KEMENTERIAN TENAGA DAN SUMBER ASLI

User's Guide to the ACCESS TO BIOLOGICAL RESOURCES AND **BENEFIT SHARING ACT 2017** *[Act 795]*

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Contents

List of Acronyms and Abbreviations

ABS	Access and Benefit-Sharing
BR	Biological Resource
CA	Competent Authority
CBD	Convention on Biological Diversity
CHM	Clearing House Mechanism
COP	Conference of the Parties
DNA	Deoxyribonucleic acid
EU	European Union
FAO	Food and Agriculture Organisation
FRIM	Forest Research Institute Malaysia
GR	Genetic Resource
ILC	Indigenous and Local Communities
IPR	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MARDI	Malaysia Agricultural Research and Development Institute
MAT	Mutually Agreed Terms
MLS	Multilateral System
MOP	Meeting of the Parties
NCA	National Competent Authority
NGO	Non-governmental Organisation
NFP	National Focal Point
PIC	Prior Informed Consent
PGRFA	Plant Genetic Resources for Food and Agriculture
RNA	Ribonucleic acid
R&D	Research and Development
SMTA	Standard Material Transfer Agreement
TK	Traditional Knowledge associated with Biological Resource
Act	Access to Biological Resources and Benefit Sharing Act 2017 [*Act 795*]
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples

Background

Biological resources (BR) (whether from plant, animal or microorganisms) are utilized for different purposes – example, for basic research or the development and commercialization of products. Those using these resources include research institutions, universities and private companies operating in a wide range of sectors, such as, the pharmaceutical, biotechnology, agricultural seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage industries. Similarly, commercialization of products derived from indigenous peoples' traditional knowledge associated with BR (TK) has yielded huge benefits. Yet, the huge financial benefits accruing was not shared equitably with the country providing such resources and indigenous TK holders. Against this backdrop, an international treaty; the CBD was adopted. Its third objective aims to rectify the inequality where it requires the resource user to share in a fair and equitable way the benefits arising from the utilization of the resources with the resource provider, as well as, indigenous and local communities (ILC) in return for any access to the resource of the associated traditional knowledge. This is known as the access and benefit sharing concept or ABS, in short. The ABS concept was further developed by a supplementary agreement to the CBD; the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (the Nagoya Protocol).

Malaysia as one of the megadiverse countries in the world stands to lose if its rich biodiversity and traditional knowledge associated with BR are accessed freely and exploited without the concomitant sharing of benefits. The benefits would in turn help biodiversity conservation and support the practices of innovations by ILC.

Malaysia became a party to the CBD in June 1994 and its membership took effect in September 1994 in accordance to Article 36 of the Convention.

Pursuant to that and in anticipation of becoming a party to the Nagoya Protocol, Malaysia in October 2017 enacted the Access to Biological Resources and Benefit Sharing Act 2017 [*Act 795*]. It regulates access to BR or TK associated with biological

resources and the sharing of benefits arising from their utilization within Malaysia for research and development.

This Act also aims to provide a mechanism for a fair and equitable sharing of the benefits arising out of the utilization of BR or TK associated with biological resource thereby contributing to the conservation of biological diversity and the sustainable use of its components, as well as, the social welfare of the ILC.

Purpose of this Guide

This **User's Guide** intends to facilitate those intending to access BR or TK associated with regulated under the Act. The main goal of this Guide is to clarify the regulatory requirements and access procedures, such as, application of permit and seeking prior informed consent under the Act. The target audience of this Guide is broad, including users from private and public sectors, universities and civil society. It is presented in a simple form and avoids complex scientific, legal and technical jargon. It is intended as well to serve as a reference tool for regulators and policy makers.

This Guide neither deal directly with matters relating to Malaysia's international obligations under the CBD, the Nagoya Protocol and other international instruments and processes; nor does it link to, or interpret, the provisions of the CBD and the Nagoya Protocol.

This Guide also does not attempt to deal comprehensively with ABS laws of the two States that have state laws on ABS, in particular, the Sarawak Biodiversity Centre Ordinance 1997, Sarawak Biodiversity Centre (Amendment) Ordinance 2003, Sarawak Biodiversity Centre (Amendment) Ordinance 2014, Sarawak Biodiversity Regulations 2016[1], and Sabah Biodiversity Enactment 2000. Subsection 1 (3) of the Act provides that the Act or any provisions of the Act will come into operation in the state of Sabah and Sarawak on a gazetted date to be appointed by the Minister with the approval of the relevant state. In other words, if the resource falls under the jurisdiction of the State of Sabah and Sarawak, their ABS laws must be complied with until such time as the Act or its provisions come into operation for the respective State. Resource users are therefore advised to seek further information from the relevant Competent Authority (CA) in Sabah and Sarawak if the BR or TK fall within their jurisdiction.

Throughout this Guide, the terms "user" or "resource user" and "provider" or "Resource Provider" are used, depending upon the context. "User" or "resource user" refers to an individual or an entity that uses BR or TK for research and development. Users include researchers, a private company that develops pharmaceutical,

[1] Collectively can be found at http://www.sbc.org.my/research-regulations-permit/ordinance-and-regulations.

nutraceutical or cosmetic products for sale, horticulture industry, and their agents or any intermediary such as a middle man. In some context in particular in relation to access procedures, they are referred to as "applicant". "Provider" refers to persons who provide or supply BR or TK. "Resource Provider" has a legal meaning defined in the Act which will be discussed in Chapter 3.

1. Overview of the Act

The Access to Biological Resources and Benefit Sharing Act 2017 [*Act 795*] sets out the requirements for access to BR or TK in Malaysia for R&D activities. It seeks to implement the CBD and the Nagoya Protocol by establishing an ABS regime in relation to access to BR or TK and the sharing of benefits arising from their utilization.

The Act seeks to implement the international obligations under the CBD and the Nagoya Protocol, to balance the rights of all stakeholders and ultimately to protect our biodiversity as one of the 12 megadiverse countries in the world. The Ministry of Energy and Natural Resources (formerly known as Ministry of Natural Resources and Environment) as the lead agency in promulgating the law, conducted more than 20 consultations with stakeholders including the relevant government agencies including state governments, researchers from universities, public and private institutions and non-governmental organizations (NGOs). The ABS Bill was translated into Bahasa Malaysia to enable effective consultations with the ILC and Orang Asli- and Orang Asal-based NGOs. The development of the Act involved the examination of the national ABS-related laws of more than 23 countries, regional ABS decisions, legislations and framework agreements, and relevant guidelines and best practices.

Adopting the approach of the CBD and the Nagoya Protocol, the Act deals with BR as a whole rather than focusing on sector specific measures for specific species.

The key components of the Act include the following:

- **Permit**

  As a general principle, any local or foreign individual or corporation who intends to access BR or TK for commercial, or potentially commercial or non-commercial purpose must obtain a permit. The permit is needed through the chain of utilization of the particular BR and TK. A change of use requires the user to apply for a new permit.

"Access to a biological resource" means taking the resource from anywhere – from its natural habitat such as a forest, or place where it is kept (in a seed bank or research institute), grown or found including in any market place.

ABS permit is not required if the research is for a non-commercial purpose and:

i) The research and development activity is under a public higher education institution, research institution or Government agency within Malaysia;

ii) The exchange of BR is between persons within a public higher education institution, public research institution or Government agency within Malaysia; or

iii) The access to a BR is by any person outside Malaysia or in a private institution within Malaysia from a permit holder who possesses a valid permit to access for the purpose of carrying out or continuing any research for non-commercial purpose.

The permit is issued by the relevant CA in the prescribed format with the necessary unique identifier endorsed on it – that is a unique identification code or mark that distinguishes the resource.

- **Prior Informed Consent (PIC)**

One of the accompanying documents required to be submitted along with an application for a permit is the PIC obtained from the ILC where their resource or TK is accessed.

PIC is required for any access to:

i) BR on land to which ILC have a right established by law. This includes not just ownership rights but as well, other rights established by case law, such as rights to occupy or use the land; or

ii) TK with a BR held by the ILC.

- **Benefit Sharing Agreement**

  Another accompanying document required to be presented for the application of a permit is the Benefit Sharing Agreement, entered into with the resource provider who gave access to the BR or TK. This is only if the purpose of the access is for commercial or potential commercial purposes. No such agreement is required if the access is purely for a non-commercial purpose.

  The benefit sharing agreement must be agreed to by the person seeking access and the one providing the resource or the TK. This means that the terms of the agreement are mutually agreed.

Once the relevant PIC is obtained, and the benefit sharing agreement entered into, the application for a permit must be submitted to the CA of the State from where the resource or TK will be accessed. If the application is approved, a permit to access will be issued by that CA.

The permit will specify the use for which access is granted, as well as, other conditions for its use.

Institutional Framework

The institutional governance structure is divided between the Federal and the State governments. At the Federal level, the NCA is chaired by the Secretary General of KeTSA. It plays a coordination role at the national level and handles all matters at the international level, such as, liaising with the CBD or Nagoya Protocol Secretariat and implementing the country's international obligations. The NCA also establishes measures for the purpose of monitoring and tracking of a BR accessed to ensure resource users comply with the regulatory process. The NCA also functions as a CA for all ex-situ collections where the origin of the BR cannot be ascertained with due diligence and which are not within the jurisdiction of any other CA.

Each state nominates a CA. Such CA has jurisdiction over all matters relating to access to a BR including the issuance of permit and collection of fees. See **Annex 1** for the full list of the CA.

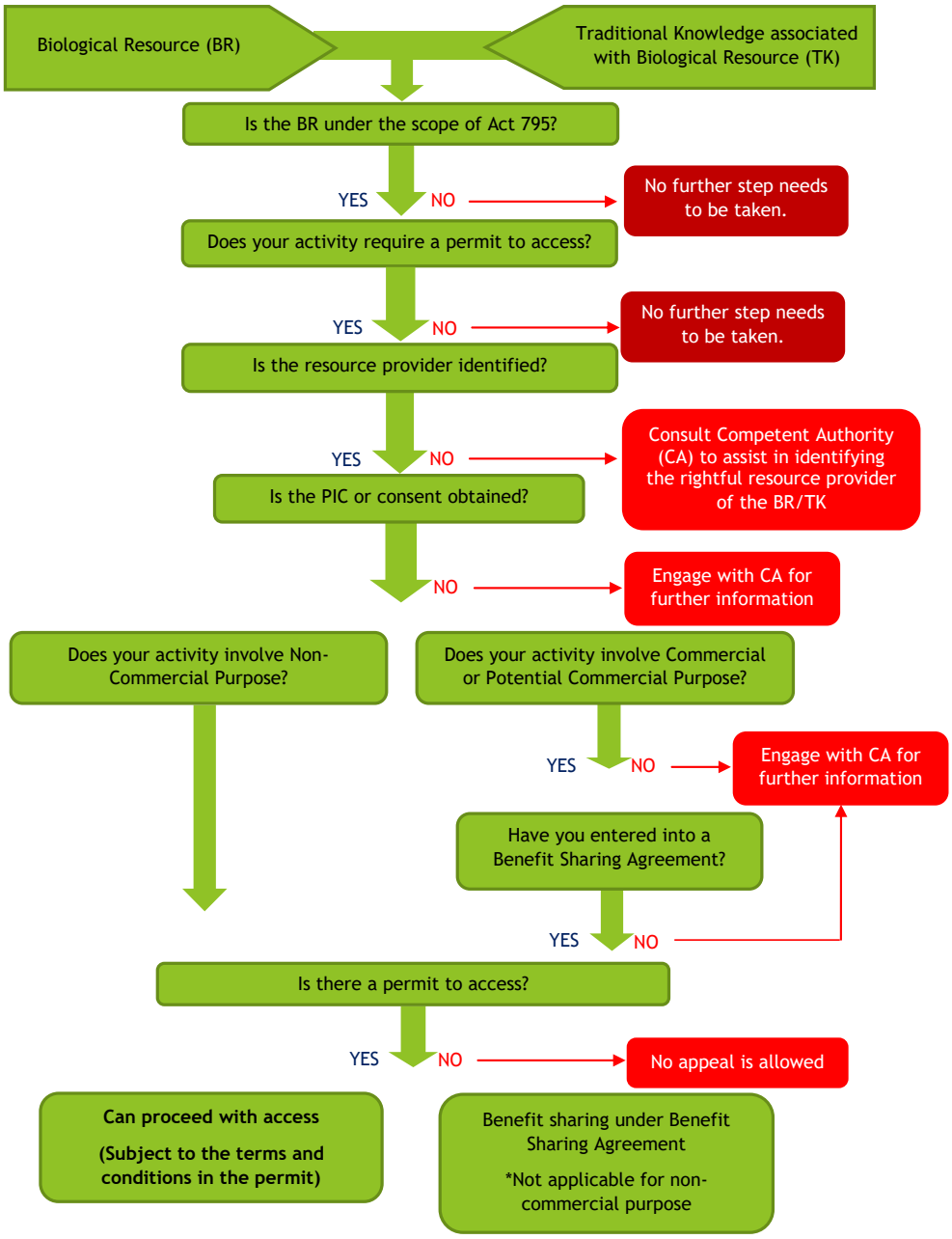
There is also an Advisory Committee established by the NCA to advise the NCA or the CAs on matters relating to the implementation of the Act. It consists of persons with experience, knowledge and expertise in scientific, legal, technical, ethical and other relevant disciplines.

In addition, a CA must establish an Advisory Body comprising ILC to deal with matters relating to ILC and TK. The members of the body are nominated by ILC and chosen by the respective CA.

Finally, the CA may establish other committees to carry out its functions whenever necessary.

2. Access and Benefit Sharing Process

Figure 1: **An overview of the Access and Benefit Sharing Process**



In order to gain access to the BR or the TK, here is a step-by-step guide that a User may follow. The general procedure is explained as follows:

- Check whether the resource falls within the scope of the Act

Before one proceeds to apply for a permit, first determine if the resource to be accessed falls within the scope of the Act. This can be done by looking into the definition of relevant terms in the Act in particular 'BR', 'genetic resource', 'derivatives' and 'microorganisms'. If the answer is in the affirmative, then look into the nature of the activity that is to be carried out. The applicant can check with the CA whether or not the resource intended to be accessed and the activity is regulated by the Act. No further step is necessary if the resource and activity do not require a permit to proceed. *(See Scope for more information)*

- Identify rightful Resource Provider

Regardless whether the activity has commercial or potential commercial intent, or non-commercial intent, it is a mandatory requirement that the applicant to first obtain the PIC from the relevant ILC or consent of the Resource Provider, as appropriate. Later chapters will show how to determine the rightful Resource Provider. The procedure for getting the PIC of ILC will be as established by their customary laws and practices, community protocols and procedures. (*See PIC Protocol for more information*)

In relation to a Resource Provider other than the ILC, consent must also be obtained for access to their resources. This consent could be in the form of a benefit sharing agreement in the case of commercial research. Further to this, consent is also necessary from the person holding the physical resource if such person is different from the Resource Provider. Consult local CA to assist in identifying the rightful Resource Provider.

- Comply with other written laws

One must bear in mind that the Act is in addition to and not in derogation of the provisions in other laws relating to forests, wildlife, animals, fishery and international

trade in endangered species. This means that if there are other laws governing the access, the applicant must comply with them. For example, you may need a permit from the forest authorities to enter the forest. Also, a special permit is required for conducting research or study on totally protected wildlife under the Wildlife Conservation Act 2010; such a special permit must be obtained in addition to the permit under the Act. In other words, a permit under this Act does not legitimize all activities regulated under other relevant laws. As such, it is advisable that such permits to be obtained *before* making any application for access under this Act to expedite the processing of the ABS permit application by the CA.

- Enter into benefit-sharing agreement

The requirement to enter into a benefit sharing agreement is not needed for non-commercial purpose activity. However, it is compulsory to share benefits fairly and equitably with resource provider, if the activity has commercial or potential commercial intent that could generate revenue. Therefore, the User must enter into a benefit-sharing agreement with the resource provider based on mutually agreed terms. *(See Mechanisms for Benefit Sharing for more information)*

- Permit Application

Once all of the above requirements are met, the Applicant can submit an application for access permit to the CA. Access is granted if application is approved and a permit issued. Usually, the permit will attach terms and conditions, such as: the area for the access, the duration of the permit, the use of the resource, the non-transferability of the permit. The Applicant is responsible to carry out the access activity in accordance with these terms and conditions and must also fulfill the requirements in the benefit-sharing agreement. Failure to apply for a permit is an offence under the Act. Failure to comply with such terms and conditions in the permit is also an offence under the Act. Failure to fulfill the provisions in the benefit-sharing agreement is a breach of contract, which leads to legal consequences. *(See System of Obtaining Permit & Offences for more information)*

3. Scope of the Act

The Act regulates access to all BR and / or TK and the benefit arising from the utilization for R&D for commercial or non-commercial purposes. It provides a framework or system for access which includes the application of permit, the mechanics of obtaining Prior Informed Consent and the establishment of Benefit Sharing Agreement.

3.1. Who are regulated by the Act?

This Act regulates any *user* of a BR and TK. The term "user" is not defined in the Act as it intends to capture any person, regardless of citizenship, foreigners or Malaysian who wish to access the BR, i.e. take the BR and / or TK for basic research or product development. "User" predominantly refers to researchers working either in public or private higher education institutions, research institutes and companies or industries involved in the development of pharmaceutical products, traditional medicine, agriculture, cosmetic and other products.

Intermediaries are covered by the Act. An intermediary act as an agent or in an intermediate capacity like a broker for a person seeking access. In essence, an intermediary can be an entity or individual who acts as a go-between the initial provider, and the final user. Intermediaries may include research institutes, universities, supplier companies or any other organization carrying out such functions. An intermediary must be authorized by the user to carry out that function. It is pertinent to note that a person is deemed to have accessed BR if there is reasonable prospect that the resource taken will be subjected to research and development. In other words, if the person takes BR and sells it to third party, knowing that such resource will be used for research by the third party, he is deemed to have accessed the BR under the Act. Whether the person has knowledge or if there is reasonable prospect will be determined by the relevant CA.

<u>Scenario 1</u>
Individual 'A' buys *petai* from the Orang Asli in Kampung Ulu and sells it to Company X for research. A is said to have accessed BR. Individual A must first obtain a permit

for access. Company X must also obtain a permit for access. Company X may absolve individual A from obtaining a permit by naming A as its authorized intermediary.

Scenario 2
Institute 'A' possesses data on TK of Orang Asli in Kampung Ulu. A national research centre accesses a plant based on lead of its use provided by ILC. It conducts research on the plant with the view to developing a drug for commercialisation. The centre then forwards the plant to GSK in France to conduct further research. The centre is considered as an intermediary.

Scenario 3
A company or institute has collected BR under the Act. It contracts a third party to farm the resource and propagate it for its use. The third party is not an intermediary.

3.2. Who are excluded from the Act?

This is decided predominantly by the activity that will be carried out by the person. If the activity does not involve R&D then the person is not regulated by this Act. This will be discussed in Chapter 6.

Person or class of persons exempted under Section 60 of the Act

The Act empowers the Minister to exempt any person or class of persons from the scope of the Act. This must be based upon the recommendation of the relevant CA and in consultation with the NCA and the relevant advisory body if the interest of ILC may be affected. The Minister must publish the exemption in the Gazette. Any user may contact the NCA or relevant CA to seek clarification as to whether the exemption applies or not to the user before proceeding to the next stage.

3.3. What are the resources covered by this Act?

The Act uses the term 'BR' instead of 'genetic resource'. This is deliberate so as to cover a wide range of resources and irrespective of whether the resource contains functional units of heredity – that is it can reproduce itself - like a seed. Thus, the

scope of the Act is broad enough to keep abreast with the rapid evolving technology and advances in knowledge in relation to research derived from nature.

Biological resource is defined in the Act to include genetic resources, organisms, microorganisms and parts thereof of the genetic resources, organisms, microorganisms or derivatives, the populations and any other biotic component of an ecosystem with actual or potential use or value for humanity, and any information relating thereto. This essentially refers to all living things, their derivatives and related information.

Genetic resource in the Act refers to any genetic material containing functional units of heredity such as DNA (deoxyribonucleic acid) and, in some cases, RNA (ribonucleic acid) found in any plant, animal, microorganism, fungi or other origin that has actual or potential value for humanity. Examples of genetic resources are seeds, sperms or individual organisms. It also includes DNA extracted from a plant, animal or microbe such as a chromosome, a gene, a bacterial plasmid or any part of these. Human genetic material (DNA) is included as it contains functional units of heredity; the DNA carries information which is passed from parent to offspring[2].

Microorganism means any organism of microscopic size and parts of organism of microscopic size, including pathogens, viruses and viroids.

Derivative includes biochemical compounds that occurs naturally in the resource and that is derived, developed or synthesized, from the BR; or results from the metabolism of the biological or genetic resource, or part, tissue or extract, whether or not it contains functional units of heredity. For example, latex is produced by a rubber tree as the tree metabolizes – but the latex is not able to reproduce itself (so it contains no functional units of heredity). The intention here is to capture the valuable biochemical compounds that occur through natural process, as well as those produced through human intervention, such as extraction, concentration, dilution or synthesis. In other

[2] Note that access to human genetic resource is specifically mentioned in s. 15(3)(f) of the Act. The individual from whose body the biological (including genetic resource) is taken is defined as a provider: s. 4 of the Act.

words, access to 'isolated derivative' (e.g. access to biochemical without accessing simultaneously the genetic resource) is covered by the Act. Examples of derivatives include aromas, biochemicals in cells, resins, snake venoms and something derived from biological and genetic resources (including human genetic resources) such as varieties, strains or breeds, blood, proteins, oils, gums, genes, seeds, spores, pollen, urine, bark, wood, leaf matter, and the like; as well as the products derived from, patented on, or incorporating manipulated compounds and/or genes [3] and synthetic (man-made) biochemical compounds. These are the compounds that industry needs and develops into products.

Information refers to the intangible component of biodiversity. It includes any available data relevant to the BR, genetic resource or derivatives and the TK obtained from a variety of sources including publications, reports, research result and direct consultation without the need to access to physical resource.

Traditional knowledge associated with a biological resource (TK) is also recognized as a resource covered by the Act. TK is formal or informal knowledge accumulated over centuries from experience, and transmitted orally from generations to generations, and collectively owned by the ILC. Such TK is unique as it may exist in the form of agricultural practice, living skills, technologies or local beliefs that enables the community to achieve a relatively stable livelihood in their surroundings. The type of widely held knowledge includes traditional uses of tropical herbs or plants with healing properties for medicine. Statistic show that a vast number of the research in pharmaceutical, nutraceutical and cosmetic industries are based on or depend on leads provided by TK. Under the Act, access to TK is distinct or isolated from access to the BR.

BR can be sourced from *in-situ* conditions that is found in naturally occurring environment. This includes those resources that exist within the ecosystems and natural habitat. BR can also be sourced from place where it is grown. This refers to the case of domesticated or cultivated species. Domesticated or cultivated species are

[3] Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008.

cultured (breeding selection) with different genetic composition and characteristics as compared to the same species in the wild state to cater to human needs. This includes industrial crops like rubber and oil palm. Often these resources develop their distinctive properties over time and through cumulative research activity.

Lastly, a BR can be sourced from the place where it is kept, that is in *ex-situ* collections. This includes those resources and their components kept in human-made collections or conserved outside their natural habitat such as gene banks (seed banks and in the field), zoos, botanical gardens, pollen storage, research institutions and any other similar conservation centers. In Malaysia, major *ex-situ* collections can be found in the Forest Research Institute Malaysia (FRIM), Rimba Ilmu in University Malaya, Malaysia Agricultural Research and Development Institute (MARDI), Kinabalu Park, Sabah Forestry Department, Sarawak Forestry Department and such like.

Interestingly, the Act also covers resources sourced from the "market". Market is not defined nor clarified in the Act. The intention is to cover resources sold in physical market like malls or virtual online market that offers information relating to BR.

From a legal perspective, an Act must only regulate matters within its jurisdiction. The Act will only regulate BR that falls within the national jurisdiction, namely, those kept, grown or found in Malaysia. However, if the country of origin of the source can be established – that is, it is from Malaysia or from an ILC in Malaysia – then even if it is accessed from outside the jurisdiction, it is possible to suggest that the Act will cover such resource or TK.

It is worth noting that **human genetic resource**[4] is governed under the scope of this Act. A resource provider is defined to include an individual from whose body a BR (such as blood, DNA) is taken. Note that human genetic resources are not included within the framework of the Nagoya Protocol[5].

[4] Paragraph 12(2)(f) and 15(3)(f) of the Act will be enter into force at a later date determined by the Minister.
[5] COP 10 Decision X/1

3.4. What resources are excluded by the Act?

Resources listed in Annex 1 of the International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA)

Resources specifically listed under the Multilateral System of the International Treaty on Plant Genetic Resource for Food and Agriculture (ITPGRFA) are not covered by the Act. This is because Malaysia is a party to this treaty. Under the treaty, access to the listed resources are to be shared freely among parties. These include food crops and forage crops used for food and agriculture under its Multilateral System (MLS). The MLS has its own framework for sharing benefits gained from commercialization of such resources accessed according to the mutually agreed terms expressed in a Standard Material Transfer Agreement. This mechanism emphasizes benefit sharing through information sharing, technology transfer, capacity building and, monetary and non-monetary benefits. The lead agency in Malaysia regulating the MLS is MARDI.

Living Modified Organisms (LMOs)

This Act does not regulate access to living modified organism (LMO) for which intellectual property rights (IPR) have been granted and subsist. LMO is defined in the Biosafety Act to mean any living organism that possesses a novel combination of genetic material obtained through the application of in-vitro nucleic acid techniques or the fusion of cells beyond the taxonomic family. The logic behind this is that these LMOs are owned by the IPR holder and are no longer the national patrimony of the state. Any use of such LMOs would be governed by relevant IPR laws.

Plant Variety

This Act does not regulate access to plant variety for which breeder's right has been granted and subsists under the Protection of New Plant Varieties Act 2004. The logic behind this is that these plant varieties are owned by the breeders and are no longer the national patrimony of the state. Any use of such plant varieties would be governed by the relevant Act.

Resources exempted under Section 60 of the Act

The Minister may from time to time exempt a specific BR, or a specific collection of BR including future additions to the collection for such purpose to be specified from the scope of the Act. The Minister must do so by order published in the Gazette. Any User may contact the NCA or relevant CA to seek clarification as to whether the exemption applies or not before proceeding to the next stage.

3.5. What are the activities covered by this Act?

The Act regulates the activity of "taking" and for the purpose of "research and development". These two ingredients must be present to constitute "access". "Take" is defined in the Act to encompass all actions and methods in obtaining a BR, whether through physical acts such as harvesting or capturing or through obtaining related information in digital form. The second ingredient, "research and development" includes the study or systematic investigation or technological application by analyzing, sampling, bioassaying and inventorising or other methods for any purpose including taxonomic research, and potential commercial product development, whether the R&D is for commercial or potential commercial purpose; or for non-commercial purpose.

Examples of R&D activities for purposes of the Act include the following:

- Biotechnology (Genetic Modification, sequencing genes or genomes etc.);
- Breeding and / or selection;
- Production of compounds naturally occurring in genetic material;
- Horticulture;
- Conservation;
- Taxonomic research;

- Basic research.

R&D for commercial or potential commercial purpose essentially refers to the R&D to increase scientific knowledge and understanding with the intention to obtain profit, or to develop commercial products such as specialty enzymes, enhanced genes, or small molecules which can be used in crop protection, drug development, the production of specialized chemicals, or in industrial processing.

R&D for non-commercial purpose refers to academic or non-profit oriented research which uses the BR to increase knowledge or understanding of the natural world, or increase research capacity.

For purposes of the Act, the following are examples of activities regulated under the Act:

- Collecting plant by indigenous community on behalf of a third party who will conduct R&D on the BR collected;

- Harvesting wild mushroom by a student for research thesis;

- Collecting plant for accessing fungi;

The Act distinguishes between commercial and non-commercial utilization of BR. The distinction is necessary to promote and encourage research activities while ensuring that the Act can be implemented in an effective manner. Thus, the framework and procedures on access for non-commercial research purpose are simplified, taking in account the need to address the change of intent of the research to commercialize the resource as a result of the research outcome. Detail procedures can be found later.

3.6. What are the activities excluded by the Act?

Any activity other than that involving R&D is not covered by the Act.

The Act provides a list of activities that are not regulated by the Act. It is a non-exhaustive list which states explicitly the kind of activities which are not intended to be regulated by the Act. The following are further examples of activities excluded from the Act:

- Use and exchange of BR among the ILC;
- Sale of commodities for consumption purposes;
- Harvesting natural produce such as honey and oil for sale;
- Propagation of flora;
- Harvesting wild orchids for ornamental purposes;
- Bee keeping.

3.7. Who is the Resource Provider under the Act?

Federal Government, State Authority, institutions holding BRs in ex-situ condition, ILC and individuals can be the resource provider, depending on where the resource is to be taken from, *and* where the resource originates. This is predicated on the principle that the State has the sovereign right over any natural resource within their jurisdiction. Note that the definition of Resource Provider in the Act is not exhaustive. A Resource Provider may not hold the resource or provide the physical material. For example, the resource taken from the Resource Provider may be housed in an ex-situ collection and be accessed from this collection. It is important to note that the benefit sharing agreement must be entered into with the Resource Provider where the access is for commercial or potential commercial purposes.

Federal Government or respective State Authority are deemed as the resource providers for all BR growing or found within their state jurisdiction. For example, Negeri Sembilan's State Authority is the resource provider for plant 'A' found in *in-*

situ conditions in the Berembun Virgin Forest in Negeri Sembilan. As noted earlier, the State nominates the CA for dealing with all matters under the Act.

If such plant A is held in *ex-situ* conditions in the botanical gardens in Pahang, Negeri Sembilan's State Authority should remain as the resource provider. In other words, the **Federal Government or respective State Authority** is deemed as the resource provider for all BR that originate from their State, even if the resources are kept outside the state. This also includes resources kept in ex-situ conditions by a private body or available for sale in market place - if the resource is clearly identified as originating from the state. Then the CA refers to the CA of the said originating State – which in this example is the state of Negeri Sembilan.

If the origin of the BR cannot be ascertained with due diligence, and the BR is held in *ex-situ* conditions by a **public body** (government department, agency or public higher education institution), the said body is deemed as the resource provider. For example, MARDI holds a rice accession whose origin cannot be ascertained. MARDI is deemed as the resource provider for such rice accession. In this case, the CA refers to the CA of the place where MARDI is located.

If the origin of the BR cannot be ascertained with due diligence, and the BR is held in private land or in *ex-situ* conditions by a private body, the **Federal Government or respective State Authority** is deemed as the resource provider. For example, Ali has planted on his private land in Penang medicinal plant B whose origin cannot be ascertained. The Penang's State Authority is deemed as the resource provider. In this case, the CA refers to the CA of Penang.

Note that as regards human genetic material the individual from whose body the resource (example DNA or blood derivative) is taken is the provider of the resource. It is logical to assume that the CA of the place where the person resides will be the regulatory body.

ILC is the resource provider in two situations. First, as the provider of BR where such resource is on the land to which they have an established right in law. Secondly, as the provider of traditional knowledge as to the function and use of the resource. "Indigenous community" is defined in the Act as the aborigines (or the Orang Asli)

Peninsular States, or natives (or the Orang Asal) in Sabah and Sarawak. Additionally, they must speak an aboriginal or a native language and habitually follow and embody a traditional way of life, customs and beliefs. In Peninsula Malaysia, there are 18 ethnic groups of Orang Asli subdivided into three main groups namely Negrito (Semang), Senoi and Aboriginal-Malay; whereas in Sabah and Sarawak, there are 64 ethnic groups. As of 2013, Orang Asli in West Malaysia comprises of 50.0% of Sarawak's population and 47.4% of Sabah's population. The main groups in Sarawak are Orang Ulu or Dayak which is made up of many other ethnicities; while in Sabah the main groups are the Dusun, Murut, Paitan and Bajau[6]. "Local community" is also defined. It means a group of individuals who have settled together and continuously inherit production processes and culture or a group of individuals settled together in a village or area and under an eco-cultural system. This in this modern society essentially refers to the farmer community. In this case, the CA refers to the CA of the place where the ILC is located.

As alluded to earlier, although the scope of the Act includes **human genetic resources**[7]. The **individual** is the resource provider for the genetic resource found within his or her body. For example, Ali is approached by a research assistant in University Hospital for consent to use his blood sample for research. Ali is the resource provider in this case. The CA refers to CA of the place where the individual resides.

3.8. Is provenance or legal status of the BR important?

Yes in all situations, particularly if the BR is acquired from a commercial supplier. Any user should be aware that Resource Provider refers to the original provider and not the commercial supplier. Users are advised to check the provenance and legal status of this BR before acquiring it. Shipments of unsolicited BR that are not accompanied by appropriate documentation that demonstrates compliance with laws and regulations may be seized and held until the user can prove that the legal

[6] International Work Group for Indigenous Affairs, ' Indigenous peoples in Malaysia' < http://www.iwgia.org/images/stories/sections/regions/asia/documents/IW2013/Malaysia.pdf > accessed 8 December 2014

[7] Paragraph 12(2)(f) and 15(3)(f) of the Act will be enter into force at a later date determined by the Minister.

requirements of the provider country are met. The resource should not be dealt with used until its legal status is established.

3.9. What happens when a person - which includes any company or institution – is either accessing a BR or TK for R&D when the Act comes into operation without a permit; or is in possession of such a resource without a benefit sharing agreement after the Act comes into operation?

Scenario 1: Subsection 63(1) of the Act

Where any person is accessing the BR or TK on the date of the coming into force of the Act. Accessing is a continuous act of taking the material or TK from the resource provider. The taking is for R&D[8].

Then that person must apply for a permit under section 12 (for commercial purpose) or section 15 (for non-commercial purpose), as applicable.

Person includes an entity (such as a company or institution) or anyone holding a material ex-situ in a collection centre. This would include such bodies as IPharm and IMR.

Scenario 2: Section 63(3) and 63(4) of the Act

If after the Act comes into force, any person (includes any entity or institution) is in *possession* of the resource or associated TK for which he or it must get a permit and benefit sharing agreement, and there is no such agreement, then he must enter into such an agreement. This is only in 2 situations, namely:

(1) There is a new use of the resource or associated TK. Example he used it as a skin lotion. Now he wants to use the same material to grow hair.

(2) There is a development of a new product with that same resource or associated TK. He created a skin lotion. Now he wants to create a drug for a disease.

[8] See definition section 4.

Once the benefit sharing agreement is concluded, then the CA will issue a permit under section 12 of the Act.

3.10. What are Small Farmers' Rights?

Breeding activities, horticulture or other agricultural-related activities which involve R&D fall within the ambit of the Act. For practical purposes, the Act does not intend to stifle the farming practices of small farmers. The Act recognizes the potential impact of the Act in relation to small farmers and strives to preserve the small farmers' rights' as established under the Protection of New Plant Varieties Act 2004. In line with this, the Act explicitly excludes such activities of small farmers to save, use, exchange and sell farm-saved seed or propagating material and conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping from its purview. "Small farmer" here refers to the size of the holding for farming operations that does not exceed 0.2 hectare.[9]

[9] Protection of New Plant Varieties (Prescribed Size of a Holding) Regulations 2008. PU(A) 390/2008.

4. Prior Informed Consent (PIC)

4.1. What is Prior Informed Consent (PIC)?

In order to have access to any BR or TK held by ILC, it is a mandatory requirement for the resource User to obtain the Prior Informed Consent (PIC) from the relevant ILC.

PIC is a term of art and a fundamental concept of the ABS regime in the CBD and the Nagoya Protocol. Under the Act, PIC is the authorization obtained by the resource user from the relevant ILC. The elements for PIC under the Act are the same as for Free Prior Informed Consent (FPIC) under international law such as the UN Declaration on the Rights of Indigenous Peoples (UNDRIP).

PIC must be obtained in accordance with the ILC's customary laws and practices, protocols and procedures. To facilitate users in obtaining such PIC, the government has developed – in close collaboration with the relevant ILC - a Prior Informed Consent Protocol. PIC must be obtained prior to the commencement of the access activity and free from any form of coercion, inducement or threat. There must be a full disclosure of all information that is relevant for securing the consent.

ILC are considered vulnerable to exploitation by external actors. The development of the PIC Protocol establishing the process for obtaining the PIC is aimed at preventing any possible abuse or misuse of the right of ILC to their resources and associated TK. The PIC Protocol lays down the steps to be followed in the process of obtaining such PIC. (*See PIC Protocol in* ***Annex 2***)

4.2. Who must obtain PIC?

Any person who wishes to have access to a BR or TK held by ILC must obtain the PIC from the representative, organization or body identified by the ILC, in accordance with its customary laws and practices, protocols and procedures and the process set out in the Prior Informed Consent Protocol. This is regardless of whether such access is for commercial, potential commercial or non-commercial purpose.

A researcher or the institution carrying out pure research activity with no commercial intent must still obtain permission from the relevant ILC by way of PIC, even though he is exempted from obtaining a permit (as explained earlier).

4.3. From whom PIC must be obtained?

The PIC must be obtained from the relevant ILC that is the "owner" of the BR or the TK holder. The ILC is deemed to be the "owner" when such ILC has a right *as established by law* to the land where the BR is found. ILC is said to have a right on the land as established by law such as when the land inhabited by the ILC is gazetted or declared as Aboriginal Reserve or Aboriginal Area under the Aboriginal People Act 1954, or a right of occupancy is granted under the said Act by the State Authority. Court decisions have extended this right. Thus, additionally, the ILC is entitled to the aboriginal or native customary title of the land if there is a continuous occupation[10] of the land by the aboriginal community that "has its origin in and is given its content by the traditional laws acknowledged by and the traditional customs observed by the indigenous inhabitants of a territory"[11].

The ILC may be represented by a community representative/s (i.e. Village Headman, Tok Batin and Penghulu), a representative institution or body (such as a cooperative set up by the community). However, where no such representative or organization can be identified, then the consent must be obtained from the holders of the TK within the ILC or with the Federal Government or State Authority.

4.3.1. What if the TK is shared by more than one ILC?

With approximately 53 ethnic groups in Malaysia[12], it is likely that traditional knowledge associated to the BR will be shared by more than one ILC living in different areas. Therefore, it is advisable for the resource user to seek clarification or consult the head of a particular indigenous community or anyone from the ILC with regard to this issue.

[10] Sagong Tasi v Kerajaan Negeri Selangor [2002] 2 MLJ 591.
[11] Nor Nyawai & Anor v Borneo Pulp Plantations [2001] 6 MLJ 241, by Ian Chin J.
[12] http://www.bbec.sabah.gov.my/japanese/downloads/TEK_study_2011/01%20Traditional%20Knowledge%20and%20Biodiversity%20Conservation%20in%20Sabah.pdf. [as at 2011]

In this circumstance, the resource user must identify all communities who are holders of the traditional knowledge associated with the BR and the PIC must be obtained from their duly identified representative or organization.

If after exercising all necessary efforts it is not practicable in all the circumstances of the case to ascertain all such holders, and this can be proved to the satisfaction of the CA. Then the resource user must obtain the PIC from those representative(s) or organization that he is able to identify.

4.4. What if there is a claim from another ILC after the application is approved (late claim)?

If after the application is approved, there is a claim by any ILC that it is the rightful holder of the traditional knowledge associated with a BR, the community should refer this matter to the CA. The CA will determine the claim in accordance with the following steps:

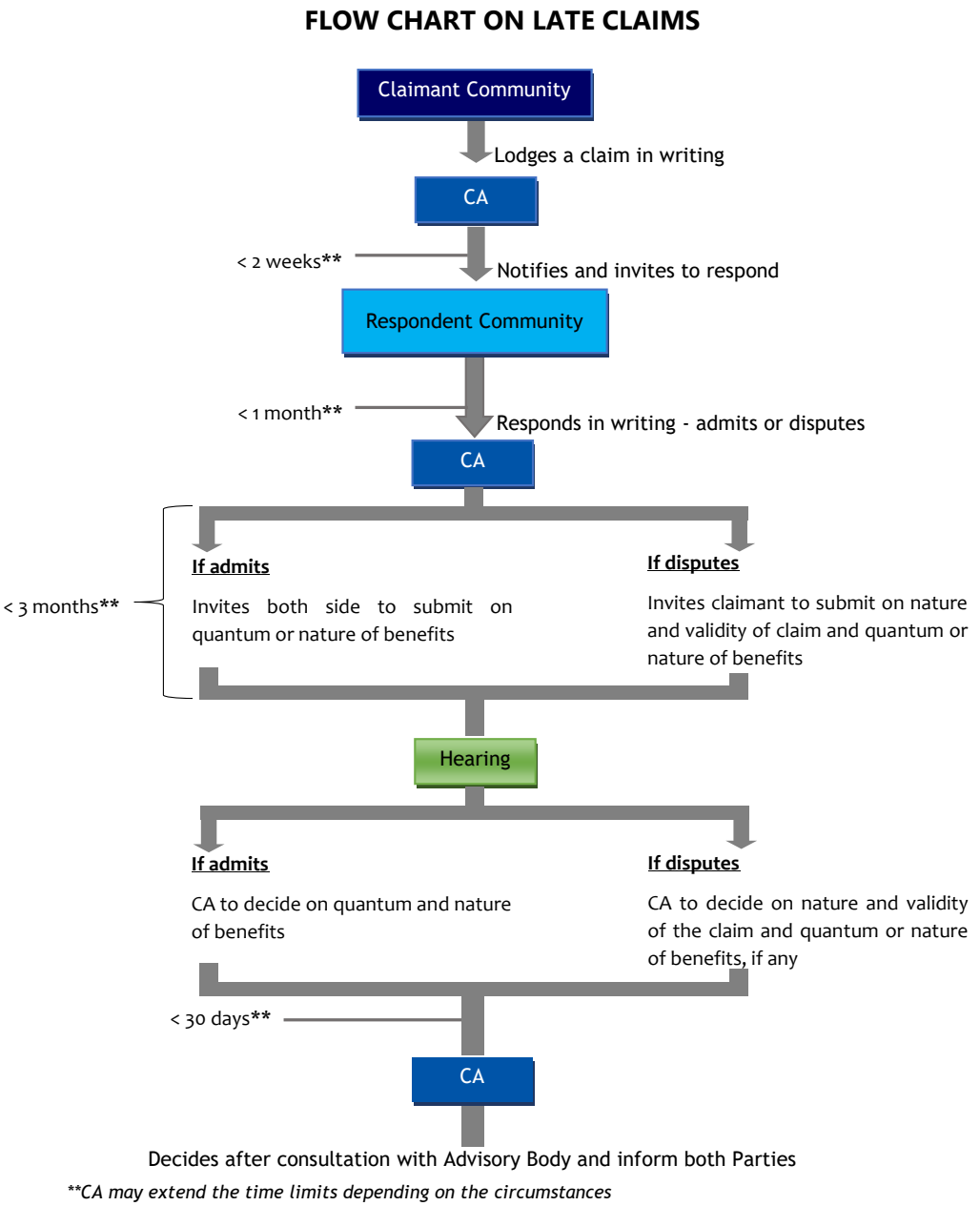
- Consult the ILC whose PIC has been obtained and benefit sharing agreement has been entered into to determine the validity of the claim ("original ILC");

- Request the ILC who has made the claim ("new ILC") to prove its claim. Such evidence to substantiate the claim may include publication of relevant knowledge by authors in an article or book, old manuscript, record by the community's traditional leader / healer, record of previous communication with the user and such like;

- If it is proven by the new ILC that they are also the rightful holder of the TK, the CA will declare that the new ILC is entitled to share benefits under the benefit sharing agreement;

- Thereafter, the CA will determine the nature of benefits or the quantum in consultation with all the ILC concerned, that is, the original ILC or ILCs if there is more than one, and the new ILC.

Figure 2: Process for determining a claim by an ILC after approval given



***CA may extend the time limits depending on the circumstances*

It is worth noting the following:

a) The user who has got the approval will not be affected as regards the benefits that he is required to give.

b) The scope for the determination of the competing claim relates only to the sharing of the benefits.

c) The determination of benefits to be shared with the new ILC will be within the scope of the benefit sharing agreement. For example, the benefits agreed under the benefit sharing agreement with the original ILC are the payment of 6% royalty and the opportunity to work in the user's company. The same benefits now will be shared with the new ILC, without affecting the total benefits agreed to be provided by the user.

4.5. When PIC should be sought?

PIC must be obtained in advance, before the commencement of any access activity that is the taking of any BR or obtaining any TK.

4.6. What information must be disclosed in obtaining PIC?

Before commencing access to the BR or TK, resource user must make full disclosure of all relevant information to the relevant ILC. This must be in a local language understandable by the ILC. The key is to ensure that the community is truly informed with information that is accurate, objective and sufficient. This will instill trust and allow for a continuing good relationship between the parties.

The following information should be provided in order for the relevant ILC and the CA to determine whether or not PIC and the permit should be given:

i. The details of the proposed project: methodology, the type and quantity of resources sought (if possible, provide the local and scientific name of the resources), frequency, purpose of the project, starting date and duration of the activity, geographic prospecting area, identification of

where the research and development will take place, and how the research and development is to be carried out.

ii. Any foreseeable consequences of the project, specifically including but not limited to the possible destination of knowledge or material acquired.

iii. A preliminary assessment of the likely social [13], cultural [14] and environmental[15] impact at each stage of the proposed access activity.

iv. Information regarding the legal entity and affiliation of the applicant and its sponsors, including identification of participating individuals, financing and collaborating organizations (unless there is a non-disclosure provision which is reasonable in the circumstances), local bodies involved, and possible third-party involvement.

v. Personnel likely to be involved in the execution of the proposed project (including indigenous people, private sector staff, research institutions, government employees).

vi. All intended uses and new uses, i.e. for commercial interests, as that may require new or additional PIC.

vii. Procedures that the activity or project may entail.

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[13] According to Akwe: Kon Guidelines, *Social impact assessment* is a process of evaluating the likely impacts, both beneficial and adverse, of a proposed development that may affect the rights, which have an economic, social, cultural, civic and political dimension, as well as the well-being, vitality and viability, of an affected community - that is, the quality of life of a community as measured in terms of various socio-economic indicators, such as income distribution, physical and social integrity and protection of individuals and communities, employment levels and opportunities, health and welfare, education, and availability and standards of housing and accommodation, infrastructure, services.

[14] According to Akwe: Kon Guidelines, *Cultural impact assessment* is a process of evaluating the likely impacts of a proposed development on the way of life of a particular group or community of people, with full involvement of this group or community of people and possibly undertaken by this group or community of people: a cultural impact assessment will generally address the impacts, both beneficial and adverse, of a proposed development that may affect, for example, the values, belief systems, customary laws, language(s), customs, economy, relationships with the local environment and particular species, social organization and traditions of the affected community.

[15] *According to* Akwe: Kon Guidelines, *Environmental impact assessment* is a process of evaluating the likely environmental impacts of, and proposing appropriate mitigation measures for, a proposed development, taking into account interrelated socio-economic, cultural and human health impacts, both beneficial and adverse.

viii. Indications of some form of benefit-sharing arrangements, if possible.

ix. All legal options available to the community, including its right to forbid access to, or the use of, the resources and TK.

x. A protocol of acknowledgements, citation, authorship, and inventorship, anonymity and confidentiality in any subsequent publications.

If the community requests specific additional information, the applicant should provide such information as soon as possible. The PIC system should be viewed as an on-going interactive process that begins with an informative and understandable disclosure and explanation of the access activities, followed by a discussion of the issues related to potential benefit-sharing, biodiversity conservation, intellectual property and other relevant issues.

4.7. How to obtain PIC?

This forms an essential part of the PIC system because all affairs of the indigenous governance are regulated by the community's formal or informal customs, which includes the use and protection of land and resources. Hence, ILC's customary laws and practices, community protocols and procedures must be respected at all times, during the entire process.

There must be due respect of the ILC's unique law, governance system, customs, practices and culture. Users must go through a proper consultation process, and documentation to foster transparency in the entire PIC process. *(See PIC document format)*

Users are advised to consult the CA regarding the procedures for obtaining the PIC of each ILC as each ILC may be unique and distinct and in accord with its particular and local customary law and practices. Therefore, each ILC may have its own set of detailed procedures of granting PIC. In other words, there will be no "one size fits all ILC".

However, there are some common features of the procedures that are set out in the PIC protocol. Accordingly, users are advised to carry out the following steps to obtain PIC from the relevant ILC.

1) Consult the relevant CA on the necessary format of the application or specific terms and information required and any other requirements or conditions for the application of PIC.

2) Identify the rightful owner of the BR or holder of the TK in accordance with the Act.

3) Establish a consultation process and information exchange with the ILC concerned to make full disclosure of information related to the activity, and during the discussion, clarify concerns and/or doubts and respond to the ILC's requests for any further or specific information or documentation. (Refer to the PIC Protocol in Annex 2 for further details.)

4) It is worth noting that the communities should be given ample time to deliberate on the matter.

5) Once the decision is made by the community in accordance with their customary laws and practices, protocols and procedures, and if it is in the affirmative, a PIC document as appears in Annex 2 with particulars will be issued and provided to the applicant. This concludes the PIC process and thereafter access must be in compliance with the terms and conditions in the said PIC document.

4.8. What is the Best Practice Approach?

PIC is a process, and it involves many stages prior to and after the PIC is granted. Therefore, it is advisable to apply best practice standards to build or maintain the relationship and confidence between the resource user and the provider.

The following are some of the best practices that the user should adopt:

- The user should obtain the PIC well in advance, before accessing a BR or TK.
- The resource provider should be given the opportunity to collaborate with and provide consent or objections to the research or development before it takes place. So he should be consulted within a reasonable time frame for him to consider the information available and likely consequences attached to the activity.
- All information provided must be accurate and up to date.
- Note that BRs are to be used only for the purpose expressly specified at the time of the PIC negotiation and as later stated in the PIC document. Such 'use' refers to different category of use, for example, pharmaceutical, nutraceutical, cosmetic, agricultural or any other use. A new PIC must be obtained before any change of use.

4.9. What should be done if there is a change in the purpose (from non-commercial to commercial)?

Resource User is required to obtain a new PIC, unless otherwise stated in the PIC.

4.10. What should be done if there is a change of use (for example, from cosmetic to pharmaceutical use) of the BR and/or TK?

Resource User is required to obtain a new Prior Informed Consent, unless otherwise stated in the PIC.

4.11. Is there a standard form for PIC?

Yes. The PIC document is in Annex 2 of this User's Guide.

4.12. What about access to resources that do not belong to the ILC?

Access to resources that do not belong to the ILC does not require PIC. However, the consent of the owner of the resources must first be obtained before a permit can be issued by the relevant CA. The law does not prescribe the way in which the consent must be obtained, or the format in which the consent must comply with. As such, any such consent will be determined by ordinary rules and market mechanism.

5. Mechanisms for Benefit Sharing

5.1. What is benefit sharing?

Benefit sharing is the sharing of benefits - both monetary and non-monetary - with the resource provider arising from the utilization of the BR or the TK. It is in recognition of the provider's rights as well as an acknowledgement of the provider's contribution to the management, scientific and development process in relation to the BR or TK. It manifests the concept of equity, which requires benefits to be shared fairly and equitably with resource providers and contributors. Importantly, the benefits can be ploughed back to ensure the continuance of the conservation of the biodiversity and its sustainability and the preservation and enhancement of the traditional knowledge system.

5.2. What is a benefit sharing agreement?

A benefit sharing agreement is a legally binding contract entered into between the resource user who intends to use the BR and/or TK, and the Resource Provider. Similar to a contract, the agreement is legally enforceable by the contracting parties. The benefit sharing agreement is based on mutually agreed terms, meaning it sets out the terms and conditions agreed to willingly by both the contracting parties. Additionally, the terms and conditions must also be fair and equitable. Any non-compliance with the terms and conditions of the contract amounts to a breach of the contract and any aggrieved party may enforce the contract specifically and/or claim damages for the breach.

5.3. In what circumstance is the user required to enter into a benefit sharing agreement?

5.3.1. Access for commercial or potential commercial purpose.

It is mandatory to enter into a benefit sharing agreement with the relevant Resource Provider for any access to BRs and / or TK, *for commercial or potential commercial*

purposes. This must be done before the application for access permit is made to the relevant CA.

5.3.2. Change of utilization purpose.

After a permit for non-commercial purpose is granted, and if there is any change in the purpose of utilisation from non-commercial to commercial or potential commercial purpose, a benefit sharing agreement must be entered into. Meanwhile, the user may continue to access the BR or TK subject to the terms and conditions of the existing permit.

5.3.3. Access for non-commercial purpose.

While it is necessary to negotiate the benefits in the case of access for commercial or potential commercial purpose, it is good practice to provide benefits for non-commercial research and development activities. For example, for pure academic research, parties can expressly state the sole purpose of using the BR is purely for academic research and the outcome is to be contributed to add to the corpus of knowledge for society. The CA may also impose some form of benefit sharing as one of the conditions upon issuance of permit. It is also important to take note that the relevant ILC may request, upon issuance of their PIC, for benefits to be shared.

5.4. What is the information required for benefit sharing agreement?

The following provides an indicative list of the typical information necessary for inclusion in a benefit sharing agreement, in line with Regulations 9:

- Full details of the parties to the agreement, i.e.:
    - If the resource user is an individual, his / her name, identification or passport number and corresponding address; and

- If the resource user is an institution, its name, registration number and registered or business address;

- Details regarding time and frequency of entry to the area for collection;
- Description of the BRs, including type and quantity of BR to be collected, and the geographical / ecological area of activity;
- Description of the TK to be accessed, including its source;
- Purpose of access (for commercial, potential commercial or non-commercial);
- The intended use of the BR and TK (if any);
- Any limitations on the possible use of the BR;
- A commitment to enter into a fresh agreement in case of any change of use;
- Ownership of data and results of research;
- Benefit sharing both monetary and non-monetary;
- Matters relating to biodiversity conversation;
- Conditions in relation to IPR.

5.5. What are the legal clauses that should be included in the benefit sharing agreement?

In addition to the above indicative list of information for a benefit sharing agreement, a benefit sharing agreement should also include all or any of the following:

- Renegotiation and review clause for any change of the terms of the agreement;

- Third party clause: obligations imposed in the event of transfer of BR to third parties;
- Obligation to respect, preserve and maintain the knowledge, innovations, and practices of local and indigenous communities;
- Obligation to protect and encourage the customary use of BR in accordance with traditional practice;
- Termination clause of the agreement;
- Treatment of confidential information;
- Provisions regarding the sharing of benefits arising from the utilization of BRs and their products (including samples);
- The consequence for the breach of contract / agreement;
- Contact details of the institution, including address, phone number, fax and email address;
- Name of a contact person in the institution, including a certified copy of the person's identification document and his designation in the institution;
- The contact details of the recipient of the BRs if this is someone other than the resource user;
- Period of the agreement;
- The time frame of the anticipated R&D.

A model benefit sharing agreement as a guide is in **Annex 3**. The agreement proposes mandatory and optional terms for inclusion in the agreement.

5.6. What kind of benefits can be expected to be shared?

Generally, there are 2 types of benefits that can be negotiated with the Resource Provider. Users are advised to negotiate benefits in the best interest of both parties, by considering local conditions and the capability to fulfill these benefits.

The benefit sharing negotiation is a free and open process. Hence, both parties may propose the kind of benefits for inclusion.

The following provides a non-exhaustive list of monetary and non-monetary benefits:

Monetary benefit	Non-Monetary benefit
• Access fee / fee per sample collected or otherwise acquired • Up-front payment • Milestone payment • Payment of royalties • Research funding • Venture capital funding • License fee • Payment of salaries • Flat fee	• Sharing of R&D results, including access to research data and collections, products and technologies developed • Participation in access activity or product development or employment opportunities • Collaboration and contribution • Consensual transfer of BR and / or knowledge under fair and most favorable terms • Technology transfer • Contributions to the local economy • Food and livelihood security benefits • Training and capacity building • Acknowledgment of the origin of the resource, recognition and promotion of TK • Recognition and / or co-ownership in IPR • Co-authorship of publications

5.7. How to determine whether the benefits shared are fair and equitable?

There is no specific formula to determine whether or not the benefits shared are fair and equitable. After all, the agreement is entered into freely between the contracting

parties, and parties are entitled to negotiate and renegotiate until there is agreement. This would indicate that they are satisfied that the terms and conditions are fair and equitable.

Having said that, it is pertinent to note that certain Resource Providers are in a weaker position at the negotiating table as compared to certain users. For instance, the level of understanding of indigenous peoples may not be as the industry players seeking access with regards to the range of complex issues pertaining to research and development activities, technologies and market mechanism. It is therefore advisable for the user to ensure that the negotiation process and the ultimate agreed benefits conform to internationally recognized best practices. The user should ensure that the provider understands and is well informed in arriving at their decision. The Agreement must be developed through comprehensive consultation and transparent negotiation between the parties, involving a full disclosure of necessary information. See further the PIC Protocol in **Annex 2**. ILC are also free to engage advisers or lawyers to help them negotiate the agreement.

The Resource Provider may revoke any PIC granted and not enter into the benefit sharing agreement if the terms and conditions are not fair and equitable from their point of view.

5.8. What if the agreed benefits no longer fair and equitable?

Any party should have the right to review the terms and conditions in the benefit sharing agreement. However, this right to review must be provided for in the agreement. Such review can also be done if the parties agree to do so.

5.9. What if parties need to amend the benefit sharing agreement?

Parties may proceed to amend any provisions of the benefit sharing agreement without the need to get any prior approval from the CA, subject to the terms and conditions provided for in the permit.

5.10. Must the benefits be shared with the government?

Yes. In the following circumstances:

a) When the Federal Government or State Authority is the Resource Provider

   (i) when they are the physical resource provider for all BR growing or kept within their state jurisdiction.

   (ii) when they are the 'state of origin' where the BR originate from their state and kept in ex-situ conditions.

   (iii) if the resource is held in private land or in ex-situ conditions by private body and the origin of the BR cannot be ascertained with due diligence.

   (iv) when the TK holder (the relevant community) cannot be identified.

b) Where the Federal Government or State Authority is not the Resource Provider, there must be payment of a percentage of any monetary benefits derived under the benefit sharing agreement to the Federal Government or respective State Authority. The percentage will be communicated to the applicant when the permit is granted. This will be on a case by case basis with the discretion of the particular state. This is relevant in the following scenarios:

   (i) When the Resource Provider is the public body (government department, agency or public higher education institution) holding the resource in ex-situ conditions, where the origin of such resource cannot be ascertained with due diligence and benefit sharing agreement is entered into with the public body;

   (ii) When the Resource Provider is ILC, as the provider of BR where such resource is on the land which they have an established right in law or as the provider of knowledge, where they are holders of such traditional knowledge and benefit sharing agreement is entered into with the relevant ILC.

(iii) When the Resource Provider is an individual in respect of the genetic resource[16] found within his or her body and benefit sharing agreement is entered into with the individual.

5.11. Where would the monetary benefits go after they are paid to the government?

The Act mandates the CA to channel any payment received by the Federal Government or respective State Authority under any benefit sharing agreement (whether by way of benefit sharing or a payable percentage as discussed above) for conservation of biological diversity and the sustainable use of its components. The fund may be used for the purposes of conservation of wildlife and ecosystem, granting fund for projects related to biodiversity, climate change, and international waters, land degradation, the ozone layer, and persistent organic pollutants. This is truly the objective and spirit of the ABS regime promulgated under the CBD and the Nagoya Protocol - that is, the creation of a self-functioning system to achieve the goal of maintaining the diversity of life on earth.

With regards to benefits obtained under the benefit sharing agreement in situation where the TK holder (the relevant community) cannot be identified, such benefits must be applied for the interest of ILC as appropriate and upon advice of the respective Advisory Body.

[16] Paragraph 12(2)(f) and 15(3)(f) of the Act will be enter into force at a later date determined by the Minister.

6. System of Obtaining Permit

6.1. What is a permit?

A permit is a document signifying the decision of the government to grant access to the BR or the TK to the applicant. A permit is issued by the designated CA from where the resources or TK is accessed (*See Annex 1*). The permit issued by the CA and made available to the Access and Benefit Sharing Clearing House Mechanism established under the Nagoya Protocol becomes the internationally recognized certificate of compliance[18] which serves as evidence of legitimate access to the resource and TK covered under the permit.

6.2. How many types of permit are there?

There are two types, namely:

(a) Access for Commercial or Potential Commercial Purpose; and

(b) Access Non-Commercial Purpose.

6.3. Who should apply for a permit?

It is compulsory for anyone who intends to have access to BR and/or TK to apply for a permit. As explained earlier, access means the taking of BR and/or TK for purpose of R&D.

This will include bioprospectors who wish to conduct research and development activity with commercial or potential commercial interest, most commonly in the pharmaceutical and medical industry, and herbal industry. The permit to access the material or associated TK is effective throughout the chain: from the collection to discovery phase to investigate commercial potential up until the commercialization phase of the new product. This applies across the board, whether you are from the

[18]Nagoya Protocol on Access to Genetic Resources and The Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, Article 17(2)

private sector, a local or foreign company, public sector, public university, government agency or others.

Also, as a general rule, users who are interested in pursuing pure research activity with no commercial interest are obliged to apply for a permit before accessing the BR or the TK. For example, a researcher from Nottingham University who wishes to carry out analytical taxonomic studies on BR must apply for a permit in order to have access to such resource.

Furthermore, intermediaries are also required to get a permit, unless they are named as an agent in the permit application by the applicant (user) to act on behalf of the applicant with limited rights and are bound by the terms and conditions to be imposed by the CA. *(See earlier explanation on "intermediaries").*

6.3.1. What are the exemptions to applying a permit?

In accordance with Section 18 of the Act, the following research activity and personnel are excluded from applying for a permit. This is to ensure that the routine research activities of public institutions will not be affected inhibited by the law. Note that the said Section refers to 'research' per se and not 'research and development'. This differentiates the R&D with commercial intent from the pure research.

Category 1
Persons employed or studying and carrying out research, in or under the authority of, a public higher education institution, public research institution or Government agency within Malaysia.

> *Scenario 1*: A researcher in FRIM conducting research on a plant kept in the lab that originates from Berembun Forest Reserve is exempted from obtaining a permit under the Act.
>
> *Scenario 2*: A PhD candidate in University of Malaya doing her thesis based on a microorganism kept in the campus lab is exempted from obtaining a permit under the Act.

Scenario 3: A researcher in FRIM intends to conduct taxonomic research in Berembun Forest Reserve is *not* exempted from obtaining a permit under the Act.

Scenario 4: A researcher in FRIM intends to conduct research on a plant to be taken from Berembun Forest Reserve is *not* exempted from obtaining a permit under the Act.

Scenario 5: A researcher in FRIM conducting research on a plant kept in the lab that originates from Berembun Forest Reserve intends to develop a product (commercial purpose) arising from the research is *not* exempted from obtaining a permit under the Act.

Scenario 6: A researcher in FRIM is asked by a permit holder to carry out research on specific research area on a plant obtained from Berembun Forest Reserve is exempted from obtaining a permit under the Act (similar to Category 4 below).

Category 2
Exchange of BR between persons within a public higher education institution, public research institution or Government agency within Malaysia for non-commercial purpose. For instance, researcher A in FRIM passes microorganism X to researcher B in FRIM for further research. Researcher B is exempted from obtaining a permit.

Category 3
Exchange between the public higher education institutions, public research institutions or Government agencies within Malaysia. For instance, researcher A in FRIM shares the microorganism X with a Phd candidate in University of Malaya, the Phd candidate is exempted from obtaining a permit.

Category 4
Persons or a private institution, within or outside Malaysia who access a BR from a permit holder or the person or institution under Category 1, at their request to further carrying out or continuing any research for non-commercial research. The 'third party' is exempted from obtaining a permit. For instance, due to the lack of

technological know-how or capacity, FRIM sends microorganism X to a company in US for further research on the material. The company in US is exempted from obtaining a permit. This is to facilitate research by allowing the national researcher to send resources abroad for further analysis. Having said this, it is important for the permit holder or the person or institution under Category 1 to bear in mind the prohibition in transferring such BR to a third party without the prior approval from the relevant CA [Section 19 of the Act]. This clause also does not intend to act as a backdoor when it comes to collaboration by a national researcher with a foreign research institution for a full-blown research project which requires the foreign research institution to obtain a permit under the Act. Furthermore, if the resource or TK is from Sabah or Sarawak, a user must refer to Sarawak's and Sabah's State ABS law on Export Permit (Sarawak), Export License (Sabah), Wildlife Conservation Act 2010 (for license or special permit under Wildlife Conservation Act) or make inquiry at the Royal Malaysia Customs Department for more information.

6.3.2. If I am exempted from applying for a permit, am I regulated by any rules or terms and conditions?

Yes. Even though your research is facilitated by doing away with permit application, you are still bound by the requirements in the Act and Regulations. Notably, even if the permit requirement is exempted, the PIC of ILC is still required if the resource or TK belongs to ILC.

No person or institution referred to in Category 1 in paragraph 6.3.1. above is allowed to transfer any BR or TK or results of research in relation to the resource accessed to a third-party user who does not fall under Category 1 without the prior approval of the CA. 'Transfer' includes allowing a third party to take over the research, or sharing a BR and research results to enable a third party to conduct similar research or further research on the resource. The CA has the discretion to decide on the request for any transfer, and if approval is given, terms and conditions may be imposed. 'Transfer' should be distinguished from 'carrying out or continuing any research for non-commercial purpose'. The latter refers to a situation where assistance is needed due to the lack of technological skills and know-how; in which case resources are handed over to a third party to allow for specific research to be conducted. In this situation,

you only need to notify the CA and this may be made subject to terms and conditions as may be imposed by the CA.

The research must be purely non-commercial. Once the purpose is changed to commercial or potential commercial, meaning that a potential product is anticipated or patent right is to be obtained, you must proceed to apply for a permit for commercial or potential commercial purpose. Similarly, the third-party transferee abovementioned must also apply for such a permit.

In any event the institution or government agency must maintain a register to record particulars of the researcher utilizing the BR, the exchange of resource by researchers within the institution / agency or with other institutions/agencies, and finally, the third party who is carrying out or continuing research at the request of a permit holder or the person or the institution.

The researcher in the institution/agency must record the particulars stated above as required by the institution or agency.

6.3.3. If I am exempted from applying for a permit, can I request a third party from a private institution to assist to carry out certain specific research?

Yes. This is allowed under the Act where assistance is needed due to the lack of technological skills and know-how – subsection 18 (c). You need to notify the CA and the access by the third party may be subject to terms and conditions as may be imposed by the CA.

6.3.4. If I access the resource from a person or institution referred to in Category 1, do I need to apply for a permit?

Yes, if it amounts to 'transfer' and not 'carrying out or continuing research for non-commercial purpose' at the request of the permit holder or the person or institution. Any third-party user who does not fall under Category 1 must apply for a permit, unless otherwise decided by the CA. If the access constitutes 'carrying out or

continuing research for non-commercial purpose', then a permit is not needed but such access is subject to any terms and conditions as may be imposed by the CA.

6.4. How is the access for non-commercial purposes facilitated?

Instead of negotiating and entering into a benefit sharing agreement with the resource provider which may take time to conclude, the applicant to obtain a permit needs only to submit a duly signed statutory declaration, which is a statement on oath (Second Schedule of the Act) declaring that the applicant does not intend to use the resource for commercial or potential commercial purpose together with relevant undertakings. Further, as discussed above certain group of researchers in public institutions are also exempted.

6.5. When to apply for a permit?

A permit must be applied before the commencement of any 'taking' activity. [For what constitutes 'taking' see paragraph 3.5. above.]

6.6. Are there other laws I need to pay attention to?

One must bear in mind that the Act is in addition to and not in derogation of, the provisions in other laws relating to forests, wildlife, animals, fishery and international trade in endangered species. For example, a special permit is required for conducting research or study on totally protected wildlife under the Wildlife Conservation Act 2010. Such a special permit must be obtained before access may commence. In other words, a permit under this Act does not legitimize all activities regulated under such other relevant laws. As such, it is advisable to obtain any such permits *before* any application under this Act so as to expedite the processing of the ABS permit application by the CA. The CA will refuse to grant a permit if there is no compliance with the requirements of any other written law.

6.7. What is the information needed to apply for a permit?

- Details of the applicant;

- BR and / or TK to be accessed;
- Place and location of the BR and / or TK intended to be accessed
- Purpose of research, i.e. for commercial or potential commercial or non-commercial purposes;
- The use of the BR and / or TK, i.e. for pharmaceutical / nutraceutical / cosmetic / agricultural or any other fields;
- Proposed single or multiple taking;
- Proposed quantity to be taken;
- Details of the resource provider;
- Details of the authorized intermediary, if any;
- Details of the holder of the TK intended to be accessed, where applicable;
- Confirmation that the benefit sharing agreement between the resource provider and the applicant has been entered into, where applicable;
- Confirmation that the PIC of the relevant ILC granting the BR and/or TK has been obtained, where applicable;
- Any other information as may be required by the CA

6.8. What are the documents needed to apply for a permit for commercial or potential commercial purposes?

The accompanying documents required for application are the following:

- Certified true copy of the PIC of ILC in the prescribed format, if BR or TK to be accessed belongs to ILC;

- Certified true copy of the benefit sharing agreement entered into between the applicant and the resource provider;

- Original Declaration as in Annex 4A (for an individual) and as in Annex 4B (for an institution or entity) duly affirmed by a Commissioner for Oaths;

- If the applicant is an individual, certified true copy of the Identity Card / passport of the applicant;

- If the applicant is a company, certified true copies of the Memorandum of Articles of Association/Constitution and other relevant forms;

- Any other document as may be required by the CA.

6.9. What are the documents needed to apply for a permit for non-commercial purposes?

The accompanying documents required for application are the following:

- Certified true copy of the PIC of ILC in the prescribed format, if BR or TK to be accessed belongs to ILC;

- Original Statutory Declaration in the prescribed format (Schedule 2 of the Act) duly affirmed by a Commissioner for Oaths, in the case of access for non-commercial purpose;

- Original Declaration confirming the details of the applicant and the application in the prescribed form duly affirmed by a Commissioner for Oaths;

- If the applicant is an individual, certified true copy of the Identity Card / passport of the applicant;

- If the applicant is a company, certified true copies of the Memorandum of Articles of Association / Constitution and other relevant forms;

- Letter from local collaborator issued by a local public higher education institution, public research institution or government agency or an application for such exemption;

- Any other document as may be required by the CA.

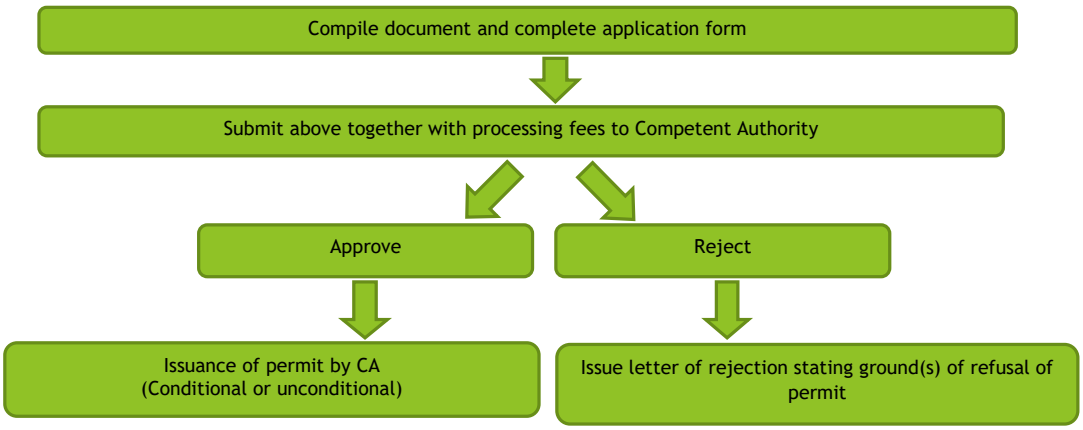
6.10. Can the requirement of local collaborators be exempted?

The requirement to have local collaborators is only applicable for access for non-commercial purpose. Even then, this requirement can be exempted if the CA is satisfied that the applicant is a non-profit organization based or registered in Malaysia, and the research activity will involve local researchers and a program for capacity building.

6.11. How to obtain a permit?

The system of obtaining a permit is universal for any peninsular State for any purpose, and applicable for both access to BR or TK. Application for permit can be accessed online at https://www.myabs.gov.my/.

Figure 3: Steps for applying for a permit



The system of obtaining a permit to access begins with the compilation of all relevant documents, including the PIC (if it involves resources or TK of ILC) and benefit sharing

agreement (in the case of access for commercial or potential commercial purpose). The application for the permit must be made in the prescribed form (see regulation 5) together with the above documents and the processing fee to the relevant CA. The CA then decides whether to approve or reject the application.

The applicant may be granted a conditional or unconditional permit. A CA is entitled to impose any terms and conditions as it thinks fit for the issuance of the permit. The applicant is granted access to the BR and / or TK specified upon the issuance of the permit.

The application may be rejected on the grounds for refusal set out in the Act: (see section 12.3). Access is absolutely prohibited if the permit application is rejected. The applicant must be informed of the rejection in writing.

6.12. How much is the fee for the application?

The fee payable upon application is prescribed in Schedule 2 of the Regulations. It is a standard fee applicable to all peninsular States.

6.13. Is there a standard permit?

Yes. The form of the permit is provided in Schedule 1 Form 2 of the Regulations. The permit contains the following information:

- Unique Identifier of the permit;
- Name of the permit holder;
- Permit issuing authority (the relevant CA);
- Date of issuance;
- Subject matter (BR and / or TK) covered by the permit;
- The permitted use of the BR and / or TK;

- The purpose – commercial or potential commercial or non-commercial purposes;
- Place and location of the BR intended to be accessed;
- Quantity that may be taken;
- Details of the resource provider;
- Details of the holder of the TK;
- Confirmation that a benefit sharing agreement has been entered into, where applicable;
- Confirmation that the PIC of the relevant ILC has been obtained, where applicable.

6.14. What does a permit signify?

A permit will serve as evidence of the following:

- PIC of the CA has been obtained. This also accords with the provisions of the Nagoya Protocol.
- PIC of the ILC, if relevant, has been obtained;
- Benefit sharing agreement has been entered into, if relevant;
- The origin of the BR accessed, namely the region where the BR originated;
- Legitimate permit holder, an individual or a legal entity;
- Permitted use, namely for pharmaceutical, nutraceutical, cosmetic, agricultural or other use.

6.15. What are the grounds for rejecting an application?

A CA shall refuse to issue the permit if the applicant falls into any of the following grounds:

a) The applicant

- Committed an offence under the Act;
- Adjudicated a bankrupt or, in the case of a company, has been wound up;
- Originated from or otherwise based or operating in jurisdictions which do not provide for adequate and effective measures that requires BR utilized within their jurisdiction to be accessed in accordance with PIC and that MAT be established as per the Act.

b) The application

- Incomplete application;
- Wrongly declared purpose.

c) Compliance

- Failure to comply with the requirements of the Act or any other written law;
- Failure to establish a benefit sharing agreement (in the case of permit for commercial or potential commercial purpose);
- Failure to obtain the relevant PIC, if necessary.

d) The nature of the resource

- Any threatened taxa;
- Any endemic species;
- Any rare species;
- Any species protected under any federal or state law;

unless the CA is satisfied that such access does not undermine the conservation and sustainable use of biodiversity.

e) The use / research

- For the development of biological or chemical weapons, or for military or terrorist purposes;
- Contrary to the national or State interest;
- Associated with genetic use restriction technology;
- Contrary to ethical values;
- Contrary to public interest;
- Contrary to related international agreements or instruments to which Malaysia is a Party.

f) User country

- Failure to provide for adequate and effective measures to address situations of non-compliance under this Act.

g) Access resulting in adverse implications

- Adverse effects on the livelihood or cultural practices including religious, ceremonial or other traditional or customary practices of ILC;
- Adverse environmental impact which may be difficult to control and mitigate;
- Cause genetic erosion or affect any function of the ecosystem;
- Adverse effect on food security.

It is worth noting that the list of grounds of refusal is not exhaustive. The CA may reject an application for grounds not listed above. This stems from the recognition by the CBD that natural resources are the sovereign rights of a country. Any decision to grant or refuse access remains in the discretion of the government, with due process observed.

6.16. How will the decision of the Competent Authority be made?

The CA has full discretion in making its decision in accordance with the provisions in the Act. However, if it relates to matters pertaining to ILC and TK, then it must seek the advice of the Advisory Body set up by the CA on such matters. The CA must take the advice of the Advisory Body into account in making the decision.

The CA may also seek the advice of the Advisory Committee before reaching a decision. The Advisory Committee is established by the NCA comprising persons with experience, knowledge and expertise on matters relating to the scientific, legal, technical, ethical, and other relevant disciplines.

Finally, a CA may as it thinks necessary establish a committee to assist in carrying out its function. This includes any matter that could help the decision making process by the CA.

6.17. Are there timeframes in relation to the application stipulated in the Regulations?

Yes. Regulations 6 and 7 provide for such timeframes.

Regulation 6 requires the CA to issue an acknowledgement of receipt of the application within 14 days, if the application is complete.

If the application is incomplete, contains error or any unauthorized alteration or is not accompanied by the prescribed fee, the CA must duly inform the applicant within the 14 days.

Under Regulation 7, the CA must communicate its decision to the applicant—

(a) in the case of an application for permit for commercial and potential commercial purposes, within 90 days from the date of the acknowledgement of the receipt of the application; and

(b) in the case of an application for permit for non-commercial purposes, within 60 days from the date of the acknowledgement of the receipt of the application.

If the CA is unable to decide whether to approve or refuse the application within the stipulated time, the CA may extend the time to a further time which must not exceed 60 days. The applicant must be informed of such an extension of time.

6.18. What are the terms and conditions that can be imposed on the permit?

These terms and conditions are set out in Regulation 8(2). Note that these terms and conditions are not exhaustive. This means that the CA can impose other relevant conditions that it deems necessary.

6.19. Can the Competent Authority impose additional conditions after permit has been issued?

Yes, the CA may at any time after issuing a permit impose additional conditions, or amend or revoke any earlier condition. The CA must give the permit holder a written notice of the intention to impose any additional condition and an opportunity to make written representations within the timeline specified in the notice. Thereafter, the CA will decide and give the permit holder written notice of its decision. The decision will take effect on a date specified in the written notice.

6.20. What should be done if there is a change in the purpose (from non-commercial to commercial)?

It is mandatory for the permit holder to enter into a benefit sharing agreement with the Resource Provider and to obtain a new PIC, if relevant, and thereafter make a fresh application for permit for commercial or potential commercial purpose to the CA.

6.21. What should be done if there is a change of use (for example, from cosmetic to pharmaceutical use) of the BR and / or TK?

It is mandatory for the permit holder to determine whether change of use is prohibited by the benefit sharing agreement entered into with the Resource Provider and the PIC,

- If the answer is in the affirmative, then the permit holder must first obtain a new PIC and enter into a fresh benefit sharing agreement or vary such terms in the existing agreement. Thereafter the user must apply for a permit to the CA.

- If the answer is negative, then the applicant must make a fresh application for a permit to the CA.

6.22. Can a permit be transferred to a third party?

No. Any transfer or assignment of any right, duty, liability or obligation under the permit is strictly prohibited by the Act. It is an offence to do so. Any third party interested in that particular resource accessed must apply for a permit. This is applicable to a permit for commercial or potential commercial purposes. There is no such prohibition for permit for non-commercial purpose in the Act. The CA may impose specific terms and conditions which can include such a prohibition, when granting the permit for non-commercial purpose on a case by case basis.

6.23. If I access the resource from a permit holder, do I need to apply for a permit?

It depends. If the holder of a permit for non-commercial purpose requests assistance to 'carrying out or continuing research for non-commercial purpose' in areas where it lacks technological skills and know-how, then the resource may be passed on to a third party to allow for such research to be conducted. In this situation, a permit is not required to be obtained. However, the access may still be subject to terms and conditions as may be imposed by the CA. In the case of accessing the resource from the holder of a permit for commercial or potential commercial purposes, the law is silent. This means that you need to refer to any specific terms and conditions imposed on the permit itself on a case by case basis.

6.24. Can a permit be revoked or cancelled?

The CA may at any time cancel or revoke any permit issued under the Act**.**

6.24.1. What are the grounds for revoking a permit?

A permit may be revoked on all or any of the following grounds:

a) the permit holder has contravened any provisions of the Act;

b) the permit holder has contravened any of the conditions of the permit;

c) the permit was issued as a result of false, misleading or inaccurate information;

d) the permit was obtained improperly or illegally; or

e) the permit holder has been convicted of an offence under this Act.

6.24.2. Will I be notified of the revocation?

Yes. The permit holder must be given an opportunity to be heard by the CA. Thereafter, the CA will decide and notify immediately the permit holder and the NCA of the decision and grounds for the revocation.

6.24.3. What should I do if my permit has been revoked?

Once the permit has been revoked, access to the BR or TK is forbidden. The permit holder must immediately surrender the permit, any research results and related documents, and the accessed BR to the CA that issued the permit. Failure to do so constitutes an offence punishable under the Act.

6.24.4 Can the permit holder appeal?

Yes. If the permit is revoked, the permit holder may appeal to the High Court within 30 days after being informed in writing of the revocation. The Court has the discretion to confirm or set aside the decision appealed against.

7. Monitoring and Tracking, Reporting, Compliance and Enforcement

Part A: Monitoring

7.1. What is monitoring and tracking?

Monitoring and tracking is a system intended to support compliance with the obligations under the Act and Article 17 of the Nagoya Protocol. In general term, it may consist of a non-exhaustive list of monitoring and tracking tools which (1) detects cases of biopiracy; (2) requires users to keep documentation on the BR or the TK that they have granted access to, in connection with the permit and the conditions attached to the permit; (3) requires users to make periodical report to the CA; (4) requires users to provide relevant information at specific checkpoints; (5) requires users to notify the NCA when a patent application is made; (6) formalizes the access permit as the internationally recognized certificate of compliance; (7) links national efforts with the international community under the Nagoya Protocol.

The aim of establishing a monitoring and tracking system is to enhance transparency about the utilization of BR[21] and TK. With a proper monitoring and tracking system in place, it becomes possible to traverse a series of transactions backward and forward in time, even in instances where some ambiguity may exist. It also makes it convenient to follow events pertaining to the resources, and to accurately recreate those events, when adequate documentation is available. As the time frame of obtaining PIC, and or entering into a benefit sharing agreement up until granting access and thereafter could be long, such a system would be useful for tracking the use or the status of genetic resources[22].

[21] G S Nijar, 'The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries', 2011, South Centre Geneva & CEBLAW) 8
[22]G M Garrity and others, 'Studies on Monitoring and Tracking Genetic Resources: An Executive Summary' <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3035216/>

7.2. Who is responsible for establishing measures for monitoring and tracking?

The obligation of establishing measures for monitoring and tracking the BR or the TK falls to the NCA, assisted by the CA and relevant agencies. All stakeholders must work closely together with the aim of ensuring that the measures established are effective in curbing biopiracy. The Act requires that checkpoints be designated and that users must be required to produce the permit at the designated checkpoints.

7.2.1. What are the mandatory requirements of designating checkpoints?

A checkpoint must be effective in tracking any unauthorized access and use of a BR or TK. Practically, the designated checkpoints must include offices or authorities dealing with applications for IPR, product registration, product market approval and public research funding grants.

7.2.2. How are matters in relation to IPR dealt with under the Act?

Firstly, the users must ensure that the permit does not prohibit or impose any terms and conditions in relation to the IPR. Users must take note that any breach of the terms and conditions in the permit is an offence punishable with fine and/or imprisonment. Secondly, the users must also ensure that in the event there is a benefit sharing agreement between the users and the resource providers, such agreement does not prohibit or provide for covenants in relation to the IPR. Any breach of the covenants in the agreement will render the defaulting party being sued in court. Thirdly, should it be allowed under the permit and the benefit sharing agreement, users must notify the NCA in writing within 30 days from the date of any *patent* application made in or outside Malaysia.

7.2.3. What is the National ABS Clearing House Mechanism (ABS CHM)?

This is a National ABS Clearing House Mechanism (CHM) established by the NCA in compliance with the Nagoya Protocol. The CHM serves as a means for sharing

information on ABS with potential users and resource providers. This is to facilitate access by users by creating a one-stop information hub or portal containing all access requirements and details applicable to all states in Malaysia.

The main source of information in the CHM is that provided by the CAs as required by the Act. This information may include access application procedure, prior informed consent protocol, application fees, timeline for decision-making, area and mapping of each state, permit granted and any other information as may be decided from time to time.

7.2.4. How does the Act handle private and confidential information?

The Act recognizes the following as confidential information:

(a) if it is culturally sensitive; or

(b) if disclosed, it may –

i. damage a person's commercial interests;

ii. result in a risk to the biodiversity; or

iii. be detrimental to the national interest.

The CA determines the confidentiality of information based on paragraph (b)(i) above. However, the applicant needs to apply for any information to be classified as confidential. Confidential information will not be disclosed on the webpage of the National ABS CHM nor will it be made publicly accessible to any unauthorized personnel in any method not recognized by the law.

Part B: Reporting

7.3. Do I have to keep a record and report on access?

Permit holders must keep a record of the following and furnish the same to the NCA and CA within 30 days after a BR is taken:

a) the description of the BR or the TK accessed;

b) the date or dates of taking of such resource;

c) the place where the resource is taken;

d) the size of the BR (weight or physical dimension);

e) the quantity of the BR taken;

f) the common and scientific name of, or given to the BR;

g) the location where the BR is kept;

h) the particulars about any subsequent physical disposition of the BR, including the names and addresses of others having possession of the BR or part of the BR.

Such record must be kept during and for 20 years after the use has been concluded.

7.4. Can I dispose of the BR?

Permit holders may dispose of the BR by offering the same to the CA. If the CA does not wish to accept the same, the permit holder must dispose of the BR in a manner as may be determined by the CA. After such disposal, the permit holder must furnish a report of the disposal to the CA.

Part C: User Measures

7.5. How does Malaysia help enforce ABS law of other countries?

The NCA is tasked to establish user measures aiming at preventing the use or commercialization within Malaysia of a BR or TK which is not accompanied by a permit or its equivalent as required by the law or other regulatory requirements of a Party to the Nagoya Protocol. Such measure would require a user to provide a relevant permit or its equivalent as evidence of compliance. In the spirit of cooperation, Malaysia recognizes any notification by a CA of the other Party to the Nagoya Protocol to be *prima facie* evidence of its content.

Compliance

7.6. Who is responsible for compliance?

The responsibility to comply with the law rests with the users of the BR and/or TK.

7.6.1. What are the responsibilities of the National Competent Authority to ensure compliance?

The NCA, assisted by the CA, is responsible to make sure that the user complies with the law. Thus, it needs to do the following to facilitate and ensure compliance:

(1) Coordinate the implementation and enforcement of the Act by the CAs;

(2) Create awareness and provide training, education and information relating to access and benefit sharing in relation to a BR;

(3) Keep and maintain a register of permits issued by the CAs and information relating thereto;

(4) Establish measures under subsection 30(2) with the aim of monitoring and tracking of a BR accessed;

(5) Establish and maintain a clearing house mechanism.

Part D: Enforcement

7.7. Who is the enforcement officer?

The CA has the power of enforcement. The Minister must appoint enforcement officers upon the recommendation of the respective CAs. An enforcement officer will have the power to carry out enforcement measures in respect of any non-compliance of the law. The implementation of any measures for the purpose of enforcement must be coordinated or in-line with that of the NCA.

7.8. What are the options?

The Act provides a variety of enforcement measures in the event of non-compliance with the law, or any offence committed under the Act.

Some of the options open to the CA include the power to:

i) Investigate;

ii) Arrest;

iii) Search and seize with or without warrant;

iv) Enter premise;

v) Access computerized data;

vi) Seizure of things;

vii) Stop, search or seize conveyances;

viii) Require attendance of persons acquainted with the case; or

ix) Verbally examine persons acquainted with the case.

7.9. What are the legitimate grounds to trigger enforcement process?

There are several circumstances recognized by the law which can trigger the enforcement process.

Any of the following grounds gives the enforcement officer the right to initiate the enforcement process, namely if the enforcement officer:

i) Finds the commission or attempt to commit or abet the commission of an offence relevant to this Act; or

ii) Reasonably suspects of anyone engaged in committing or attempting to commit or abetting an offence.

7.10. What are the additional powers of an enforcement officer?

For the purpose of executing the duty of enforcement, there are some other additional powers conferred on an enforcement officer. These include:

i) To require the production of records, accounts and documents and to inspect, examine and copy any of them;

ii) To require the production of any identification document from any person in relation to any case or offence under this Act;

iii) To make such enquiry, as may be necessary, to ascertain whether the provisions of this Act have been complied with.

8. Offences

8.1. What are the key offences provided for under the Act?

Section	Offence	Penalty
12(6)	Any person who accesses a biological resource or associated TK for commercial or potential commercial purposes without a permit.	• where such person is an individual, to a fine not exceeding RM500,000.00, or to imprisonment for a term not exceeding 10 years or to both; or • where such person is a body corporate, to a fine not exceeding RM5,000,000.00
12(6)	Any person who contravenes any condition imposed on the permit for commercial or potential commercial purposes.	
13(7)	Any person who contravenes the use in relation to the biological resource as specified in the permit for commercial or potential commercial purposes.	• where such person is an individual, to a fine not exceeding RM200,000.00, or to imprisonment for a term not exceeding 10 years or to both; or • where such person is a body corporate, to a fine not exceeding RM500,000.00
13(7)	Any person who contravenes any additional condition imposed on the permit for commercial or potential commercial purposes.	
14(2)	Any person who contravenes the Act by transferring the permit or assigning any right, duty, liability or obligation under the permit to any other person.	• where such person is an individual, to a fine not exceeding RM200,000.00, or to imprisonment for a term not exceeding 10 years or to both; or • where such person is a body corporate, to a fine not exceeding RM500,000.00

Section	Offence	Penalty
15(7)	Any person who accesses a biological resource or TK for non-commercial purposes without a permit.	• where such person is an individual, to a fine not exceeding RM100,000.00, or to imprisonment for a term not exceeding 7 years or to both; or • where such person is a body corporate, to a fine not exceeding RM1,000,000.00
15(7)	Any person who contravenes any condition imposed on the permit for non-commercial purposes.	
16(7)	Any person who contravenes the use in relation to the biological resource as specified in the permit for non-commercial purposes.	• where such person is an individual, to a fine not exceeding RM100,000.00, or to imprisonment for a term not exceeding 7 years or to both; or • where such person is a body corporate, to a fine not exceeding RM500,000.00
16(7)	Any person who contravenes any additional condition imposed on the permit for non-commercial purposes.	
21(2)	Any person who is not an authorized intermediary but has in his possession or under his control a biological resource or TK and supplies, sells, offers or advertises for sale or offers for profit, gain or benefit to a person who requires a permit.	• where such person is an individual, to a fine not exceeding RM500,000.00, or to imprisonment for a term not exceeding 10 years or to both; or • where such person is a body corporate, to a fine not exceeding RM5,000,000.00
28(5)	Any permit holder who fails to surrender the permit, research results and related documents and the accessed biological resource upon revocation of permit.	• where such person is an individual, to a fine not exceeding RM200,000.00, or to imprisonment for a term not exceeding 10 years or to both, and in the case of a continuing offence, to a further fine not exceeding RM5,000.00 for each day where

Section	Offence	Penalty
		offence continues after conviction; or • where such person is a body corporate, to a fine not exceeding RM500,000.00 and in the case of a continuing offence, to a further fine not exceeding RM10,000.00 for each day where offence continues after conviction.
31(2)	Any person who fails to notify the National Competent Authority within 30 days from the date of patent application.	• where such person is an individual, to a fine not exceeding RM100,000.00, or to imprisonment for a term not exceeding 7 years or to both; or • where such person is a body corporate, to a fine not exceeding RM500,000.00

8.2. Is the director of a body corporate personally liable if the body corporate is convicted of an offence under the Act?

Yes. The Act extends personal liability to directors of the body corporate; and as well to its manager, secretary or other similar officers or any person purporting to act in such capacity or manner or responsible for the management of any of the affairs of the body corporate or assisting in such management of the body corporate. Once the body corporate is convicted, such person is deemed to commit that offence and be liable to penalty applicable to an individual unless he could prove that the offence was committed without his knowledge, consent or connivance and that he took all reasonable precautions and had exercised due diligence to prevent the commission of the offence.

Annex 1

Competent Authorities

COMPETENT AUTHORITY	BIOLOGICAL RESOURCE	REGION
Ministry of Federal Territories	All covered under this Act	Federal Territory of Kuala Lumpur, Labuan and Putrajaya
Johor State Economic Planning Unit	All covered under this Act	Johore
Kedah State Economic Planning Unit	All covered under this Act	Kedah
Kelantan State Economic Planning Unit	All covered under this Act	Kelantan
Melaka State Economic Planning Unit	All covered under this Act	Malacca
Negeri Sembilan State Forestry Department	All covered under this Act	Negeri Sembilan
Pahang State Economic Planning Division	All covered under this Act	Pahang
Penang State Economic Planning Unit	All covered under this Act	Penang
Perak State Economic Planning Unit	All covered under this Act	Perak
Perlis State Economic Planning Unit	All covered under this Act	Perlis
Selangor State Economic Planning Unit	All covered under this Act	Selangor
Terengganu State Economic Planning Unit	All covered under this Act	Terengganu
Sabah Biodiversity Council	All covered under this Act	Sabah
Ministry of Urban Development and Natural Resources	All covered under this Act	Sarawak

Annex 2

PIC Protocol

Proposed Standard Protocol for Prior Informed Consent

This Protocol for Prior Informed Consent (PIC Protocol) is the outcome of a study commissioned by the Ministry of Energy and Natural Resources (KeTSA) (formerly known as (Ministry of Natural Resources and Environment (NRE) under the NRE-UNDP/GEF Project on Developing and Implementing a National Access and Benefit-Sharing Framework in Malaysia. It benefited from the inputs from the study commissioned by the NRE in its project in collaboration with the United Nations Development Programme (UNDP) on Capacity Development for the Formulation of a Policy and Regulatory Framework for Access and Benefit-sharing of Biological Resources in Malaysia; the Protocol for Prior Informed Consent (PIC) adopted by the State of Sarawak and the Melangkap Community Protocol developed by the Melangkap Community in Sabah. This PIC Protocol was developed after comprehensive consultations with stakeholders at the national and state levels and with feedback from, and participation of, indigenous communities from: Kampung Ulu Geroh (Perak), Kampung Paya Mendoi (Pahang), RPS Iskandar (Pahang), Kampung Kiding, Ba'Kelalan and Kampung Semadang (all from Sarawak) and Melangkap (Sabah). Communities-based NGOs were also consulted.

This PIC Protocol serves as a guide to users of biological resources and traditional knowledge associated with biological resources to ensure compliance with subsection 23(2) of the Act 795. The provision requires those wishing to access biological resources and/or associated traditional knowledge to obtain the PIC of the concerned ILC, in accordance with their customary laws, community protocols and procedures. This PIC Protocol sets out the minimum standards for compliance. Users are advised to fully understand the spirit of the Protocol. Finally, if there is a specific protocol developed by a particular indigenous community in relation to access and benefit sharing (ABS), such protocol shall prevail.

Protocol for Prior Informed Consent of Indigenous Communities for access to their biological resources and traditional knowledge associated with biological resources

When to obtain PIC

1. The Prior Informed Consent (PIC) of indigenous communities shall be obtained before the commencement of any access activity.

Timeline for obtaining PIC

2.1. The timeline for determining the outcome of an application for PIC shall be decided by the community concerned in accordance with the community's requirements and practice.

2.2. There should be sufficient time for the relevant community to access, understand, analyse and discuss information pertaining to the proposed access application. As a general rule, the time used by the community concerned to deliberate on an access application shall not be less than two weeks and shall not be more than three months.

Entity from whom PIC sought

3. The PIC of indigenous communities shall be obtained from the community as represented by the head of the family or his duly appointed representative in accordance with the process stated in paragraph 6.

Process for obtaining PIC

4. The PIC of the concerned community shall be obtained in accordance with the local cultural norms, customary laws, protocols and procedures, as the case may be.

5. The process shall be based upon any existing community governance organizational structure.

6. To obtain the PIC of a community the following steps shall be followed:

   i. The applicant must apply by a letter in writing in the Malay language to the Chairman of the Village Community Management Council (*Majlis Pengurusan Komuniti Kampung – MPKK)* and the Tok Batin.

   ii. The Chairman and the Tok Batin shall convene a meeting of the MPKK or if there is a Traditional Knowledge (TK) Committee, a meeting of the said TK Bureau/Committee. The meeting will deliberate and decide whether the application should be approved or refused and the terms and conditions to be imposed, if the application is approved.

   iii. The MPKK or the Tok Batin may call a general meeting of all the community members to deliberate and decide on the matter based on the recommendations provided by the MPKK/TK Committee. Notice of the meeting must be sent to each household as well as non-resident members of the community on a best endeavour basis and also be communicated by word of mouth. A notice of the meeting must also be placed on the community notice board. Adequate notice for the meeting must be given.

   iv. The community may require the applicant or any other relevant person to provide further information or input on the proposed project.

   v. Decisions at any meeting relating to the application shall be by a simple majority of the community attending the meeting as represented by the head of the family or his duly appointed representative.

   vi. The decision will be communicated to the applicant by a letter in writing issued by the MPKK, signed by the Chairman and Tok Batin, and bearing the official stamp of the MPKK. Any PIC shall also set out the terms and

conditions. The decision of the meeting shall be communicated to all members of the community including those who did not attend the said meetings shall be informed of the outcome of the application.

The chart depicting the process for obtaining the PIC is appended as **Annex 2c**.

7.1. Meetings and decisions should take place at times and locations and in languages and formats determined by the community concerned.

7.2. The minutes of the meeting will be recorded and documented.

8. The consent must be freely given, that is free from coercion, undue pressure or inducement. Any consent that does not conform to the criteria in paragraph 6 above shall be of no effect.

9. The applicant shall provide to the concerned community information pertaining to the proposed application that is accurate, objective, clear and sufficient to allow the relevant community to arrive at an informed decision. At a minimum, the information should cover, but is not limited to, the following aspects:

i. The details of the proposed project: methodology, the type and quantity of resources sought (if possible, provide the local and scientific name of the resources), frequency, purpose of the project, starting date and duration of the activity, geographic prospecting area, identification of where the research and development will take place, and how the research and development is to be carried out.

ii. Any foreseeable consequences of the project, specifically including but not limited to the possible destination of knowledge or material acquired.

iii. A preliminary assessment of the likely social [23], cultural [24] and environmental[25] impact at each stage of the proposed access activity.

iv. Information regarding the legal entity and affiliation of the applicant and its sponsors, including identification of participating individuals, financing and collaborating organizations (unless there is a non-disclosure provision which is reasonable in the circumstances), local bodies involved, and possible third party involvement.

v. Personnel likely to be involved in the execution of the proposed project (including indigenous people, private sector staff, research institutions, government employees).

vi. All intended uses and new uses, i.e. for commercial interests, as that may require new or additional PIC.

vii. Procedures that the activity or project may entail.

viii. Indications of some form of benefit-sharing arrangements, if possible.

ix. All legal options available to the community, including its right to forbid access to, or the use of, the resources and TK.

[23] According to Akwe: Kon Guidelines, *Social impact assessment* is a process of evaluating the likely impacts, both beneficial and adverse, of a proposed development that may affect the rights, which have an economic, social, cultural, civic and political dimension, as well as the well-being, vitality and viability, of an affected community - that is, the quality of life of a community as measured in terms of various socio-economic indicators, such as income distribution, physical and social integrity and protection of individuals and communities, employment levels and opportunities, health and welfare, education, and availability and standards of housing and accommodation, infrastructure, services.

[24] According to Akwe: Kon Guidelines, *Cultural impact assessment* is a process of evaluating the likely impacts of a proposed development on the way of life of a particular group or community of people, with full involvement of this group or community of people and possibly undertaken by this group or community of people: a cultural impact assessment will generally address the impacts, both beneficial and adverse, of a proposed development that may affect, for example, the values, belief systems, customary laws, language(s), customs, economy, relationships with the local environment and particular species, social organization and traditions of the affected community.

[25]According to Akwe: Kon Guidelines, Environmental impact assessment is a process of evaluating the likely environmental impacts of, and proposing appropriate mitigation measures for, a proposed development, taking into account interrelated socio-economic, cultural and human health impacts, both beneficial and adverse.

x. A protocol of acknowledgements, citation, authorship, and inventorship, anonymity and confidentiality in any subsequent publications.

10. If the community requests specific additional information, the applicant should provide such information as soon as possible.

Outcome of PIC process

11. The terms and conditions that may be imposed for the grant of the consent may include, but not be limited to, the following:

i. binding commitment to enter into a benefit-sharing agreement when additional quantity of the resource is required or if the research yields a prototype which has a commercial value;

ii. a binding commitment to notify the relevant community if there is an application for a patent and to supply relevant information relating thereto; and upon the grant of the patent to forthwith supply to the community a copy of the grant and information in relation thereto;

iii. restriction to access certain areas;

iv. submission of progress report on the status of research periodically as may be determined by the community;

v. declaration of the resource and the quantity collected;

vi. community involvement in the resource collection;

vii. the community must be given priority for contract farming or to carry out activities relating to the terms agreed through negotiation;

viii. duration for the consent including the right to extend the term;

ix. compliance with the concerned community's customary norms and practices;

x. appointment of local research collaborator (whether from local government or indigenous community) by the indigenous community;

xi. submission of a description of the research results and all discoveries made in the course of the activity that might affect the interests of the community;

xii. whether the relevant community requires further PIC to be given where the applicant becomes subject to a merger, reorganisation, transfer of rights, acquisition by another entity, or joint venture; or whether to include in lieu of the requirement of a further PIC that the terms and conditions will be binding on the new entity, assignee or transferee; and

xiii. compliance with all legal requirements enforced by government agencies such as Forestry Department.

12. If the terms and conditions for the grant of PIC are not met, the community may review the consent given and either reaffirm or withdraw the PIC. The community shall not withdraw the PIC without reasonable grounds.

13. In the event of any dispute, applicants must be able to provide evidence that the community concerned has sufficient understanding of the project to be said to have given their informed consent, and to prove that the consent was given without any pressure, intimidation or illegitimate activity. This may require the participation of an independent third-party observer. This observer could be appointed by either party and consented to by the other party.

Formalisation of consent

14. The PIC shall be in writing ('the PIC Document') and state the decision and the terms and conditions agreed to by the community at its meeting, and shall be in a language understood by the relevant community.

15. The PIC Document shall stipulate, among others, the following:

    i. the parties involved;

    ii. the resources involved;

    iii. the quantity allowed to be taken;

    iv. the duration of the consent;

    v. terms and conditions imposed (see paragraph 11); and

    vi. the responsibilities of each party.

Benefit-Sharing Agreement

16. If more quantity of the resource for which the PIC has been granted is needed by the approved applicant to continue the research or if the research yields a prototype which has a commercial value, the approved applicant shall forthwith inform the community.

17. The parties shall then negotiate and enter into the appropriate benefit-sharing agreement:

    i. for the supply of raw material and processing; or

    ii. relating to the commercialisation of the product.

18. The negotiations for the benefit-sharing agreement shall be conducted by members of the community elected at the general meeting which decides upon the approval of the PIC application under paragraph 6.

19. The first Agreement involves activities such as collection of raw material, contract farming and processing. The types of benefits include the payment for the purchase from the community of raw material and payment to the

community for processing the raw material with a provision for the review of the payment terms. The second Agreement contains terms of benefits relating to the sale of products derived from the utilisation of genetic resources and TK associated with it. These include monetary and non-monetary benefits.

20. The timeline to enter into the agreement will be decided through negotiations between the concerned communities and the applicant.

Verification of PIC

21. In considering whether the relevant community has given PIC to the application, the following matters must be taken into consideration:

i. whether the relevant community had adequate knowledge of the laws and regulations governing ABS;

ii. whether the relevant community was able to engage in reasonable negotiations with the applicant;

iii. whether the relevant community was given adequate time:

a) to consider the application for PIC;

b) to negotiate the benefit-sharing agreement;

iv. where applicable, whether the relevant community has received independent legal advice about the application and the legal requirements for PIC;

v. whether a benefit-sharing agreement was entered into upon fair and equitable terms.

Prohibited acts

22. Subsequent to the submission of the application for PIC and during the period for which the application is pending, the following acts or omissions are prohibited:

    i. by the applicant:

        a) the employment or use of force, threat, coercion, intimidation, at any degree or in any manner;

        b) bribery or promise of money, privilege, benefit or reward other than what is presented by the applicant as a potential benefit arising from the proposed project;

        c) clandestine or surreptitious negotiations with any member of the relevant indigenous community;

        d) donations to the relevant community or to any of its members for the purpose of influencing the decision of the community;

        e) holding of unauthorised meetings or similar activity with any member of the relevant community with the intention of unduly influencing the outcome of the PIC process;

        f) deliberately delaying the progress of the PIC process.

    ii. by the indigenous community and/or any of its members and/or any of its duly authorised representatives and/or institutions:

        a) solicitation and acceptance or receipt of gifts, money or other valuable things from the applicant intended to unduly influence the outcome of the PIC process in favour of the applicant;

b) consorting with the applicant or with any person connected to or mediating for the latter intended to unduly influence the outcome of the PIC process in favour of the applicant;

c) negotiating, mediating or transacting business with the applicant without proper authority from the relevant community;

d) giving or promising to give consent in consideration of any offer, promise, future reward, privilege or benefit from the applicant other than what is presented by the applicant as a potential benefit arising from the proposed application.

23. The commission of any prohibited act shall be a ground for invalidating any PIC obtained.

24. The Parties shall carry out their obligation in good faith to facilitate the carrying out of the approved activity and in particular the indigenous community shall ensure that the research activity is not undermined or interfered with.

Confidentiality

25.1. The PIC and the information, including the details of resources and TK and the terms and conditions governing the grant of the PIC, must be kept confidential. No third party should be allowed access to such document without the approval of the Tok Batin and the Chairman of MPKK. Access by the community members should be allowed upon request.

25.2. All information supplied by the applicant under paragraph 11 (xi) must be kept confidential.

Annex 2a

PRIOR INFORMED CONSENT
_____ COMMUNITY
(Non-Commercial Research)

We, the undersigned, in representation of the indigenous or local community named here _____ *(name of community)*, ("our Community") holder of the traditional knowledge associated with biological resource specified below ("our Traditional Knowledge") and / or biological resource specified below on land to which we have a right ("our Biological Resource"), hereby confirm that:

- Our Community wishes to provide our Traditional Knowledge and / or our Biological Resource *(to delete as appropriate) (collectively referred to as 'resource and / or information')* to *(name of applicant)* _____ ("the User").

- This decision has been taken:

  a) on the basis of information provided to us about the User and the use of our resource and / or information which we have read and understood; and

  b) following the process as recommended by the Prior Informed Consent Protocol; and

  c) through a culturally appropriate process of discussion and consultation in accordance with our customary laws and practices, protocols and procedures.

- _____ [*give name(s) of information-providers*] are authorised to provide our resource and / or information to the User in accordance with this PIC although we may nominate persons or entities to provide such resource and / or information to the User from time to time.

- We understand that our participation is entirely voluntary and consent is given free from coercion, duress or misrepresentation.

- We understand that we may withdraw our participation, or any part of it, at any time without explanation or consequences, provided always that a benefit sharing agreement has not been entered into, and that, if we do, *will be subjected to the terms and conditions in such agreement OR *are entitled to request our resource and / or information be removed from the User's records and / or collection and excluded from any future analyses.
  **delete whichever inappropriate*

- We are providing such resource and / or information to the User on the basis that we will retain all our IPR as recognised by law, unless otherwise agreed to in a benefit-sharing agreement. There will be no assumption of transfer of ownership rights in any such intellectual property to the User or any of its partners, agents or members as a result of any contribution by us of such resource and / or information to the User.

- We are providing such resource and / or information to the User on the basis that it will not be put to commercial use by the User, or any of its partners, agents or members or any other third party. In the event that there is an intention of using such resource and / or information for commercial use, a benefit-sharing agreement must first be entered into with the Community, in accordance with the Access to Biological Resources and Benefit Sharing Act 2017 and our customary laws and practices, protocols and procedures.

- Any transfer of our resource and / or information or any data in relation to or derived from our resource and / or information or the results of research to a third party is strictly prohibited unless and until a written confirmation has been granted by the Community and that the interest of the Community is fully protected by the User.

- We are providing such resource and / or information to the User on the basis that sensitive information about personal identity as well as confidential information will not be disclosed, published or otherwise revealed to any other party whatsoever except with specific prior written authorization.

- We understand that if we have any questions about the operation of the User or the use of any resource and / or information which we have provided, or if we have any complaints or concerns relating to the User, we may contact the User's managers / person-in-charge who will discuss our queries or concerns with a view to reaching agreement on an appropriate solution.

- Other terms and conditions:

  _____

  Details of traditional knowledge associated with biological resource (and its use):

  _____

  Details of biological resource:

  _____

Dated:

Witnessed by,

_____
(Signature / Thumb print)
Name of Community:
Name of representative:
NRIC No.:

_____
(Signature / Thumb print)
Name:
NRIC No.:

Interpreted into _____language by

Witnessed by,

_____
(Signature / Thumb print)
Name:
NRIC No.

_____
(Signature / Thumb print)
Name:
NRIC No.

Three (3) copies of this PIC must be prepared and signed. A copy of this form will be left with the community, a copy will be kept with the User and a copy will be kept by the relevant Competent Authority. This form can be accessed / downloaded online at https://www.myabs.gov.my/

Annex 2b

PRIOR INFORMED CONSENT
_____ COMMUNITY
(Commercial or Potential Commercial Research)

We, the undersigned, in representation of the indigenous or local community named here _____ *(name of community)*, ("our Community") holder of the traditional knowledge associated with biological resource specified below ("our Traditional Knowledge") and / or biological resource specified below on land to which we have a right ("our Biological Resource"), hereby confirm that:

- Our Community wishes to provide our Traditional Knowledge and / or our Biological Resource *(to delete as appropriate) (collectively referred to as 'resource and / or information')* to *(name of applicant)* _____ ("the User").

- The User intend to use our resource and / or information for purposes of commercial or potential commercial research with a view to develop a product in the field of *(pharmaceutical / neutraceutial / cosmetic / food / etc)* _____.

- This decision has been taken:

  a) on the basis of information provided to us about the User and the use of our resource and / or information which we have read and understood; and

  b) following the process as recommended by the Prior Informed Consent Protocol; and through a culturally appropriate process of discussion and consultation in accordance with our customary laws and practices, protocols and procedures.

- _____ [*give name(s) of information-providers*] are authorised to provide our resource and / or information to the User in accordance with this PIC although we may nominate persons or entities to provide such resource and / or information to the User from time to time.

- We understand that our participation is entirely voluntary and consent is given free from coercion, duress or misrepresentation.

- We understand that we may withdraw our participation, or any part of it, at any time without explanation or consequences, provided always that a benefit sharing agreement has not been entered into, and that, if we do, *will be subjected to the terms and conditions in such agreement OR *are entitled to request our resource and / or information be removed from the User's records and / or collection and excluded from any future analyses.
  **delete whichever inappropriate*

- We are providing such resource and / or information to the User on the basis that we will retain all our IPR as recognised by law, unless otherwise agreed to in a benefit sharing agreement. There will be no assumption of transfer of ownership rights in any such intellectual property to the User or any of its partners, agents or members as a result of any contribution by us of such resource and / or information to the User.

- This PIC does not give the User the right to access our resource and / or information until a benefit sharing agreement has been concluded and entered into with the Community, in accordance with the Access to Biological Resources and Benefit Sharing Act 2017 and our customary laws and practices, protocols and procedures.

- Any transfer of our resource and / or information or any data in relation to or derived from our resource and / or information or the results of research to a third party is strictly prohibited unless and until a written confirmation has been granted by the Community and that the interest of the Community is fully protected by the User.

- We are providing such resource and / or information to the User on the basis that sensitive information about personal identity as well as confidential information will not be disclosed, published or otherwise revealed to any other party whatsoever except with specific prior written authorization.

- We understand that if we have any questions about the operation of the User or the use of any resource and / or information which we have provided, or if we have any complaints or concerns relating to the User, we may contact the User's managers / person-in-charge who will discuss our queries or concerns with a view to reaching agreement on an appropriate solution.

- Other terms and conditions: _____

Details of traditional knowledge associated with biological resource (and its use):

_____

Details of biological resource:

_____

Dated:

Witnessed by,

_____
(Signature / Thumb print)
Name of Community:
Name of representative:
NRIC No.:

_____
(Signature / Thumb print)
Name:
NRIC No.:

Interpreted into _____language by (if any),

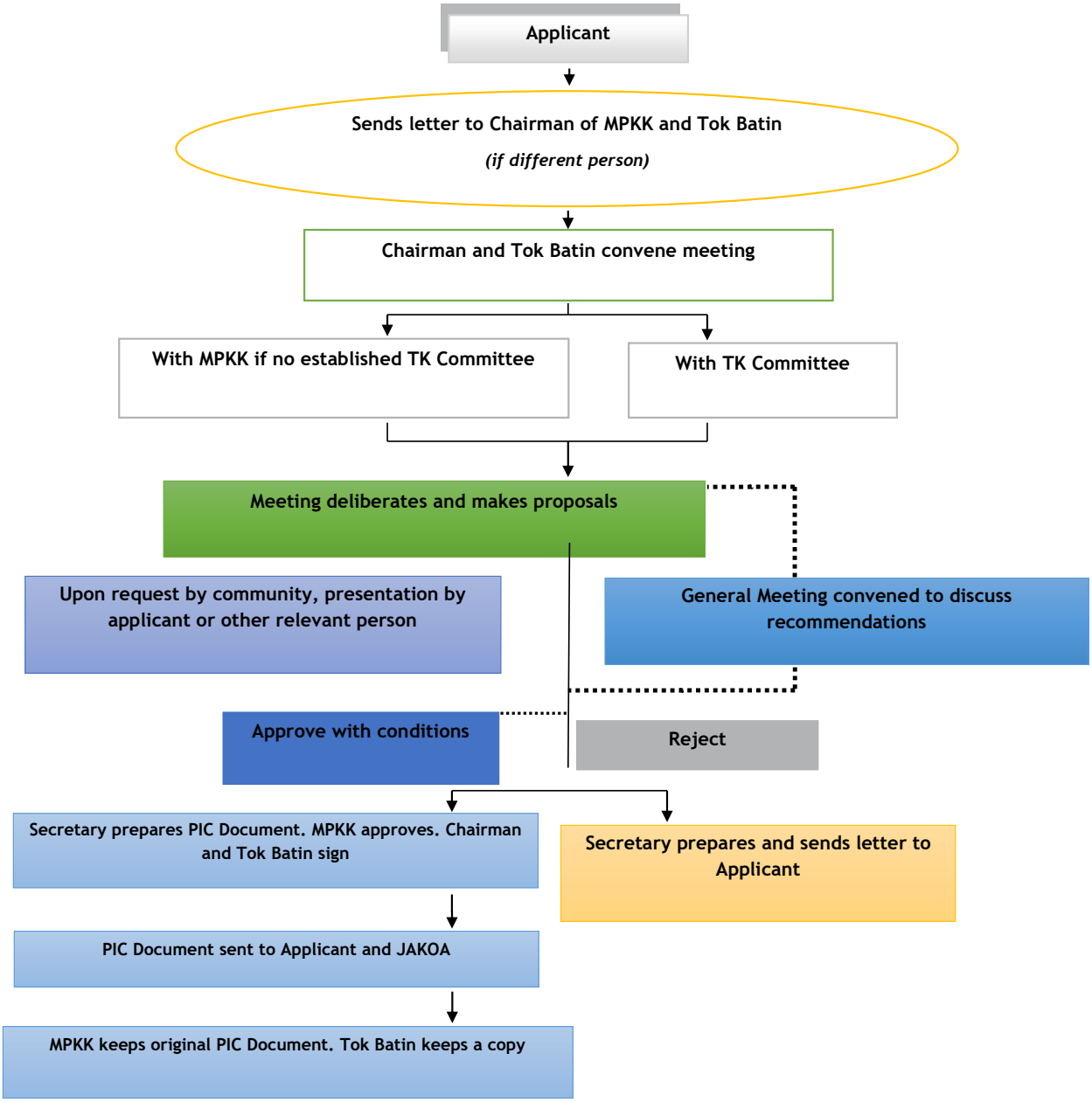
Witnessed by,

_____
(Signature / Thumb print)
Name:
NRIC No.:

_____
(Signature / Thumb print)
Name:
NRIC No.:

Three (3) copies of this PIC must be prepared and signed. A copy of this form will be left with the community, a copy will be kept with the User and a copy will be kept by the relevant Competent Authority. This form can be accessed/downloaded online at https://www.myabs.gov.my/.

Annex 2c


Applicant
Sends letter to Chairman of MPKK and Tok Batin
(if different person)
Chairman and Tok Batin convene meeting
With MPKK if no established TK Committee
With TK Committee
Meeting deliberates and makes proposals
Upon request by community, presentation by applicant or other relevant person
General Meeting convened to discuss recommendations
Approve with conditions
Reject
Secretary prepares PIC Document. MPKK approves. Chairman and Tok Batin sign
Secretary prepares and sends letter to Applicant
PIC Document sent to Applicant and JAKOA
MPKK keeps original PIC Document. Tok Batin keeps a copy

Annex 3

Model Benefit Sharing Agreement

Draft (1) (10 March 2017)

PROPOSED MODEL BENEFIT-SHARING AGREEMENT

THIS AGREEMENT is made this ..... day of ..... (*month)*(*year*)

Parties

BETWEEN

[If company**]**

(*Name*) (*Company No.* ..... *)* a company incorporated under the laws of Malaysia and having its registered office *or* principal place of business *or* address at ..... (*address*) referred to as the 'Access Party'.

[If person**] /**

(*Name*) (*IC number / Passport No.*) of (address) referred to as the Access Party.

AND

(*Name*)(*IC number*) ..... the 'Provider'.

If with community:

(*Name*) (*IC number*) ..... for and behalf of himself and all other members of the community known as ..... at Long / Ulu ..... referred to as the 'Provider'.

Preamble

A. The Access Party seeks access to the Biological Resource [and associated Traditional Knowledge][26] from the Provider as described in **SCHEDULE 1** of this Agreement.

B. The Provider is willing to provide such Biological Resource [and associated Traditional Knowledge] upon the terms and conditions stated in this Agreement.

C. The Access Party warrants that it has completed all the necessary procedures and has secured the prior informed consent of the Provider in accordance with the Access to Biological Resources and Benefit Sharing Act 2017 and all relevant regulations and protocols made under it.

NOW THE PARTIES TO THIS AGREEMENT AGREE AS FOLLOWS:

1. Definition

In this Agreement unless the context otherwise requires, the following terms must bear the following meanings:

Access means the taking of a biological resource from its natural habitat or place where it is kept, grown or found including the market place, for the purpose of research and development;

Access Party means a person, organisation or other entity that seeks and / or has been granted the right to access particular biological resources and / or associated traditional knowledge;

Agreement means this instrument and all Schedules to this Agreement as the same may be amended, modified or supplemented from time to time in accordance with these provisions;

[26] Where applicable.

Act refers to the Access to Biological Resources and Benefit Sharing Act 2017 and the regulations and protocols made under it;

Benefits mean the monetary and non-monetary payments or awards arising out of the utilisation of biological resources and associated traditional knowledge;

Biological resource includes genetic resources, organisms, microorganisms, derivatives and parts of the genetic resources, organisms, microorganisms or derivatives; populations and any other biotic component of an ecosystem with actual or potential use or value for humanity; and any information in relation thereto;

Commencement Date means the **[***date of this Agreement or any other date***]**;

Commercial use / commercialisation means the use of the biological resource or associated traditional knowledge for the generation of any kind of actual or potential economic profit. It includes any sale, lease, licensing of the biological resource, and / or products generated from its use through actions such as filing a patent application, obtaining IPR or other tangible or intangible rights. It includes any transfer of the biological resource to a for-profit organisation and the acts of making, importing, offering for sale, selling or using the product or stocking such product for the purpose of offering for sale, selling or using;

Derivatives mean a naturally occurring biochemical compound derived, developed or synthesized, from a biological resource or resulting from the genetic expression or metabolism of the biological or genetic resource, or part, tissue or extract, whether it contains functional units of heredity or otherwise, and information in relation to derivatives;

Force Majeure means circumstances including but without limitation to any act of God, act of government, embargo or other circumstances affecting the performance of the obligations under this Agreement by any of the parties;

Genetic resource includes any material of plant, animal, microorganism, fungi or other origin that contains functional units of heredity and that has actual or potential value for humanity;

Intellectual Property means any copyright, trade mark, service mark, industrial design, patent or any other form of intellectual property, any application for such protection, and any confidential information in relation thereto which are subsisting at the relevant time;

Net Sales Value means in relation to any of the Products the price charged to the customers less any sales tax but without deduction or any discounts or rebates granted to the customers; **[**OR the price as invoiced after deducting normal trade discounts actually granted, sales commission, any costs of packaging, insurance, transport (or freight), sales tax and import duties or any government levies**]**

Prior Informed Consent refers to the free assent to grant access based on complete and accurate information that is provided well in advance to the Provider by any party seeking access;

Product or products means the products which are manufactured from the biological resources and associated traditional knowledge accessed including any modification thereof;

Provider includes an indigenous and local community, or individual that possesses the resource, or indigenous and local community where the resource is on land to which they have a right as established by law, or indigenous and local community where they are the holders of the traditional knowledge and shall, where the context admits, include members of the indigenous and local community;

Quarter Year means each period of three months during the term starting on the Commencement Date;

Term means the agreed period during which this Agreement continues in force pursuant to clause …….(where applicable);

Traditional Knowledge includes the accumulated knowledge that is vital for the conservation and sustainable use of biological resources and/or which is of socioeconomic value, and which has been developed over the years within, and by, any ILC.

2. Consideration

2.1. In consideration of the Access Party entering into this Agreement, the Provider grants the Access Party access to the Biological **Resources** (and associated Traditional Knowledge) specified in **SCHEDULE 1** and in the **areas** and **terms** specified in **SCHEDULE 2** of this Agreement.

2.2. In consideration of the Provider granting access, the Access Party must access and **use** the Biological Resources (and associated Traditional Knowledge} only as specified in, and in accordance with, this Agreement.

2.3. The Access Party agrees to provide the Provider with the **benefits** specified in **SCHEDULE 3** of this Agreement *[Or the following benefits: to specify]*.

2.4. The Access Party is the applicant for, or intends to apply for, (*or is in possession of)* the appropriate permit under the relevant provisions of the Act and the relevant Regulations to access the Biological Resources [and associated Traditional Knowledge] specified in **SCHEDULE 1** of this Agreement and in the areas specified in **SCHEDULE 2** of this Agreement.

2.5. This Agreement, in conjunction with an access permit issued under the Act, gives the Access Party access to Biological Resources [and associated Traditional Knowledge] specified in **SCHEDULE 1** of this Agreement, subject to **clause 2** of this Agreement.

2.6. This Agreement constitutes a Benefit Sharing Agreement for the purposes of the Act.

3. Pre-conditions, commencement and duration of term

3.1. This Agreement takes effect only if:

(a) the Prior Informed Consent of the Provider has been secured by the Access Party in compliance with the Act;

(b) an access permit has been obtained by the Access Party for the proposed access to Biological Resources [and associated Traditional Knowledge] specified in this Agreement in compliance with the Act;

(c) the Access Party has obtained all other necessary consents, licences or permits under any written law to carry out the access.

3.2. The Access Party must supply the Provider with certified copies of the documents signifying the consents, permit and agreement referred to in **clause 3.1.** before the commencement of this Agreement.

3.3. This Agreement commences on the date the last of the matters specified in **clause 3.1** is complied with by the Access Party and the documents referred to in **clause 3.2** are delivered to the Provider and the Agreement shall continue for a period of *(state number of years)* from the date of this Agreement.

4. Change of use

4.1. If the Access Party wishes to change the use of the Biological Resources [and associated Traditional Knowledge] from that specified in this Agreement, it must apply in writing to the Provider of its intention for the change of use.

4.2. The Provider in its discretion may decide whether or not to accede to the request for the change in use.

4.3. The Provider may, if it accedes to any request by the Access Party for the change of use, require the Access Party to enter into fresh benefit sharing arrangements.

4.4. In such event, the fresh benefit sharing arrangements will supersede and replace the benefits stated in **SCHEDULE 3** of this Agreement.

4.5. In all other aspects, this Agreement shall remain in force.

5. Records, Accounts and Inspection

5.1 The Access Party must supply to the Provider written report of the status and progress of the research and development in relation to the Biological Resources [and associated Traditional Knowledge] accessed.

5.2 The report must be in both the English language as well as the Malay language and must be provided in both a hard and digital copy.

5.3 The report must be submitted to the Provider at four (4) monthly-intervals beginning from the date of commencement of this Agreement.

5.4 The Access Party must provide oral briefing to the Provider of the status and progress of the research and development in relation to the Biological Resources [and associated Traditional Knowledge] accessed as and when requested by the Provider at a time and place mutually agreed to by the Parties.

5.5 The Access Party must:

(a) Keep true and accurate accounts and records in sufficient detail showing the quantity, description and value of the products sold to enable the amount of all royalties or other sums payable under this Agreement to be determined;

(b) At the reasonable request of the Provider from time to time, allow the Provider or its agent at the Provider's expense to inspect those accounts and records and, to the extent that they relate to the calculation of those royalties or other sums, to take copies of them;

(c) At its own expense, obtain and submit to the Provider, within one (1) month after the end of each Year in respect of which royalties are payable under this Agreement, a certificate by the Access Party's auditors that the statement submitted to the Provider pursuant to **Schedule 3, clause 1(a)(iv)** in respect of each Quarter is true and accurate.

5.6 Following any inspection pursuant to **clause 5.5(b),** if the Provider's auditors certify to the Provider and the Access Party that the amount of royalties paid in respect of any Quarter Year pursuant to **Schedule 1, clause 1(a)(i)** falls short of the amount of Royalties which were properly payable in respect of that Quarter Year, the Access Party must within one (1) month of the date of the certificate pay the **shortfall** to the Provider, together with reasonable costs and expenses incurred by the Access Party in making the inspection.

5.7 The provisions of this **clause 5** are to remain in force and effect after the termination of this Agreement for any reason, until the settlement of all subsisting claims of the Provider under this Agreement.

6. Review

6.1 The benefit sharing provisions as specified in **SCHEDULE 3** of this Agreement may be reviewed by the Parties.

6.2 A request for the review may be initiated by either Party to this Agreement by giving a notice in writing.

6.3 The Parties must agree on a date, time and place for the review.

6.4 Any change in the benefit sharing provisions must be agreed to by both Parties and signified by signing a new document setting out the changes. These changes will supersede the benefits set out in **SCHEDULE 3** in so far as they cover the same subject matter.

6.5 The new document will supplement **SCHEDULE 3** and be titled as '**Schedule 3A'**.

6.6 In all other aspects, this Agreement shall remain in force.

7. No sharing, transfer or assignment

7.1 The Access Party must not share the Biological Resources [and associated Traditional Knowledge] accessed with, or transfer them to, a third party that is not

a party to this agreement unless it has first obtained the consent in writing of the Provider.

7.2 The Provider may give its consent if the sharing is for the purpose of the further research and development of the Biological Resources [and associated Traditional Knowledge] and if the Provider decides that its interest is not adversely affected.

7.3 The Provider shall not assign the benefits or obligations under this Agreement to any person.

8. Confidentiality

8.1. The Parties must not use or disclose confidential information of the other Party without their prior written consent.

8.2. Notwithstanding **clause 8.1**, confidential information may be disclosed without it constituting a breach of this Agreement where the information is:

(a) in the public domain;

(b) required by law to be disclosed;

(c) disclosed to Party employees or agents in order to comply with this Agreement.

9. Indemnity

The Access Party must indemnify and hold harmless the Provider from and against any losses, damages, claims, demands, suits and liabilities that arise due to the Access Party's acts or omissions or that of its employees or agents.

10. Termination

10.1. The following events constitute causes for either Party to terminate this Agreement:

(a) Where either Party is in breach of any of the terms of this Agreement and such breach is not remedied within 30 days after receipt of written notice of the breach concerned;

(b) Failure of the Access Party to make any payment that has become due;

(c) Where the Access Party ceases to carry on business, enters into winding up, liquidation or bankruptcy proceedings.

10.2. Upon the occurrence of any of the events set out in **clause 10.1**, the aggrieved Party must send a written notice of its intention to terminate the Agreement, provided that in respect of **clause 10.1(b)** the Provider may extend time for payment for such period as it deems fit and impose payment of …. (as agreed between parties) % per annum interest calculated on a daily basis for the late payment pro-rated to the period of the delay.

10.3. Upon the termination or expiration of this Agreement, the Access Party must—

(a) immediately cease the use of materials relating to the utilisation of the biological resources and associated Traditional Knowledge accessed under this Agreement as well as any research results and related data;

(b) surrender to the Provider the said materials and any research results and related data.

10.4. The Provider may, in lieu of **clause 10.3 (b)**, require the Access Party to dispose the materials and results and to provide evidence of this disposal to the satisfaction of the Provider.

10.5. The termination or expiry of this Agreement does not relieve the Access Party from its obligations to pay amounts due and owing to the Provider nor affect either Party's rights to receive and recover damages as a result of the breach.

11. Survival of Agreement

Without prejudice to clause 10.5, the provisions relating to the following matters shall continue after the termination of the agreement:

(a) Records, accounts and inspection as stated in **clause 5.6**;

(b) Benefit-sharing;

(c) Indemnity.

12. Settlement of disputes

12.1. In the event of any dispute between the Parties concerning the interpretation or implementation of this Agreement the Parties must seek solution by negotiation.

12.2. If no agreement can be reached by negotiation, the Parties may jointly seek the good offices of, or request mediation by, a third Party.

12.3. Any proceedings under this clause must be conducted with due regard to the customary laws, practices or protocols of the Provider.

12.4. Any expenses arising from the proceedings under this clause must be borne by the Access Party unless it is proved that the Provider is in breach of its obligations.

12.5. Either Party may initiate the proceedings under this clause upon giving the other Party two (2) month notice in advance of its intention to do so.

12.6. Parties must, to the extent possible, continue to perform their respective obligations even during the duration of the dispute proceedings save in respect of an obligation which is the subject matter of the dispute proceedings.

12.7. Nothing in this Agreement shall prevent either Party from referring this matter to the court in Malaysia for adjudication after exhaustion of the processes provided in **clauses 12.1** and **12.2** and within a reasonable time after the said exhaustion.

13. Access Party's further obligations

13.1. The Access Party must ensure that in carrying out the access it must not cause any adverse **environmental impact**.

13.2. The Access Party agrees to **preserve and respect the Traditional Knowledge** and practices of the Provider and other native communities so far as these are known, made known, or discoverable through due diligence [where applicable].

13.3. The Access Party is **solely responsible** for claims regarding its acts or omissions.

13.4. The Access Party must be **responsible for the payment** of any fees or expenses for securing any permit, licence or consent as applicable under the Act and any other written law or regulation.

14. The Provider

14.1 The Provider gives no warranties regarding the identity or quality of the Biological Resources or the information relating to the use of the associated Traditional Knowledge.

14.2 The Provider will not be liable for any damage to the Biological Resources or any habitat arising out of the activities of the Access Party.

14.3 The Provider, where the context admits, includes the members of the native community of the Provider.

15. General

15.1 The Agreement represents the **entire agreement** between the Parties. Any previous negotiations, discussions, terms or agreements are superceded by this Agreement.

15.2 If any part of this Agreement is held invalid, void or unenforceable it will be **severable** and not affect or invalidate this Agreement.

15.3 Any reference in this Agreement to the Provider must, where the context permits, **refer to acts** carried out on the written instructions and with the written authority of the Provider.

15.4 This Agreement does **not constitute** a partnership and the Parties do not represent each other, unless specifically agreed to in writing in any specific matter.

15.5 The laws of Malaysia shall apply to the whole of this Agreement, and each Party agrees to submit to the jurisdiction of the Malaysian courts.

15.6 The Parties agree that in performing their respective duties they shall not undertake any activities deemed **illegal** under the laws of Malaysia.

15.7 All the terms and provisions of this Agreement must be binding upon and inure to the benefit of the Parties and their respective **successors and assigns**, where permitted.

15.8 The failure or delay of either Party to insist upon the strict performance of any of the terms of this Agreement must not be construed as a **waiver** of the terms but the same shall continue and remain in force and effect.

15.9 The **subject headings** in this Agreement are included solely for the purposes of convenience and must not be deemed to explain the meaning, construction or interpretation of any provision in this Agreement.

15.10 Neither Party will be liable to the other on account of any default in the performance of this Agreement caused by **Force Majeure**.

15.11 Any **notice** required or permitted by this Agreement to be given to either Party must be in writing and must be addressed to the Party at the address set out below.
_____ (*state address and names of the Party to whom notice must be given under this Agreement*) _____.

15.12 Unless expressly waived, time whenever mentioned shall be of the essence.

IN WITNESS the Parties have duly executed this Agreement on the day and year first above written.

Signed by (*name*))
[*for and on behalf of*])
the [*Access Party*])
In the presence of (*name*))

Signed by (*name*))
[*for and on behalf of*])
the [*Provider*])
In the presence of (*name*))

SCHEDULE 1

BIOLOGICAL RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

1. Biological Resources to be accessed:
   (Include name of the species, or lowest level of taxon, to which the resources belong (if known). If the species composition of samples is not known, list the sampling method(s) and the types of organisms likely to be collected.)

   _____

   _____

2. Associated Traditional Knowledge:
   (Include details of the knowledge, its use, source of the knowledge, such as, for example, whether the knowledge was obtained from scientific or other public documents, from the Provider or from another group of indigenous persons.)

   _____

   _____

3. Storing of data and other materials during the Agreement:
   (Include details of the location and type of storage of samples, the location and format of associated Traditional Knowledge documentation, and other materials used by the Access Party. Also include details of any biological resources the Access Party may retain after termination of the Agreement.)

   _____

   _____

4. The use for which the Biological Resource and associated Traditional Knowledge is being accessed.
   (State for example: with a view to develop a product in the field of pharmaceutical, nutraceutical, cosmetic, food etc.)

   _____

   _____

SCHEDULE 2

AREA FOR ACCESS AND TERMS RELATING THERETO

1. **Access Area**: *(List the areas from which the Biological Resources must be taken, including latitude and longitude references.)*

2. **Time and Frequency of Entry to Access Area**: *(List the anticipated dates and times of entry to the access area(s), including the duration of each visit.)*

3. **Quantity of Biological Resources to be Collected**: *(List the anticipated quantity of each Biological Resource to be collected in the access area.)*

4. **Quantity of Biological Resources to be Removed**: *(List the quantity of each Biological Resource to be removed from the access area.)*

5. **Potential Environmental Impacts**: *(List the potential environmental and biodiversity impacts of accessing the Biological Resources and the efforts that must be made to avoid these impacts.)*

The Access Party must supply details of each information for verification by the Provider.

SCHEDULE 3

BENEFITS

The benefits to be provided by the Access Party to the Provider are as follows (*subject to negotiation and agreement by the Parties)*:

1. Monetary benefits

a. An up-front payment of RM _____, payable within _____ days of the commencement of the Agreement;

b. Milestone payments of RM _____ payable upon _____ (*state the event upon completion of which the payment must be made*);

c. Payment for raw material supplied at the rate of ..... ;

d. Payment for collection of materials in the sum of ..... ;

e. Payment for other activities (*distilling etc*) payable as follows: .....

Royalties: rate and modalities of payment

i. If a product or products arising from the utilisation of the Biological Resource and associated Traditional Knowledge accessed is commercialised, used or otherwise disposed of on a commercial basis at any time, a minimum rate of RM ..... per year or ..... % of the Net Sales Value of those products (whichever is higher) must be paid by the Access Party to the Provider ('Royalties').

ii. The sum must be paid to _____ (*designate account and account holder*).

iii. The sum must be paid within _____ days of receipt of the payments received from the sales of the product or products.
[*OPTION: The royalties must be paid within ……. days of each Quarter Year*.]

iv. Within ……days after each Quarter Year the Access Party must send to the Provider written statements showing:
(a) The quantity of the products sold or otherwise disposed of on a commercial basis by the Access Party, its servants or agents;

(b) The Net Sales Value in respect of that quantity of Products disposed of on a commercial basis by the Access Party, its servants or agents during the Quarter Year;

(c) The amount of Royalties payable within that Quarter Year;
And the Access Party must forthwith pay to the Provider the Royalties in respect of that Quarter Year in accordance with **clause 1(i)** of this Schedule.

v. The Royalties due must be made without deduction of withholding taxes or duties that may be imposed except in so far as the Access Party is required to deduct the same to comply with any applicable law.[27]

vi. The payment of the Royalties must be accompanied with a statement setting out the types of Products sold, the total Net Sales Value and the period to which the Royalties payment relate.

(b) Non-monetary benefits

i. **Technology transfer**

The Access Party must provide the following to the Provider and its members:

[27] Note that royalties are liable to income tax: ss. 4(d), 15 of the Income Tax Act 1967 (Act 53). The Act defines royalties. Sections 2 and 109 deal with withholding tax if the Access Party is a foreigner.

(a) Train / employ local researchers from amongst the Provider and its members in scientific and practical work;

(b) Establish facilities for research or communication infrastructure accessible to the Provider and its members;

(c) Share samples of material / deposit copies of specimens in repositories designated by the Provider, if required and where appropriate;

(d) Transfer technologies relating to the research and development of the biological resources accessed to the Provider, including technology protected by IPRs and / or relevant to conservation and sustainable utilization of biological diversity;

(e) Share research results, including scientific data, in a format suitable for the Provider;

(f) Admittance to any ex-situ facilities of the Access Party of biological / genetic resources and databases;

(g) Provide access to scientific information in a form legible to the Provider relevant to conservation and sustainable use of biological diversity.

ii. **Intellectual Property Rights (IPR)**

(a) The Access Party agrees to joint ownership of IPRs with the Provider arising out of the utilisation of the Biological Resource and associated Traditional Knowledge accessed.

(b) The Access Party must notify the Provider before applying for IPRs.

iii. **Other non-monetary benefits**

The Access Party must provide the following to the Provider: (*Provider to consider, as appropriate, as and if agreed to by Access Party)*

(a) Acknowledgement of contribution in publications and / or products

(b) Strengthening capacities for technology transfer to Providers

(c) Develop institutional capacity-building;

(d) Assist in the development of human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

(e) Make contributions to the local economy;

(f) Provide food and livelihood security benefits;

(g) Develop infrastructure of social amenities (roads, bridges etc);

(h) Provide assistance for educational needs.

Annex 4

Statutory Declarations

Annex 4A

To:
(insert name of relevant Competent Authority)

STATUTORY DECLARATION

I, *(insert name of applicant and NRIC No. / Passport No.)* of *(insert address)* do solemnly and sincerely declare that: -

1) I am not an undischarged bankrupt;

2) I have not committed any act of bankruptcy as defined under Section 3 of the Bankruptcy Act 1967.

3) I am not in default under any agreement to which I am a party or by which I may be bound and there is no pending litigation, arbitration or administrative proceedings, as the case may be, that might materially affect my solvency.

4) I make this declaration in full knowledge and awareness of your reliance on this declaration as an inducement or basis to issue permit to me or to a third party.

5) I have not committed an offence and there is no pending litigation, arbitration or administrative proceedings against me under the Access to Biological Resources and Benefit Sharing Act 2016 ("the Act") or any of its regulations.

6) I am fully aware that it is a criminal offence to induce you to issue the permit on the basis of a false declaration.

7) Should during the term of the permit issued under the Act you find this declaration to be false or incorrect, you are at the liberty to:

    a) cancel the permit,

b) demand the return of all the biological resources accessed;

c) prohibit any further use of such biological resources, traditional knowledge associated to the biological resources and any information relating thereto and research results accrued therefrom; and

I will do so without any delay or dispute.

8) I undertake to notify you immediately should any of the following occur after this declaration:

a) Adjudged a bankrupt; or

b) Committed an offence under the Act; or

c) Subject to any litigation, arbitration or administrative proceedings under the Act or which may affect my solvency; or

d) Occurrence of any event that may affect my solvency.

And I make this solemn declaration conscientiously believing the same to be true, and by virtue of the provisions of the Statutory Declarations Act 1960.

Subscribed and Solemnly)
Declared by the abovenamed)
At)
In the State of)
This day of 20)

Before me,

.....
Commissioner for Oath

Annex 4B

To:
(insert name of relevant Competent Authority)

STATUTORY DECLARATION

We, *(insert name of the directors and NRIC No. / Passport No.),* both of *(insert address)* do solemnly and sincerely declare that: -

(1) We are the Director(s) of *(insert name of company and registration no.),* a company incorporated in Malaysia and having its business address at *(insert business address)*;

(2) As at the date hereof, there are no winding-up proceedings against *(insert name of company and registration no.)*;

(3) *(insert name of company and registration no.)* is not in default under any agreement to which it is a party or by which it may be bound and no litigation, arbitration or administrative proceedings, as the case may be, might materially affect its solvency;

(4) *(insert name of company and registration no.)* have not committed an offence and there is no pending litigation, arbitration or administrative proceedings against *(insert name of company and registration no.)* under the Access to Biological Resources and Benefit Sharing Act 2017 ("the Act") or any of its regulations;

(5) We make this declaration in full knowledge and awareness of your reliance on this declaration as an inducement or basis to issue the permit to *(insert name of company and registration no.)*; and

(6) We are fully aware that it is a criminal offence to induce you to issue the permit on the basis of a false declaration.

(7) Should during the term of the permit issued under the Act you find this declaration to be false or incorrect, you are at the liberty to:

a) cancel the permit,

b) demand the return of all the biological resources accessed;

c) prohibit any further use of such biological resources, traditional knowledge associated to the biological resources and any information relating thereto and research results accrued therefrom; and

We will do so without any delay or dispute.

(8) We undertake to notify you immediately should any of the following occur after this declaration:-

a) *(insert name of company and registration no.)* has been wound up; or

b) Subject to liquidation proceedings; or

c) Committed an offence under the Act; or

d) Subject to any litigation, arbitration or administrative proceedings under the Act; or

e) Occurrence of any event that may affect the solvency of *(insert name of company and registration no.)*.

And I / We make this solemn declaration conscientiously believing that the same to be true, and by virtue of the provisions of the Statutory Declaration Act, 1960.

Subscribed and Solemnly		)
Declared by the abovenamed		)
At		)
In the State of		)
This day of	20	)

Before me,

.....
Commissioner for Oath

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