

BIODIVERSITY
DRAFT REGULATIONS
2024

**THE ENVIRONMENTAL MANAGEMENT AND CO-ORDINATION (ACCESS TO BIOLOGICAL RESOURCES AND
BENEFIT SHARING) REGULATIONS, 2024**

(Legislative Supplement No.--- of 2024

LEGAL NOTICE NO.

THE ENVIRONMENTAL MANAGEMENT AND CO-ORDINATION ACT (No.8 of 1999)

**THE ENVIRONMENTAL MANAGEMENT AND CO-ORDINATION (ACCESS TO BIOLOGICAL RESOURCES AND
BENEFIT SHARING) REGULATIONS, 2024**

ARRANGEMENT OF REGULATIONS

PART I – PRELIMINARY

- 1—Short title and Commencement
- 2—Interpretation
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- 4 Application

PART II – CONSERVATION OF BIOLOGICAL DIVERSITY

- 5—Environmental Impact Assessment License.
- 6— Conservation of threatened species.
- 7—Inventory of biological diversity.
- 8—Local community biodiversity measures
- 9—Monitoring
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- (d) Ecological space or
- (e) Community interest;

“Community Protocols” means a broad range of practices or procedures both written and unwritten, developed by indigenous people or local communities in relation to their traditional knowledge, territories and associated biological resources

“derivative” is a biochemical compound derived, developed, synthesized or engineered, 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;

“Digital Sequencing Information” it is a biological data associated with, or derived from, genetic resources such as nucleotide sequences and epigenetic, protein, and metabolite data.

“endangered species” means any species which is in danger of extinction throughout all or a significant portion of its range (due to man-made or natural changes in the environment);

“access permit” means a permit that allows a person to access genetic resources issued under regulation 4;

“Authority” refers to National Environment Management Authority

“biological resource” includes—

- (a) the genetic resources, organisms, microorganisms, derivatives and parts of the genetic resources;
- (b) the populations and any other biotic component of an ecosystem with actual or potential use or value for humanity; and
- (c) any information relating to paragraphs (a) and (b);

ACCESS PERMIT RENEWAL

	Citizens	Foreigners
(i) Individual application.....	30,000.00	50,000.00
(ii) Corporate application.....	50,000.00	100,000.00

“inventory” means a detailed list, report or record of resources, or the process of making such a list, report or record;

“material transfer agreement” means an agreement negotiated between the holder of an access permit and a relevant lead agency or community on access to genetic resources and benefit sharing;

“mutually agreed terms” means an agreement between the providers and users of genetic resources and/or traditional knowledge associated with genetic resources;

“natural environment system” means relatively intact ecosystems of unique value, such as perennial and seasonal wet lands, highly diverse aquatic ecosystems, or ecosystems promoting a high concentration of rare and unusual species;

“non-commercial” means for academic purposes or non-profit oriented;

“permit” means a written authorization issued by a Competent National Authority under these Regulations;

“permit holder” refers to an owner of a permit issued by a Competent National Authority under these Regulations.

THIRD SCHEDULE (r.11)

FORM OF ACCESS PERMIT

This permit is hereby granted to M/s

.....
.....

..... (insert name, contact address and description of applicant) in accordance with regulation 11 of the Environmental Management and Co-ordination (Access to Biological Resources and Benefit Sharing) Regulations, 2023 for the collection of the following genetic resources:

.....
.....

.....(insert description of the biological resource, its derivative product(s) or intangible component(s) as stated in the Materials Transfer Agreement) located at.....

..... (Insert geographical description of the location of the biological resources)

This permit is issued subject to the Regulations and all agreements concluded pursuant to its grant, and maybe suspended, cancelled or revoked should the holder breach any of those agreements and the conditions of issue and those contained in the Regulations.

M/s.....(insert name of applicant) being the holder of this permit, including his agents and assignees, undertake to abide by the conditions of this permit and to promptly report to the National Environment Management Authority any matter that may prejudice the interests of Kenya and other parties concluded pursuant to the grant of this permit.

Signed:.....Date:.....

Director General,
National Environment Management Authority.

Dated the.....of.....2023

FOURTH SCHEDULE

FORM OF A PRIOR INFORMED CONSENT (PIC)

PRIOR INFORMED CONSENT (PIC) FOR ACCESS TO AND UTILIZATION OF(Biological resource to be accessed and its utilization)

(The title is derived from the access demand. The user has to state clearly what is being accessed. This comes last)

This Prior Informed Consent here in referred to as the PIC agreement is entered on this date _____ by and between: *(the date is entered by the last signatory ,in most cases the national competent authority granting the PIC)*

I. Stakeholders *(the key stakeholders to be party to the PIC are to be clearly mapped out)*

Providers:

Insert the legally mandated providers at the national, county and local community where possible

The Users

Insert all the users who will be party to the agreement. These include the institutions where the collected material and resultant progenies, derivatives, extracts, DNA/RNA, Digital Sequence Information and compounds ,data analysis /storage will be used within the value chain on research and development

II. WITNESSETH

These are whereas clauses on general principles of engagement for the providers and users *(In general it states the guiding laws, the parties to the agreement and the areas of mutual agreements)*

III. NOW THEREFORE, IT IS HEREBY AGREED by the parties as follows:

This section state significance of the project. broad impact and intellectual merit which range from, but not limited to conservation (ex-situ and in-situ), scientific collaborations, benefit sharing and technology transfer

For example, significance /contribution of the project in the following areas but not limited to (this a very important area that brings out relevance of the project)

- Legal framework ,policy and institutional arrangements*
- Locality of the projects and activities*
- Contributions to science -the innovations the project brings on board*
- Capacity building*
- Partnerships-in line with CBD/Nageya protocol -scientific*
- Ethical compliance including respect to IPLC rights*
- Contribution to resource mobilization strategy*

IV. PARTNERSHIP FRAMEWORK

These include the agreed the roles and responsibilities of each partner in the project, an agreed procedure on sample quantities and collection protocol including labelling, verification, coding and key repositories. This is based on the outcome of the consultation process and stakeholders mapping and their roles. Key areas include

- a) *The parties, providers, and users (the lead institution)*
- b) *The access demands. That is what is being accessed and utilized (this informs the title of the PIC)*
- c) *Experimental. Details, what will be done where and by whom (informed by what has been agreed and involvement of the providers); Field (where), Lab work where and why, Data analysis and storage, whereby whom and why*

- d) *Declarations of previous undertakings -eg accessed genetic resources and data related to the project/program where stored and access.*
- e) *Protocols for access and verification*
- f) *Involvement of resource providers in the activities where appropriate*

V. Benefit sharing

A clear demonstration of outputs on benefit sharing both monetary and non- monetary as envisaged under Nagoya Protocol and the country's domestic laws. This may include but not limited to:

a. Non-monetary benefits

Outcomes on technology transfer quite key arising from ;Capacity development within the scientific community e.g skills, short term and long-term training, exchange programmes etc for both providers and users; equipment, infrastructure Capacity development at community level (rural target groups);Baseline IP audit; Dissemination of results. An outline of results uptake, inception meeting, scientific workshops to the relevant stakeholders, publications among others.

- i. *Capacity building on skills – Training at certificate levels, diploma ,undergraduates, Masters, Phds,Post doc. State the number for both providers and users and at what level will benefit or have benefited from the program/project*
- ii. *Specialized training and exchange program; Specialized course eg a method of detecting a rat poacher while in the office. Target group Wildlife rangers ,10 in number for 5 days etc,Pablo and team will be visiting the antartic to see exi-situ preservation of biological resources accessed from Sudan etc*

iii. *Technologies being transferred*

iv. *Facilities and equipment . State facilities and equipment that will be acquired by the project and where will they be hosted. This is determined from the provided detailed approved project proposal*

v. *Outreach plan ; Inception and project completion ; Media assets ,sensitization/awareness creation ,publication etc.*

Monetary benefits

This will include the project seed money or venture capital, incentives, upfront, royalties, milestones, bonuses etc

-State the program/projects grants-as per the grant letter

-Any employed on the project/program

-IP assets exploitation and share of benefits -IPR on Patents and media assets for example

VI. COMPLIANCE WITH LEGAL REQUIREMENTS

1. The users complying with the permit requirements for access and utilization of the stated biological resources;
2. Provisions with the Intellectual Property rights;
3. Consider issues of third party transfers and ownership;
4. Applicable laws and dispute resolutions. This to consider the accessed material utilization value chain and jurisdictions.
5. Amendments
6. These PIC agreed terms will form the basis for the collaborative Memorandum of Agreement (MOA/MAT) and Material Transfer

Agreement (MTA) to be signed between the(users) and providers.....

IN WITNESS THEREOF, the parties execute these agreed terms, and(provider) give consent to(user) under the(project) to undertake research and collect(biological material) for the proposed project activities.

FOR APPLICANTS:

THE USERS

Name of authorized entity
Position in institution/Rank
Institution and address
Email address
Signature
Date
Institutional stamp

THE PROVIDERS

Name of authorized entity
Position in institution/Rank
Institution and address
Email address
Signature
Date
Institutional stamp

Every page should be signed by the legal entity

FIFTH SCHEDULE- (r. 2)
FORM OF MUTUALLY AGREED TERMS

MEMORANDUM OF AGREEMENT

FOR

COLLABORATIVE RESEARCH ON----- KENYA

BETWEEN

XXXXXXXXXX

AND

XXXXXXXXXXXXXXXXXX

(PROVIDER OF BIOLOGICAL RESOURCES)

ARRANGEMENT OF ARTICLES

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MEMORANDUM OF AGREEMENT BETWEEN:

XXXXXXXXXXXXXXXXXXXX

and

Provider of Biological Resources

PREAMBLE

Whereas:-

1. Kenya is endowed with vast biological resources and is among the mega biodiversity rich countries globally, wherein the Constitution of Kenya is the crystallization of the welfare of the people of Kenya including the need for conservation and use of natural resources of Kenya, wherein the sovereign rights over biodiversity are vested in the State in trust for the people, and under Article 2 (5&6) the general rules of international law and any treaty or convention ratified by Kenya forms part of the Laws of Kenya.
2. Access to biological and genetic resources and associated knowledge is governed by various Multilateral Environmental Agreements (MEAs) including but not limited to CBD, Nagoya Protocol, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), Convention on International Trade on Endangered Species (CITES) and World Intellectual Property Organization Treaties (WIPO) among others, subject to domestic legislation
3. Access to biological/genetic resources and associated knowledge of Kenya is subject to the existing domestic laws, and subject to Access Permit, research licenses, Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and Material Transfer Agreement (MTA) between providers and users
4. -----
5. The governments of Kenya and -----are desirous in undertaking collaborative research in infectious diseases including xxxxxxxxxx, which is part of fulfillment of the cooperation in their bilateral agreements.
6. Research & Development (R&D) in biodiversity is key to conservation and sustainable use of biological resources for development done through partnerships in research and capacity building.

7. Resource management is devolved whereby we have shared responsibilities between the national government and the County governments including grant of user rights. The role of communities as custodians of indigenous knowledge and their contribution to conservation of biological diversity, they are entitled to equitable share of the benefits derived from utilization thereof and associated knowledge as per Kenya's Constitution, CBD and the Nagoya Protocol.

8. Under the Wildlife (Conservation and Management) Act 2013, KWS is mandated to conserve and manage wildlife wherever they may be found in Kenya including conducting research for the benefit of the people of Kenya, and KWS is a competent authority for prior informed consent (PIC), mutually agreed terms (MAT) and material transfer agreements (MTA) for wildlife resources and associated knowledge on behalf of the Government of Kenya.

9. XXXXXXX

10. YYYYYYY

This Memorandum of Agreement (MoA) recognizes the role of research and development for informed decisions on biodiversity conservation and livelihood support through control of vector xxxxxxxxxxxs and xxxxxxxxxxx.

Parties to this MoA consent to implement the project -----in line with the provisions of the CBD and its Protocols (Nagoya and Cartagena) and relevant national legislations.

NOW THEREFORE through the implementation of this MoA, the parties hereto have agreed to pursue their common goals as hereunder:

ARTICLE 1: DEFINITION AND INTERPRETATION OF TERMS

In this MoA unless in consistent with the context, or otherwise specified, the following words and phrases shall have the meaning set out below:

1.1. Access shall mean obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio- prospecting, conservation, industrial application or commercial use as defined in the laws of Kenya.

- 1.2. Accession shall mean a sample or specimen of biological or genetic material and/or information held in any legally approved repository centers, such as herbaria or gene banks.
- 1.3. Acquisition shall mean obtaining biological material or resources through collection under the approved permit.
- 1.4. Affiliate shall mean any corporation, firm, limited liability company, partnership or other entity that directly or indirectly controls or is controlled by or is under the common control of a party to this Agreement.
- 1.5. Benefit sharing shall mean sharing of benefits from access and utilization of biological resources and biological materials, and their derivatives, progeny, genetic information associated knowledge whether, commercial or otherwise as stated in this MoA and as defined in the CBD, Nagoya Protocol, Kenya Constitution 2010, Wildlife Conservation and Management Act 2013, and the relevant Laws of Kenya, where applicable.
- 1.6. Biodiversity shall mean variability among living organisms from all sources including, inter alia, terrestrial, marine, and other aquatic ecosystems and ecological complexes of which they are part, this shall include diversity within species, between species and ecosystems.
- 1.7. Biological resources shall mean genetic resources, organisms or part thereof, population, or any other biotic component of an ecosystem and their derivatives with actual or potential use or value for humanity.
- 1.8. Confidential Information shall mean scientific, business or financial information that has been reduced to writing and marked as "Confidential", provided that such information does not include information in public domain or available from others sources who are not under a confidentiality obligation to the source of information, information which has been made available by its owners to others without a confidentiality obligation, information which relates to potential hazards or cautionary warnings.
- 1.9. Conservation area includes but not limited to an area legally designated for conservation of biodiversity and shall include protected and unprotected areas.
- 1.10. Derivatives shall include but not limited to modified or xxxxxxxxxmodified extracts and any compounds or chemical structure based on/or derived from plant, microbial and animal biological and/or genetic resources and their progeny, including analogues
- 1.11. Designated Repositories shall mean institutions mandated to keep in safe custody different categories of biological resources, including voucher specimens and new taxa, deposited with them by various users.

- 1.12. Genetic materials shall mean any materials of plant, animal, microbial or other origin containing functional unit of heredity.
- 1.13. Genetic Resource shall mean information contained in any genetic material or their derivative of actual or potential use or value for humanity.
- 1.14. Holotype shall mean the organism known to have been used when the species was formally described.
- 1.15. Intellectual Property shall mean without limitation, intellectual property rights including patent rights, and unpublished patent applications, any invention improvements and all discoveries that may be not predictable, including all know how, trade secrets, research plans and priorities, research results and created reports, statistical models and computer programs and related reports, and market interests, trademarks, copy rights, plant breeders rights, and product ideas of any of the parties and affiliates in existence at the time of execution of this agreement or subsequently developed or acquired independently of this agreement.
- 1.16. Know how shall mean knowledge and skills that enables a person to accomplish a particular task or to operate a particular device or process.
- 1.17. License shall mean a written agreement granting permission to use an intellectual property right within a defined time context, market line or territory.
- 1.18. Material Transfer Agreement (MTA) shall mean a contract between the resource provider and recipient. For purpose of this MoA shall also include a contract from KWS authorizing the use of biological resources and associated knowledge.
- 1.19. Partners shall mean institutions party to this MoA.
- 1.20. Principal Investigator(s) shall mean the person or persons designated by parties to this MoA responsible for the scientific and technical conduct of the MoA's project activities.
- 1.21. Prior Informed Consent (PIC) shall mean permission given by the competent provider national authority and where possible in collaboration with county governments and local communities in the form of a signed agreement with legal entity prior to accessing genetic resources, in line with an appropriate national legal and institutional framework on access of biological diversity, biological resources or associated knowledge.
- 1.22. Products shall mean any subject of invention and any commercially valuable or otherwise useful material, compound, isolate, or useful combination of compounds, isolates or other materials discovered, recovered, obtained, derived, resulting or otherwise isolated from

scientific research conducted on a research specimen or sample acquired from an authorized source, or any derivative of such material or compound, or other isolate, or discovery which is or may be patentable and/or protected under Intellectual property laws of Kenya and developed from research specimen acquired from the resource providers.

1.23. Progeny shall mean any xxxxxxxxmodified descendant and/or hybrids from research specimens such as virus from virus, cell from cell or organism from organism that are cultivated by the user.

1.24. Project Implementation Committee shall mean key body within the governance structure of the project responsible for the research and management aspect of the project essential to the ensuring the delivery of the project outputs and the attainment of project outcomes.

1.25. Provider shall mean the custodian of biological or genetic resources associated knowledge as defined under the constitution and Kenyan laws. For all purposes and intent KWS shall be the Provider on behalf of Government of Kenya and County governments under this MoA as per the Wildlife (Conservation and Management) Act 2013, Environment Management and Coordination Act 1999 and Constitution of Kenya.

1.26. Repository shall mean designated facility within institutions where different categories of biological reference collections, including voucher specimens, are preserved. For this MoA, XXXXXXXXXXX, XXXXXXXXXXX and XXXXXXXXXXX shall host such designated facilities.

1.27. Research specimen shall mean the biological resources, progeny, derivatives or product the recipient has authority from resource provider(s) through the PIC, Wildlife Permits and other relevant permits issued by KWS, National Environment Management Authority (NEMA) and National Commission for Science Technology and Innovation (NACOSTI) or which otherwise were originally and lawfully collected from Kenya.

1.28. Sample area of origin shall mean the locality from which the biological or genetic material is accessed.

1.29. Sample shall mean any distinct part of biological or genetic material or resource including its derivatives, compounds, extracts, progeny, modified or xxxxxxxxmodified.

1.30. Research Data shall mean all recorded information generated during the implementation of this MoA.

1.31. Technology shall mean technical information, product standards, know-how, formulation system, standards and data, equipment,

procedures for the manufacture, and sales marketing program for the delivery of said product under this MoA

1.32. Technology transfer shall mean the movement of or flow of technical knowledge, data, design, prototypes, materials, inventions, software, and or trade secrets from one purpose to another purpose.

1.33. Third party shall mean any person, company, organization and or any other legal entity that the parties to this MoA may consult, collaborate with, and enter into an agreement with either severally or jointed pursuant to the provisions of this MoA or in the discharge of the party's obligations as set out here.

1.34. User shall mean the recipient of the biological material or genetic resources and their derivatives including associated knowledge. For all purposes and intent XXXXXXXXXXXX, XXXXXXXXXXXX, XXXXXXXXXXXX WUHS, shall be the Users under this MoA.

ARTICLE 2: SCOPE

Scope of what is accessed and utilized

ARTICLE 3: OBJECTIVES

The principal objectives of this MoA are:

- 3.1. To contribute toward realisation of the objectives of the Convention on Biological Diversity, biodiversity conservation, sustainable use and equitable share of resultant benefits from utilization of biodiversity among the stakeholders
- 3.2. To enhance Kenya's biodiversity conservation and management by understanding the taxonomy and ecology of xxxxxxxx and how biodiversity links with health as it contributes to xxxxxxxx control a neglected disease through research, monitoring, and information dissemination.
- 3.3. To provide a platform to promote technical capacity strengthening, scientific research and technology transfer between ----- and Kenya.
- 3.4. To contribute to an efficient system or mechanism of linking in-situ and ex-situ conservation of xxxxxxxx and xxxxxxxxs.
- 3.5. To collaborate in executing, implementation of the project xxxxxx in Kenya" (x is a copy of statement of work (annex I) and a project proposal (annex II).x

ARTICLE 4: INSTITUTIONAL OBLIGATIONS

4.1 Joint Partner obligations

- 4.1.1. The partners are to comply with the terms of this MoA.
- 4.1.2. Develop relevant governance structures to operationalize this MoA including Standard Operating Procedures (SOPs) for implementing projects and engaging students under this MoA.
- 4.1.3. Undertake joint resource mobilization and ensure that the grant will be used exclusively for approved objectives, activities, and budget items in accordance with the relevant funding agreements.
- 4.1.4. Provide adequate project location facilities, local technical installations and other physical project framework, as specified in the project documents.
- 4.1.5. Comply with all relevant domestic legislations and international obligations defined in the Multilateral Environmental Agreements (MEAs) where Kenya is party to (as provided in the Constitution of Kenya, Article 2 (5) (6).
- 4.1.6. Establish a code of best practices on Access and Benefit Sharing (ABS) value chain including setting up an ABS Intellectual Property desk office to promote and facilitate R&D based ABS contribution to valorization of genetic resources of Kenya.

4.2 -----partner institution

- 4.2.1. Provide Biological resource technical expertise in the joint research project
- 4.2.2. Identify and develop appropriate technologies and build capacity for understanding of Kenya's xxxxxx and xxxxxxxxxx xx biodiversity through research and technology transfer
- 4.2.3. Support taxonomic revision and characterization of xxxxxxxxxx taxa, where necessary.
- 4.2.4. Contribute to the development and implementation of effective xxxxxx ecological monitoring programs through joint fieldwork to enhance control and management of -----
- 4.2.5. Ensure that all biological specimens and data collection in Kenya under this MoA are sufficiently and accurately labeled as per KWS and ----- requirements, and are deposited in approved designated repositories.
- 4.2.6. Develop a database in consultation with KWS for monitoring collections value chain linking ----- ex-situ and in situ

conservation.

4.2.7. Provide a list and duplicate specimens and database of previously collected biological materials from Kenya.

4.2.8. Support digitization of ----- biodiversity collections at XXXXXXXXXXXX.

4.2.9. Support the Kenyan partners to establish capacity for -----through technical expertise and technology transfer

4.2.10. Support outreach programs that will contribute to conservation, management and sustainable utilization of Kenya's -----

4.2.11. Contribute to the development of ----- biodiversity ecological monitoring tools, systems and procedures for collections in compliance with PIC, MTA and MAT.

4.2.12. Train Kenyans in -----

4.3 Obligations of Kenyan partner institutions

4.3.1 Obligations of local partner

4.3.1.1. Coordinate activities ----- Kenya"

4.3.1.2. Review and establish ex-situ collections of xxxxxxxxxxxs and xxxxxxxxxxxs including but not limited to living libraries of xxxxxxxxxxxs and xxxxxxxxxxxs based on code of best practices at XXXXXXXXXXXX (PIC, MAT, MTA) in compliance with Nagoya Protocol.

4.3.1.3. Together with partners, review and update biological information on xxxxxxxxxxxs and xxxxxxxxxxx fauna in Kenya.

4.3.1.4. Develop a database in consultation with KWS for monitoring collections value chain linking ex-situ and in situ conservation.

4.3.1.5. Ensure that the resultant benefits arising from this project are used in line with Nagoya Protocol Article 9 and all the pertinent international laws.

4.3.1.6. Together with the other partners participate in the proposed research on the -----

4.3.1.7. In partnership with partner institutions build capacity for -----biodiversity resource managers and local communities in field ecological surveys.

4.3.1.8. Supervise and/or co-supervise MSc, PhD and Postdocs students with faculty advisors of -----

- 4.3.1.9. Develop uptake feedback pathway mechanism for R&D as per the Nagoya Protocol, Articles 16 to 19.
- 4.3.1.10. Together with ----- digitize and avail -----biodiversity data as per the approved data sharing policies.
- 4.3.1.11. Jointly develop outreach programs that will contribute to conservation, management and sustainable utilization of Kenya's ----- biodiversity.

4.3.2 Obligations of Provider

- 4.3.2.1. Develop guidelines for PIC, MAT, MTA, and outreach materials to create stakeholder awareness for effective implementation of this project in line with the Laws of Kenya and the Nagoya Protocol.
- 4.3.2.2. Develop a database in consultation with ----- for monitoring collections value chain linking ex-situ and in situ conservation.
- 4.3.2.3. Work with -----I to use reasonable efforts to comply and enforce users adherence to relevant permitting processes in line with the Environmental Management and Coordination Act (EMCA, 2015), Wildlife (Conservation and Management) Act 2013, Science Technology and Innovation Act 2012 and all the other Laws of Kenya.
- 4.3.2.4. Ensure that resultant benefits are used in line with Nagoya Protocol Article 9 and all the pertinent international laws.
- 4.3.2.5. Act as link between project partners and local communities, while at the same time support the indigenous local community governance ABS through grant of PIC.
- 4.3.2.6. Together with the other partners participate in the proposed research project -----
- 4.3.2.7. Develop uptake feedback pathway mechanism for -----R&D as per Nagoya Protocol Article 16 to 19
- 4.3.2.8. Build capacity of participating institutions through outreach programs on access to the country's xxxxxxxxxx and xxxxxxxxxx biological resource requirements

ARTICLE 5: ACCESS TO GENETIC RESOURCES AND ASSOCIATED KNOWLEDGE.

5.1. Kenya has sovereign rights over its natural resources where access and user rights are subject to international obligations where Kenya is party to, and national legislations.

5.2. In the event that the parties seek to access biological materials and genetic resources, derivatives, progeny, extracts, genetic information and associated knowledge held in situ both in protected areas and outside protected areas in pursuance to this MoA, prior informed consent and material transfer agreements shall be executed by all relevant providers and users in accordance with all applicable laws.

5.3. The -----partner will make existing electronic inventory records of all biological materials of Kenyan origin under their custody available to the Government of Kenya through -----and Provider.

5.4. -----partner agrees to provide duplicate genetic resources specimens, derivatives and database in their custody collected during this project and in previous undertakings to the Government of Kenya through designated repositories in Kenya.

5.5. All access and transfer of biological material, resources, derivatives, progeny and associated information shall be subject to a Materials Transfer Agreement (MTA) (a copy of which is attached to this MoA as Annex XX) between provider and users as defined in this MoA.

5.6. All accessed and transfer of biological materials, resources, and derivatives shall be subject to an MTA between Provider, ----- and the designated recipient repositories. The biological materials, resources, their derivatives, progeny, products and associated information shall remain the property of the Government of Kenya.

5.7. All specimens collected from the wild, including accessions from ex-situ specimens of Kenyan origin shall be deposited in designated repository resource centres including gene banks and data bases.

5.8. In this respect, this MoA is the MAT for the project titled -----in Kenya”, and shall form the basis of Provider granting a Prior Informed Consent (PIC) for the project.

5.9. When biological materials are accessed outside a protected area, KWS will provide a PIC jointly with relevant stakeholders as provided under the Wildlife Conservation and Management Act of 2013, and KWS is the competent authority for granting of PIC on wildlife resources within Kenya under the Wildlife Act.

- 5.10. Databases of all specimens accessed, transferred and utilized will be developed and kept in duplicate by the parties for tracking, monitoring and evaluation.
- 5.11. Guidelines shall be developed for ----- repository and transfer of biological resources from the ex situ collections based on the instruments of PIC, MAT and MTA as per the Laws of Kenya.
- 5.12. Given that the user partner institutions to this Agreement----- have previously accessed Kenya's biological resources for utilization in various projects and purposes, by signing this Agreement and the users providing an inventory of records of all activities and all collected biological resources, progeny, derivatives and associated information, the resource provider will release the users, and assume to have complied with CBD and Nagoya Protocol, and through appropriate MTA, transfer the biological resources to the national designated repositories.

ARTICLE 6: INTELLECTUAL PROPERTY (IP) RIGHTS AND PROTECTION

- 6.1. Project implementation Committee will establish an intellectual property (IP) technical committee with clear TOR's for Management of the IP rights resulting from undertaking the Project under this MOA.
- 6.2. The Project implementation Committee will undertake IP audit before, during and towards the end of the project to show the baseline and progress of existing and generated intellectual property. All generated and potential IP will be recorded in special notebooks and all parties to the IP generated will sign specific IP agreements as per the standard operating procedures.
- 6.3. All partner institutions will submit their IP policies to the Project Management Office and harmonized appropriately under this MoA.
- 6.4. The accessed biological and genetic resources shall remain the property of the Government of Kenya and all voucher specimen duplicates will be deposited in designated repositories at XXXXXXXXXXXX and other designated repositories as per the established standards in conformity with the Nagoya Protocol instruments of PIC, MAT and MTA.
- 6.5. The users will provide and keep clear records of biological and genetic resources, progeny, derivatives, products and associated information with potential IP before commercialization that will be negotiated between the users and provider under this MoA for further development.

- 6.6. The partners shall periodically review the results of joint research projects to determine if any research findings including processes and methods constitute intellectual property and determine which intellectual property is subject of legal protection.
- 6.7. In consultation with all the other partners, when filing for protection and administration of IP arising from research under this MoA and application for IP rights will be accompanied by PIC, Access permit and voucher specimen reference.
- 6.8. Transfer of generated IP rights by partner to new ownership will be subject to authorization by the provider and consultations by all partners under this MoA.
- 6.9. Technology jointly developed and owned shall not be transferred to a third party without the written consent of all parties.
- 6.10. Intellectual property generated from the project shall be jointly applied for and remain the joint property of the partners, with any revenues arising from commercialization of the products being equitably shared (as provided in Article-----of this MoA on Benefits Sharing).
- 6.11. Prior to any disclosure of proprietary information by any partner concerning specific aspects of this collaboration the partners shall execute a separate Confidentiality Agreement.
- 6.12. Any decision relating to the commercial exploitation or to the manner of disposal of the intellectual property right shall be made jointly by the parties taking into consideration the intellectual property policies of each institution in particular the role of the inventor.
- 6.13. Material for publication or presentation arising from the project shall be submitted for clearance by the Project Implementation Committee to ensure that no inventions or innovations or discoveries are published prior to protection by applicable intellectual property laws or by trade secret.
- 6.14. In all activities including scientific publications resulting from the project including scientific papers, reports, books and proceedings of conferences, seminars, workshops and exhibitions will be authored jointly as appropriate to reflect where the relevant contributions have been made and in so doing quoting the names of authors and the partners. Such acknowledgement shall include but not be limited to display in equal prominence of the full names and symbols or logos of all institutions including the donor.
- 6.15. All the parties herein agree to respect rights of indigenous knowledge holders and shall negotiate with particular indigenous communities should any indigenous knowledge be used for any purpose in this project and PIC granted by the said communities.
- 6.16. Project Implementation committee will develop procedures for data and publication access as outlined in the SOPs. Project

Implementation Committee will classify data deemed as restricted and non-restricted establishing access procedures through an Information Transfer Agreement.

6.17. Responsibility for expenses relating to registration, administration and further development and exploitation of the invention (including funds to the inventors to carry out further work to bring the invention to a stage where it can be commercially exploited, researching for commercial outlets, advertising expenses, and fees for patent advocates) will be agreed upon by all parties.

ARTICLE 7: TRANSFER TO THIRD PARTIES

7.1. A partner in this project may transfer biological resources, derivatives, progeny, products, compounds, extracts and associated information to third parties only after consultation with all the other partners, and a written consent from the Provider (KWS).

7.2. Sub-contractors and third parties shall enter into legally binding undertakings with the partners before they can handle any resources and/or functions in the project. Such agreements will be annexed to and will form part of this MoA.

7.3. The partners may assign, transfer or otherwise dispose, in whole or in part, to third parties any rights or obligations under this MoA after a written permission is sought and procured by all the parties to this MoA.

7.4. The Recipient shall ensure that the collection, storage, transfer, utilization, disposal and exportation of the genetic resources complies with all applicable Laws of Kenya on the protection of human health and the environment, on taxes, on customs and any other concern.

7.5. The Recipient shall indemnify and keep the provider its trustees, appointees, employees, agents and the State harmless from any claim, action and damage or cost deriving from or in connection with the Recipient's acquisition, use, storage or disposal of the materials.

ARTICLE 8: BENEFITS SHARING

8.1. Benefits resulting from utilization of biological resources by all partners will be used in accordance with the CBD and Nagoya Protocol and in line with the Constitution of Kenya and the domestic legislations such as Wildlife Conservation and Management Act 2013 and EMCA 2015.

8.2. Partners shall take inventory of all potential and derived benefits guided by the IP audit reports and develop agreeable benefit sharing plan.

8.3. Benefits shall include both monetary and non-monetary on the R&D value chain, which will include both academic and commercial steps. These benefits will be shared in accordance with the benefits sharing plan (provided in Annex V) and utilized as stipulated in the Nagoya Protocol Article 9.

8.4. The monetary benefit arising from IP commercialization shall include upfront, milestones and royalties as determined case by case. Copyrights shall be based on 15% royalty payments. Others will attract minimum of 10%. Payment will be annual based on submission audit report.

8.5. In the event of development and commercialization of a technology from the utilization of the accessed biological resources, the providers will be given access and use of the technology and where possible, one of the production sites to be at the country of origin. The venture to be owned on a 50:50 basis and in the event of sale of ownership rights by the user, the country of origin is given priority.

8.6. The benefits-sharing plan shall consider the communities living adjacent to the project sites and their indigenous knowledge.

ARTICLE 9: CONFIDENTIALITY

9.1. All research, development and commercialization information created by parties to this MoA shall be considered confidential information, subject to express written agreement to the contrary.

9.2. Where the release of research and development information created pursuant to this MoA is required for the procurement of permits, licenses and other approvals necessary for the effective execution of this MoA, or otherwise to comply with national legislation, regulations and policies the users shall:

- a) Provide such information as requested with the express stipulation that the same shall be considered confidential.
- b) Supply such information as part of compliance mechanisms in national processes.

9.3. Research and development information regarding discontinued activities that have not resulted in the development of a commercially applicable product to this MoA shall be placed in the public domain after a minimum of five (5) years or in accordance to the Laws of Kenya. Aspects of publications will be handled as per article 10.9 on administration.

9.4. Partners will execute confidentiality agreement as per SOP.

ARTICLE 10: ADMINISTRATION OF THIS MEMORANDUM OF AGREEMENT

- 10.1. The parties will establish coordination mechanisms for implementation of this MoA and the various projects.
- 10.2. Parties will establish project implementation committee with clear TORs.
- 10.3. This project implementation committee shall be constituted as per the project document. The project implementation committee will be drawn from the partner institutions and will comprise the Principal Investigators (PIs).
- 10.4. Project implementation committee will develop the Standard Operating Procedures (SOPs) in line with the projects objectives and the Nagoya Protocol.
- 10.5. Research performed under this MoA shall be in accordance with the “statement of work” (Annex I), and the SOPs.
- 10.6. Meetings, decision-making and monitoring will be done by the project implementation committee
- 10.7. The project will have an inception workshop to be held at the beginning of the project and a closing workshop at the end of the project as per the approved work plan
- 10.8. ‘Targeted products meetings’ will be held ad hoc whenever specific-product-oriented efforts yield promising and potentially exploitable results.
- 10.9. Decisions on scientific, technical and organizational aspects of the project will be handled by project implementation committee based on the approved work plans. There will be frequent meetings to review progress on R&D related to the project.
- 10.10. Final decisions on intellectual property protection and commercialization will be handled by the project implementation committee who will prepare a report and present it to the providers.
- 10.11. The inventory of project equipment bought under the grant shall be established and will remain in the custody of the host institution.

Article 11: REPORTS

11.1. Research Reports:

- a) All research activities undertaken shall be recorded in official research and field notebooks.
- b) All participating researchers shall prepare research reports as per the SOPs on a quarterly basis.

11.2. Payment reports

- a) This will be as defined under the benefit sharing arrangement.

11.3. Copyright reports

- a) This will be as defined under the benefit sharing arrangement.

11.4. Records

- a) An inventory of all the relevant records shall be identified.
- b) Records shall include among others, permits, licenses, database.
- c) The partners will ascertain that the project records are safely kept and available for inspection, external and internal audit.
- d) The project records shall consist of scientific reports, legal, ethics and IP reports, letters, memos, financial reports and partnership reports, minutes of all meetings, among other project documents.
- e) After expiry of the project, the records shall be kept for a minimum of five years, subject to the laws of Kenya.
- f) Records based on sales to be well kept by the user and availed to provider upon request. The records will be kept for a minimum period of five (5) years after project completion

11.5. Verification of records

- a) The users agree to permit identified auditor by the provider to examine their books and records from time to time during their ordinary business hours.

11.6. Donor narrative and financial reports

- a) Both narrative and financial reports shall be prepared according to institutional financial arrangements and the donor requirements.

11.7. Declaration by the users to the provider

- a) The users shall declare reports to the provider on financial position, technology transfer, IP, accruing IP royalties, dividends, income, pertinent investments, and distribution of partner shares, among others, derived from the utilization of the biological resources accessed under this project.
- b) Partners commit to availing all the records pertinent to the project for inspection.