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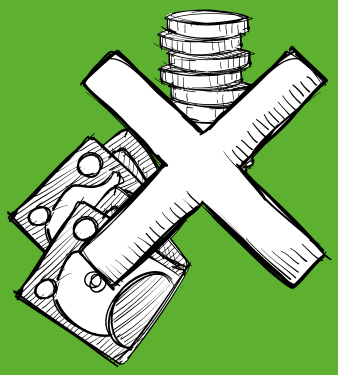

# The ABS Contract Tool: Version 3.0

## A hands-on and practical tool for drafting contracts governing access and benefit-sharing in the context of use of biological resources without declared immediate commercial application

Morten Walløe Tvedt
in collaboration with
Olivier Rukundo

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# The ABS Contract Tool: Version 3.0

A hands-on and practical tool for drafting contracts governing access and benefit-sharing in the context of use of biological resources without declared immediate commercial application

## Caveat:

This ABS Contract Tool is a collection of contractual clauses that can be used in ABS transactions, together with their justification and practical application. This tool is based on an academic analysis and use of this tool in any way is the sole responsibility of the person using it. The author, the organisation that funded this academic work or publisher do not assume any responsibility whatsoever for the use of the ABS Contract Tool. Before using any of these clauses in a contract, the user must confirm this by e-mail:

mwtvedt@gmail.com

## Feedback:

This is an 'Open Source' contract. If you use one or more of the clauses in this tool, please share your final version of your contract and any relevant experiences with the author, if feasible:

mwtvedt@gmail.com

# Author's foreword and caveats

This ABS Contract Tool 3.0 is a new version of a contract tool initially commissioned by the International Union for the Conservation of Nature (IUCN). It is a practical-academic analysis of functional contract clauses that can be used in bio-innovation transactions. It reflects experiences gained in practical contract drafting with countries after the finalisation of the 1.0 version. The ABS Contract Tool versions 2.0 was launched in Cape Town at the Pan African meeting of the ABS Capacity Building Initiative.

This ABS Contract Tool version 3.0 is designed so that it can continually evolve and will be updated into new versions as more experience and lessons learnt on ABS contracts are gained. Further experience and discussions with peers will provide new insight on how clauses can be drafted more effectively. Please follow the future updates and new versions of the tool. All comments and suggestions on this contract tool are warmly welcome. Legal research in this area is a moving study object and this ABS Contract Tool will continue to evolve and be updated based on the experiences and lessons learnt from its practical use.

I would like to greatly acknowledge Olivier Rukundo has contributed to developing the ideas behind version 2.0 and 3.0. He has also contributed developing the legal text. The collaboration with Olivier in delivering capacity building programs in ABS contract development and negotiation at both a regional and national levels on behalf of the ABS Capacity Development Initiative have generated lessons learned that have informed contract drafting in the field of ABS.

The analytical work carried out in collaboration with Tomme R. Young enabled me to continue with my later work in the area of contract law. I am indeed grateful and indebted to Tomme.

The collaboration with the ABS Capacity Development Initiative for more than a decade has been crucial for my work on ABS contracts. Funding to undertake this study has been provided by the Initiative. This tool will support the Initiative's work in the countries and regions where it operates including those beyond. Gratitude also goes to Andreas Drews, Hartmut Meyer, Suhel al-Janabi and the rest of the team. Thanks to Elizabeth Karger for language editing of version 2.0 at the critical moment when I lost my previous editor.

My deepest gratitude goes to partners in Bhutan, in particular Tashi Yangzome Dorji and Chencho Dorji at NBA and Singay Dorji in UNDP. I would like to extend my thanks to the Environmental Affairs Department in Malawi and in particular Mphatso Martha Kalemba, Chifundo Chinyama and Lilian Chimphepo for our close collaboration and for the insight gained on workable contracts through ABS implementation and negotiations. The practical experiences of the work with Botswana has also informed this version. Gratitude also to be extended to the partners in the COMIFAC Secretariat and notably Chouaïbou Nchoutpouen for support and collaboration. Thanks to partners in Namibia, especially, Henry Michael Ndengejeho and Betty Kauna Schroder.

Many more participants in contracts trainings have contributed concrete wording for specific clauses during the various trainings are too many to list here: We nonetheless want to thank them wholeheartedly for their very valuable inputs.

A special thanks to my good friend and great colleague Fran Humphries for a very profound reading and commenting on the draft to the tool version 2.0.

On our way through life, we meet wonderful people, some of whom unfortunately leave us far too early. I am very grateful for having met and worked with Dr. Juliana Santini from Brazil. It is still unbelievable that you are not among us.

Morten Walløe Tvedt,
Professor at Inland Norway University of Applied Sciences,
July 2023

# Contents

# The ABS Contract Tool: Version 3.0

## 1 Setting the scene: Substantive rules in ABS contracts

### 1.1 The mission and a caveat

A contract is a legally binding instrument between two or more parties. It is the practical legal tool that can make Access and Benefit-sharing (ABS) work in practice, providing legal certainty and sufficient flexibility to cater for each individual situation. This ABS Contract Tool provides example clauses to make ABS work and is made mainly for situations where **the user states that its objective is to conduct research without immediate commercial application.** As such, the relevant users will typically be scientific or research institutes. Contracting with commercial companies or commercial research institutions raises additional challenges. Many forms of research without immediate commercial purpose have the potential to produce useful findings that can be used for commercial purposes and this contract tool takes this into consideration. Experience has shown that provider countries can draw non-monetary benefits from securing their rights to findings even when the scientific or research institution does not declare an immediate commercial objective. This contract tool has a particular view to designing clauses that can be used to secure such non-monetary benefits.

The purpose of this publication is to provide a practical tool to guide parties that may be involved in or preparing to enter into an ABS contract. This tool is the response to numerous requests to provide a ready-made set of generic templates of ABS contracts that can serve any country and any user, including right-holders on both the provider and user side of an ABS transaction. It is impossible, however, to design a standard contract that will suit every ABS-related contractual situation. It is important to keep in mind that each ABS situation or transaction has its own particular circumstances and specificities. Different types of users and sectors use genetic resources and associated traditional knowledge in specific ways and for various purposes. While some elements of an ABS contract may be standardised, others need to be handled flexibly and be adapted on a case by case basis in light of the legal and factual context.

Any template for an ABS contract, including the ones discussed here, cannot be used without adapting and tailoring it to the concrete situation in which it will be used. When adapting the wording used in the sample contract, users of this contract tool should revisit the 'rational' behind the clause and the 'critical issues to be aware of' which are discussed in the each chapter of this ABS Contract Tool. For a practical and comprehensive handbook on drafting ABS contracts, you can refer to the book Drafting Successful Access and Benefit-sharing Contracts by Young and Tvedt. The ABS Contract Tool is the result of an academic analysis and is not a ready-made contract. The author and any associated institutions do not take any legal responsibility for any results our outcomes that may arise further to the use of this ABS Contract Tool. To this end, it is advised to always seek qualified legal advice when negotiating and concluding a contract. This tool should thus be used as an adjunct aid and is not intended to substitute qualified legal advice.

The first version of this tool was developed at the time when the author was at the Fridtjof Nansen Institute (FNI) on the request of the UNEP GEF Project "Advancing the Nagoya Protocol in Countries of the Caribbean Region", executed by the International Union for the Conservation of Nature (IUCN). The second version of this ABS Contract Tool was been developed at the request of the ABS Capacity Development Initiative. This 3.0 version is an update based on lessons learnt in practical experiences and feedback from countries. Please follow the future updates and new versions of the tool and contribute to the continuous improvement of the tool. All comments and suggestions are warmly welcome.

This tool can be used to make ABS contracts more functional. A copy-paste approach to drafting contracts is not possible and this is certainly not the aim of this publication. When drafting contracts, the modules and templates have to be adapted to the specific situation, ideally with technical and legal advice of trained practitioner in the area of contract law. A core caveat is that anyone using this tool remains fully responsible for their contract. The provider of this ABS Contract Tool accepts no responsibility for specific results and outcomes of a given contractual transaction.

### 1.2 Using "private law contracts" rather than relying on permits

The Convention on Biological Diversity (CBD) mentions two tools for regulating access to genetic resources: 'prior informed consent' (PIC) and 'mutually agreed terms' (MAT). Neither the CBD nor the Nagoya Protocol (NP) explain in detail what is in-

tended by these two legal tools. One observation by Young and Tvedt (2017)[1] is that experience has shown that providers of genetic resources should use private law contracts rather than administrative permits to govern access and benefit-sharing. A 'private law contract' is a legally binding agreement, negotiated between its parties and that governs their respective rights and obligations.

Many countries have already established ABS legislation based on a permit system or are in the process of doing so. This was observed in the ABS GIZ Caribbean Study (2016),[2] where all the empirical material provided for the study was in the form of permits and not contracts. A permit issued as a result of an administrative decision by the public authorities of the provider country will, in most jurisdictions, only be binding on the receiver in the country issuing the permit and will not be recognised as being legally binding in other jurisdictions. A publicly issued permit can work for legal questions that are to be dealt with within the provider country. Many countries depend on or apply a permit system with the intention of regulating questions that arise *after* the user has left their jurisdiction. The permit is often an authorisation to do or not do something and it is only enforceable in the jurisdiction in which it is issued. It is an administrative step that does not contain the same obligations as the contract between the parties. A public permit from one country *does not create* legal obligations and rights outside the national jurisdiction where it was granted. It cannot be enforced beyond the national jurisdiction in which it is issued and it has no legal force in other jurisdictions.

Countries often refer the legal tool, 'Mutually Agreed Terms', which is the term used in the CBD. Since many provider countries have a system using permits and MAT, the MAT should be a binding private law contract. Often information contained in the permit may be quite useful in laying the foundations for the negotiation of contracts, *i.e.* as an application for a permit is an opportunity to seek information on the interests and intention of the other party. What is important is for providers to have binding and enforceable MATs in line with private contract law principles and rules. In which case a MAT should be an ABS contract.

The contract must have clear terms and conditions to become binding and enforceable on the user. It must also have a format recognised across borders. A contract will per se be also binding in other jurisdictions, *i.e.* that of the user if it is well drafted and if it contains binding and enforceable provisions. An ABS contract must be comprehensive and regulate the relationship between the parties in detail. Generally, in contract law, there are established practices and background law, which can be used to support their interpretation. This is not so for ABS contracts, since it is a new legal area, therefore the contract must regulate all relevant aspects. It should be noted that the user country's legislation, which is established as part of the implementation of the NP, does not directly resolve the core challenges relating to contracts. An ABS contract can expect little interpretative support by other sources of law and must govern all necessary aspects of the transaction.

Drafting good contracts requires the involvement of qualified and experienced contract lawyers. It is often not sufficient to involve lawyers with experience in international environmental law since drafting a treaty or a piece of legislation draws on different skills than those required for drafting contracts. Therefore, this ABS Contract Tool must be absolutely used together with guidance from a lawyer who is qualified and has experience in private law.

## 1.3 Methodology– how to use this tool

The method applied in this tool looks closely at three elements for developing an understanding of ABS contracts. It breaks down the ABS contract into fundamental topics or clauses and for each introduces:

1. A discussion of the rationale behind each clause;
2. Suggestions for contractual language; and
3. Core questions that the drafter must reflect on when adapting the clause to the specific situation.

1. The first element under each clause explains the rationale for including (or leaving out) specific clauses and their significance in making the ABS contract binding and enforceable. It also explores why certain clauses are not suitable to be in an ABS contract and how they may prevent an ABS contract from being functional, that is binding and enforceable. The various articles in this tool are connected and interlinked. Therefore, removing one article might alter the totality and balance in the tool. Section 1 for each article also explores why and how this article contributed to the contract to be binding, enforceable and consequently functional.

1 Tomme R. Young and Morten Walløe Tvedt, Drafting Successful Access and Benefit-sharing Contracts. Nijhoff: Brill. 426pp. 2017

2 Tvedt MW. Studying Existing ABS Arrangements in Selected CARICOM Member States. Bonn: GIZ; 2016. p. 24. https://tinyurl.com/26wbjpbz

2. The second element is to give example clauses, which propose contractual language, often referred to as templates. This ABS Contract Tool does not, however, provide a ready-made text. Many people wrongly believe that ABS contracts can be based on a completely standardised contractual language. It is risky for a party to a contract to 'copy and paste' general language from previous contracts for use in another situation. Each situation is unique and the parties themselves are responsible for the contract they sign. One must recall that every transaction has its own set of circumstances. The genetic resources, the users and uses are always different and the contract needs to respond to case by case situations. In theory, a contract can be drafted from scratch each time; in practice however, contract clauses are reused. The most important thing is, therefore, to draft clauses that will be binding and enforceable. A template or clauses that are often used should be evaluated and redrafted on the basis of lessons learned. People seldom have access to the practical experiences of others, so copy-pasting texts from previous contracts devised by others will often not provide the information needed about the extent to which the clauses worked. In this tool, the contract clauses use a format in which parts that will always need to be changed are put in brackets and marked in yellow such as this: [CONTRACT-SPECIFIC TEXTS THAT MUST BE ADDED here the text could either suggest alternatives to choose from or the topics that must be dealt with.]. For some clauses there are some general observations that are not supposed to be written into the contract clause; they are written *[In turquoise and italics so it is easy to separate this type of text from the previous one in yellow]*.
3. The third element, which appears under each clause, are the questions the person drafting the contract must clarify with particular attention in each individual concrete situation. The answers to these questions must be taken into consideration in the actual contract.

## 1.4 Challenges with ABS contracts

For ABS contracts to work, several obstacles need to be overcome. The drafter should be aware of these challenges or obstacles when drafting the contract.

- ABS covers a broad spectrum of value chains. For some types of value creation the biological material accessed will be identical or close to identical to the product on the market. Often, an initial step in the value chain is to deposit material in *ex situ* collections where the mandate of the institution is to make the deposited material accessable. In more complex value chains there is a longer time lag. The material is first accessed, then researched, and developed, into a novel product or process that can be launched in a market. This is different from almost all other types of contract, where both parties fulfill their obligations at the same time.
- Use of material is a dynamic process where the material or parts thereof are transformed into new formats. One example is when biological samples of the material results in digital information or synthetic form of material. The contract needs to foresee these types of changes of the expression of genetic information.
- Research and development are dynamic processes and can take a variety of different paths. The text of a contract is static when is has been agreed to.
- A core challenge is to draft language in a manner that is able to capture the benefits to be shared regardless of when these benefits will be created or materialise along the value chain.
- Value creation and harvest-points in value chains are diverse.
- The intention of the user at the point of access has often been introduced as a core criterion in ABS contracts. Often, intention refers to *commercial* or *non-commercial* intentions or purposes of the research. This is also reflected in Art 8 of the Nagoya Protocol.[3] Art. 8 a) encourages its members to apply 'simplified measures' for 'non-commercial research purposes'. The purpose or intent of a person is, however, difficult to know, and it has no objective expression that can be verified.
- When the materials is going to the service provider who is not the final user but has potential to return information.

**Solutions** to these challenges need to be found to make ABS contracts more functional. Here are some responses:

- A solution to the time-gap challenge is to require upfront payments when it is feasable. The solution to this challenge is to include upfront and ongoing benefit-sharing, e.g. through access fees, collaboration in research, investment in research facilities in the provider country, and engagement of their students and experts. If this is not possible, a solution for a balanced contract is to leach property rights to the provider. At the same time, two types of future obligations should be created. This includes making the end-product or process available to the provider at a reasonable (self-cost) price and binding obligations for monetary payments in the case of commercialisation.
- A second aspect of a solution is to build in mechanisms that can trace the link between provider and user. The user is the actor who can best demonstrate the link between a genetic resource and a product in the market.[4] Making the user report in a credible and verifiable manner is a solution.
- These challenges also call for opting for technology-neutral manners to formulate obligations. Technology-neutral contract

3 NP Art. 8 regulates this as an obligation on its members to: (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

4 Tvedt MW, Eijsink V, Steen IH, Strand R, Rosendal GK. The Missing Link in ABS - The Relationship between Resource and Product. Environmental Policy and Law. 2016; 46(3-4):228-37.

language provides dynamic clauses in the contract without introducing uncertainty. Increasing digital use of genetic information require new manners to deal with these challenges.
- The contract should not specify obligations in a narrow manner. At the same time, the obligations cannot be too unspecific because ambiguity leaves the contract uncertainty. The most important way of avoiding this is to be *specific but not too narrow* when drafting substantive obligations.
- A Contract must be drafted so that the stated obligations can be fulfilled, complied to and, if needed, enforced by a court. A clearly drafted contract with enforceable obligations will reduce the need to actual seek a remedy from a court.
- The contract should, as much as possible, try to include everyone along the value creation as a party to the contract.
- The solution is to regulate commercialisation scenarios in any type of ABS contract. A non-commercial contract can regulate what happens in the case of commercial success. This does not necessarily have to be complex but creates more predictable legal conditions. To this end, template clauses will make the drafting of scenarios into the contract a less complex task.

In the following sections, we take a closer look at the types of clauses that need to be included in ABS contracts. The point of drafting a good contract is to ensure that all parties can fulfill their obligations without disagreements or going to court, and for this to happen a valid, binding, enforceable and functional contract is necessary.

## 1.5 Recommendations to contract drafting

### 1.5.1 Be clear, specific and dynamic, but not narrow

The part of the contract that requires the most attention at the drafting stage are the substantive clauses – these are the obligations and rights to be embodied in the contract. There has been a tendency in the past to be very brief and use general formulations in the substantive clauses. This approach does not lead to drafting good and functional ABS contracts. Contract obligations must be **clearly** defined with **specific** language stating when the obligation will be triggered, the content of the obligation, methods for calculating payments, and specify how each obligation shall be fulfilled. Finally, the contract needs to specify the consequences and actions that will be taken when one of the parties fails to meet any of its obligations.

Drafting **dynamic** clauses: At the same time as the obligations are made specific, they need to be dynamic as to embrace new and unpredictable results from their uses. One feature of such contractual obligation is to formulate them in a technological neutral manner. Drafting legal language in a technological neutral manner consists of using wording that will be apt to grasp new technological developments. For example, using the term a 'medium for saving data' rarther than specifying saying a 'harddisk'. By using the technological neutral term, a 'medium for saving data', one does not need to review the legal text when technology advances. And to choose wording that will grasp a plurality of research results, also those that are not easily predicted at the point of time of access.

In ABS, samples are accessed before the user conducts the research and development. The challenge for ABS contracts is to negotiate before utilisation occurs, i.e. before anything is done with the resources, which could possibly result in value and potential benefits. An ABS contract must move beyond regulating obligations that are relevant at the time of access and anticipate potential outcomes linked to the utilisation of the resource.

To overcome this major challenge, it is necessary to develop feasible scenarios for the research and development. Here, 'scenario' means typical pathways that the user can probably be expected to follow according to the relevant sectors' and its associated trends and practices. The substantive obligations and the manner in which they will be fulfilled will build on these scenarios, which are regulated by the contract. The contract must also be able to cover unforeseen events, research results and the development of different products, meaning that obligations cannot be formulated in a *narrow* manner. At the same time, the language of the contract must be clear and specific so that a judge will be able to ascertain whether the obligations have been complied with or not according to the facts of the case.

### 1.5.2 Avoid ambiguity

In all legal drafting we can learn from language theory. A legal term needs to reflect reality as concisely as possible. Between a legal term and the real world, there is the human understanding of the term. The more ambiguous a term is, the higher is the risk that others will not understanding the same reference in the real world to be possible to be subsumed under that particular term or concept. The more corresponding a legal term is to the phenomenological occurrence in the real world, the more clarity the contract provides. Therefore, as a practical lesson is that a term with no reference to actions or phenomena in the real world are not useful in contract drafting.

### 1.5.3 Opt for the positive regulation rather than attempt prohibitions

In the past, ABS agreements have often included an obligation "not to commercialise", "not to seek intellectual property rights" or "not to access traditional knowledge". A common feature of these obligations is that it is problematic on various fronts to prohibit and enforce such actions in a contract. Contractual obligations that seeks to prohibit actions are impossible to enforce in the courts unless these are spelled out with clear and corresponding

legal consequences, including verifiable trigger points and enforcement mechanisms that a court can objectively refer to.

When outcomes arising out of research and development lead to a product or process that is eligible for patent protection and all patent requirements are met, one cannot prevent such protection from being secured on the basis that traditional knowledge had been used illicitly or in breach of a contract. A contractual obligation is not a reason per se to prevent the granting or invalidating of a patent.

What is needed in a contract is to clearly regulate actions by stipulating clear and enforceable consequences should these actions take place. Instead of prohibiting a set of actions, opt for positive consequences that are would be triggered. Then the contract would play along existing invention and power structures. Then the obligations can be connected to non-monetary and financial achievements or results.

### 1.5.4 Regulate the whole scenario in the original contract

Many first-generation ABS agreements are weak in terms of defining clear obligations and trigger points at different stages of contract execution. In non-commercial ABS contracts, it has often been stipulated through a come back clause that, in the event of commercialisation, or change of intent, or third party transfer, the user shall come back to the provider and negotiate terms and conditions for commercial activities and applications that may have not been foreseen at the time of concluding the initial non-commercial contract. The problem with this approach is that this type of come-back clause does not lead to an enforceable agreement. It is legally and practically impossible to impose an obligation on someone to come back (from another country) to the negotiating table and make agreements on a given utilisation or application that was not foreseen in the initial contract.

Therefore, obligations that are not formulated in a contract from the onset have almost no chance of later becoming part of a contractual relationship. If these obligations and possible scenarios are not foreseen or governed from the outset, they remain voluntary and cannot be enforced as binding contractual obligations. The wording of the obligations must therefore be such that all relevant scenarios are stipulated in a clear and unambiguous manner. Thus, one core issue to have in mind is how contract clauses can cover relevant scenarios and translate them into binding language.[5]

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### 1.5.5 Structure for drafting the substantive obligations

There is a set of typical actions a user is likely to take. The substantive obligations always need to deal with certain topics, which should, to the extent possible, be included:

1. **Drafting contractual scenario from access to possible commercialisation:** There are several typical actions a user can undertake, which allows draft clauses to serve as points of departure for developing contracts. By drafting contractual obligations like this, rather than mirroring general statements like 'utilisation of genetic resources shall trigger benefit-sharing', a contract becomes clearer, binding and enforceable.
2. **Define clear trigger points and resolve evidential challenges:** A 'trigger point' is, for example, the research result, product or process that will create an obligation in the contract. When choosing what will be the trigger points, one must carefully consider how these trigger points will be chosen and defined in the text. Another key consideration is to stipulate clearly how the provider country shall obtain information and evidence of whether the trigger points have been reached. The trigger points should preferably be externally verifiable, meaning it is possible to find out whether the event has occurred in ways other than having to depend on information provided by the user.
3. **Clear consequences of the obligation being triggered:** The contract must specify clear consequences of the obligation being triggered and how it has to be fulfilled. The substantive clause needs to be defined clearly to specify what the triggered obligation is, e.g. what kind of a benefit is to be shared; a method of calculating the benefit; the date and how the obligation should be met. Thus, parties to the negotiations also need to determine whether the obligation shall have an end point where the contractual obligation of the user to the provider has been fulfilled.
4. **Remedies in lack of full compliance (breach of contract):** The most neglected question in ABS contracts is often the remedies in cases of breach of contract. The contract must provide a remedy for cases where an obligation is not complied with or in situations where there are sufficient *prima facie* evidence of breach of contract. The argument has often been that this question can be left to the general contract rules, such as 'compensation' of the loss. In the case of ABS, however, it is almost impossible for a provider country to prove a case for *economic loss* as a result of a breach of an ABS contract clause. In some ABS contracts, remedies were placed at the end of the agree-

5 1. Ibid..

6 1. Ibid..

ment and were detached from the substantive obligations. It is better when substantive obligations have specific remedies. A general remedy is not an effective means of dealing with breach of specific obligations. Ideally, the remedy should be tailored to suit each substantive obligation in the contract.

# I. ASPECTS CONSERNING THE PARTIES

## 2 Parties to the contract: Understand them and their interests

### 1. Rationale behind the clause

Understanding the parties to the contract is a very basic element of the contract. The legal personality of the parties to the contract is, however, a largely neglected topic.[7] If the identity of the parties to the contract is not completely clear, the contract will not be binding or impossible to enforce. Here, three legal issues and one strategic issue related to the parties to the contract right have been identified.

The first legal issue is that any party to a contract must be recognised as a ***juridical person***. A natural person has the power to represent him- or herself. There are also juridical persons that are entities recognised by law (in law referred to as 'juridical persons'). A juridical person is a non-human legal person that is not a single natural person but an organisation recognised by law as a fictitious person such as a corporation, government agency, NGO or International (inter-governmental) Organisation (such as United Nations). The documents, which lead to the establishment of this entity, will be decisive to the question of legal personality (incorporation document). Legal personality is a problem for not legally constituted groups of people such as certain indigenous peoples or local communities, which will need to be recognised to become a party to a contract. A contract signed with someone without legal personality is not possible to enforce. The legal person must also be legal in the sense that that a contract is only binding for the legal entities that have signed the contract and agreed to it. Another legal person different from the one signing will not be bound by the contract nor bear legal consequences form the contract. As an example, a daughter company of a multinational corporation will only bind *that* particular limited company. This means that a contract with a daughter company will not bind the sister companies in the same multinational corporate structure.

The second legal issue is that a legal person must also have ***legal capacity*** to be bound by a contract, meaning a person must have the legal ability to form a contract, i.e. the *capacity to contract*. A legal person who is unable to do this, e.g. due to age or mental impairment, lacks the capacity to contract. A person under legal guardianship completely lacks the capacity to contract and a contract signed by that person is void.

The third legal issue is that the person signing on behalf of the legal entity also has to have the ***competence to bind*** the entity to the contractual obligations. This question can sometimes be determined from the documents establishing the entity (incorporation documents), where the representatives of the entity are listed. Normally, more than one person will be authorised to legally bind an entity, it can be the director, however this prerogative has to be clearly stipulated in the legal statutes or incorporation document of the company. At the same time, not everyone working there, e.g. at a university or a company, is authorised to bind their employer to a contract. The negotiator must ask oneself the question as to whether he or she has the legal competence to bind their employer to a contract; most often the answer to this is that one cannot. The signatories to the contract must produce authoritative and verified documentation confirming their authorisation to *act on behalf* of the entity and bind it to the contract. This is particularly complex for public institutions like universities or research institutes as they might be constituted on the basis of an array of different legal provisions: an act (statutory organ), foundation (criteria set out in a grant document) or as a private entity. No employee of the university, including researchers and professors, officers and staff, is authorised to bind the university unless he or she has been delegated authority to do so. Such authorisation must be evidenced in writing. In cases where the signatory has no authorisation, the contract will normally have no legal effect on the entity.

Finally, the strategic question is a consequence of the principle of contract law that only signatories to the contract are bound by its obligations. A contract has no binding effect on non-parties. If the provider knows that more than one entity will be collaborating in using the biological samples to which access is been granted, all of them should become a party to the contract.

An ABS contract must bind all relevant entities that ultimately have the capacity to fulfill the obligations. For example, in a large corporation, research and development may in fact be conducted by a separate company from that which will be involved in the commercial sale of products. A university might undertake bioprospecting, whereas a company might fund the research and obtain commercial rights to the outcome of the research on the basis of a contract concluded with the university. This is a strategic assessment with considerable legal and practical consequences. Understanding the arrangements on the user side is extremely important when the user is a scientific institution claiming to be a non-commercial user.

7 For further reading, see Young and Tvedt 2017, Chapter 4.

### 2. Example of contract language

This contract, hereinafter referred to as "the Contract", is made on the [date] day of the Month of [month] [year] by and between

Department of [right authority according to ABS acts] in the Ministry of [NAME] of the Government of [COUNTRY], hereinafter referred to as "the Provider" having its principal place of business [ADDRESS],
and
[CONTRACT Research Institute], having its principal place of business at [ADDRESS]; [TYPE OF LEGAL ENTITY, CONSTITUENT DOCUMENT, REGISTRATION NUMBER] hereinafter referred to as "the User"; represented by [NAME, DOCUMENT] producing authorisation to act on behalf on the User, based on the document [REFERENCES TO THE DOCUMENTATION OF INCORPORATION DOCUMENTS AND AUTHORISATION];

and [INSTITUTE], having its principal place of business at []; [TYPE OF LEGAL ENTITY, CONSTITUENT DOCUMENT, REGISTRATION NUMBER], hereinafter referred to as "the User"; represented by [NAME, DOCUMENT] producing authorisation to act on behalf on the User, based on the document [REFERENCES TO THE DOCUMENTATION OF INCORPORATION DOCUMENTS AND AUTHORISATION].

### 3. Core questions to adapt the clause to special situations

One special observation for this clause, which is not unusual in an ABS contract, is that there is more than one party on either the user or provider side. Entering into a contract with more than one party on the user side, raises questions regarding the legal relationship between the users and their respective responsibilities vis-a-vis the provider. This will make the rest of the contract more complex. Each clause must then be thought through with a view to how the obligations take into account their respective obligations. One question is whether they will be individually or jointly and severally responsible for any obligations.

The following clauses in this tool have been drafted assuming that there is one party on the user side, meaning that this additional level of complexity associated with having more than one party is not accounted for. Based on the information above, several questions need to be clarified:

- Does the research institute or university have the legal capacity to bind itself to a private law contract?
- Who can sign on behalf of the research institute? This may not be an easy question to answer. The company documents will state who can sign on its behalf. For a public research institute this is not as clear-cut.
- Find out what kind of entity the user is. The name of the institution does not always disclose the types of activities undertaken by the institution. Even if the name is 'research institute' the work carried out can be highly commercial and often scientific institutions have a broad patent portfolio. Institutions can also have dual commercial and non-commercial mandates. Researchers in public universities working in biochemistry or medicinal fields are also often affiliated or are even owners of private companies, which are not necessarily linked to their affiliated university. In these cases, the obligations on these private companies have to be specified in the contract.
- In corporation law, the type of the company is often described by an abbreviation. One example is the German "GmbH" or English "limited", which refers to a company with limited responsible capital and a specific way of organizing its responsibilities. Such abbreviations are associated with a number of rules in corporate law of the home country, where the company was incorporated. The legal consequences arising from these different types of companies vary among countries as corporate law is not harmonised. The company type may have implications for what they can do to fulfil a contract, including decision-making structures. This means that understanding the type of company being party to the contract are contracting with is a core issue.
- What is the link between the research institute and commercial actors? A possible tip is to find out about the university's patenting practices, which may indicate that there are relationships between the research institute and commercially oriented entities. The funding scheme of the research activities enabled by the ABS contract is important to understand its potential commercial results.

## 3 Relationship to (research) project funding

### 1. Rationale behind including clauses about funding

Research institutions and universities are typically funded by third party entities. It is rather rare that research funding is only provided through the core budget of a university or research institute. More often than not, the funding agency is either a company, a development agency or a research funding agency. Any research funding scheme needs to be reflected in the contract, since it not only influences the motivations for the project but also has bearing on how the final results may be used and exploited. Therefore, the funding which enables an ABS contract is useful information in the negotiation and needs to be reflected in the drafting of the contract. Consequently, ABS contract clauses need to take into account how resources and any results generated from their utilisation will be used beyond the given research project.

In cases where the funding is provided by a **development aid agency**, the logical motivation would be to provide promote the development objectives and aspirations of the country but this may not necessarily be the motivation of all users involved. This needs to be taken into account in the contract and will be of importance for allocating property rights covering the research results to the country providing samples.

For a project funded by a **research agency**, the logical motivation is scientific interest. Often, scientific institutions emphasise their non-commercial interest in a project. A user with no stated commercial interest in the material accessed should not be concerned about waiving any potential property rights arising from the research. Countries are increasingly focusing their research funds towards resolving problems for society by providing new products and services to the public. Research funding agencies often impose reporting requirements on the nature and number of patents sought and acquired on the basis of the research results. Public research institutions may have offices specialised in obtaining patents over new inventions developed at these institutions, e.g. a Technology Transfer Office. In 1980 the United States of America had an important shift in public policy regarding public funded research by the introduction of the Bayh-Dole Act. The Act provides conditions upon which inventions arising or resulting from US federal funding can be commercialised. The act imposes an obligation on researchers to disclose in the patent that the invention is subject to limited right by the US government requiring a worldwide, non-exclusive license. In 2018 changes in the Act made the rights of the US government in such inventions stronger.

For these reasons, it should not be assumed that an scientific institution only has non-commercial intention. Therefore, an ABS contract without an immediate commercial purpose needs to account for potential property rights and scenarios for commercialisation. In situations where a researcher only states non-commercial intentions, the logical consequence is that the researcher should be open to leaving full ownership or complete property rights over any research results to the provider. This would put the provider in a stronger position with respect to potential commercialisation.

In the case where a **company is funding** the project at a non-commercial scientific institution, the contract needs to be drafted like a commercial contract, even if the entity carrying out the research directly has limited commercial interest in the research results. Typically, when funding comes from private sources, there is a very high likelihood that the results from the activity will end up being used for commercial purposes and applications.

Generally, it is good to require that a copy of the funding agreement for the project is included as part of the ABS contract. This will contain important information relevant to the contract.

## 2. Example of contract language to build in the research project behind the access

The four alternative situations described above need to be reflected in the wording of the contract clauses.

> The Contract concerns aspects that are central to the implementation of the [development aid project/ research project/ assignment research project/ with 'in kind' funding from the research institution XXX]. The Contract also regulates aspects concerning subsequent research or research results enabled by this Project, included but not limited to any product or process enabled by the Project or Contract.
>
> [Quote the objective of the Project].
> [The implications from the objectives of the Project for [the Provider country and/or indigenous peoples or local communities] shall be formulated as part of the next article which spells out the deliverables that will be beneficial to the Government of [Provider country] as a result of this project.]
>
> Insofar as samples, material, information or knowledge are explored or used for any other purpose than specified or allowed in the Contract, the User, as a consequence of the breach, shall pay [Provider country] [and/or each of the participants involved in the collection of samples] a fixed sum of [US XX,XXX] and such uses shall trigger the same obligation as covered by this Contract.

## 3. Core questions to adapt the clause to special situations

Generally, the contract should include terms and conditions governing the grant, which should be clearly reflected in the operative clauses of the contract. This will ensure that the interests of the provider country are taken into account and that the contract is in line with the broader objectives and aspirations underlying the project. Translating the research objectives of the project into specific obligations in the contract makes it easier to foresee and provide for potential commercialisation scenarios.

Experience has shown that in a case of no immediate commercial application the research institution will often advocate that its obligations should end when the project-funding cycle ends. This is not recommended as benefits (monetary and non-monetary) usually occur beyond the lifetime of the funded project. Obligations need to follow the path of value-creation from the point of time when the material is provided until it is used to its full potential.

## 4 Deliverable from the funding project to the provider country

### 1. Rationale behind including the funding project

Research projects funded through development aid typically involve the transfer of equipment, materials or other non-monetary benefits. Both research or development aid projects specify what the expected research results, deliverables to the provider country and outcomes from the project will be in the project description. The rational for including this in the contract is to make these benefits binding for the parties to the contract.

### 2. Example of contract language

The deliverables to the [Provider country] from the funding project, are as follows:

- [INCLUDE ANY NECESSARY INFORMATION REGARDING THE GOALS OF THE CONTRACT SHALL ACHIEVE.]

[Could be the quantifiable deliverables.] This Contract implements the [reference to the funding project] Project which aims at developing including but not limited to [list them] or other results enabled by this Contract.

### 3. Core questions to adapt the clause to special situations

From the provider perspective, it is important to specify what the country expects to get as an outcome out of the project. Including this as an obligation in the contract will require the user to deliver and carry out its activities in line with the stated expectations of the provider country. As the contract should not only be limited to the results described, it should use the wording "including but not limited to […] or any other results enabled by this contract or project.

From the perspective of the provider country, it is a good idea to establish a priority list of non-monetary benefits that may be obtained, e.g. technology transfer, capacity building support etc. and their strategic impact on the technological and developmental situation of the country. It is important to understand the development and technological needs of the country and see how benefit-sharing can contribute.

## 5 Non-monetary benefit-sharing arrangements

### 1. Rationale behind the clause

There is a choice between obtaining benefits upfront or waiting for other benefits that arise further down the line, if the process reaches the development and production stage. The provider must determine what can realistically be obtained in terms of benefits at the time of access. Strategically, the provider might insist that the initial research on the biological samples is done in the provider country rather than sending samples out of the country.

Benefit-sharing or payment arrangements should be included in the contract and these should be made legally binding and enforceable on the user from the earliest point possible. How the contractual obligations are worded will depend on the concrete situation and types of benefits that the user commits to share. The wording in the contract must be as a clear, precise, and as specific as possible. Choosing wording such as "fair and equitable" or other terms that are open to subjective interpretation, such as "reasonable", will not create a binding obligation on the user. Subjective references will ultimately dilute what ought to be a binding obligation, making it vague and unenforceable.

Obligations in relation to providing training as part of a benefit-sharing arrangement need to be detailed, e.g. the amount and duration of trainings, responsibility for expenditures (including travel costs, housing or scholarships) of the participant(s), and preferably specifying the host institution. The qualifications the participants will obtain by attending this training must also be specified in detail.

Provider countries can set strategic priorities, such as building up institutional and technological capacities. A provider country may insist that each partner to the ABS contract provides either top-of-the-range equipment for a laboratory or equipment adapted to local needs, which can support the sustainable use or conservation of the resource. Equipment needs to be specified in terms of quantity and quality, preferably the specific model and capacity.

In situations where the relevant project received a grant from another institution, the fixed sums corresponding to the project grant should be specified. From the provider perspective, it is important to ensure that the applicable obligations of the user are fulfilled before any samples are taken out of the jurisdiction. Other clauses might stipulate that the provider will only provide access in exchange for a promise of later payments. Therefore, the provider should, where possible, seek to obtain more immediate non-monetary contributions upfront. The contract should, in any case, specify clear time limits for the fulfillment of these obligations and consider tailor-made remedies to deal with cases of non-compliance.

### 2. Example of contract language

**Non-monetary technology transfer and capacity building**

The Users shall undertake the following technology transfer: [XXX]

[Define the relevant technology upon which access is sought].

The rationale for sending material out of [Provider country] is that there is no capacity for the laboratory [describe in detail how this contract obliges the User to contribute to build capacity in the Provider country].

The User shall organise, fund, and supervise [FIXED NUMBER] Master degree students (a twelve-month program at [institution]) and [FIXED NUMBER] PhD students (xx-month program at [INSTITUTION]). Participants shall be selected on the basis of [describe a procedure or criteria]. The User shall cover all expenditures, travel, stay and [FIXED LUMP SUM FOR LIVING EXPENSES], set at a fixed rate to [XXX US] which shall be paid [PROCEDURES]. [SPECIFY ANY OTHER OBLIGATION ON THE PARTICIPANTS.]
The User shall within the limits of the funds available under the Project [specify the fixed sum allocated to the Provider in the Project], support the establishment of the following facilities at [PROVIDER COUNTRY INSTITUTION]: [SPECIFY THE CONCRET DELIVERABLES.]

The following provides a list of deliverables that could be listed to ensure that concrete obligations are specified. This is, however, with the understanding that the actual obligations in an individual ABS contract will depend upon specific circumstances of each individual case.

- Cryopreservation facilities – to enable [the institution] to start its own cryo bank. The facilities shall be model [DETAILS ON THE MODEL]. The facilities shall be installed and functioning as of [PRECISE DATE].
- Greenhouse facilities [SPECIFIC CAPACITY AND SIZE]. The facilities shall be installed and functioning [PRECISE DATE].
- Solar power producing [XXX] Watt and battery with the capacity [XXX]. The facilities shall be installed and functioning [PRECISE DATE].
- The User shall provide training of [FIXED NUMBER OF STAFF] for maintenance. Training shall be finalised at the latest 6 months after the respective date the Provider has approved for the installation and functionality.
- The User shall cover any maintenance costs for [A FIXED NUMBERS OF YEARS] years.

### 3. Core questions for adaptation of the clause to special situations

When drafting this clause, the challenge is how to get the most comprehensive contribution from the user. This is a question of negotiation, which is not covered here.

Studies of past ABS agreements have shown that contract language in relation to these obligations has often been vague and not precise enough. The consequence of not establishing clear, precise, and detailed obligations is that these important elements of the contract can ultimately be interpreted as voluntary commitments and not binding obligations in so far as the user is concerned.

# II. ABOUT THE MATERIAL TRANSFERRED UNDER THE CONTRACT

## 6 Specifying the material transferred – identifying what is accessed

### 1. Rationale behind the clause

The description of the subject matter, which is transferred according to the ABS contract, is at the core of establishing the rights of the user and the obligations of the provider. The subject matter in the wording of the CBD and NP is 'genetic resources', as defined in Art. 2.

There are mainly two ways to describe what the user gets from the provider: 1) The contract itself can stipulate the samples and material accessed; 2) the contract can establish a system for the provider country to approve each shipment of samples that are collected during the project period.

In the situation where soil or water is collected for a later determination of the organisms contained therein, the contract has to reflect this and include later isolated organisms as part the subject matter of the contract. When water or soil is exchanged with the material other organism in those elements may be identified and can as such be subject matter under the contract.

The contract can specify how the samples shall be exported, e.g., live whole organisms, parts of an organism, ready-made assays (a technical manner to prepare biological material for testing), screened genomes or synthesised molecules. The manner in which samples are taken have implication on the types of uses that can be undertaken. If the sample is capable of reproduction at the time of access, the user can be expected to use the material in breeding or cultivation. The contract needs to reflect the biology of the

material: plants can often be biologically reproduced given access to a seed. Live animals, when accessing both females and males, allows for establishing a breeding nucleus. Semen, eggs or embryos of animals may also allow for reproduction and breeding. Micro-organisms can be reproduced easily. When these types of samples are exchanged, contractual obligations must take these biological properties into account when regulating the rights and obligations. One of the most difficult technical issues in ABS is how to trace products back to the original material. Bar coding can be an effective manner to track the material. Specification of the samples in the contract and the duplicate in an *ex situ* collections are both measures to improve traceability.

What does not need to be as specified in detail in the contract is the way in which the samples are to be collected. Since the ABS system of most of countries stipulates that both a contract and a permit, the permit or its equivalent can set the methodologies, procedures and requirements for the sampling and handling of the material in the provider country.

Wording in previous ABS agreements reviewed by the author have failed to adequately address remedies in the case of breach of obligation.

### 2. Example of contract language

#### Describing the biological samples or material

The Users are authorised to collect and export accessions of
- [XXX Describe in quantities and qualities the accessed material]
- [Quantities of the] [type of biological sample living or processes?]

All samples provided for the Project under this Contract (the "materials") shall be listed in Annex 1, which shall include the name and amount of the materials, and the Party providing these materials (the "Provider").

Organisms transferred in soil or water are subject matter of this Contract also in the case when they are not listed in Annex 1.

In the case where no physical material or samples are being exchanged, Annex 1 shall indicate "none" and specify the databases and reference number identifying where to find digital sequence data.[8]

8 This clause was inspired by Art 4.1, in Corporate Research Agreement, of March 13, 2018, https://www.lawinsider.com/contracts/4FzpMt56ZUb1pYZ4T3p6fN/american-alliance/1016708/2018-03-13.

As mentioned above, a more flexible manner of listing the materials accessed under the contract is to include the material in an annex. When several different species and sub-groups are to be collected, a table describing the material is a good way to proceed.

| *Scientific* and common names | Part of samples or material to be utilised | Physical state of resource | Quantity | Justification for export/ justification for amount collected | Locality / source information (coordinates) |
|---|---|---|---|---|---|
| Name in local language(s)<br>Name official language(s)<br>*Latin name* | | | | | |

### 3. Core questions when adapting the clause

Questions of which the parties must be aware when drafting the contract:

- Should the contract include legal mechanisms for access to new samples under the same contract? Or should any new samples rather be regulated by a new contract? The latter would allow the provider country to learn from its experiences from the first contract and possibly adjust when new samples are required.
- Is the chosen and specific remedy applicable for all types of breach? How can the contract establish remedies that can be easily enforced in the case of breach of contract? Since it is almost impossible to determine in economic terms what the "full compensation for the harm sustained" would be, the remedy clause should as much as possible be formulated to include a standardised amount. The amount, if too low, will not provide strong incentives to comply with the contract.

## 7 Sampling beyond the allowed

### 1. Rationale behind the clause

Collection of samples happens in another country often governed by the permit in the provider country. Since the permission will not be enforceable in the user country jurisdiction, the contract can make this obligation valid and enforceable.

### 2. Example of contract language

**Consequences of sampling beyond the described**

In the case the User has sampled biological material different from the one described in any permit, or different from any permission which has been granted; or in larger amounts than agreed, or in any other divergent manner according to the permit or contract, the User shall be liable for damages in the form of compensation to [Provider country] or any other entity in the Provider country which has suffered a loss from any such act.

### 3. Core questions when adapting the clause

The most important part in this section is that the contract can set rules on the enforcement regarding activities that are not those prescribed in the permit or contract.

## 8 Unintentionally collected material

### 1. Rationale behind the clause

When sampling often the main samples carries along other organisms than those described as intentionally collected. Often the valuable material is a microorganisms in, on or together with the material collected. Typically this is material that is carried in the water, soil or air that follow with the samples. The rational is to ensure that the contract obligations cover and apply equally to any unintentionally collected material.

### 2. Example of contract language

**Unintentionally collected material**

The obligations under the Contract apply equally to material collected or used unintentionally. Unintentionally collected material includes, but is not limited to, microorganisms or any other organism (symbionts, pathogens, parasites or alike or different) in or on the samples, in soil or water collected with the samples or otherwise. The User shall, without any delay, notify the Provider when any such material is identified.

### 3. Core questions when adapting the clause

The core issue to be alert is not to make this obligation narrower so interesting unintentionally collected material is covered by the obligations.

## 9 Responsibility for the state of the material

### 1. Rationale behind the clause

Research and development are often costly and time-consuming. ABS agreements have often included a clause, which stipulates that the provider cannot be held liable for the state of the accessed material. Although not perhaps entirely necessary, such clauses are meant to safeguard the interest of the provider. The second element in this safeguard for the provider refers to the supply chain and a new requirement for more of the same material. The third element of this safeguard places the risk for the research and development clearly with the user.

### 2. Example of contract language

**State of materials**

The Provider shall not be held responsible for the quality, availability, purity (genetic or other) or any other aspect of the material being accessed by the User. The User shall not have any claims against the Provider, its trustees, officers, employees and agents, in regard to sampling, acquisition, use, storage, disposal or alike of the materials.[9]

The Provider is not obliged to or responsible for providing a larger quantity of the same or similar material upon the request of the User.

The Provider assumes no responsibility for the outcome of research and development, nor responsibility if the material lacks the desired properties or characteristics that the User seeks to identify and use.

9 This clause was inspired by Art 4.3, in Corporate Research Agreement, of March 13, 2018, https://www.lawinsider.com/contracts/4FzpMt56ZUb1pYZ4T3p6fN/american-alliance/1016708/2018-03-13.

### 3. Core questions to adapt the clause to special situations

The main question the provider must clarify is whether there are features of the material other than those mentioned in the example above, where the liability of the provider country needs to be limited.

## 10 Obligation to maintain samples

### 1. Rationale behind maintaining samples

Maintaining duplicates of the samples and material in the provider country serves several functions. First, it can contribute to conservation (*ex situ*). Second, the material will be made available for research potentially also for other researchers. Maintaining a sample in *ex situ* collection is particularly important when the ABS contract has no immediate and declared commercial objective. Retaining the samples can promote research and development by others. Third, by maintaining samples allows the provider country to keep copies of the material that can be used as reference or for tracking purposes, if any questions about the contract arise. Most MATs in the past required that the user destroys the samples after research. This is not necessary when the research has been concluded and value already created.

### 2. Example of contract language

#### Obligation to maintain samples

The Parties recognise the value of conserving samples for future research and development and their value in long-term research.

The User shall take all actions to store the samples at an institution in [the Provider Country] [or in a collection outside the Provider Country which can safeguard the resources].

For each live specimen of an organism sampled, the User shall deposit the DNA of any samples in the collection [NAME OF THE INSTITUTION] in the Provider country. If it is technically impossible to deposit a copy, a tissue or another non-vital part of any kind, the sample, shall be deposited in the collection [NAME OF THE INSITUTION] in the Provider country.

The samples or any related information or knowledge shall not be made available to any person or any legal person, without the consent of the Provider country and the conclusion of a new contract.

### 3. Core questions to adapt the clause to special situations

The drafter of the contract needs to consider the ability of the provider country to store the samples. Asking for the user to improve storage capacities of the provider country could be a type of a non-monetary benefit-sharing arrangement.

One topic to be aware of is that if these samples are stored in a private institution or service provider the collection needs to be bound by clauses that respects the rights of the provider country. One question which has been raised in some practical situations is whether the collection or service provider should become part of this contract too. An alternative is that there is a specific contract for the relationship between the collection and the provider country.

## 11 Establishing contractual responsibility for collecting material in nature

### 1. Rationale behind the clause

Collection of material in the wild is typical and should preferably be in part regulated in an access permit. The consequences of breach of the terms and conditions for the collection should be made into a breach of the contract. The reason is that it is impossible to regulate all obligations in a permit, hence the need to include all obligations in a contract to make them legally binding and enforceable. This will enable the provider to enforce such breaches even after the user has left its jurisdiction. There are several situations where this can be useful: Where the user does not follow the conditions of collection in the permit or causes environmental damages. Placing the remedies in the contract improves the enforcement ability compared to only stipulating consequences of breach in terms and conditions governing the permit.

### 2. Example of contract language

#### Conditions for collecting material in [Provider country]

All collection shall be done/conducted by the User [CONSIDER A MORE SPECIFIC DESCRIPTION] accompanied by the [RELEVANT INSTITUTIONS] officials designated by the [RELEVANT NATIONAL AUTHORITY].

The User shall have access to the collection site for a period of [SPECIFY TIMELIMIT] from the [SET THE DATES]. In the case where the User violates or deviates without consent from the rules regarding the collection, sampling or

handling of the samples stipulated in this Article this shall be considered a breach of this Contract.

The Provider shall be fully compensated for any ecological, biological or similar harm, including any economic or non-economic loss suffered by indigenous peoples or local communities. The loss shall be calculated as follows: [INCLUDE A METHODOLOGY FOR CALCULATION].

### 3. Core questions to adapt the clause to special situations

The crucial question for the provider country is how to establish obligations in the contract for actions taken while collecting wild material and/or undertaking other activities in the provider country.

## 12 Specifying who is authorized to handle the material

### 1. Rationale behind defining authorized persons

ABS contracts can specify that the material exchanged ought to be used in one project. In that situation, the provider safeguards its interests by including a list of legal and natural persons (institutions or individuals) authorised to use the material. The list of authorised persons may be only expanded subject to notification and subsequent authorisation by the provider. For research funded by a research funding agency or development aid funds, the project application normally lists and describes affiliated individuals, including their roles in the funded project due to the requirement of the funding agency. This requirement is not burdensome on the user and it helps provide clarity for the provider country.

### 2. Example of contract language

The User shall authorise the individuals who are carrying out the activities on their behalf under this Contract by listing their names, passport number [social security number] in an annex to this Contract.

Additional names or any amendments shall be made only under the authorisation of the Provider, at the e-mail address: [Include an email account and other contact details in the Provider country for notifications under the Contract that can be accessed by all the persons involved in contract aspects.]

### 3. Core questions to adapt the clause to special situations

While drafting the contract, one issue to be aware of is the mechanism for involving additional authorised persons in activities covered by the contract so as to create binding and enforceable obligations upon all authorised persons that are identified in the contract. This will be essential to avoid any ambiguity as to who should discharge obligations in relation to specific activities covered by the contract.

# III. PROPERTY RIGHT ASPECTS

## 13 How to define biological material into written subject matters of contractual obligations

### 1. Rationale behind the clause

The description of the subject matter, which is transferred according to the ABS contract, is at the core of establishing the respective rights and obligations that are incumbent to both the provider and the user.

When writing a contract the parties are not bound by the definitions in the CBD. Definitions and wording in a contract should be tailormade with precision to the particular situation that is being regulated. In particular, the subject matter transferred through the contract needs to be defined with precision.

The subject matter in the wording of the CBD and NP is 'genetic resources', as defined in Art. 2. This term does not provide the specificity or certainty required by a contract, as they are different interpretation of what the term means and what is applies to. There are longstanding and divergent views on whether or not digital sequences data are covered by this term, which further shows disagreement in its interpretation. A contract cannot use such imprecise terminology and be expected to create binding and enforceable obligations on the user.[10] The fundamental assessment is whether the subject matter of the contract can be understood by everyone. The challenge is to formulate the definition so specific

10 Tvedt, M. W. and P. J. Schei (2014). The Term 'Genetic Resources': Flexible and Dynamic while Providing Legal Certainty. Global Governance of Genetic Resources. S. Oberthür and K. G. Rosendal. London, Routledge: 18-32; Tvedt, M. W. (2013). "Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sectors." Law, Environment and Development Journal 9(2): 129-140; and, Young, T. R. and M. W. Tvedt (2017). Drafting Successful Access and Benefit-sharing Contracts. Leiden, Brill Nijhoff.

and self-explaining that it makes sense for both biologists and lawyers.

Applying definitions contained in international treaties and conventions will create ambiguities as these will be open to various interpretations. This is not a sound way to draft a contract.

Wording in previous ABS agreements reviewed by the author have failed to adequately address remedies in the case of breach of obligation. The following clause provides an example of a remedy that can be envisaged to address a breach of a substantive obligation.

A contract shall provide the two parties with absolute certainty to know precisely the content of the knowledge. This can only be achieved if the subject matter is defined crystal clear leaving no room of interpretation. The definition is the point of departure for the drafting of the substantive obligations concerning property rights and benefit-sharing obligations. As substantive obligations can only be functional if one kwon with certainty the subject matter to which the obligation is connected clarity on this point is crucial.

## 2. Example of contract language dependent on the type of organism

### Specifying the aspects concerning the plant samples into subject matters of obligations

A plant sample [includes/covers/reaches on to] any seeds or propagating or multiplication material of any kind.

A plant sample includes/covers any part of plant,

a) the vegetative material, including leaves, roots, straw, flowers, fruits, or any other, including but not limited to any extract in any form.
b) any bioactive [elements/compounds] or organic composition [molecules, amino acids, proteins, lipids, glucides, enzymes] or any other bioactive element in or [isolated/generated] from the vegetative material.
c) every sub-cell element/parts, including DNA, RNA, or any other element carrying genetic information.

A sample covers any information in the material, or which is extracted from it by any method, or genetic information in any format, or data generated therefrom, including but not limited to genetic information, biochemical content, or bioactive, or any other information in or extracted or analysed from the samples.
A samples also includes any microorganisms in or on the plant, including but not limited to parasites or pathogens on or in the plant material.

This definition of the subject matter for a plant is drafted to target any and all possible manners in which the biological material, including the genetic and other information, will be used. This means that the definition has to go beyond defining the subject matter for plant in a static and only material format but be sufficiently clear to include other use of dematerialised information associated with the plant.

When the material accessed is of animal origin the manner to construct the subject matter in language needs to be informed by the manner in which the techniques and technologies to which the samples will be utilised.

The definition might need to be adjusted to target of the subsequent use of the accession, this definition will be totally or partly adequate and needs to be adapted.

### Subject matter – animal material

An animal sample [can be] whole animal (living or dead), semen, eggs, embryos, any kind of tissue or alike, including but not limited to any extract in any form.

Any animal sample, tissue or cellular structure covers the entire bioactive elements/compounds or organic composition [molecules, amino acids, proteins, carbohydrates, lipids, glucides, enzymes] or any other bioactive element in or isolated/generated from the material.

It includes every/any sub-cell element/parts, including DNA, RNA, or any other element carrying genetic or other information.

Any animal sample covers/includes any information in the material, or which is extracted from it by any method, or genetic information in any format, or data generated therefrom, including but not limited to genetic information, biochemical content, or bioactive, or any other information in or extracted or analysed from the samples.

A samples also includes/covers any microorganisms or any other organism in or on the animal, including but not limited to parasites or pathogens on or in the animal material.

Animal blood sample or alike [or different] includes any blood component (including but not limited to platelets, red cells, white cells, plasma or other components), microorganisms, including but not limited to parasites, viruses or bacteria or any other element in the sample (being a pathogen or anti-body or alike).

For animals the manner the sample is taken, live animal, blood sample, semen or egg, impacts its potential uses. Therefore, the definition of the material becomes even more important as a fruitful definition for the obligations.

In the discussions and negotiations leading to the Nagoya Protocol one topic was whether pathogens should be exempted from the scope of ABS. There is nothing in the CBD itself justifying such an argument. In the current situation regarding Covid-19 access to and exchange of genetic material necessary to deal with the emergency needs to be rapid. This requirement for a rapid access process does not mean unregulated access. It should rather call for a standard contract that meets the needs both of researchers and of providers. Providers of material from microorganisms are often likely to be the ones most in need for free access to the final product.

### Subject matter – virus, bacteria or fungi

A sample of virus, bacteria or fungi includes the organism itself or parts thereof,

Any sample of virus, bacteria or fungi covers the entire bioactive [elements/compounds] or organic composition [molecules, amino acids, proteins, carbohydrates, lipids, glucides, enzymes] or any other bioactive element in or [isolated/generated] from the material.

It includes every/any sub-cell [element/parts], including DNA, RNA, or any other element carrying genetic or other information.

Any virus, bacteria or fungi sample [covers/includes] any information in the material, or which is extracted from it by any method, or genetic information, or any information about the function of the virus, bacteria or fungi, in any format, or data generated therefrom, including but not limited to genetic information, biochemical content, or bioactive, or any other information in or extracted or analysed from the samples.

### 3. Core questions when adapting the clause

These are some things that parties must be aware of when drafting the contract:

- Is the way in which the material is described accurate enough to really capture the subject matter that is covered under the contract. The example language should be adapted in case of an access request for taxonomic kingdoms not covered here as for example chromista.
- Is the remedy applicable for all types of breach? How can the contract establish remedies that can be easily enforced in the case of breach of contract? Since it is almost impossible to determine in economic terms what the "full compensation for the harm sustained" would be, the remedy clause should be formulated using standard amounts or estimates. The amount, if too low, will not provide strong incentives to comply with the contract.

## 14 Establishing 'ownership', property rights or bundle of rights

It is essential to clarify the question of 'ownership' or 'property rights' or 'use rights' in the contract. The modern view of 'ownership' is that it includes a 'bundle of rights' connected to a material (subject matter), making it more accurate to talk about 'property rights'. This 'bundle of rights' all refer to the subject matter as defined in the previous section, and specify the rights to use and corresponding limitations. This 'bundle of rights' should also describe what property rights will remain with the provider country.

The question of 'ownership' or 'property rights' is different from that of 'sovereign rights' as set out in the CBD Art. 15 and Nagoya Protocol. 'Sovereign rights' confers a legal status in international law and guides development of domestic legislation. These 'sovereign rights' under the CBD and the Nagoya Protocol squarely refers to the right of a country to provide access to their natural resources. Ownership, on the other hand, is normally regarded as a private law concept inside the jurisdiction of a country. To put it briefly, States apply their sovereign rights to regulate inter alia the question of ownership or property rights. The CBD and Nagoya Protocol do not give any guidance on the question of ownership or property rights.

An ABS contract needs to specifically describe each right that the provider confers to the user in relation to the material or samples. This could include the right to use the material in research, product development and commercial processes. The contract should be drafted to specify how various rights are regulated and what remedies will be triggered in the event that any of the obligations is breached.

The question of how to regulate 'ownership' or property rights is one of the topics, which is likely to cause disagreement in contract negotiations. Especially commercial users will want the contract to give them unlimited rights to the material, including commercialisation and protection of their investment in research, time and money. In other instances Users also ask for co-ownership. Where they are willing to give ownership to the provider on the genetic material but would propose co-ownership on the genetic infor-

mation and value addition. Retaining the ownership of genetic information is only useful to the provider if the provider can make something out of it, typically retaining property rights will give the proves a stronger negotiation position later. However, if the provider can claim co-ownership with the outcome of the research and whatever the user will do with the genetic information in future it might be a win-win situation.

There are examples in practice where a university has performed research on material on behalf of a company. Even in a situation where the university declared no immediate commercial interests or purpose, the company may have a commercial interest in these research results. Therefore, in a contract where there is no declared commercial interest, the situation involving interesting potential commercial findings needs to be anticipated and regulated in the contract..11 It is typical for businesses funding research at public universities to acquire property rights over the samples and results from the research related to them. From a provider country perspective, however, retaining ownership and property rights is crucial as it maintains its legal position to use any outcome of the research.

The question of property rights is also linked to whether the (first) user shall enjoy an exclusive right to do research on the material, or whether the provider will wish to keep open the possibility that access to the same material will be allowed for competing researchers and companies. For a provider country, the transfer of 'property rights' to the material or the granting of a 'right of use' is a core policy question. Regardless of whether ownership or property rights to genetic material has been clarified in the ABS legislation of the provider country, the contract must provide clarity regarding the property rights it transfers or retains to the samples and any results from their use.

## 14.1 Property rights in situations without no immediate declared commercial purpose

### 1. Rationale behind the clause

If a researcher has no intention to commercialise any outcomes of the research, there is absolutely no reason for the provider to transfer any property rights. In this case, the user should logically have no objection to the property rights over research results being retained by the provider country.

Universities and research institutions have often had difficulties accepting that property rights of the material remain with the provider country. In some cases, this has even been the barrier that has prevented parties from entering into a contract. It is somewhat contradictory that a scientific institution, with purely non-commercial interest, would refuse to accept that the provider should maintain its rights over the material and any commercially valuable research result or findings arising from its use. Claiming property rights for the university is only relevant when the research results have potential commercial value.12

Many early ABS agreements prohibited commercial use, stating that the user must come back to the provider and negotiate new terms and conditions for commercialisation. From a contract law perspective, this is not functional for the following reasons:

- The user has no strong incentive to come back and negotiate such a new contract . The strongest clause can oblige the user to initiate negotiations but cannot compel the user to agree to anything. A party cannot be forced to sign a contract as this would render the contract void.
- The respective negotiation positions are different from those of the original contract. The bargaining position is also different from the time of access. The user possesses and holds the research results, putting it in a stronger position.
- A clause obliging the user to initiate new negotiations cannot be enforced by a court.
- It is difficult to prohibit commercialisation of a product or a process. An additional weakness is that the agreements often do not provide for legal clarity on what is commercial or non-commercial.
- Going to court to prohibit certain actions is also counter-productive with regard to getting products to the market. It is better to opt for a percentage of the sales of a successful potential product or process rather than to prohibit commercial use.
- One reason why ABS agreements have often postponed obligations in relation to commercialisation could be explained by the fear to be bound by certain obligations early in the process and rather wait and keep options open for future negotiations. This fear is often based on uncertainty and lack of predictability as to what the product or process might look like on the market. Including detailed rules in the initial contract is the only viable solution. If contract clauses are drafted *specifically but not narrowly*, they will be able to cover outcomes of commercialisation that may be at first sight difficulty to predict.

From the perspective of the provider, the initial non-commercial contract needs to regulate any potential commercial scenarios and applications. This means that for several scientific users, there will

11 Art 4.2, in Corporate Research Agreement, of March 13, 2018, https://www.lawinsider.com/contracts/4FzpMt56ZUb1pYZ4T3p6fN/american-alliance/1016708/2018-03-13: "All Materials shall remain the property of the Provider and will be used by the receiving party (the "Recipient") solely for the Project."

12 It is interesting to observe that Kew Garden in London, UK, has a comprehensive clause retaining 'ownership' to the material in their collection:
"All Kew Materials are the exclusive property of Kew and Kew shall retain all Intellectual Property Rights in the Kew Materials, any amendments or improvements to and anything derived from, the Kew Materials."https://tinyurl.com/3ed4m8as

be clauses in the contract that will never be triggered, as the commercial phase would in principle never occur or materialise. This approach is not uncommon. In any standard contract for computer programs, there are many clauses that are binding but do not have any real impact on the user of the software.

A research project is often defined and rolled out according to certain milestones that need to be attained in its implementation, e.g. determination of a biochemical structure, a DNA sequence, publishing a publication, applying for a patent etc. and that reaching each of them has certain contractual consequences. A contract may specify more milestones than are foreseen by the researchers themselves. Clauses in a contract should be linked to these milestones. If milestones are not foreseen and therefore not attained or realised in the research project but are nonetheless regulated by the contract, the only non-onerous consequence for the researcher is that the contract will contain additional language, which will be relevant and which will have no legal effect or implication for the researcher as regard to his project.

Taking into account future and commercialisation scenarios in a contract can also reduce bureaucracy for universities as they will not need to renegotiate exiting contracts. These clauses are of crucial importance when users without no declared immediate commercial plans go beyond producing merely scientific results. Some scientific institutions even have specialised departments that are dedicated to addressing issues linked to potential commercialisation, such as Technology Transfer Offices (TTOs). These department are often responsible for securing patent rights and licenses that may arise from university's inventions.

The clause on property rights need to relate to the definition of the subject matter in previous chapter. This clause is build up retaining all the subject matters listed in the previous article as under the property rights of the provider. If the contract negotiations lead to the result that one or more of those detailed categories are not covered, the contract needs to specify the limitations in its wording.

## 2. Example of contract language

### Property rights, retention of rights and allocation of rights

The [Provider country] retains the property right in the following subject matters:
[Include here the parts of the definition of the subject matter that the provider retains property rights to.]

This list of subject matters includes the subject matters technically isolated by the Users. The Government of [Provider country] [Any entity with such legally conferred rights according to national acts] retains or is granted ownership or property rights to any other outcome from any activity undertaken by any use of samples or information (including, but not limited to, [THE RELEVANT OUTCOMES FROM THE RESEARCH PROJECT ARE OFTEN POSSIBLE TO READ OUT OF THE PROJECT DESCRIPTION; FOR EXAMPLE: feed protocol, nutrition technology, recipes, types of feed, nutritional requirement of species, rearing protocols or any data or information].)

[Since the Project is [a Scientific Research Project/ Research Project/ Development Aid Project], the overall principle of property rights is that any results from the Project or enabled by the Project (by activities related to the material from [Provider Country] or any results there from) belong to [Provider Country].]

Research results enabled by any use of any of the subject matters mentioned in the previous paragraph are covered by the same property rights for the Provider country.
Research results enabled by any use of any of the subject matters mentioned in the previous paragraph are covered by the same property rights for the Provider country.

## 3. Core questions to adapt the clause

These examples of contract language may sound strict to the user. However, if no commercial uses are foreseen or intended, there is no rationale for the provider to transfer any property rights to the user.

Three questions must be considered in this concrete situation:

- Is the description of the subject matter (material and results) adequately described in terms of claims of property rights?
- Are there any additional rights that need to be specifically regulated?
- Which remedies are adequate for this contractual obligation?

If the situation in the country is so that other persons than the State have the property rights over the samples or the 'genetic resources' there might be room for drafting terms and conditions in relation to property rights in this clause differently and should be revised accordingly.

When a contract gives limited rights to the samples to a party being a foreign user, the general legal situation inside the jurisdiction in the provider country continues. A contract will not alter the existing property rights according to more general sources of law.

# IV. ABOUT THE USE AND BENEFIT-SHARING OBLIGATIONS THEREFROM

## 15 The most important right of the bundle – free use of any result

### 1. Rationale behind

In many situations, the most valuable right is for the provider to have an unconditional right to the research results and any commercial or non-commercial use and application of them. Access to research results together with the right to use them for commercial or societal purposes is probably the most valuable non-monetary benefit-sharing arrangement. Many contracts fail to include this essential clause. For example, if a pathogen is taken from a country, there is a good chance that that this pathogen causes more damage in that given country than elsewhere. For the provider country, free or low-cost access to any research results or product or processed developed based on these biological samples would be one of the most valuable benefits. Giving out samples for research without a clause requiring this type of free or low.cost access to any product or process that may arise out of the use of the samples would give away a very valuable non-monetary benefit.

### 2. Example of contract language

#### Unconditional use-right

[The Provider Country] has an unconditional right, without any charge, to experimental, commercial or developmental use of any result, product or process enabled by the samples under this Contract.

This right to use exists independently of any intellectual property rights that may be obtained from the use of the samples and includes an unconditional right to non-exclusive licenses for any outcome arising from this Project. Any utilisation of samples including knowledge or results achieved from any activities described in the Project description [the said Project], shall be made available to [the Provider Country] without any charge, whether or not these results are subject to intellectual property rights.

[The property rights of the Government of [the Provider Country] extend and include rights to any diagnostics, treatment or [INSERT ANY PRODUCT FROM THE RESEARCH OF PARTICULAR IMPORTANCE FOR THE PROVIDER] or any vaccine, medicine or any other treatment. The user shall ensure that any vaccines or [medicines or] techniques are made available to the population of [the Provider Country].]

[The User shall make available to the Provider Country any product or process enabled by the subject matter of this Contract or developed as a result from activities that have been made possible under this Contract [from the User's own product chains, or by extending such obligation on any entity that is allowed to use any results, products or processes].

[The User and the Government of [the Provider Country] are jointly and severally liable and obliged to make these products or processes available to the participants who participated in collection under this contract.]

In the event that the User commercialises any product, technology or process derived from/ enabled by the use of the sample or any other outcome of the project without consent of the Provider, the Provider shall be entitled to [XXX]% of the gross turnover of sales or licencing fees generated or received or any other revenue collected.

### 3. Core questions concerning the unlimited use rights

This clause can be expected to cause a lot of discussion in the contract negotiations. At the same time this is a clause that the provider should not accept to leave out.

## 16 Strategic decision-making: Scientific publication or applying for a patent

### 1. Rationale behind the clausen

For an scientific user of genetic material, the research results from any of the above-mentioned activities raise the question of whether to publish the findings in a scientific journal or to hold back on publication until such time as a patent application has been filed. Even though they are funded by government, universities and institutes' performances are often evaluated on their intellectual property portfolios and the number of publications they have in scientific journals. In addition, universities have potential to make money from licensing their patents. Here, the commercial positioning of the scientific institutions becomes visible. Scientific institutions need to balance the often-competing interests of publishing research findings at the earliest possible time with the need to apply and secure patents as soon as possible to protect their exclusivity on the research findings.

From the perspective of a provider country, the strategic interest is mostly different. The provider country will have no immediate interest in scientific publication. The provider might have a strong interest in the use and transformation of its resources into commercially viable products or processes in cases where contracts ensure payment of a fair share of the turnover as well as providing access to the new products or processes. Here, new and interesting perspectives arise. Previous ABS agreements have often prohibited users from applying for a patent or any other intellectual property rights. In terms of monetary gain, a patent is far more valuable than a publication. Thus, the question is whether it is in the interest of provider countries to allow non-commercial research, if the interest of the research institution's sole intention is to publish scientific findings with no stated intention of creating new products or processes? On one hand, one could argue that it is in the general interest of humanity to advance science and progress. Unless a research project gives something back to the provider country, the incentive for the provider country to allow the research being carried out is not strong. This illustrates how the interests of scientific users and providers can differ in relation to the two imperatives: (i) patenting to protect exclusivity and generate benefits from the subsequent exploitation of the patent (ii) publishing research findings to advance the research and innovation objectives of the institutions.

Therefore, the provider should contribute to make the important decision as to whether to publish or apply for patent when any (scientific) research results that are ready to be published are obtained. The rationale for such a procedural saying is even stronger when the contract is weak on the monetary benefit-sharing system.

### 2. Example of contract language

#### Making the decision between publishing or applying for a patent

When the User identifies a research result that is worthy of being published in any form, the User shall immediately, and before any information has been disclosed, write an analysis exploring the commercial potential of the research results. This analysis shall immediately be shared with the [Provider Country]. The Provider shall within 14 days require the Technology Transfer Office (TTO) or alike of the [NAME] university to start the patent application process. Lack of response from the Provider shall be interpreted as not requiring a patent application process to be initiated. Initiating a patent application shall suspend the right of the user to publish, in any manner that can be considered 'prior art' in any patent system until the patent application has got its priority date. This delay of the publication shall not prevent the research to use the findings in activities that will not rendered the results as prior art for purpose of seeking exclusivity through a patent.

The [Provider Country] has an exclusive right to commercialise or make decisions relating to commercialisation relating to any of the subject matters or processes. This includes a right to access and repatriate the samples or biological material, including progeny (regardless of the number of generations or the breeding with other individuals not belonging to the material collected under this contract) or genetic or biological parts thereof or information or knowledge at any location at any time, without any benefit-sharing obligations from the Provider to the User.

In the case of publication or oral presentation of the research results or any other product or products covered by this Contract, full acknowledgement is to be given to the source of the samples and research collaboration.

### 3. Core questions to adapt the clause to special situations

The difficult assessment here is considering the potential of the research results to be commercialised in the market. From the point of view of the provider country, one needs to have a clear strategic idea about the use of patents. The provider country must define which institutions are most suitable to undertake this kind of assessment on their behalf. This entails also ensuring that the provider country has the capacity required to follow up on all activities undertaken by the user.

## 17 Publication of research results

### 1. Rationale behind establishing rights to decision-making in publication

ABS contracts that have no immediate disclosed commercial purpose could lead to findings or research results that have commercial potential. Therefore, the decision to publish the results needs to take into account potential commercial interests of the provider country.

### 2. Example of contract language

**Publication or transfer of research results (information sharing)**

One of the core scientific outcomes of research projects is a peer reviewed publication. This Contract does not limit the Users from publishing research results in relation to the Project in peer reviewed scientific publications, subject to the procedures set out in the previous article. Any such publication should be shared with the Provider prior to submission. When published, the Provider shall receive a soft copy and two hard copies of the publications.

In case of publications or oral presentations of the research results or of any other product covered by this Contract, full acknowledgement is to be given to the Provider, the Project enabled by the Contract, and the following clause shall be printed in the publication:

"The government of [Provider Country] has commercial rights or other further use rights in products or processes developed based on the research results in this scientific publication, and any use requires a contract of use with the Government of [Provider Country]."

### 3. Core questions to adapt the clause to special situations

The core issue to be considered here is the need for timely publication versus the legitimate need of the provider country to secure any commercial or other use rights.

## 18 Intellectual property in ABS contracts

### 1. Rationale behind the clause

ABS contracts often mention intellectual property rights and in particular patents in dedicated clauses. This is a core clause since it deals with the relationship between the commercial and non-commercial use of samples.

What has been the practice in past is for ABS contracts regulating situations which do not involve immediate disclosed commercial purpose, was to include clauses stipulating that the user is prohibited to apply for intellectual property rights especially patents. A prohibition on patenting holds no functional and legal effect as regards to patent law application. Contract law and intellectual property law are two distinct bodies of law with distinctive rules governing them. It is impossible to enforce a contract clause that prohibits a user from seeking an intellectual property right. The patent offices have no competence in assessing or rejecting a patent application based on breaches of contract consideration. Thus, a breach of contract will not be recognised by the patent office and it will have no effect in relation to rules and criteria for obtaining patent protection.

What is even more problematic is that such clauses are often formulated as a prohibition to apply for a patent on the 'genetic material accessed'. A user will never apply for a patent on the accessed sample and a patent claim will almost never describe what is understood as a 'genetic resource' according to the definition of the CBD. If the contract prohibits a patent on the genetic resources and the patent claims cover an invention that is deemed not to fall under the definition of this term, this patent application will not constitute a breach of contract. The prohibition could even make it financially beneficial to the user to seek to hide whether a patent has anything to do with the project covered under the contract.

Strategically, trying to prohibit the user from obtaining a patent is probably not going to produce the maximum return on the use of the material.

In cases where the user claims to have no immediate commercial intentions or ambitions, there should be no problem with assigning any commercial rights over the results to the provider. There is a contradiction between asking for access without any immediate commercial purpose and at the same time being firm in claiming property rights to commercialisation. If a 'non-commercial' user objects to the provider being allocated these rights, this should raises the suspicion or alert the provider that the user could indeed be contemplating potential commercial applications or the securing of IPRs. To this effect, it would be advisable for the provider, when negotiating, to secure a clear and detailed right to any unforeseen and unexpected commercially interesting results or IPRs that may arise or be generated out of the project.

The following procedural rule has the potential to secure limited rights for the provider country to the invention protected by a patent. The following example is based on the standard contractual clause used by the U.S. government for inventions developed using public funds in the USA. Publicly funded research in the US is obliged to introduce the following text in the first paragraph in the patent application:

Description
[0001] This application claims the benefit of U.S. Provisional Application No. [research grant application], filed on [date], which is incorporated by reference herein in its entirety. This invention was made with government support. The government has certain rights in the invention.

The purpose of the clause is to make it clear that the US government retains limited rights over the invention. The quotation is a formulation, which is copy-pasted in patent applications, where the U.S. government enjoys this limited right. The idea of this wording is that provider countries could require the same to secure their interests in a patent as the US government does.

## 2. Example of contract language

### Rights to invention leading to a patent

In the event that the User takes any steps towards the commercial use or commercial activities concerning any parts of the subject matter under the Contract, the User shall at any stage of the innovation process involve researchers from the Provider country in a manner such as they qualify as or are recognised as the co-inventors to a patentable invention.

Prior to applying, while writing a patent application, concerning a product or process, method, data or information arising from the use of the material provided, its progeny or genetic or biological parts thereof, information or knowledge that was enabled by the subject matter in this Project, the User shall notify the [Competent National Authority/ National Focal Point] and write an assessment of whether any researchers from the [Provider Country] have contributed to the invention in a manner qualifying to be recognised as a co-inventor in the invention. This assessment done by the User shall be submitted to the Provider in a report before the patent application is sent to any patent office.
The property rights of the government of [Provider Country], as follows from Article XXX, includes a right to 50% of the revenue from the royalty of the gross licensing fees, or sales or any other revenue derived from any patent enabled by the subject matter under this contract.

The [Provider Country] has an unconditional right without any charge, to experimental, commercial or developmental use of any result, product or process enabled by the samples or by this contract, this includes an unconditional right to a non-exclusive license for any use of any invention related to this contract by relevant users in the [Provider Country]. The Users shall issue a use license without any time-limits to any use in [Provider Country]. The [Provider/ Focal Point] has the discretion to determine which users will benefit from a non-exclusive license on a case-by-case basis taking into account the commercial needs of the patent holder.

The User shall not transfer the patent to any persons or any entity outside the Parties to this Contract. [This includes to persons affiliated with XXX but not under the liability or responsibility of XXX.]

In an event of the unauthorised transfer of the patent, the Provider shall automatically be the owner of the patent and retain the right to the patent. [In the event of transfer to the other User under this Contract, this clause applies equally.]

In any patent application on an invention enabled by this Contract, the following text shall be included on the front page and in paragraph 001 in the description of the invention:

"This invention was created in the performance of a [Name of this Contract/ Cooperative Research and Development Contract] with the [National Institutes of [NAME OF THE PARTNER IN THE PROVIDER COUNTRY]. The Government of [Provider country] has rights in this invention, including but not limited to the unconditional right to non-exclusive licenses to use it for domestic purposes. In the event of transfer of this patent, the patent shall become the full property of [Provider Country]".

The User shall provide due recognition to the Provider and make mention of the Provider, as owner of the sample, in any application for an IPRs including patent. In the event that a patent is granted on the bases of the use of the sample, the User commits to cover all/or part of maintained and renewal fees of the acquired patent(s).
[Insert a suitable remedy for breach of this clause.]

## 3. Core questions to adapt the clause to special situations

A first reading of this example clause may appear as imposing a rather strict obligation on the user. This wording of this obligation is justified as the starting point is that the user is engaging without any declared commercial purpose or interest. When following this logic, it should not be problematic for the user to also to accept that the provider retains and is allocated property rights over the resulting inventions. Since we know that many universities and publicly funded projects use patents to protect research results and that many universities have specialised units for applying for patents and licensing them, it becomes clear that even a 'non-commercial' contract must provide legal certainty and clarify intellectual property entitlements. In the event that user does not accept this, the provider should reassess whether the objective really has no commercial immediate purpose.

## 19 Taxonomic research and scientific activities

### 1. Rationale behind the clause

The contract should be as precise as possible in describing research activities. It should also be as precise as possible in describing the obligations triggered by the milestones reached by the user in relation to the use of the material. Special attention needs to be given to remedies in case the material is used for any other purpose than those authorised under the contract. Also for taxonomic research and scientific activities there is need for introducing non-monetary sharing.

### 2. Example of contract language

#### Taxonomic research and scientific activities

The User shall use the living or non-living material exchanged or progeny thereof for non-commercial, scientific research activities. Non-commercial research activities include, but are not limited to, taxonomic phenotypic characterisation and conservation in a method suitable for the material (freezer, cryo or other adequate method). The right to store the material does not extend to preparing an assay that could be made available to others than the User.

At the final stage of each and any of these activities, the User shall share information, records or knowledge with the Provider. In addition to the reporting at the completion of each activity, information shall be shared periodically, in a complete manner on a bi-annual basis where all information, records or knowledge is shared with the provider on 10 July and 10 January.

In the case samples or any parts thereof are deposited in a collection or send to another institution for species identity, the User shall include the retention of the rights to the provider country accepted by the depository agreeing that:

"The government of [Provider country] has commercial rights or other further use rights in relation to this accession and consequently in products or processes developed based on the research results, including those presented in an scientific publication. Any use requires a contract of use with the Government of [Provider country]."

If the case of breach of any of these obligations, the User shall [INSERT A PROPER REMEDY].

### 3. Core questions to adapt the clause

When drafting this section, the text needs to reflect the activities the user plans to conduct on the material. The application for an access permit from the provider country can serve as an important source of information about the user's intentions and which other entities will be involved in the relevant activities. Information provided at the permitting stage should also shed light on which entities which will be involved in the activities. Information about the planned activities can also give a good indication of the kind of outcomes that can be expected from the activities and, more importantly, explain how the provider can obtain benefits generated from the described activities.

There is a close connection between 'conservation' of the samples and third-party exchange. It is common practice, for example, in taxonomic and other types of research to send microbes to public collections for safe storage. If the *researcher* agrees, the sample goes into a pool of accessible microbes and can be transferred to any third-party for use by the *ex situ* collection. In such a situation, a clause guaranteeing that the provider country maintains property rights over the deposited material must be included.

## 20 Aspects related to the biological samples

### 1. Rationale behind regulating aspects of the biological samples

ABS contracts regulate relationships between parties in situations involving the grant of access to biological material. What happens to the samples and offspring down the value chain is a core question for the contract.

### 2. Example of contract language

#### Aspects related to transfer of samples

The User is the one with best insight in the plans and possibilities to know and foresee future use of the samples. Therefore, the User is obliged to inform the Provider of any collaboration with non-commercial or commercial entities that might have an interest in any use or commercialisation of any of the subject matter described in the Contract or subject matter or methods enabled by the Contract.

The first User shall, as part of the Contract, design a flow chart for its project which includes the next steps for any research or development that is either planned or consid-

ered likely with the samples, parts thereof or information or knowledge enabled there from.

As this Contract has no immediate commercial objectives on the side of the User, transfer of the samples or any other of the subject matters under the property rights of the Provider country according to Art. [XXX] holds the potential of realising commercial values enabled by this Contract. The User shall in the event of any such transfer be guided by the property rights of the Provider country, and the following steps shall be followed:

1. The User shall notify the Provider about the intention to transfer;
2. The Provider shall be invited to present a contract for the transfer or allow for the User to secure the interests of the Provider in the contract with the next user;
3. The User shall not transfer any samples or other subject matters before a contract securing the interests of the Provider have been signed.

If the User transfer samples or parts thereof to any individual outside the circle of authorised personnel or individuals is made without the above steps having been followed, it represents a consequential breach of this Contract and the User is liable to pay the Provider a fixed sum of US. [XX,000].

Any false information or any actions considered disloyal shall make the User liable to paying [Provider country] a fixed sum of US [XX,000].

In the event that a new user have concluded a new contract with the Provider country, the conclusion of that contract shall free the User from any responsibility of that successor.

### 3. Core questions to adapt the clause to transfer

The most complex question in ABS contracts is the transfer to next users. The contract has only legally binding effect upon its parties. The User, as the party to the contract, must take care of the interests of the Provider and not those of the next user. The challenge is how to ensure that the actions of the next user are regulated in line with the interests of the Provider. To solve this challenge, the contract must be drafted in a way that any new or additional user would be bound by the same obligations as those incumbent on the initial user. In this way, the obligations of the first user would be transferred and binding to any subsequent user. The first User could then be responsible to uphold the interests of the Provider vis-a-vis the next user, unless of course a new contract has been concluded between the new user and the Provider. This could be concretely given effect by including a clause in the contract that provides that the User will only be free of the responsibility to uphold the interests of the Provider after the Provider has given his consent and authorisation for the new user to engage in any activity.

## 21 Reproduction of living material: breeding or multiplication

### 1. Rationale behind the clause

This clause covers activities that the user can undertake when live material is exchanged. In a situation where the material has the capacity to reproduce, multiplying and/or breeding it needs to be specifically regulated in the contract. For living samples, specifically samples with capacity to multiply, which are brought in part of breeding programs or are reproduced significant biological and biotechnological differences calling for nuancing the contract language in categories: animals, plants, fungi, bacteria and viruses.

### 2. Example of contract language

#### Plant material with ability to be reproduced

The User shall have a right to use plant samples for multiplication and breeding as long as the material is not bred with other plant material.

In a case where samples under this Contract are crossed or bred or used by any other means with plant material not obtained under this Contract the property right to the material extends to any generation.

When using the samples in plant breeding, a full record of the history of crosses or breeding lines of the plant breeding shall be kept and made available to the Provider in bi-annual reports. Full records concerning information or knowledge, included but not limited to the history of crosses or breeding lines,

The User shall after breeding or hybridisation or after application of any other technique or technology share with the Provider the improved crosses or breeding lines or material to be made available for the breeding program or alike in the Provider country.

If the User uses any material or subject matter listed in Art. [XXX] differently than foreseen in this article, the rights of the User under this Contract automatically cease and the obligations continue. The Provider has a right to [INSERT A SUITABLE REMEDY].

### Reproduction of living material of animals

The User shall have a right to establish a breeding program, breeding nucleus, broodstock or alike of the accessed material [reference back to the article where the accessed material is defined] for scientific purposes. This breeding program, breeding nucleus, broodstock or alike shall be kept separate from other specimens, egg, semen or embryos of any species. This scientific use allowed includes a right to breed new generations of live material.

The property rights retained by the Government of the Provider country, as specified in article [XXX], extends to any live samples, brood stock or progeny, their eggs, semen or embryos, as results from breeding, hybridisation or any other techniques.

When using the samples to set up a breeding nucleus, a full pedigree and record of the offspring shall be kept and made available to the provider in bi-annual reports. Full records concerning information or knowledge, included but not limited to pedigrees, nutrition schemes or reports on fertility or growth or disease resistance, shall be kept and shared with the provider on a bi-annual basis.

The User shall after breeding or hybridisation or by any other technique or technology, share the improved breeding line or material, eggs, semen, embryos or live animals to be reintroduced in the breeding program, breeding nucleus, broodstock or alike in the Provider country.

If the User uses any material or subject matter listed in Art. [XXX] differently than foreseen in this article, the rights of the User under this Contract automatically cease and the obligations continue. The Provider has a right to [INSERT A SUITABLE REMEDY].

### Reproduction of living material of bacteria, viruses, or fungi

The User shall have a right to establish a culture or alike of the accessed material [reference back to the article where the accessed material is defined] for scientific purposes. This culture or alike shall be kept separate from other specimens of any species. This scientific use allowed includes a right to cultivate new generations of live material.

The property rights retained by the Government of the Provider country, as specified in article [XXX], extends to any live samples, the culture as such, parts thereof or alike, as results from any techniques or technology of any kind.

When using the samples to set up a culture or alike, a full record of any steps shall be kept and made available to the provider in bi-annual reports. Full records concerning information or knowledge, included but not limited to any observations or tests or alike on the material, shall be kept and shared with the provider on a bi-annual basis.

The User shall after multiplication, breeding or hybridisation or alike by any technique or technology, share the culture, improved line or material to be reintroduced in the Provider country.

If the User uses any material or subject matter listed in Art. [XXX] differently than foreseen in this article, the rights of the User under this Contract automatically cease and the obligations continue. The Provider has a right to [INSERT A SUITABLE REMEDY].

## 3. Core questions to adapt the clause to special situations

The wording of a clause about reproduction of live samples needs to be adapted to plants, animals, bacteria or any other taxonomic group respectively for the purpose of targeting the relevant value chains. This is a type of clause that needs to be drafted or at least adjusted specifically in relation to the relationship between the user and provider. One of the strategic questions here is whether the provider shall have access to information about the breeding.

## 22 Research on bioactive compounds

### 1. Rationale behind the clause

One core activity in bioprospecting is to determine the biochemical properties of material, which can be non-commercial or commercial in nature. This is for instance when characterisation is done by a public scientific institution – with declared non-commercial interest – and than is used by other users with commercial interest. This usually happens through publications but also sometimes by contractual transfer of the results or through research collaboration. When a useful property (or characteristic) has been found, it is a small step to publishing, patenting an invention, or commercialisation. Several industries, e.g. cosmetics, pharmaceutical etc., use biological samples for such testing, although this testing per se may be done without any immediate commercial goal.

A typical next step, after searching for biochemical properties, is to conserve the samples and make them available for testing. This is often done by preparing the samples for testing the material for the purpose of finding interesting properties in the material, as ready-made *assays*. These assays can be investigated in larger collections without needing to access the samples in nature.

One example is Marbank in Norway, which is a state-funded scientific research institution, where collected material is made into such assays. From a research-funding perspective, this promotes the efficient use of investments in research. Obliging the institution to ensure that such assays are made available to others as a condition of receiving the funding hold potential to spur research and lessen the costs of bio-discovery.

The property rights of the Provider in section 12 above, extends to the assays. These property rights ensure the Provider a right to one aspect with high potential commercial value.

### 2. Example of contract language

#### Testing the samples for bioactive compounds

The User has a right to test the samples for bioactive properties. Results from such testing shall be shared with the Provider without any delay. The results from such testing is the property of the Provider country.

The User has the right to use the material to prepare a ready-made assay from the samples. The User has the right to make the samples available in assays, but not to give access to the assays to third parties to this contract. The User shall keep a record of the entities seeking access to the assays from the respective sources. The geographical origin of the biological material in the assay shall not be disclosed to the one who is testing the assay for a bioactive property.

A condition for allowing testing with the assays is that the tester (not party to this Contract) agrees to a contract with the User holding the assay, stating that:

"The Government of [the Provider country] has commercial rights or other further use rights in products or processes developed based on the research results presented in this publication. Any use requires a contract of use with the Government of [the Provider country]."

In the case the tester requests access to the material or more knowledge about the sample in that assay, the User shall facilitate contact and immediately send notice to the owner of the material.

[Insert a suitable payment for using these assays.]

In the event of breach, the User will be liable for damages [INCLUDE A MANNER TO CALCULATE THE LOST ECONOMIC OPORTUNITY].

### 3. Core questions to adapt the clause to special situations

If the assays are to be made available to other users, the contract must regulate the conditions of their use. Making assays from samples collected without any immediate commercial interest is a common approach. When the assays are prepared, it is a small step from 'non-commercial' use to making them commercially available. Therefore, the contract must treat the situation as being commercial.

## 23 Research results from sequencing, screening or scanning – digital sequence information

### 1. Rationale behind the clause

Sequencing, screening, and mapping the genome, generation of genome and protein sequences and related data, and using the data for further research are typical activities conducted with samples of biological material. The information contained in DNA, RNA, proteins, or also other molecules which are constituents of

the samples is transferred into digital format. The use of this digitalised data and information opens a new set of possible applications (or uses) of the biological material, in a dematerialized way.

There are ongoing discussions in various international fora on whether so-called digital sequence information (DSI) falls within the scope of the respective international instruments and whether benefit-sharing rules should apply when accessing and using DSI stored in private and public database. DSI is a topic in various global regimes, the CBD and its Nagoya Protocol, in the Food and Agriculture Organization (FAO) both in its Commission on Genetic Resources for Food and Agriculture (CGRFA) and in the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), in the United Nations Convention of the Law of the Sea (UNCLOS) and its agreement on Biological Diversity Beyond National Jurisdiction (BBNJ), and in the World Health Organization (WHO) negotiating a Pandemic Treaty and a new version of the International Health Regulations. At the COP-15 of the CBD, the decision to negotiate a multilateral approach to benefit-sharing was taken. Also, the agreed text on BBNJ mentions DSI and benefit-sharing.

Currently, there is no internationally agreed definition for the term DSI. It serves as place holder in the negotiations. Based on the outcomes of expert discussions within the CBD[13] and reflections amongst scholars, a certain set of information generated from biological material would certainly qualify as DSI. In general, it is assumed that DSI refers to data and information derived from molecules that are characterised by a sequential structure of a specific set of building blocks. This specific sequence embodies information that triggers defined activities of this molecule in driving and regulating cellular functions. Examples are DNA, RNA, and proteins. Other sequential molecules are for example starch or lignin. But their very monotonous sequence of only one or very few building blocks seems not to embody information that gives these molecules an active role in steering cellular mechanisms. Some scholars advocate to extent the scope of the benefit-sharing discussion in the CBD and other international fora to "natural information (biotic)" meaning any information extracted from biotic sources[14] but this perspective was not taken up by CBD negotiators yet.

Despite this lack of definition and as the issue is still yet to be resolved, the CBD as well as UNCLOS already agreed in December 2022 and March 2023 that a multilateral approach on the sharing of the benefits arising from the use of digital sequence information on genetic resources has the potential to meet some of the criteria identified to arrive to a solution on DSI. The modalities and prospective functioning of this multilateral approach still needs to be negotiated and fleshed out. Important in the context of this ABS Contract Tool is that the DSI-decision of the CBD recognized that national ABS-systems with their rights and obligations following the bilateral approach of the CBD and specified by the Nagoya Protocol are not affected. Countries can still regulate the use of genetic resources including the generation, use and benefit-sharing arising from the use through national legislation and regulation as well through ABS contracts with the users accessing these genetic resources and generating or accessing DSI that is under the control of the country. This would of course not be applicable to DSI that is already stored in databases which do not set terms and conditions related to the use of DSI stored within their purview.

The freedom of contract leaves flexibility for drafting contractual wording that captures property rights and sharing of benefits from these digital subject matters with the provider of the samples. When using the freedom to contract, one must recall that technology progresses at a fast rate. Therefore, contractual obligations must be written as 'technology neutral' as possible. 'Technology neutral' means that core words and concepts in a legal text are formulated in such a way that they do not become outdated when new technology changes or advances. The freedom of contract concerns all aspect, like the subject matter and the obligations to share. Typical activities in the current technological situation are screening and scanning of the DNA and alike. The choice of the words 'screening and scanning' is precise. It can easily become too narrow and requires a swiping technology neutral wording as 'or any other manner'.

When drafting ABS contracts that also intends to regulate DSI, existing obligations on side of for example academic users will play an important role. As a rule, public research funding organizations require that research results arising from their grants must be published, preferentially in open-access journals.[15] These results include sequence data, any other genetic information or information on synthetically made DNA. In addition, scientific journals usually require that DNA- or protein sequences published need

13 Houssen et al. 2020. Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use. Study published by the Secretariat of the Convention on Biological Diversity https://www.cbd.int/doc/c/c5f4/3855/ce31213aea2ec29bb43588f5/dsi-ahteg-2020-01-03-en.docx
Secretariat of the Convention on Biological Diversity. 2020. Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources https://www.cbd.int/doc/c/911e/cc8b/de7d7fba3a8374ba4a2fbf53/dsi-ahteg-2020-01-07-en.docx

14 Vogel et al. 2021. Bounded openness: A robust modality of access to genetic resources and the sharing of benefits. Plants People Planet 4: 13–22 https://doi.org/10.1002/ppp3.10239 and further references in this publication

15 See for example the "Guidelines on Implementation of Open Access to Scientific Publications and Research Data in projects supported by the European Research Council under Horizon 2020": https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/oa-pilot/h2020-hi-erc-oa-guide_en.pdf
and Art. 29 "Dissemination of results — open access — visibility of EU funding" of the H2020 Programme "Annotated Model Grant Agreement": https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf#page=245

to be uploaded to public databanks as proof.[16] The data stored in most of these databanks are available to third party users without any conditions. Absent clear terms and conditions governing the access, use of DSI and related benefit-sharing requirements in certain databases, the multilateral approach under discussion in several international fora may still be the best approach. However, it will be also important, going forward and alongside with the multilateral approach, to find ways in which the use DSI contained in these databases will be regulated through clear contractual obligations that guarantee compliance and benefit-sharing. That being all said, the de facto rule remains that when negotiating and concluding bilateral contracts that deal with DSI in other contexts, it is important to include technology neutral clauses that ensure that access, use of DSI and related benefit-sharing obligations are clearly stipulated and regulated.

## 2. Example of contract language

### Property rights, use rights, publication and enforcement of digital information or data associated with biological material and samples

Making research or results available in the form of digital information or data associated with biological material and samples or other dematerialised format shall only be allowed under this Contract by a prior notification to [institution] in [Provider country]. Such notification shall include the accession number, full contact data of the collection, web address(es) where the information is made available to the public.

The property rights retained by the Provider to the samples includes digital sequence information or data associated with the biological material or samples (e.g. genome, DNA, RNA, proteins, molecules, biochemical compounds or similar sources). Sequencing, screening or scanning or applying any other method to transform biological or genetic information into digital or other forms of information storage shall not alter the property rights of the [Provider country] as stipulated in this Contract.

In the event that the User identifies a potentially commercially interesting application, the User shall immediately make any digital sequences data or information available to the provider by means of transferring digital information.

In any digital publication of sequence data or any other digital expression of the samples or results from the samples, full acknowledgement is to be given to the Government of [Provider country], the project enabled by the Contract, and the following clause shall be enclosed in the digital publication:

"The Government of the [Provider country] has commercial rights or other further use rights in products or processes developed based on the research results or other research outcomes presented in this publication. Any use of such research outcome requires a contract of use with the Government of [Provider country]."and the following clause shall be enclosed in the digital publication:

## 3. Core questions to adapt the clause

Technological development is moving fast which challenges the link between transfer of material in and property rights to research results enabled by them. It becomes important to seek to establish contractual obligations that are technology neutral. It is becoming easier and cheaper to produce and share dematerialised information on biological resources which are highly valuable assets. One other important point is that although technologies and processes such as genome editing and synthetic biology are still at relatively new and at an early stage of development, they are evolving rapidly. This means that in the future, the cost and time needed to generate knowledge and information and to then transform it into marketable products and processes will continue to decrease.

In order to enforce property rights to digital sequences, data and associated information, these should only be made public behind a click-and-accept system that is binding on the person accessing the data or information. This is similar to what happens when accepting conditions of access to online publications or governing software utilisation purchased online. The system, however, needs to be designed in a way that it generates a message back to the provider of the biological material.

Lessons can be drawn from 'open source' computer software. Open-source software is a type of computer software in which source code is released under a license in which the copyright holder grants users the rights to study, change, and distribute the software to anyone and for any purpose. Open-source software may be developed in a collaborative public manner, meaning that any use of the software must also be made open on the same terms and conditions. Digitalised genetic information is more comparable to software than the biological samples. Access to digital genetic sequence data could introduce a system for sharing back information on any use or research based on these digitalised resources.may be developed in a collaborative public manner,

16 See for example the "Reporting standards and availability of data, materials, code and protocols" of the scientific journal Nature: https://www.nature.com/nature/editorial-policies/reporting-standards#availability-of-data

meaning that any use of the software must also be made open on the same terms and conditions. Digitalised genetic information is more comparable to software than the biological samples. Access to digital genetic sequence data could introduce a system for sharing back information on any use or research based on these digitalised resources.

## 24 Commercialization without intellectual property rights

### 1. Rationale behind the clause

Intellectual property rights (IPRs) give the right to the IPR holder to exclude others from using the invention. The clause mainly illustrates how to commercialise products and processes linked to the subject matter without having registered an IPR. The clause makes reference to patents but consideration of other types of IPRs, like plant breeeders' rights or trade sectrets, may be also relevant in the situation described. This entitlement does not guarantee a sale, revenue or profit in and of itself. Commercialisation often involves securing a patent or another form of IPR but not always. A patent may also have no commercial value whatsoever. The fact that the patent has no commercial value does not change the fundermantal fact that others will still be prevented from using the invention linked to it and make a useful product or process similar to those described in the patented invention. To fully regulate the question of commercialisation, the contract also needs to regulate situations where the user commercialises anything based on the samples.

One example of commercialisation where there is no patent is the use of the ready-made assays. This could be relevant for the clauses on the transfer of material that does not become the subject of a patent.

One example of commercialisation where there is no patent is the use of the ready-made assays. This could be relevant for the clauses on the transfer of material that does not become the subject of a patent.

### 2. Example of contract language

**Commercialisation without intellectual property right protection**

In the event that the User commercialises any product or process linked to the subject of the clause [REFERENCE TO THE ARTICLE ON PROPERTY RIGHTS] of this Contract without any patent right, the Provider shall be entitled to a minimum of [XX %] of the gross turnover of sales or licensing or any other manner to collect a revenue.
obligation. The rationale behind the clause is to ensure that windfall-profits are equally shared between the users and the providers.

### 3. Core questions to adapt the clause to special situations

The obligation to pay a share of the gross turnover from a product in cases where there are no intellectual property rights is more complicated to monitor. It is more difficult to identify externally verifiable trigger points for benefit-sharing that cover all the possible and associated actions.

## 25 Unforeseen research results

### 1. Rationale behind regulating unforeseen research results

This clause is meant to be a catch-all clause that captures unforeseen research results that could potentially be interesting for the Provider in terms of their use and exploitation or commercial applications. Since the project has no immediate declared commercial objectives, any windfall-profits should be shared according to a predetermined contractual obligation. The rationale behind the clause is to ensure that windfall-profits are equally shared between the users and the providers.

### 2. Example of contract language

#### Unforeseen research results

The Users shall inform the Provider about any unforeseen research results that are of potential commercial or use interest to [Provider country], prior to any disclosure of this information to the public or non-parties to this Contract.

In the unforeseen situation of a product or process being developed or pursued or value addition arising or enabled by the Project or in the event the User commercialise any product or process linked to the aspect of the subject matter of this Contract with or without any patent right, the Provider shall be entitled to 50% of the gross turnover of sales or licensing or any other manner to collect revenue.

Since the property rights to any of aspects of the subject matter mentioned in Article [XXX] are property of the [Provider country], the User shall and will be held responsible for any unauthorised transfer or use.

### 3. Core questions to adapt the clause to special situations

This wording takes a wide approach to cover different situations where the user states that the objective of the project is non-commercial.

# V. GENERAL RULES

## 26 Obligations on the user to provide information: reporting and records

### 1. Rationale behind reporting obligations

When establishing reporting routines, two issues need to be considered and balanced (i) the purpose of the reporting, i.e. to monitor and enforce the terms of the contract and the (ii) risk of establishing a too comprehensive, onerous and bureaucratic reporting requirement. An onerous reporting requirement can be counterproductive. An ABS contract suffers from imbalance in relation to access to information: the user has access to all verified information whereas the provider must trust the information provided or generated by the user. Therefore, a contract must have clearly stated obligations upon the User to make information available to the Provider. The contract must also clearly state liability consequences to address situations in which the information provided is not accurate or verifiable.

### 2. Example of contract language

#### Obligation to provide information, reporting and liability for failure to provide information

It is assumed that the User is the one with best insight in the plans and possibilities to know and foresee future use of the samples or any other subject matter under the Contract. The User shall inform the Provider of any collaboration with any entity that might have an interest in any use or commercialisation of any of the subject matter described in any Article of this Contract or subject matter or methods enabled by this Contract.

The first user shall, as part of this Xontract, design a flow chart for its project which includes the next steps for any research or development that is either planned or considered likely with the biological material or samples, parts thereof or information or knowledge enabled there from.

The User shall provide a report to the Provider, [every sixth month or another period] after collecting the biological material or samples [set a fixed date] under this Contract, the Users shall provide a report to the Provider containing, but not limited to the following:

- A summary of all biological resources collected under this Contract (including collection locations, summary of taxa collected and isolated), the summary shall include photos of the specimens.
- Information of any bio-discovery, included but not limited to, new species, sub-species or special new discoveries or any genetic characterisation of the biological material or samples;
- The discovery of any lead or insights included but not limited to bioactive components, anti-bodies, or any products or processes;
- Summary of information or data associated with the biological material or samples, or any other dematerialised results;
- Publications and conference presentations arising from research.

The User has an obligation to seek clarity in any planned future applications or uses of any of aspects of the subject matter discussed in Article XXX above.

All reports provided by the Users under this Contract shall be provided in hard copy and digital copy in English [can be changed to any other agreed language].

Any false information or any actions considered disloyal shall be considered a breach of this Contract and shall make the User liable to paying Provider country a fixed sum of [US xx,000].

### 3. Core questions to adapt the clause to special situations

The reporting requirements need to be adjusted to the particular research or development situation.

## 27 Payment obligation

### 1. Rationale behind the clause

Payment obligations have to be formulated in a different manner whether we are dealing with a commercial or non commerxial user. For non-commercial users, the payment obligation could be replaced by an 'annual guarantee' that none of the subject matter owned by the provider country has generated any commercial income. This guarantee could be linked to a remedy if it later can be proved that the user has taken steps to commercialise any subject matter under the contract. An annual guarantee or verified statement by the user will increase his incentives to comply with the terms of the contract.

In the case of a commercial user, the contract clauses on payment obligations as part of the benefit-sharing need to set clear triggers that indicate when the user will have to make a payment. They must also set out the calculation methods that are clearly and unambiguously formulated. This includes clearly stipulating the manner in which payment will be made and whether or not the payment obligation will end at a specified point in time.

The trigger that activates the payment is best regulated in the clauses about use of the material and the outcome of the research and development. Both the triggers and the basis for the calculation of gross sales are based mainly on internal information held by the user company. Therefore, payment clauses must be drafted taking into account publicly available or verifiable information.

There are at least three official means of obtaining information on a company's turnover and sales: the annual tax report, the report for calculating VAT/sales tax and, according to corporate law, an obligation to provide information to the stock markets on a quarterly basis. The annual tax report is often prepared at a (highly) aggregated level referring to the total turnover of the company. Therefore, annual tax reports might provide little information about the sales of single products. The VAT comes closer to the gross sales of each product. Using these figures is a more adequate tool for calculating the basis of a payment. In the report to the market, it is in the interest of the company to give a positive picture of the company's activities. Thus, probably, the highest figure for calculation will be found in this quarterly stock-market report. When deciding a baseline for calculating the payment, one of these two figures or even a median of them could be used as the basis for the calculation. Most corporations issue quarterly earnings reports and annual financial reports. The income statement shows the results of activities for the reporting period. The statement begins with sales revenues, followed by the direct costs associated with generating those revenues.

The frequency with which the payments become due should also be covered by the contract. The tendency in old ABS agreements was to provide annual payments, which may be justified by the desire to reduce paperwork. Frequent calculations converts a potential claim into a specific and fixed sum due to be paid, which makes the legal position of the recipient of the payment more secure. In the case of bankruptcy or other deviation from business as usual, a fixed sum to be paid is the least risky option as compared to the option of receiving a potential payment on a sum which set to calculated at later date. Frequent payments also reduce potential loss in these situations.

### 2. Example of contract language

#### Method of payment

Payments under this Contract shall be made on a [bi-annual] basis. The User shall provide an audited financial report to the Provider confirming any gross turnover that triggers monetary obligations according to articles [XX]. A financial report based on the reports of VAT shall be provided to the Provider without reasonable delay after the 31 December and 30 June each year. The payments shall be made to the [FUND] and shall be paid one month after the respective [bi-annual] milestones.

The payments shall be calculated as a percentage of all payments the User receives as a result of such commercial exploitation. This shall include but not restricted to sales, income, minimum loyalty payments, upfront or milestone payments and the money's worth value of any equivalent payments in kind (for example equipment, services or shares).

The User shall keep complete and accurate records (together with supporting documentation) on the basis of which all amounts due to the Provider can be determined. Such records shall be retained for at least three (3) years following the end of the reporting period to which they relate.

Payment as compensation for breach of Contract or payment of any of the fixed sums set out in this Contract shall be done immediately after the breach of Contract has been detected by the Provider. If not received within a period of 14 days, interest at 10% p.a. shall be added.

### 3. Core questions to adapt the clause to special situations

Question to bear in mind:

- The figures that are used as a basis for the calculation.
- In each contract, the payment details need to be included in a clear and predictable manner.

The interest rate needs to be set at a level, so as to encourage the fulfilment of the contractual obligation.

## 28 Liability and remedies

### 1. Rationale behind a liability

ABS contracts have typically been weak on remedies for breach of contract, which impacts upon compliance and enforcement. One of the weakness observed is that most of the first generation of ABS contracts only included catch-all provisions on remedies at the end of the contract which were not linked to the specific obligations stipulated in the contract. These types of provisions could not provide an effective means of enforcement through remedies in case where there was a breach of any of the specicific obligations under the contract. Therefore, each clause establishing an obligation in a contract also needs to define a corresponding remedies in case of a breach of that specific obligation.

When choosing remedies in a contract one need to choose remedies and consequences that are allowed under private law. A contract cannot apply remedies from criminal law, as that would not make the contract enforceable or void as criminal law is premised on a different enforcement measures or mechanisms than private law.

### 2. Example of contract language

#### General rules on breach of contract

In a case of proven breach of contract, the User is liable to pay to the Provider a fixed sum of [US XX,000]. In the event that a breach causes environmental damage, each of the Users is liable to pay any reparation of this damage.

Any false information provided during the application phase or any contact with the authorities of [Provider country] is considered a breach of this Contract and triggers liability for any direct or indirect loss for the [Provider country] or participants in the project.

In these situations, the User is liable to pay [Provider country] a fixed sum of [US XX,000]

### 3. Core questions to adapt the rules on breach of contract

The most important assessment in situations where the level of damages is set as a fixed sum, is that it must be set sufficiently high to incentivise the user to fulfil its obligations. If the fixed sum of damages is set too low, this would be counterproductive and in that the lack of sufficient incentive could instead make breach of contract a more desirable and less costly outcome.

## 29 Suspension of rights

### 1. Rationale behind suspending the rights of the user

ABS contracts need to establish a mechanism for the suspension of the user's rights in the case of breach of contract. So far, ABS contracts have typically been "too generous" with respect to termination clauses. The main message concerning termination, which needs to be kept in mind, is that if a contract is terminated and ceases to exist, there are no further legal obligations upon the parties to that contract.

### 2. Example of contract language

#### Suspension

The Provider can suspend the rights under the contract in the following situations:

- Justified reason for the Provider to believe that the contract will be breached.
- Breach of any of the obligations in the Contract.
- Breach of any permit issued by the Provider country.
- Breach of any Acts in [Provider country] relevant to the subject matter of this contract by the User or any person associated with the User.
- Failure to conduct a payment.
- Plans on the User side of any restructuring of the User or any kind of merger or acquisition.
- Risk of insolvency or major failure of payment or bankruptcy (reason for suspecting potential bankruptcy)

Upon suspension or termination of this Contract, the User shall cease any use of subject matters, included but not limited to samples, any parts thereof, data, information or knowledge, products or processes or alike enabled by this Contract

The Users shall, upon suspension of the rights under this Contract, not use any of the data, results, information, knowledge or conclusions from the research on the accessed material for any purpose whatsoever without the prior approval of the Provider.

The Provider shall not be liable for any loss or damage whatsoever caused to the Users due to revocation of approval for access and/or termination of this Contract.

### 3. Core questions to adapt the clause to special situations

The important observation is to maintain the validity of the obligations in the contract but rather to suspend the rights according to the contract.

## 30 Settlement of disagreements and disputes

### 1. Rationale behind settlement of disagreement and disputes

ABS contracts are particular types of contracts. Facts and related technology dealt with in ABS contracts are beyond the regular areas of practice of a generalist judge. Therefore, costs and time can be saved by opting for a faster and less costly procedure for the settlement of disputes rather than going to court. This assumes, of course, that mediators possess competence in resolving the disagreement in a neutral and competent manner.

### 2. Example of contract language

#### Settlement of dispute

Any dispute arising from this Contract shall be resolved in the following manner:

Amicable dispute settlement: The Parties shall attempt in good faith to resolve the dispute by negotiation after giving a 7 days' notice of the dispute in writing.

If the dispute is not resolved by negotiation, the Parties may proceed to mediation through a neutral third-party mediator, to be mutually agreed by the Parties.

The Parties may agree to bypass mediation and proceed to arbitration in order to reduce the cost of the dispute resolution process or when it is convenient to do so.

Arbitration: If the dispute has not been settled amicably by negotiation or mediation, any Party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the Parties to the dispute. If the Parties do not agree on the arbitrator within 3 days the seat of arbitration shall be the [Specify an arbitration court. E.g. London Court of International Arbitration and the result of such arbitration shall be binding on both Parties.]

Nothing in this Article shall limit the competence of the Parties to resolve a dispute before a general court.

### 3. Core questions to adapt the clause to special situations

When choosing an alternative dispute resolution mechanism, the parties to the contract should be sure that the mechanism chosen is a better option for the parties than proceeding to court.

# VI. CLAUSES THAT ARE OFTEN USED IN CONTRACTS

## 31 Governing law

### 1. Rationale behind a clause on governing law

ABS contracts almost always include a clause about the governing law even though this is not particularly useful. It is not always clear that making reference to a governing law of a specified country will have an impact in the implementation and enforcement of a contract. Introducing such a clause in the contract does not enhance the potential to enforce the contractual obligations, but rather weakens the enforcement obligations.

The ABS contract is better drafted as a stand-alone legal document. This means that questions that in other areas of contract law could be govern by general laws need to be drafted in the ABS contract.

Choosing one particular country's law will narrow the jurisdictions in which the contract can be enforced. In most first generation ABS contracts, the tendancy has been to automatically choose the provider country as the jurisdiction in which the contract will be enforced. As users are generally domiciled and carry out their activities outside the provider country's jurisdiction, this would not be useful. In such cases breaches will most likely not happen in the provider country and it would become very difficult to enforce the terms or seek redress in the user country on the basis of a judgement rendered in the provider country. This will create an uncertain and unenforceable legal situation. Therefore, it it advisable not to choose or limit the law governing the contract to any one specific country.

### 2. Example of contract language

#### Governing law

The Provider or Users shall use the applicable law in the jurisdiction where the dispute arises or the applicable law in the jurisdiction where any part of this Contract is implemented.

### 3. Core questions to adapt the clause to special situations

A governing law clause must be well-researched to remove any uncertainty in any possible legal dispute.

## 32 Definitions in a contract

### 1. Rationale behind the definitions in a contract

Defining the core terms used in the contract is meant to increase the precision of the contractual obligations. Definitions are a "two-edged-sword". Definitions may simply be copied and pasted from other texts, which has the potential of increasing ambiguity. Defined terms in contracts can also lack precision, resulting in ambiguity and in some situations a narrower scope of the relevant obligations. Certain definitions, may in some cases, render the obligations narrower than they ought to be. In other cases, a definition may be partly in contradiction with the intended effect of operative clauses. Definitions in international law are often ambiguous and are used to a hide lack of political consensus. This kind of "constructive" ambiguity is a killer for a contract.[17]

### 2. Example of contract language

#### Definitions

The following terms shall, when used in a Contract, be accompanied by the following definitions:

**FNI** means the Fridtjof Nansen Institute.

**Project** means the research project "[NAME]" funded by the Ministry of Food and Agriculture project number [NUMBER].

17 Empirical studies of previous ABS agreements show that the inclusion of standardised definitions has made contractual obligations either imprecise or irrelevant for commercially relevant subject matter, e.g. a patent or product on the market. Notably, in one contract, the obligations referred to 'genetic resources' as defined in the CBD. The product patent and the product sold on the market related to processed food. In this particular case, the definition caused the actual and foreseeable use of the material to fall outside the scope of the obligation. The patent was not in breach of the contract because of the way the definition combined with the substantive obligation. In this case, a specific definition based on the expected use and products would have captured the intended obligations and made them binding.

Definitions that do not contribute to contractual clarity:

**Definitions**

Unless the context otherwise requires, the following terms shall, whenever used in the Contract, have the following definitions:

**ABS** means access and benefit-sharing

**Contract** means the written contract between the Provider and the User intended to be enforceable by the Applicable Law.

**Genetic Material** means any material of plant, animal, microbial or other origin containing functional units of heredity

These definitions fail to provide clarity by expanding the scope of different interpretations of any of the defined terms.

### 3. Core questions to adapt the clause

It is useful to search the contract for each of the terms defined and substitute them with the whole definition when drafting a contract. Examine the contract language and consider carefully whether a person without relevant background qualifications would understand the precise meaning of the obligation. If not, either the definition or the substantive obligation needs to be re-written.

## 33 Objectives of the contract

### 1. Rationale behind the clause

Clearly formulated and agreed upon objectives help in fostering a common understanding between parties as to what the contract ought to achieve. The extent to which the objectives will add clarity to the contract depends on how precisely they are drafted. Their legal effect on the content of a contractual obligation also depends on how contracts are interpreted. Objectives have less weight than the substantive contractual obligations. To ensure that the contract is functional, the overall and expected objectives of the project need to be reflected in the substantive obligations of the contract.

### 2. Example of contract language

The objective of this Contract is to set out conditions to regulate the access to and research on [DESCRIBE THE SUBJECT MATTER FOR THE CONTRACT], including their genetic material or information, and sharing of resulting benefits and the sharing of resulting benefits including any monetary turn over created by the User.

[INCLUDE ANY NECESSARY INFORMATION REGARDING THE GOALS THE CONTRACT SHALL ACHIEVE.]

### 3. Core questions to adapt the clause to special situations

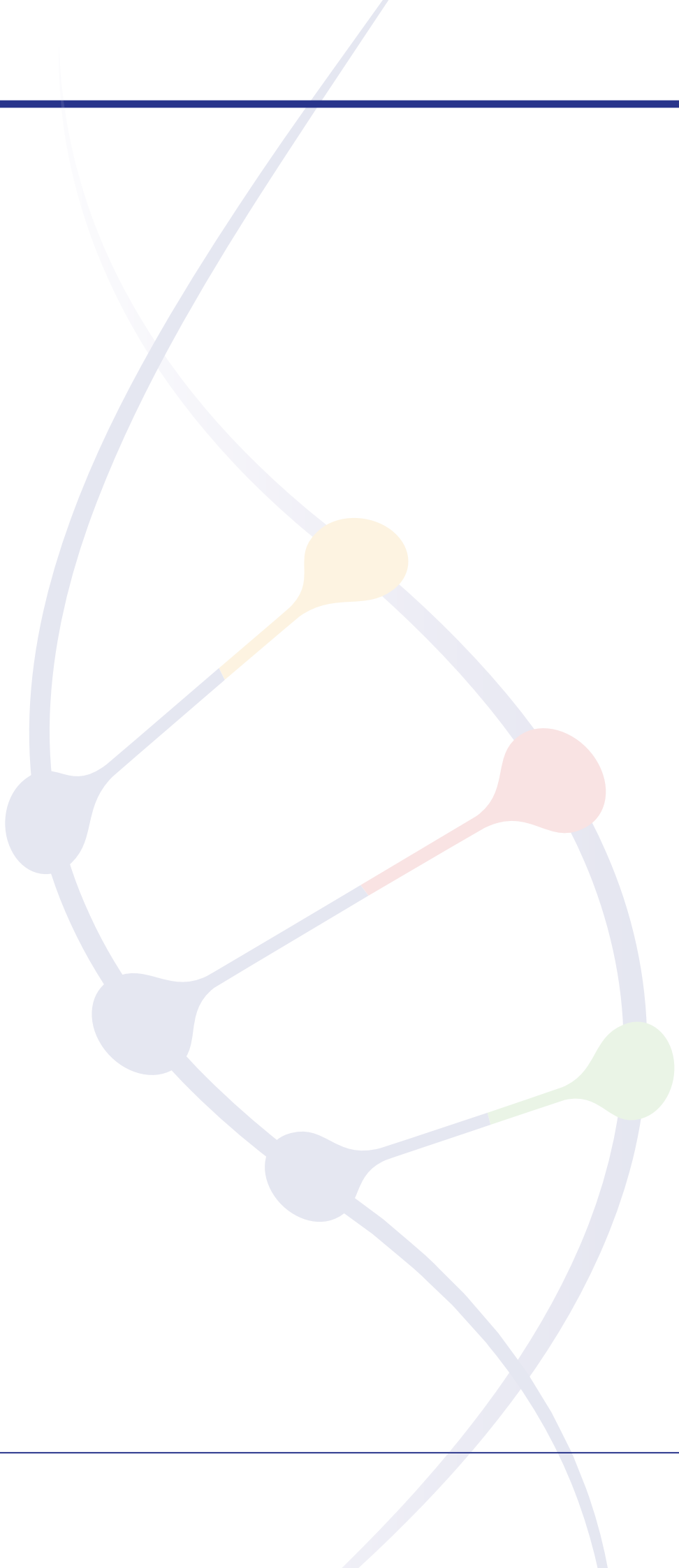
Two aspects must be assessed with respect to the objectives of a contract. First, the objectives should reflect the substantive obligations. Second, the objectives must add clarity. If these aspects are not taken into account when drafting the objectives, the text of the objectives will not contribute to the functionality of the contract.

## 34 The preamble

### 1. Rationale behind having a preamble

Many ABS agreements often contain a section describing the purpose of the collaboration between the parties. To what extent a preamble can be regarded as binding depends on the relevant country's legal tradition. A preamble does not address any core questions in the contract. A preamble gives a contract the character of an international treaty using general language. There is a danger that a preamble can cause more confusion than clarity and it is advised not to include one.

If the parties insist on a preamble, it must be carefully written to avoid contravening the substantive clauses of the contract. Doubt about the interpretation of the substantive obligations may arise if there is no coherence between the preamble and the binding parts of the contract.



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