GUIDELINES FOR PRIOR INFORMED CONSENT (PIC) TO UNDERTAKE RESEARCH AND DEVELOPMENT ON KENYA'S BIOLOGICAL RESOURCES

1. INTRODUCTION

Anyone who intends to access and utilize the country's biological resources for research and development has to obtain relevant permits. These includes Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and Material / Information Transfer Agreement from designated resource providers, Research license from National Council for Science, Technology and Innovation (NACOSTI), Access Permit from National Environment and Management Authority (NEMA), and Export / Import permit in the event of transfer of material out of the country (Annex 1).

Prior Informed Consent is a process of consultation between resource providers and users. Prior means full disclosure of the intended research by the researcher or user in a language that is fully understandable to the provider. This include discussions and provision of necessary documents such as research proposals, technical proposals , the donor agreements, Intellectual Property Policies and Legal entities of individuals and affiliate institutions. Informed means both parties have conceptualized the whole project, its outcomes and impacts in line with the Convention on Biological Diversity (CBD) and Nagoya Protocol Principals. Consent is an authority granted by the legally mandated resource provider in this case the competent government authority and where appropriate the competent indigenous local communities. The consent is granted against agreed elements which forms basis for entering into Mutually Agreed Terms (Collaborative research agreement).

2. Governing laws

This is governed by both the country's domestic legislations and key Multi-lateral Environmental Agreements the country is party to. The Multilateral Environmental Agreements include the CBD, Nagoya Protocol, Cartagena Protocol, CITES, ITPGRFA and the WIPO treaties among others. The domestic legislations governing grant of PIC include the Kenya constitution 2010, Environment (Management and Coordination) Act 2015 amendment, Wildlife (Conservation and Management) Act 2013, Seed and Plant Variety Act 2016, Science, Technology and Innovation Act 2013, Traditional Knowledge and Cultural Expressions Act 2016, Forest Act 2016 and Biosafety Act 2012.

3. Who has a right to obtain a PIC

Any legal entity accessing and utilizing biological resources and associated information for research and development. It involves both state and non-state parties. Also, it involves both foreigners and nationals.

4. The Scope

Prior Informed Consent is granted for access of biological resources such as biotrade, gene trade ,including indigenous knowledge associated with genetic resources in Kenya. This is in line with the Principles of sustainable resource utilization and ethical sourcing. This covers biological, genetic, derivatives, progenies, compounds, extracts, DNA / RNA, Digital Sequence Information and Traditional Knowledge arising from genetic resources.

5. Key elements to consider

a) The type of biological resources and associated information being accessed and the nature of utilization;
b) The parties involved i.e the resource providers and users. There is need to undertake clear stakeholder mapping during project concept development to identify the legally mandated resource providers with their key roles and responsibilities. The provider should ensure the user is the legally mandated entity for negotiations;
c) An understanding of all the relevant laws for the user, the user and provider measures as provided through the ABS clearing House Mechanism. It is important to understand whether the provider and user are parties or non-parties to the CBD and the Nagoya Protocols. Also the nature and principles of contractual laws governing utilization of biological resources;
d) The significance of the intended activity to the country. The intended research has to demonstrate both intellectual merit and broad impact in line with the country's development agenda. This areas include contribution to science, conservation, livelihoods, technology transfer and benefits;
e) Access methodologies should be very clear to inform decision making process. In case of sample collections, a clear protocol is required indicating quantities to be collected, collection procedures including labeling and coding and frequency of collection;
f) Evidence of ex-situ collection facility for collected materials. This should be a legally mandated ex-situ collection with clear IP policies and guidelines on PIC and MAT for access and utilization of deposited material, genebanks, genetic information databases etc.
g) Benefit sharing arrangements. This is a key element for the PIC. One has to demonstrate the benefit sharing arrangement as envisaged under CBD, Nagoya Protocol and Cartagena Protocol. These benefits are negotiated and agreed upon by both parties and is important to consider this step at the project conceptualization before funding. The benefits are demonstrated clearly within the work plan and budget. The benefits include both monetary and non-monetary;
h) Compliance with the relevant laws. The PIC is the basic in permitting process in the country. It is recommended one to understand all the required laws and comply. Mutually consenting on the PIC sets in the process for negotiate and entering into MAT contract and a MTA between the legally mandated resource provider and user;
i) Wavers and incentives are granted on a case to case basis.

6. Signatories

Signatories to the PIC are legally mandated entities authorized to bind the institutions they represent.

Annex 1: Flow chart (See separate sheet)

Annex 2: PIC Template

Title

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/Nagoya 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. <u>Non-monetary benefits</u>

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 ……(projecrt) to undertake research and collect ……(biological material) for the proposed project activities.

FOR APPLICANTS:

<u>THE USERS</u>

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