomy backbone, otherwise the submission cannot be completed. Names not found therein must therefore be registered before the submission and all names have to be published in order to be registered. For unidentified samples, newly described species or undescribed species or species that may not be formally described but need to be distinguished, an informal unique sample designation is provided by the submitter.

For fungi, the mandatory registration of new names in MycoBank or Index Fungorum offers an alternative to avoid this step: assuming that both sequences and new names are only registered when a manuscript is accepted, the name registration should be done first at this step and then the NCBI backbone can communicate with the name repositories to make sure names have been registered (although not yet released). These names can then be incorporated into the backbone prior to sequence submission.

The sample metadata for a sequence submission typically consist of the collection and voucher information, along with various identifiers. The metadata to be submitted should correspond to the material table as it appears in the publication, and we suggest some information to be generally included (see below) to ensure the exact link between the sequence, sample and a physical specimen.

The importance of vouchers for molecular data has been pointed out repeatedly (Mulcahy 2022, Buckner et al. 2021; Groom et al. 2021). Voucher specimens serve as physical evidence for the taxonomic identification and enable repeatability of molecular research, ranging from molecular ecological studies and molecular systematics to genomics. In addition, sampling and collection information enables local researchers to be included in the scientific process, making molecular studies more inclusive. Yet many sequences in GenBank or ENA lack voucher information or have incomplete metadata. Sometimes voucher information is missing altogether, sometimes it is cited only in the corresponding paper, but not submitted to the sequence database. For instance, in the lichenized fungal genus *Usnea*, 30% of nearly 1,500 accessions of the fungal barcoding marker ITS had issues with voucher information or lacked such information all together, not only in the original submissions but also in the associated publications (Lücking et al. 2020). In diatoms, more than 30% of the sequences lack vouchers (pers. communication Jonas Zimmermann, BGBM).

Thorough preparation of vouchers and data management needs therefore to be given proper attention, for example by training students and junior researchers. This is to prevent metadata being put together too late, typically too close to manuscript submission, which in turn can result in incomplete

data, missing specimen barcodes, and other inaccuracies. Institutions should establish mechanisms by which sequence data and specimen data can be easily and permanently linked in their own databases so that this data can be easily retrieved by their researchers for sequence submission.

A standardised INSDC vocabulary and syntax for metadata must be used, described under https://www.insdc.org/files/feature_table.html#7.2

We recommend the following data to always be included into a sequence submission and the corresponding material table in the paper

1. The taxon name or sample designation / the strain number for microbial organisms derived from cultures.
2. A DNA isolate or DNA bank ID (if it is used)
3. Country
4. For large countries, the first political subdivision (province, state)
5. Geocoordinates; for marine organisms the waterbody name/locality
6. The collector or team and the collecting number; for diatoms also, the cultivator
7. The specimen voucher citation: it is recommended to use the institution code and a collection code and a catalogue number (<https://www.insdc.org/submitting-standards/controlled-vocabulary-specimenvoucher-qualifier/>)

Unfortunately, ENA currently (October 2022) does not permit submission of stable specimen URLs; therefore, a stable institutional identifier (barcode) is the best alternative to provide unambiguous connection to voucher information available in a public database. For collections that are not (or only partially) barcoded, as is the case in many institutions, it is recommended to include the institution code along with the collector name and collection number.

4.5 Publication of sequences

Sequences must be made public immediately after the publication of the study; the full citation and the article DOI are added to the sequence entries. Note that ENA unfortunately does **not** update the citation in the actual individual records, it is only visible in the study attributes. In GenBank, submissions can only be updated by the original submitter.

Ideally, sequence data are submitted after acceptance of the manuscript, either during the subsequent copy-editing stage or by the editor requesting an updated manuscript file with the accession numbers. This allows for release of sequence data immediately after submission, and it also provides an accurate publication title and author list. Sequences should not be submitted well before submission of the intended manuscript or without the context of a proper, peer-reviewed publication. In case of

sequences generated but not used for an actual study which are intended to be shared with the public, it is recommended to provide these in the form of an associated data paper or data package with a DOI.

5. Managing legal information, rights, and restrictions related to specimens and samples

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This chapter is about archiving and managing legal information related to the usage of physical material, linking this information to specimen and sample data. It is related to the outcomes of the Synthesys+ project's task NA3.3 "Create a data standard for enabling traceability of restrictions for molecular samples", based on version 1 of the GGBN Data Standard which will provide the vocabulary and "Best practices for using the GGBN Data Standard to provide restriction and loan information". This chapter provides an overview of managing legal information, rights, and restrictions related to molecular collections and guidance for implementing their terms.

5.1 Introduction

There is a myriad of document types that can be associated with a collection item, including contracts, permits, licences and certificates [see Synthesis+ project's task NA3.3] which may impact how it can be acquired, used, shared, donated and disposed of. Furthermore, documents must be considered for items that are used, but do not become part of a collection. Items need to be managed in a way that supports compliance with any agreements associated with their collection, export, import and retention in the collecting organisation (museum, herbarium, university etc). Such management might differ for stages in the life cycle of an item, compliance with some agreements may only be necessary during initial sampling from the item's natural environment, other agreements may be effective until disposal of the item, some even longer. Legal documents can cover rights, obligations and restrictions in many areas including

- Intellectual property rights.
- Legislation related to international conventions e.g.
- Trade with protected species (CITES)

- Governing access and benefit sharing requirements (CBD - Convention on Biological Diversity, NP - Nagoya Protocol, ITPGRFA - International Treaty of Plant Genetic Resources for Food and Agriculture, and emerging topics around Digital Sequence Information and Biodiversity Beyond National Jurisdiction).
- Rights associated with domestic legislation e.g., related to export and import or with the movement and collection of endangered species.
- Consent related to human material.

Understanding an organisation's obligations, implementing the agreed terms and conditions, and what this means for managing the item needs to be easily accessible and understood; not only by the staff managing the collections but also by the users (e.g. staff, students, visiting researchers). As items are shared and use takes place, with agreement of any rights holders and in line with any restrictions, the documentation held will continue to grow and need to be managed, remaining linked to the original collections item record.

This chapter looks at:

- 1) What policies an organisation needs to have in place to be transparent about how it manages rights, restrictions, and associated risks.
- 2) An outline workflow for managing any form of right or restriction associated with an item.

5.2 Policies, Standards and Guidance

Policies, standards, and guidance support organisations in making decisions and in being transparent about the legislation, regulation and principles that will be used to make those decisions. There are many different aspects that need to be considered and these may be in a single document or part of a wider framework. Policies may be based around different concepts:

- Collections management process focussed e.g., the Collections Trust's Documentation Standard Introduction to Spectrum 5.1 (<https://collectionstrust.org.uk/spectrum/>)
- Focussed on a specific type of collection, e.g., Ambrose Monell Cryo Collection at the American Museum of Natural History (<https://www.amnh.org/research/sicg/amcc/collections-policies/acquisitions>)
- A combination with an overarching general policy approach and more detailed policies relating to different collection types e.g. the Finnish Museum of Natural History Policies ICEDIG Project Outcomes (https://riojournal.com/topical_collection/84/)

The approach an organisation will take will depend on different factors including the culture of the organisation, any legislation covering the funding and management of the organisation and any accreditation expectations set by government agencies or specialist membership organisations. Whichever policy framework is chosen there are four main areas to be considered in the policy framework which will be important in ensuring organisations can manage the rights, obligations, and restrictions as well as ethical expectations associated with their collections.

1. Collections Management

1.1. Object entry: how material entering the organisation is managed. This is important as the rights, obligations, and restrictions on the use of any item including those entering on loan, for consultancy etc. will need to be appropriately managed. Such management for items which will not become part of the collection may follow different procedures, e.g., when utilising an item covered by access and benefit sharing requirements, that will not become part of the collection, but will still be bound by obligations and restrictions.

1.2. Acquisition: how items are added to the organisation's collections. Acquisitions to collections may have conditions associated with the legal transfer that must be agreed, tracked and managed.

1.3. Loans: see chapters 2 and 3 for a detailed discussion of loans including policy.

2. Collections Use

2.1. Disposals: how items are permanently removed from the organisation's collections. This may involve the transfer of obligations.

2.2. Specialist policies such Access and Benefit Sharing, Human Remains.

3. Information Management

3.1. Data Protection: what information can be shared will depend on what laws and regulations apply to personal data e.g., the European General Data Protection Regulation (GDPR) and the organisation's approach to privacy and personal data. The uses of personal data collected when acquiring, borrowing, lending, using, and disposing of collections items, need to be made clear to donors and users of the collections. This includes who (if anyone) the personal information is going to be shared with, and how long it will be kept for. It should include circumstances where sharing data may be mandatory e.g., Declarations of Due Diligence require sharing of a person's name to whom Prior Informed Consent was granted (EU and UK regulations implementing the Nagoya Protocol Article 7) or through bilateral agreements.

3.2. Open Information: what is the approach to open data? What information if any is not accessible and why?

3.3. Rights Management and approach to Risk: what is the organisation's approach to rights management and in evaluating and understanding risks such as the risk of not having sufficient resources to adequately manage and implement the agreed terms and conditions over time or reputational risks from inadequate documentation and due diligence. The level of risk will vary depending on the significance or value of items involved, the type of right, the purpose of the project or planned use of an item, project participants as well as other considerations. The organisation's approach to risk mitigation and appetite for risk will also play a part in decision making. For example, documenting efforts to understand the rights or restrictions of the owner and what permissions may have been in place may be sufficient to approve a project in some cases. In others, the lack of explicit permission would prohibit a project from being undertaken.

3.4. Records Management, including adoption of relevant standards, who has access to what information, and retention time. For permanent collections it should be established which elements of the records should be kept permanently and which may be deleted after some time (e.g., name of the person responsible for packaging a loan, shipping costs).

3.5. Documentation standard for recording collections information: it should include recording information about: the item and its identifier, the agreement and details of the rights and any obligations including benefit sharing so that rights, restrictions and obligations pertaining to the object and its use can be tracked over time.

3.6. Access and management of Collections Information: important frameworks are e.g. the FAIR Principles - GO FAIR (go-fair.org) and CARE Principles of Indigenous Data Governance — Global Indigenous Data Alliance (gida-global.org).

4. Due diligence

4.1. Due Diligence Guidance: general Due Diligence relates to provenance research, i.e. the collection of documents and information that enables organisations to understand the history of an item. Where and when an item was collected and any conditions related to the collecting event (e.g., rights, obligations and/or restrictions contained in collecting permits, Prior Informed Consent or Mutually Agreed Terms), what the collection method was, who collected it and if applicable the export and import history. This provenance research enables organisations to understand with due diligence whether items can be acquired, loaned, used, and disposed of and under what conditions. Due Diligence involves assessing this information, along with the documented evidence, to inform any decisions regarding the acceptance or use of the material. It is vital in ensuring appropriate information is gathered, retained and available to use e.g., for CITES licence applications, or special Due Diligence declarations according to regulation (EU) 511/2014 on implementing the Nagoya Protocol. Due Diligence research may also be undertaken to determine the history of an item as well as the rights, obligations and restriction of items

already in the collection which will enable the organisation to understand what collections it holds and assess any risks associated with use.

4.2. Risk Management: it is intrinsically linked to due diligence and what is understood and known about the history of an item. It also includes consideration of personal data, business confidentiality, processes, and policy regarding data transfer. Different organisations will have different risk appetites for academic, legal, financial, or reputational risk. Organisations should have an identified risk process including how risks are assessed, a process for decision making and identified risk owner.

5. Ethical Standards

5.1. Are there national or international ethical standards that an organisation needs to consider, e.g., ICOM-code-En-web.pdf? Ethical considerations are particularly important in cases where there is uncertainty around who the right holders are, or details of the rights or restrictions are unknown.

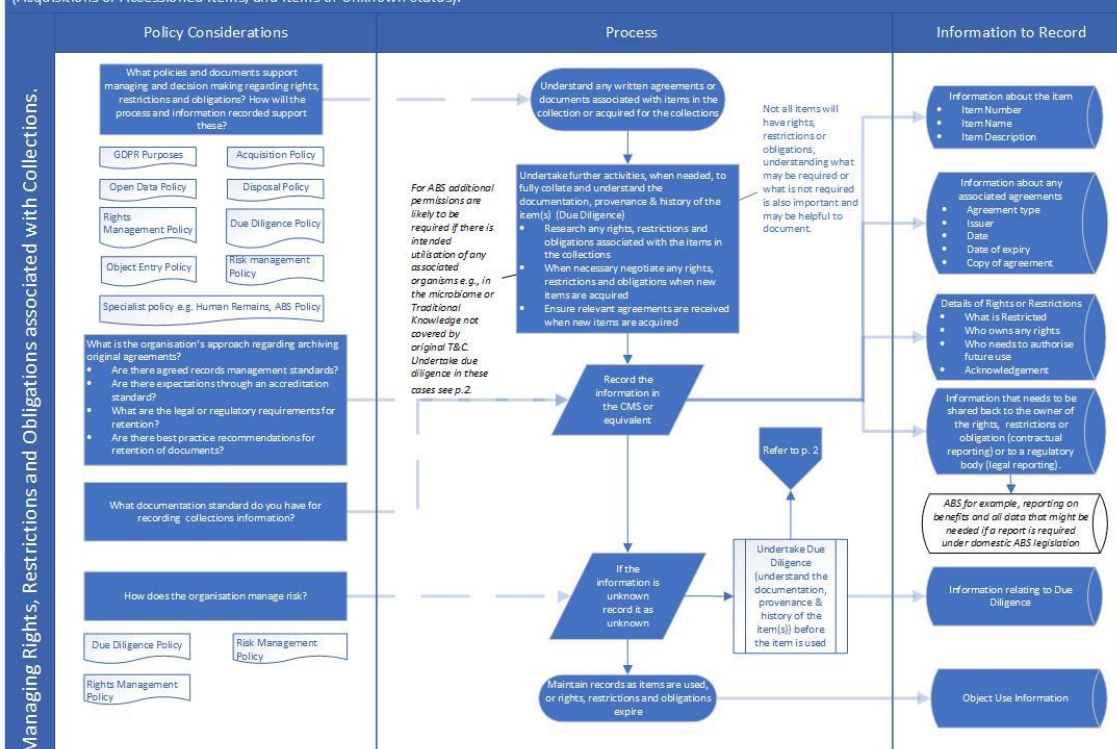
5.3 Workflows

The workflows below illustrate four basic processes covering typical situations in holding and using molecular collections. As Access and Benefit Sharing has such a major impact on the management of molecular collections there are some annotations in black italics to indicate particularly important ABS considerations, these are considered in more detail in the ABS chapter of this handbook. The workflows are based on the Collections Trusts Spectrum Documentation standard¹ and refer to:

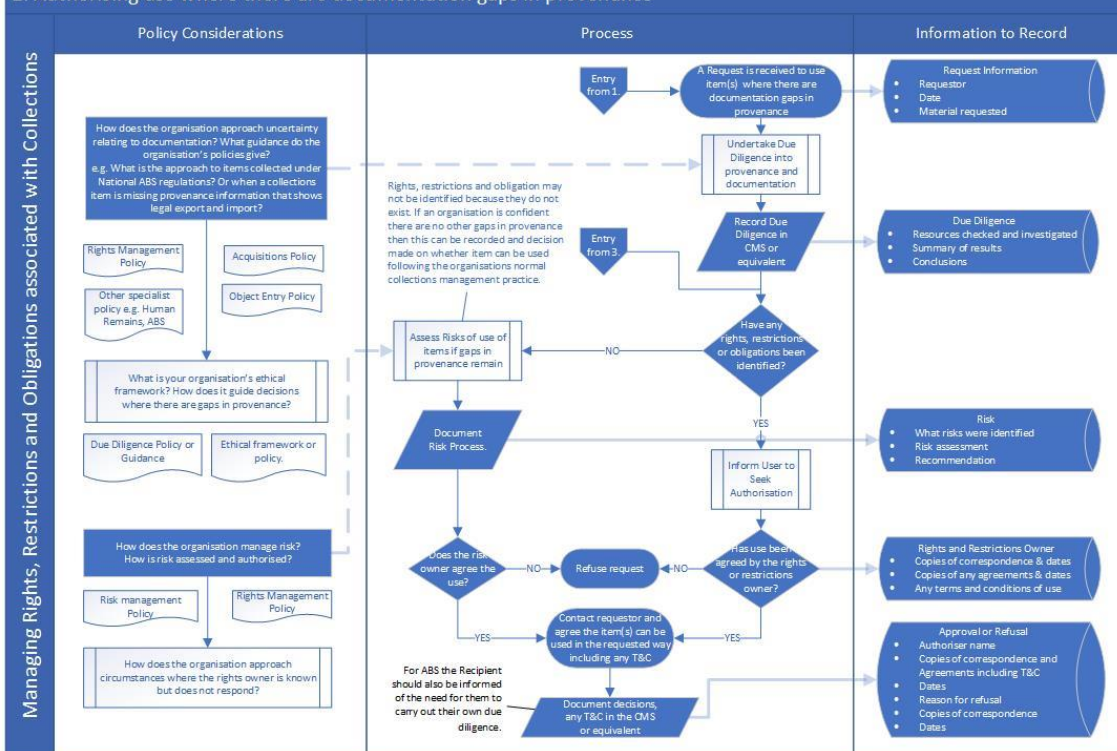
1. Rights, restrictions and obligations associated with items in the Organisation (Acquisitions or Accessioned items, and Items of Unknown Status). It focuses on understanding any agreements associated with collections entering or that have entered the collection.
2. Authorising use where there are documentation gaps which could include missing documentation giving evidence of legal collection, export and import for example missing CITES documentation, absence of evidence of Prior Informed Consent. Look at steps associated with managing requests for using collections items when paperwork is incomplete or there are uncertainties.
3. Giving Permission for the use of Items with Rights, restrictions, and obligations (Items leaving, or being used in, the Organisation). Covers what steps should be taken to agree the use of item/s by other organisations or individuals
4. Receiving Permission for the use of Items with Rights, restrictions, and obligations (Items entering the Organisation). Focusses on the steps those requesting to use item/s held by another organisation need to take to ensure they are using any material in a way that meets any terms and conditions.

Fig. 3: The workflows list the rights, restrictions and obligations-based information that should be recorded at each step. Originally a standard for UK Museums Spectrum is now used internationally and is available in Arabic, English, Dutch, Finnish, French, German, Norwegian, Polish, Portuguese, Spanish, and Swedish. [Spectrum – Collections Trust](#)

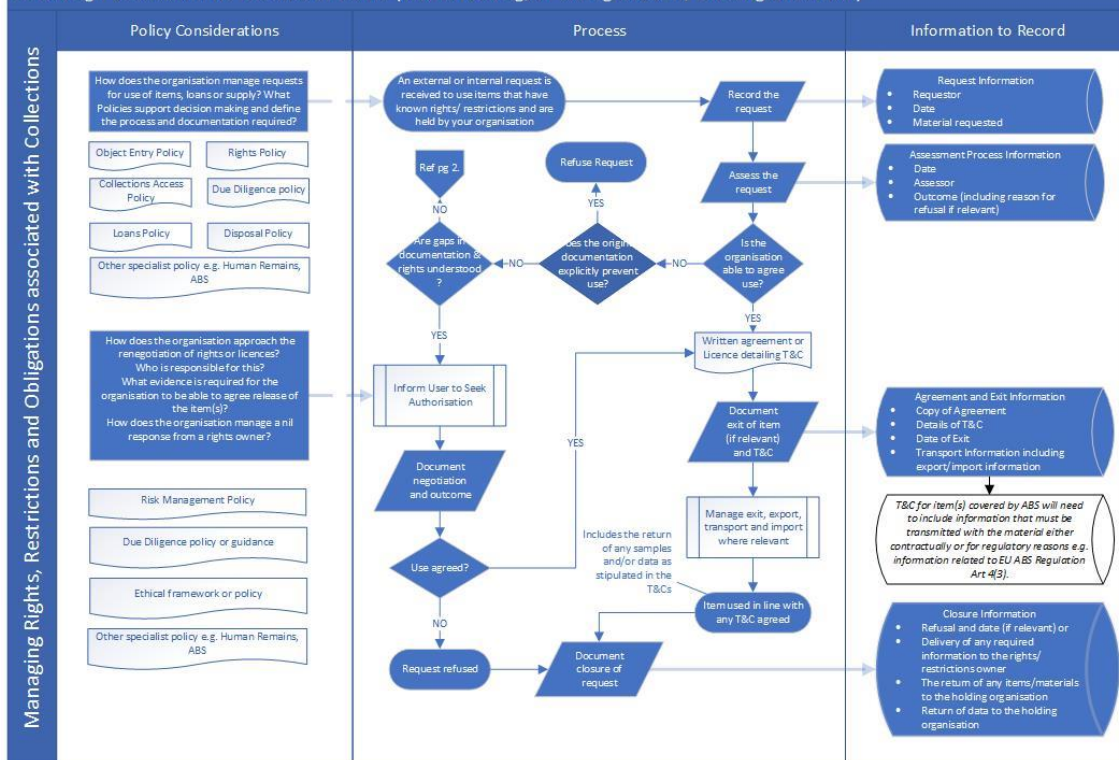
1. Due Diligence for Collections Items In or Entering the Organisation. (Acquisitions or Accessioned Items, and Items of Unknown Status).



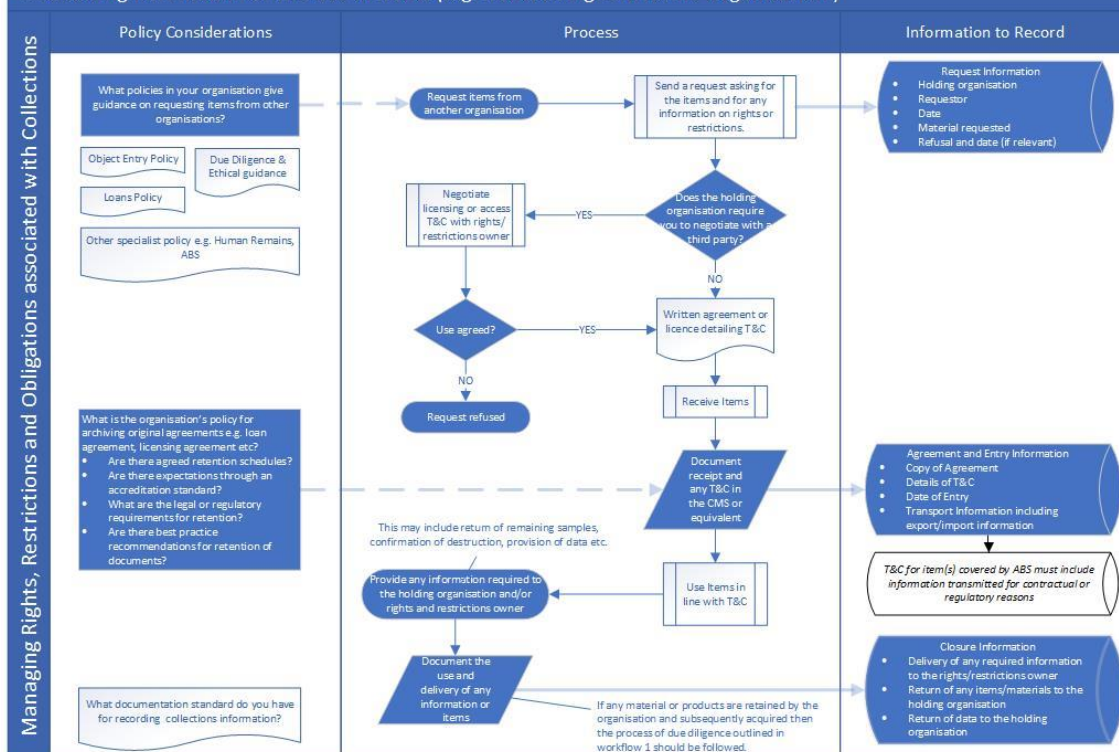
2. Authorising use where there are documentation gaps in provenance



3. Giving Permission for the use of Items (Items leaving, or being used in, the Organisation)



4. Receiving Permission for the use of Items (e.g. Items being lent to the Organisation)



The workflow on rights, restrictions and obligations associated with items in the collection or new acquisitions (1) is the prerequisite for subsequent activities on these items to be following applicable laws, regulations, and standards (workflows 2-4). The main challenge not further elaborated here is to record rights, restrictions and obligations-based information in a standardised way and unambiguously attribute it to the collection items they refer to. An approach taken by the GGBN data standard (Droege et al., 2016) is, among other controlled vocabularies, is an example for describing selected loan conditions and permit types. These elements of the standard are under development in SYNTHESYS+ Task 3.3 to provide standardised Document Types (grouped in standardised Document Categories), a standardised Typology of Contents for describing the most common permissions, duties, restrictions, prohibitions, and recommendations for implementation in collection management systems and collections infrastructures such as the upcoming Distributed System of Scientific Collections (DiSSCo). The aim is to record legal rights and obligations attached to collection items in a way that makes it possible to flag every single item accordingly, as well as recording common loan conditions that may apply. This facilitates the collection items' use, improves loan processes and enables to the point reporting.

5.4 Recording rights information

This section looks in more detail at the different information packages generated during the workflows. The precise recording of rights, restrictions and obligations will differ between organisations and relate to the size and scope of the collections, how resource is prioritised and risks managed. Recording information may vary in granularity and style, depending on the technology available to the collection staff, if and how vocabulary is controlled, the expected standards of documentation the organisation uses and needs, the mobility of the collection, whether the collection is regularly used for commercial purposes, and available personnel. Whilst some organisations may have a fully integrated CMS, others may need to use a combination of a CMS, simple database and/or paper systems. Whatever system or systems are used, understanding them, documenting how they work, and using them consistently is crucial for any organisation. The tables below are derived from the workflows provided above and list the different types of information that should be recorded to enable an organisation to track rights, use and obligations. Given our earlier comments that not all organisations will have the resources to acquire or create and maintain a fully functioning CMS, we do not discuss how records and information should link in a CMS. Instead, we have looked at what information should be documented in whatever system or systems are available. We have marked “essential” information that we consider more important to capture (e.g., presence or absence of documents related to rights, restrictions, and obligations, whether a document is still relevant for present and future use or only deals with actions in the past, such

as sampling from nature). Other information is necessary e.g., for quick reporting on legal issues related to the collection but may be recorded at a later stage of digitising the collection, or not until a specific reporting requirement arises; this may also include information stored on paper. That information is marked “Desirable” in the following table (Table 1).

Table 1: Documenting known rights, restrictions, and obligations for Items in the Organisation.

Information to be recorded	Details	Essential / Desirable
Type of Document	According to the organisations descriptor of documents (cross ref. to NA3.3)	E
Relevant for future use of collection items?	Documents may be time limited (e.g. sampling allowed from January to December 2021) and/or relevant for future use (e.g. in ABS reporting to providing country is required for every use; use is restricted to taxonomy)	E
Document name	Given by the issuer	E
Document number	Number assigned to the permit by the issuer.	D
Issued To (holder)	The name and details of who the document was issued to.	D
Issued By	Who is the issuing authority or rights holder? Name and organisational details	D
Repeatable	Can the document be used only once e.g. a CITES import license that is valid for a single transaction; or can the document be used multiple times e.g., a collecting permit that can be used multiple times during a specified period, or for a named project.	D
Start date	Date document became valid.	D
End Date	Date document expires. Note that conditions imposed in the document may continue to be enforceable even though the document has expired. Not all documents will have an end date.	ED
Status of document	Is the document pending (not yet valid); valid (in date and can be used); expired (the document is no longer in date); expired but partially enforceable (e.g. certain boilerplate clauses such as those relating to confidentiality may remain enforceable).	D
Description	Brief description the of purpose of the document (predefined definitions for document types may be used, refer to NA3.3) and any other relevant information e.g., project name if the document was issued in response to a specific project	D
Summary of obligations	Include any important obligation (duty, restriction) e.g., whether items can be shared, if renegotiation is required or material must be destroyed after use.	E
Requires reporting	information that needs to be provided back to the issuer e.g., non-monetary benefits under the NP	D
Multiple reporting / period	If more than one report is required, state the start date and end date of the period in which these reports are required, or whether reporting requirements are indefinite	D
Reporting due date	Date report must be received by.	D
Report sent	Link to report sent	D
Requires Return of Items	Whether a document requires return of any items e.g. under the terms of PIC and MAT a percentage must be returned or an export permit is for temporary export only.	E
Return due date	Date items must be returned by.	D
Items return date	Date items were returned.	D
Attachments/Links to digital or physical documents.	Attachment to copies of digital documentation, or pdf of paper documentation. Reference to where originals are archived should be included.	E
Attachments/ links to future decisions	Documentation of collection management decisions that are responding to obligations associated with this Right record e.g. loans to 3 rd parties; disposal records, if material is permanently transferred.	D

Table 1 focuses on information that needs to be recorded and retained when documenting known rights, restrictions, and obligations when item/s first enter the organisation. This covers material where all the relevant documentation has been provided and no further research is needed to understand how the item/s need to be managed or used. Examples include an object entry record following staff fieldwork where some or all the material will be returned to the country of origin and the staff member has the relevant collecting permits, Prior Informed Consent, Mutually Agreed Terms, export permits and import permits required, or an acquisition of items from fieldwork where all the necessary agreements are in place for the organisation to add the items to their collection, or an acquisition record for items acquired through donation, exchange or transfer where copies of all permits and other agreements are provided including passing on any obligations and/or restrictions.

Table 2: Recording rights information where the owner of the right, restriction or obligation is unknown.

Information to be recorded	Details	Essential / Desirable
Status of knowledge: Rights, restrictions, obligations and provenance.	unknown, due diligence underway, due diligence complete. In this context due diligence relates to the history and provenance research described in 3.1	E
Type of right, restriction or obligation investigated	Link to NA 3.3	D
Summary of due diligence findings	A summary of what has been discovered regarding rights, restrictions, obligations and provenance.	E
Sources of information used	Details of the laws, regulations, export and import information, publications and/or links to these sources.	E
Attachment to any rights or restriction documents found or negotiated	Attachment to copies of digital documentation, or pdf of paper documentation. Reference to where originals are archived should be included	D
Attachment to due diligence research report	Attachment if a written report has been completed on due diligence.	D
Date of assessment	Date assessment of due diligence was completed.	E
Assessor	Name of the person who made the due diligence assessment.	E
Risk Assessment undertaken	Is it necessary to risk assess the potential future or proposed use of these item/s? Yes / No	E
Attachment to Risk Assessment	An assessment of any risks identified, potential mitigation and management of any identified obligations (e.g. potential user needs to seek permission from rights owner) when looking at what is now known about the status of the item/s from the due diligence report and the proposed use.	D
Date of assessment	Date risk assessment was completed.	E
Assessor	Name of the person who made the assessment.	E
Summary	Summary of risk assessment including any rights, restrictions or obligations to pass on to users and any other terms and conditions e.g. users need to approach rights	E

	owner for permission and provide a copy to the holding organisation before item/s will be released on loan.	
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Table 2 focuses on information that needs to be recorded and retained when the rights, restrictions and obligations are unknown or were incomplete when item/s first enter the organisation. This covers material where the relevant documentation has not been provided and further research is needed to understand the circumstances of collection and any potential rights, restrictions and obligations to enable the item/s to be properly managed or used. Examples include an object entry record for a potential acquisition or item/s within the collection that do not meet current collections documentation standards e.g. items acquired through a bequest or purchase where copies of relevant permits and other agreements are not provided or item/s entering for consultancy where the commissioning company has not provided copies of all the relevant documentation relating to collection, export and import or passed on any obligations and/or restrictions.

Table 3: Recording Permission for the use of Items with attached rights, restrictions and obligations (Items leaving, or being used in, the Organisation).

Information to be recorded	Details	Essential / Desirable
Requester	Name of person requesting the Item/s	E
Project	Project Name	D
Material requested	List of item/s requested for use in the project.	E
Attachment or link to relevant rights records	An attachment or link to the Rights Record documented through following Table 1.	D
Attachment to record of rights research	An attachment or link to the Due Diligence Record documented through following Table 2 (only needed if rights status & provenance were unknown)	D
Attachment to risk assessment	An attachment or link to the Risk Assessment Record documented through following Table 2 (only needed if rights status & provenance were unknown and risks were identified regarding Use of the item/s)	D
Decision & if request is rejected	Is the use approved Y / N. If the use has not been agreed, record the reasons why the request was rejected.	E
Decision maker	Name of the decision maker who is authorising use.	E
Date	Date of Decision	E
Attachment of executed agreement/licence including all required t&c Attachment to agreements and collections management records associated with use.	Attachment to copies of digital documentation, or pdf of paper documentation e.g. Loan or Transfer Agreements for items leaving the organisation or evidence of an internal user receiving information regarding rights, restrictions and obligations . Attachment or link to Disposal documentation. Reference to where original agreements, licences etc are archived should be included	D
Attachment to documents procured by the Requestor	Documentation obtained from the original rights, restrictions or obligations holder e.g., the approval of the country of origin	E
Requires contractual reporting	Information that needs to be provided back to the issuer e.g., non-monetary benefits under the NP	E
Reporting due date	Date any contractual reporting should be completed	D
Report sent	Link to contractual report sent or to due diligence notification	E
Requires Regulatory reporting	information that needs to be provided to a regulator e.g., CITES label usage, or within the EU due diligence reporting according to regulation (EU) 511/2014.	E
Reporting due date	Date any Regulatory reporting should be completed	D
Report sent	Link to Regulatory report sent	E

Table 3 focuses on information that needs to be recorded and retained when organisations receive requests from external or internal users to use item/s with attached rights, restrictions and obligations. Those attached rights, restrictions and obligations may have been associated with the item/s since they

entered the organisation (and documented as in Table 1.) or have been researched so the future use of the item and any potential risks with use are understood (documented through the process in Table 2).

Table 4: Recording the Receipt of items from other Organisations.

Information to be recorded	Details	Essential / optional
Items	List or description of items received	E
Received by	Name of person receiving the item/s	E
Received for	Name of person who is responsible for the item/s	D
Attachments or links	Attachment or links to other collections management processes e.g., object entry, loan in record, rights record.	D
Attachment or link to relevant rights records	An attachment or link to the Rights Record/s documented through following Table 1.	D
T&C	A summary of Terms and Conditions	D [E if no attached Rights or loan records]
Date for return	Date by which item/s should be returned, used or destroyed, and/or data should be provided.	E
Fate of Items	Material destroyed, consumed, returned, retained (in some circumstances possibly acquired)	E
Items returned or disposed of date	Actual date the item/s were returned, used or destroyed.	E
Requires reporting to original rights holder	Information that needs to be provided back to the original rights holder e.g., non-monetary benefits under the NP.	ED
Due date	Date any report to the original rights owner is due.	D
Completed date	Date submitted and link to the report.	E
Requires Regulatory reporting	information that needs to be provided to a regulator e.g., CITES label usage, or within the EU due diligence reporting according to regulation (EU) 511/2014.	E
Reporting due date	Date any Regulatory reporting should be completed	D
Report sent	Link to Regulatory report sent	E

Table 4 focuses on information that needs to be recorded and retained when item(s) are received from another organisation. This covers material where all the relevant documentation has been provided and no further research is needed to understand how the item/s need to be managed or used as well as situations where an organisation sends item(s) without complete documentation. Collections Management processes where this might occur include research loans from another research institution accompanied by all the relevant documentation, or speculative sharing of specimens for research between scientists who do not share any documentation.

6. Compliance with ABS legal obligations

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6.1 Introduction

The aim of this chapter is to provide a summary of the context in which molecular collections manage access to genetic resources and the benefit sharing arising from their utilisation. ABS obligations and the corresponding terms constitute a large part of potential rights and obligations associated with collection items and are subject to political dynamics. The chapter therefore gives the background from which these obligations arise.

6.1.1 Convention on Biological Diversity & Nagoya Protocol

The UN Convention on Biological Diversity (CBD) came into force in 1993. It has three objectives: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources. The CBD recognises that countries have sovereign rights over their biodiversity and has been ratified by 196 countries ('Parties'; at present all UN members - except USA - plus four non-members, the EU, the State of Palestine, Cook Islands and Niue) (Greiber et al., 2012).

After the CBD came into force in 1993, many Parties noted that compliance with the benefit sharing aspects of the CBD was not legally enforceable on an international basis as there was no compulsion on recipients in other countries to comply with provider country's laws regarding benefit sharing. This led to the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity* being agreed in 2010 and coming into force in October 2014.

The Nagoya Protocol elaborated the principles Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and fair and equitable Benefit Sharing (BS) and extended them to traditional knowledge associated to genetic resources.

PIC: those wishing to access genetic resources and/or associated traditional knowledge ask permission from the Competent National Authority in the country or any other body designated by that country, usually with describing what genetic material they wish to access, what they want to do with the material, and what benefits they will share with relevant stakeholders in the country.

MAT: Terms of benefit-sharing must be mutually agreed and should cover terms on subsequent third-party use, on changes of intent, and a dispute settlement clause. In practical terms, MAT is often provided through a written permit (PIC) in the case of field work, or as part of material transfer or supply agreements from the providing country if material is being sent from the country.

BS: Countries agree to create conditions to facilitate access to genetic resources in return for the fair and equitable sharing of the benefits arising out of the utilisation of the resources accessed.

More importantly, it requires Parties to implement measures to ensure users comply with provider country's national access and benefit legislation, and to put in place measures to deal with non-compliance (<https://www.cbd.int/abs/about/>). Parties have implemented the Nagoya Protocol in different ways and in some cases the temporal and material scope of national access legislation is wider than set out in the NP (Kariyawasam, 2018). Institutions need to record the terms and conditions under which they accept material so that they can manage their collections in compliance with these terms and to inform decisions on how to use and share their collections.

Both the EU and the UK have put in place legislation that monitors compliance (regulation (EU) 511/2014) and anyone utilising genetic resources or associated traditional knowledge is required to make a “due diligence declaration” to their country's competent authority to demonstrate that those genetic resources or associated traditional knowledge are legally utilised. A declaration needs to be made on receipt of grant funding for a project involving utilisation (before the grant funded period is finished) and at the final stage of development of a product via the utilisation of genetic resources or traditional knowledge associated with such resources. Only utilisation of material falling under the scope of the Nagoya Protocol needs to be declared, i.e., material subject to EU and UK compliance laws, from a provider country that has ratified the Protocol and has laws governing access to genetic resources in place. involves proving that the material was obtained according to relevant national legislation, with prior informed consent and on mutually agreed terms (regulation (EU) 511/2014). Therefore, users will need to obtain, keep copies of the required information, permits, permissions and contracts and pass on information and relevant documents to third parties who may also want to utilise the genetic resource. The due diligence declaration will be shared with the provider country through the ABS Clearing- House (<https://absch.cbd.int/en/>), and so the relevant authorities in the providing country can check that the correct permissions were obtained and benefits shared.

The Nagoya Protocol covers benefits arising from the ‘utilisation of genetic resources’ which is defined as ‘to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (Article 2(c)). Despite this definition, the term ‘utilisation’ is interpreted in a variety of ways in national law implementing the NP.

In the EU the European Guidance document gives some help with interpretation and (EUR-Lex - 52021XC0112(02), states: “*as a type of ‘litmus test’, users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and development, and therefore falls under the term ‘utilisation’.*”

It is also worth noting, that a country’s access laws implementing the NP usually cover genetic resources bought commercially, that go on to be utilised in ways not directly associated with that commercial use. For example extracting essential oil for a component in a perfume is not utilisation, but exploring the functional genes and biochemical pathways and using them to transform another plant would be utilisation and covered under the Nagoya Protocol.

Details of national laws governing access to genetic resources and resulting benefit sharing can be found via the Access and Benefit Sharing Clearing House: <https://absch.cbd.int/en/>. This site also links to useful information such as the country's ABS focal point who can provide information on procedures in the country, including the relevant permitting authority and information on the permissions required from local and indigenous communities where necessary. In many cases, the ABS Clearing-House also provides contacts for the ABS Competent National Authority which is responsible for enacting national legislation governing access and benefit sharing and implementation of the Nagoya Protocol.

6.1.2 Digital Sequence Information (DSI)

The current system for accessing genetic resources subject to the Nagoya Protocol and sharing resulting benefits relies on national laws and bilateral agreements (PIC and MAT) between the provider country and user. However, once genetic resources are sequenced the sequences could be used without reference to the original physical material and the bilateral agreements governing its use. This has caused concern that benefits arising from “digital sequence information” (DSI) may not be shared with the provider country. In 2018 the Conference of the Parties of the CBD decided to “*establish a science and policy-based process on digital sequence information on genetic resources*” (COP-14 decisions UNEP/CBD/COP/DEC/14/20). This process considers the views of relevant stakeholders and seeks to clarify the concept and definition of DSI and will produce recommendations on the treatment of DSI under the CBD to the 15th meeting of the Conference of Parties to be held in December 2022 (<https://www.cbd.int/recommendations/wg2020/?m=wg2020-04>). At the time of writing no clear consensus has emerged on the concept and definition of DSI, and it is likely that there will be an agreed set of options. These are likely to include; fully integrating DSI into the current bilateral processes of CBD and Nagoya Protocol frameworks with PIC and MAT required; multilateral approaches covering different forms of standard MAT, payment for DSI with no PIC or MAT, arrangements for technical and

scientific collaboration; and finally no benefit sharing from DSI (in other words not considering DSI to be equivalent to genetic resources) (criteria to consider policy option on DSI on genetic resources: <https://www.cbd.int/np/dsi4.pdf>). The resolution of how DSI is treated in the negotiations at the time of writing will have an impact on how DSI is used and managed by institutions holding genetic and using resources in the future (Brink and van Hintum, 2022).

Collections need to act transparently in fulfilling the relevant national laws governing ABS. The work of Synthesys+Task 3.3 gives collection managers the vocabulary to assist in managing the terms and agreements governing their collections and the ability to refer to the various agreements in non-ambiguous terms. However, ultimately it is the responsibility of the collection to manage its agreements and any restrictions on use that these ABS agreements impose (see also Chapter 5). The resources below provide best practices and advice for managing collections within the context of ABS.

6.2 Codes of Conduct and Best Practices

Both the European Union and the UK have ratified the Nagoya Protocol (June 2014 and February 2016 respectively). The *EU Regulation on compliance measures for users from the Nagoya Protocol* which became applicable in October 2014, and the *Commission Implementing Regulation* in November 2015, are both directly applicable in all EU Member States.

The EU has produced a *Guidance Document* for users to help with interpretation.

The UK passed *The Nagoya Protocol (Compliance) Regulations 2015* to enforce the EU regulations and designated *the Office of Product Safety and Standards* as the national competent authority responsible for regulation of the Nagoya Protocol in the UK.

Since the UK has now left the EU, the EU Regulation has been transposed into UK Legislation as the UK ABS Regulations: <https://www.gov.uk/guidance/abs>.

The European Regulation on compliance measures for users from the Nagoya Protocol includes an article encouraging users to develop and implement Best Practices for fulfilling the requirements of the Regulation, and to submit these to the European Commission for Recognition. This recognition may be used by Regulators in the Member States in their ‘risk-based approach’ to working with users. The UK Regulations on ABS also encourage the use and adoption of best practices.

Several organisations have already developed best practices for Access and Benefit-Sharing which will be useful to Synthesys members. Some of these have been updated since the Nagoya Protocol, but to date only the CETAF Code of Conduct has been officially recognised as a Best Practice under the EU regulations.

- **Consortium of European Taxonomic Facilities (CETAF), code of Conduct and Best Practice for Access and Benefit-Sharing (<https://cetaf.org/resources/best-practices>)**

This is Recognised by the European Commission under Article 8 of the EU ABS Regulation – see the formal notification ([https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Commission%20Decision%20C\(2019\)%203380%20final%20-%20EN.pdf](https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Commission%20Decision%20C(2019)%203380%20final%20-%20EN.pdf)).

The Code of Conduct and Best Practices were developed by the CETAF Legislations and Regulations Liaison Group. It provides a set of declarations about compliance, referring e. g. to material acquisition, utilisation, curation, transfer, and benefit sharing. In its seven annexes, the Code provides:

- Best practices of how to implement the CETAF Code of Conduct
- A model Statement of Use that supports institutions in negotiations with providers
- A glossary of ABS terms
- A list of benefits as listed in the Annex of the Nagoya Protocol
- Very comprehensive material and practical advice on how to integrate best practices in typical workflows (by means of checklists)
- Model Material Transfer Agreements
- A data use statement

- **Consortium of European Taxonomic Facilities (UK members)**

Following the exit of the UK from the EU the CETAF Code of Conduct and Best Practices is now recognised by the UK Government.

- **Global Genome Biodiversity Network (GGBN), best practice for access and benefit-sharing (<https://library.ggbn.org/share/s/546zVMjjQTKnv44IqXvkGQ>) and code of conduct for ABS (<https://library.ggbn.org/share/s/UM5JietQR9aevtYDymHbjw>)**

These have been developed by GGBN's Policies and Practices Task Force and are modelled closely on the CETAF documents. Links to these and other ABS resources can be found on the GGBN website.

- **Results of the Pilot Project for Botanic Gardens**

Principles on ABS and Common Policy Guidelines developed by a group of botanical institutions in 2001. Though created before the Nagoya Protocol it is well used and a valuable resource for this community (http://www.bgci.org/files/ABS/Principles_on_ABS.pdf)

- **Botanic Gardens Conservation International (BGCI)**

It has a resource page with links to its own and external tools to support the Botanic Garden community.

- **Microbial Resource Research Infrastructure (MIRRI)**

It has developed a best practice manual on access and benefit sharing (<https://www.mirri.org/wp-content/uploads/2021/02/ABSbestpracticemanual.pdf>)

- **World Federation of Culture Collections**

TRUST - TRansparent User-friendly System of Transfer, implementing the Nagoya Protocol in microbiology, see <https://bccm.belspo.be/projects/trust>. As highlighted on the website, the TRUST system comprises 4 elements: administrative workflows adapted to the structure of the Nagoya Protocol; refined Material Accession Agreement (MAA) and Material Transfer Agreement (MTA); and cooperative structures for culture collections. Guidelines and a handbook are can be download (<http://bccm.belspo.be/projects/trust>).

- **Swiss Academy of Sciences Good Practice Guide for Access and Benefit-sharing**

The guide offers comprehensive information to assist scientists and research institutions in planning and performing research projects that use genetic resources and associated traditional knowledge from abroad. (<http://www.naturalsciences.ch/organisations/biodiversity/abs/goodpractice>)

Other Codes of Conduct and Best practices can be found on the ABS Clearing House site section <https://absch.cbd.int/en/>

The Union of Ethical Biotrade provides useful guidance on ethical sourcing of biodiversity used in business, particularly the natural beauty sector. They provide guidance on ABS and other useful resources.

6.3 Other resources and useful Publications

- Davis, K. & Borisenko, A. (2017).
- **GGBN Guidance on Access and Benefits Sharing**

<https://library.ggbn.org/share/s/546zVMjjQTKnv44IqXvkGQ>

- Centre for Biodiversity Genomics (2021)
- Overview of National and Regional Measures on Access and Benefit Sharing (<https://www.mybis.gov.my/pb/1633>)
- Evanson Chege Kamau (2019)

- Model agreements and country specific advice (<https://www.nagoyaprotocol-hub.de/toolsandresources-abs/>)
- ABS Clearing House website
- Various legal websites and resources:

FAO website: <https://www.fao.org/faolex/en/>

The gateway to environmental law: <https://www.ecolex.org/>

- A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements (wipo.int)

Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions

7. Literature & References cited

7.1 Policy examples from SYNTHESYS+ partners

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BOLD system

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CARE Principles of indigenous Data Governance

<https://www.gida-global.org/care>

COP-14 Decisions

<https://www.cbd.int/decisions/cop/14/20>

ECOLEX

<https://www.ecolex.org/>

FAIR guiding principles for scientific data management and stewardship

<https://www.go-fair.org/fair-principles/>

FAOLEX

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GGBN data standards

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ICEDIG Project outcomes

https://riojournal.com/topical_collection/84/

ICOM code of Ethics for Museums

<https://icom.museum/wp-content/uploads/2018/07/ICOM-code-En-web.pdf>

INSDC vocabulary

https://www.insdc.org/files/feature_table.html#7.2

Iris BG, Botanic Gardens Conservation International

<https://www.bgci.org/our-work/projects-and-case-studies/irisbg-as-a-tool-for-nagoya-protocol-implementation/>

List of national cultural heritage laws

UNESCO <https://en.unesco.org/culnatlaws/list>

MAT: GGBN standard MTA

<https://library.ggbn.org/share/s/BW3F3qiiT8W9S3qeTwMMww>

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Synthesys+

<https://www.synthesys.info/>

WIPO Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions

<https://www.wipo.int/publications/en/details.jsp?id=4504>

8. List of abbreviations

ABS: Access and Benefit Sharing, <https://www.cbd.int/abs/>

BGCI: Botanic Gardens Conservation International, <https://www.bgci.org/>

BiCIK: Biodiversity Community Integrated Knowledge Library, <https://bicikl-project.eu>

BS: Benefits Sharing

CBD: Convention on Biological Diversity, <https://www.cbd.int/>

CETAF: Consortium of European Taxonomic Facilities, <https://cetaf.org>

CITES: Convention on International Trade of Endangered Species of Wild Fauna and Flora ,
<https://cites.org/eng>

COP: Conference of the Parties, <https://unfccc.int/process/bodies/supreme-bodies/conference-of-the-parties-cop>

DSI: “Digital Sequence Information”

GDPR: General Data Protection Regulation, <https://gdpr-info.eu/>

GGBN: Global Genome Biodiversity Network, <https://www.ggbn.org>

GIDA: Global Indigenous Data Alliance (gida-global.org)

DOI: Digital Object Identifier

DSI: Digital Sequence Information

eDNA: environmental DNA

ELViS: European Loans and Visits System, <https://elvis.dissco.eu/welcome>

EMBL: European Molecular Biology Laboratory, <https://www.embl.org>

ENA: European Nucleotide Archive, <https://www.ebi.ac.uk/ena/browser/home>

EtOH: Ethanol

EU: European Union

GBIF: Global Biodiversity Information Facility, <https://gbif.org>

GCM: Global Catalogue of Microorganisms, <https://gcm.wdcm.org/>

HTS: High Throughput Sequencing

IATA/ADR: International Air Transport Association/Accord Dangereux Routier, <https://www.iata.org>

ICT: Information and Communication Technology

ID: Identification Data

IGS: Intergenic spacer

INSDC: International Nucleotide Sequence Database Collaboration, <https://www.insdc.org>

ITPGRFA: International Treaty of Plant Genetic Resources for Food and Agriculture
<https://www.fao.org/plant-treaty/en/>

ITS: Internal Transcribed Spacer

MAA: Material Accession Agreement

MAT: Mutually Agreed Terms

MIRRI: Microbial Resource Research Infrastructure, <https://www.mirri.org/>

MOSAICC: Micro-Organisms Sustainable use and Access regulation International Code of Conduct,
<https://www.fao.org/in-action/mosaicc/en/>

MTA: Material Transfer Agreement

NCBI: National Center for Biotechnology Information, <https://www.ncbi.nlm.nih.gov/>

NP: Nagoya Protocol

nuLSU: nuclear large subunit ribosomal RNA gene

ORCID: Open Researcher and Contributor ID, <https://orcid.org/>

PI: Principal Investigator

PIC: Prior Informed Consent

SRA: Sequence Read Archive, <https://www.ncbi.nlm.nih.gov/sra>

SYNTHESYS+: Synthesis of Systematic Resources, <https://www.synthesys.info>

TRUST: TRansparent User-friendly System of Transfer

WFCC: World Federation for Culture Collections, <https://wfcc.info/>

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