



THE ENVIRONMENTAL MANAGEMENT AND COORDINATION (CONSERVATION OF BIOLOGICAL DIVERSITY AND RESOURCES, ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING) REGULATIONS, 2016

ANNEX I: THE ENVIRONMENTAL MANAGEMENT AND COORDINATION (CONSERVATION OF BIOLOGICAL DIVERSITY AND RESOURCES, ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING) REGULATIONS, 2016

-----, 2016

(Legislative Supplement No.--- of 2016

LEGAL NOTICE NO.---

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

THE ENVIRONMENTAL MANAGEMENT AND COORDINATION (CONSERVATION OF BIOLOGICAL DIVERSITY AND RESOURCES, ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING) REGULATIONS, 2016

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IN EXERCISE of the powers conferred by section 147 of the Environmental Management and Co-ordination Act, 1999, (revised 2012), the Cabinet Secretary responsible for Environment, Natural Resources and Regional Development Authorities, upon recommendation of the Authority, and upon consultation with the relevant lead agencies, makes the following Regulations-

THE ENVIRONMENTAL MANAGEMENT AND CO-ORDINATION (CONSERVATION OF BIOLOGICAL DIVERSITY AND RESOURCES, ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING) REGULATIONS, 2016

| NO | MARGINAL NOTE | PROVISION |
|---------------------------|-------------------------------|---|
| PART I-PRELIMINARY | | |
| 1. | Short title and commencement. | These Regulations may be cited as the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2016 and shall come into force on such date as the Cabinet Secretary may by notice in the Gazette appoint and different dates may be appointed for different provisions. |
| 2. | Interpretation | In these Regulations, unless the context otherwise requires— “access” means 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: “access permit” means a permit that allows a person to access genetic resources issued under regulation 4; |

“benefit sharing” means the sharing of benefits that accrue from the utilization of genetic resources;

“competent national authority” means the authority be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms;

“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);

“exotic species” means any species of plant or animal or microorganism (life form) whose natural range does not, or did not in the past, exist in a specific part of, or the whole of, Kenya and which out-competes all other life forms.

“genetic resource” means any genetic resource of plant, animal, microbial or the origin containing functional units of heredity;

“habitat” means the place or type of site where an organism or population naturally occurs and includes areas colonized by introduced organisms;

“local community” means a community in whose location biological diversity resources are situated and includes a community of interest;

“holotype” means the single specimen chosen for designation of a new species;

“intangible components” means any information held by persons that is associated with or regarding genetic resources within the jurisdiction of Kenya;

“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;

“Prior informed Consent” means an international operation procedure for exchanging, receiving and handling notification and information by a competent authority, and

“threatened species ”means any species of plant or animal which is likely to become an endangered species within the foreseeable future throughout all or significant portion of its range.

3. Objectives

The objectives of these regulations shall be to-

- (a) Provide detailed processes and rules for the conservation of biological diversity in Kenya;
- (b) Provide mechanisms to protect and prevent exploitation of endangered and threatened plant and animal species;
- (c) Provide for access to and the fair and equitable sharing of benefits arising from the utilization of genetic resources;
- (d) Provide for the consultation of local communities in the process of accessing genetic resources for research, commercial and other purposes;
- (e) Ensure recognition of specific knowledge held by and role of local communities in conservation of biological resources;
- (f) Regulate the process and terms by which genetic resources can be taken out of the republic of Kenya and,
- (g) Provide for the sustainable use of bio-diversity and genetic resources;

4. Application.

(1) Subject to the provisions of section 3(2), these regulations shall apply to the conservation of all biological resources in Kenya, whether or not they are found in their natural environment, access to genetic resources and sharing of benefits that derive from those resources.

(2) These regulations shall not apply to-

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- (a) The exchange of genetic resources, their derivative products, or the intangible components associated with them, carried out by members of any local Kenyan community amongst themselves and for their own consumption;
- (b) access to genetic resources derived from plant breeders in accordance with the Seeds and Plant Varieties Act;
- (c) human genetic resources and,
- (d) approved research activities intended for educational purposes within recognized Kenyan academic and research institutions, which are governed by relevant intellectual property laws.

PART II—CONSERVATION OF BIOLOGICAL DIVERSITY

- 5. Environmental Impact Assessment Licence
A person shall not engage in any activity that may-
 - (a) have any impact on any ecosystem;
 - (b) lead to the introduction of any exotic species and,
 - (c) lead to the unsustainable use of natural resources, without an Environmental Impact Assessment Licence issued by the Authority under the Act.

- 6. Conservation of threatened species
The Authority shall, in consultation with the relevant lead agencies-
 - (a) Impose bans, restrictions or similar measures on the access and use of any threatened species in order to ensure its regeneration and maximum sustainable yield;
 - (b) Issue licenses for the establishment and maintenance of facilities for the recovery and rehabilitation of threatened species and

(c) Determine full recovery and rehabilitation measures of threatened species to ensure its restoration into its natural habitat.

7. Inventory of biological diversity
- (1) The Authority shall establish and maintain an inventory of all biological and genetic resources of the country.
 - (2) The Authority shall, every five years, in consultation with relevant agencies, undertake a comprehensive assessment of the status of such resources.
 - (3) The inventory shall include a special register of threatened, endangered and rare species of plants and animals.
 - (4) The inventory and special register shall be kept regularly updated by the Authority in between the five year period for a comprehensive assessment.
 - (5) The inventory shall be a public record and shall be accessible, in a prescribed manner, to any person on application to the Authority, and upon payment of such fees as may be prescribed.
8. Local community biodiversity measures
- (1) The Authority shall, in consultation with relevant stakeholders, develop guidelines for the recognition of local knowledge and practices by the management of biological resources.
 - (2) Every county environment committee shall develop a community biodiversity register comprising of local community practices for conserving biodiversity and uses of various biological resources
 - (3) The committee shall, advise the Authority, based on consultation with local communities in the County on procedures and terms for accessing such resources and knowledge for conserving biological resources.

- (4) The Authority shall partner with local communities and infuse their traditional knowledge and practices in the conservation of biological resources
9. Monitoring
- (1) The Authority shall, in consultation with the relevant lead agencies, monitor the status and the components of biological diversity in Kenya and identify activities and processes that threaten the sustainability of the country's biological resources.
- (2) The Authority shall take corrective measures including prosecution to deal with any threats to the country's biodiversity or components to it.
10. Conservation outside natural habitat
- (1) Any person who desires to operate a facility for the conservation of any species outside its natural habitat, shall apply for a licence from the Authority in the prescribed form.
- (2) An application under (1) above shall comply with the following requirements-
- (a) State the name of the applicant and their legal status in Kenya;
- (b) Detail the reason for desiring to operate a conservation facility;
- (c) Show evidence of approval/ concurrence of relevant Lead Agency and,
- (d) Demonstrate the suitability of the facility for conservation of the species
- (3) The Authority shall, while issuing a license to any applicant, impose such conditions necessary to ensure that the operations of the facility are not used as a way of accessing genetic resources except in compliance with these regulations or any relevant laws.

PART III –ACCESS TO GENETIC RESOURCES

11. Application for an Access permit
- (1) Any person who intends to access genetic resources in Kenya shall apply to the Authority.
 - (2) An application under (1) above shall-
 - (a) state the purpose of seeking an access permit;
 - (b) be in the form set out in the First Schedule and,
 - (c) be accompanied by such as fees set out in the Second Schedule;
 - (3) Every applicant issued with an access permit in accordance with these regulations shall strictly comply with the terms of that permit.
 - (4) Where purpose for which the permit was issued or the parties to the activity changes, the applicant shall notify the authority and apply for approval to undertake the new activities or in the new manner as if it was a new application.
 - (5) Any person who violates the provisions of this section commits an offence.
12. Prior informed consent
- (1) An applicant seeking to access genetic resources shall obtain prior informed consent from the provider of genetic resources.
 - (2) The provider of genetic resources shall either be a Competent National Authority or a local community depending on where the resources to be accessed are located and the tenure regime in that specific land.
 - (3) The Authority shall determine the relevant genetic providers from whom prior informed consent is to be obtained by the applicant
 - (4) Any person whose consent is required, and has given such consent, shall notify the Authority and issue a consent form in accordance with these regulations.

(5) The terms of such consent shall be agreed between the applicant and the genetic provider and reduced to writing.

(6) Every agreement should include the issues included in Schedule to these regulations.

13. Publication of application for access permit.
- (1) An application for an access permit shall be made to the authority in the prescribed manner
- (2) The Authority shall, upon receipt of the application, give notice thereof by publication in the Gazette or in such other manner as the Authority may consider appropriate, specifying—
- (a) the name and other particulars of the applicant;
 - (b) the activity to be undertaken for which the access permit is required ;and
 - (c) the time within which representations or objections in respect of the proposed access permit may be made to the Authority.
14. Determination of an access permit
- (1) The Authority shall consider such application for an access permit within 30 days from the date of the receipt of that application.
- (2) The decision of the Authority on (1) above shall be made in writing.
- (3) Where the applicant requires the facilitation of the Authority in identifying entities whose consent is required, and where the said entities are local communities, the period for negotiating the terms of grant of the consent shall not be taken as part of the 30 day period above.
- (4) The Authority shall publicize every application it has considered in the Kenya gazette and in atleast one newspaper of national circulation, save that the cost for such publication shall be borne by the applicant.

15. Issuance or Refusal to grant an access permit
- (1) The Authority shall, on receipt of representations or objections to the proposed access permit from the public, review the application and if satisfied that the activity to be carried out shall facilitate the sustainable management and utilization of genetic resources for the benefit of the people of Kenya, issue an access permit to the applicant.
 - (2) Where the Authority has reasonable grounds for refusing to issue an access permit, it shall inform the applicant of the reasons of such refusal in writing.
 - (3) A person aggrieved by refusal of the Authority to grant a permit may appeal to the Tribunal in accordance with its regulations.
16. Communication of decision.
- The Authority shall, within sixty days of receipt of an application for an access permit, determine the application and communicate its decision in writing to the applicant.
17. Non-transferability of an access permit.
- (1) An access permit shall be valid for a period of one year from the date of issue and shall not be transferable.
 - (2) Upon expiry, an access permit may be renewed for a further period of one year upon payment of the fee prescribed in the Second Schedule and upon such terms and conditions as the Authority may deem necessary to impose.
18. Terms, conditions of an access permit.
- (1) An access permit shall contain such terms and conditions as the Authority may deem necessary to impose.
 - (2) In addition to such terms and conditions as may be contained in an access permit, the following conditions shall be implied in every access permit-
 - (a) Duplicates and holotypes of all genetic resources collected shall be deposited with the relevant lead agency.
 - (b) Records of all intangible components of plant genetic material collected shall be deposited with the Authority.

- (c) Reasonable access to all genetic resources collected shall be guaranteed to all Kenyan citizens whether such genetic resources and intangible components are held locally or abroad.
- (d) All agreements entered into with respect to access of genetic resources shall be strictly for the purposes for which they were entered into.
- (e) The furnishing of quarterly reports to the Authority on the status of research, including all discoveries from research involving genetic resources and/or intangible components thereof.
- (f) The holder of an access permit shall inform the Authority of all discoveries made during the exercise of the right of access granted under the access permit.
- (g) The holder of an access permit shall provide the following reports–
 - (i) A semi-annual status report on the environmental impacts of any ongoing collection of genetic resources or intangible components thereof;
 - (ii) A final status report on the environmental impacts of collection of genetic resources or intangible components thereof, in the event that the collection is of duration of three months or less.
- (h) The holder of an access permit shall abide by the laws of the country.
- (3) The Authority may, on its own volition or on the application by an access permit holder, vary the conditions of an access permit.

19. Suspension, cancellation, etc, of access permit.

- (1) The Authority may suspend, cancel or revoke any access permit issued under these Regulations where the holder thereof is in contravention of any of the conditions imposed on the access permit or those implied under these Regulations, or of the agreements concluded pursuant to its grant.
- (2) The Authority shall, before suspending, canceling or revoking an access permit, give a written notice of its intention to suspend, cancel or revoke the permit to the holder thereof, and shall accordingly invite the holder to make representations within thirty days from the date of such notice.

(3) Where the Authority suspends, cancels or revokes a permit, it shall;

(a) Communicate such order suspending, cancelling or revoking the permit to the holder of the access permit in writing.

(b) Publish the order suspending, canceling or revoking the permit in the Gazette and in at least one newspaper with nationwide circulation.

20. Register of access permits. The Authority shall keep, manage and update a register of all access permits which it has granted, and the register shall be a public record of the Authority and shall be accessible, in a prescribed manner, to any person on application, and upon payment of the fees prescribed in the Second Schedule.

PART IV- MATERIAL TRANSFER AGREEMENTS

21. (1) A person shall only transfer genetic resources outside Kenya upon execution of a Material Transfer Agreement

Material Transfer Agreement.

(2) A Material, Transfer Agreement shall, address, as a minimum the issues included in Schedule to this regulation.

(3) A Material Transfer Agreement shall be executed by the exporter on the one part and the agency who has control and ownership over the resource subject of the export process.

(4) Upon execution, the user of a Material Transfer Agreement shall file the Material Transfer Agreement with the Authority.

(5) A person exporting a genetic resource shall be required to declare the resource at the port of departure and produce a copy of the Material Transfer Agreement.

(6)An exporter of a genetic resource shall deposit a holotype of the material being

exported either with the entity granting an Material Transfer Agreement or any depository gazette by the Authority for storage of such holotypes in Kenya.

(7) Any person who seeks to transfers any genetic resources outside Kenya otherwise other than in accordance these regulations commits an offence and shall be liable, upon conviction to a fine of Kshs.2,000,000 or a jail term of five years or both.

PART V - BENEFIT SHARING

22. Application of Part. This Part shall apply subject to the laws in force relating to intellectual property rights.
23. Benefits sharing.
- (1) The holder of an access permit shall facilitate an active involvement of Kenyan citizens and institutions in the execution of the activities under the permit.
 - (2) The facilitation by the holder of an access permit shall include enjoyment of both monetary and non-monetary benefits arising from the right of access granted and the use of genetic resources.
 - (3) Monetary benefits include–
 - (a) Access fees or fee per sample collected or acquired;
 - (b) up-front payments;
 - (c) milestone payments;
 - (d) payment of royalties;
 - (e) license fees incase genetic resources are to be utilized for commercial purposes;
 - (f) fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
 - (g) salaries and preferential terms where mutually agreed;
 - (h) research funding;
 - (i) joint ventures;
 - (j) joint ownership of relevant intellectual property rights;
 - (4) Non-monetary benefits include–
 - (a) Sharing of research and development results;
 - (b) Recognition;

- (c) collaboration, co-operation and contribution in scientific research and development programmes, particularly biotechnological research activities;
- (d) participation in product development;
- (e) admittance to ex-sit facilities of genetic resources and to databases by participating institutions;
- (f) transfer to Kenya of genetic resources of knowledge and technology under fair and most favorable terms, including concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
- (g) strengthening capacities for technology transfer to Kenya;
- (h) institutional capacity building;
- (i) human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- (j) training related to genetic resources with the full participation of Kenya and where possible, in Kenya;
- (k) access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- (l) institutional and professional relationships that can arise from access and benefit sharing agreements and subsequent collaborative activities, and
- (m) Joint ownership of relevant intellectual property rights.

PART V- MISCELLANEOUS

24. Confidentiality
- (1) The Authority may, on the request of an applicant of an access permit, hold some information relating to access to genetic resources as confidential.
 - (2) Where an access permit is granted, information held as confidential under paragraph (1), with respect to the relevant applicant, shall not be accessible to a person inspecting the register of access permits in accordance with regulation 17.
25. Transition
- A person carrying out any activities involving access to genetic resources immediately before the coming into force of these Regulations shall, within six months from the coming into force thereof, take all necessary measures to ensure full compliance with these Regulations.

26. Dispute Resolution The Authority shall encourage the use of Alternative Dispute resolution in disputes arising under these regulations
27. Offences A contravention or failure to comply with any of the matters provided in these Regulations shall constitute an offence.
28. Penalties Any person convicted of an offence under these Regulations, for which no penalty is specified, shall be liable upon conviction, to imprisonment for a term between one and four years, or to a fine between two million and four million Kenyan shillings, or both.
29. Repeal of the Environmental Management and Co-Ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006 These Regulations repeal the Environmental Management and Co-Ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006.

FIRST SCHEDULE (r.11)

FORM OF APPLICATION FOR AN ACCESS PERMIT

Applicants applying as individuals should fill Part I.

Applicants applying as corporate (organizations) should fill Part II.

All applicants must fill Part III.

All applicants must submit ten (10) hard copies and one (1) soft copy of this application to the Authority.

PART I- FOR APPLICANTS WHO ARE INDIVIDUALS

- (a) Name of applicant.....
- (b) Identification Card No./Passport No.....
- (c) Postal Address.....
- (d) PIN No.....
- (e) Permanent Residential Address.....
- (f) Qualifications (Curriculum Vitae to be attached).....

PART-II FOR APPLICANT WHO ARE CORPORATE (ORGANIZATIONS)

- (a) Name of Organization.....
- (b) Permanent Address.....
- (c) Registered Address.....
- (d) Registration No. (Attach copy of certificate of registration).....
- (e) Qualification of individuals in the project (Curriculum Vitae to be attached).....
- (f) Details (if any) of:
 - (i) Holding and subsidiary institutions; or
 - (ii) Individuals connected to the project.....

(g) Name of the contact person in regard to this application and the position held in the organization.....

PART III- FOR ALL APPLICANTS

1.0 Financial Details Sources:

- (i) The total budget of the project.....
- (ii) Details of any corporate or individual sponsor of the project.....

2.0 Technical Particulars

(a) What are the details of your previous collection/ research (if any) conducted in any of the East African country (Kenya, Uganda and/ or Tanzania)?

(b) With regard to genetic resources for which access is sought, the following must be provided–

- (i) Scientific names of taxa;
- (ii) Specific sites in which access will be undertaken;
- (iii) Possible location;
- (iv) Parts of the genetic resource to be collected (tissues, cells, seeds, leaves, microbes, etc);
- (iv) Derivatives and/ or products;
- (v) Quantities to be collected;
- (vi) Any known uses of the genetic resources;
- (viii) In case of genetic resources held ex-situ, details of the relevant depository institution(s).

(c) With regard to the planned collecting mission, the following must be provided–

- (i) Identification of the provider(s) of the genetic resources for which access is sought;
- (ii) Collection methods to be used;
- (iii) if there are Kenyan nationals or institutions to be used, their particulars;
- (iv) expected date of commencement and completion of the activity;
- (v) information regarding immigration status in Kenya of foreign individuals that will visit Kenya.

- (d) Proposed use of genetic resources–
 - (i) form of use to which the genetic resources will be put;
 - (ii) expected research results;
 - (iii) geographic allocation in which each element of their search programme will take place.
- (e) Details of any royalties, payments and/ or other compensation that the Applicant offers for access to genetic resources.
- (f) Will the applicant require assistance to identify and access the genetic resources described in this application? If yes, give details of the assistance that will be required.
- (g) A copy of the Prior Informed Consent document signed by the relevant lead agencies, local community or private owner of the genetic resources.
- (h) A copy of research clearance document from the National Council of Science and Technology.
- (i) Any other information in the possession of the applicant which might be useful for the National Environment Management Authority to make an informed decision in granting an access permit.

3.0 Renewal Details is this an application for renewal of an access permit?

YES.....NO.....

Access Permit No.....Granted on..... (Date)

All applicants are forewarned that it is an offence to give false information to the National Environment Management Authority punishable under the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006.

I undertake to provide progress and full reports as required under the Regulations.

I declare that to the best of my knowledge the information given in respect of this application is true.

For individual applicants:

Name of Applicant.....

Signature.....

Date.....

For Companies/Institutions–

SECOND SCHEDULE (r.9, 11, 20)

Fees

KSh.

(a) To apply for an access permit:

(i) Individual applicants.....20,000.00

(ii) Corporate applicants.....50,000.00

(b) To renew an access permit:

(i) Individual applicants.....10,000.00

(ii) Corporate applicants.....25,000.00

(c) To peruse the register of access permits:

(i) Residents.....1,000.00

(ii) Non-residents.....5,000.00

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 (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006 for the collection of the following genetic resources:

.....
.....
.....(insert description of the genetic 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 genetic 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.....of2016

JUDY WANGALWA WAKHUNGU
CABINET SECRETARY FOR ENVIRONMENT, WATER AND NATURAL RESOURCES

FOURTH SCHEDULE- (r. 12)

FORM OF A PRIOR INFORMED CONSENT (PIC)

PART A: Details of the Resource User and Local Partners/Affiliates

This part shall be filled by the person seeking to access the GR and/or associated knowledge. The person can be either an individual, corporate or organization

Resource User

- 1. Individual
 - a. Name.....
 - b. ID No. /Passport No.....PIN No/ Visa No.....
 - c. Country of OriginNationality.....
 - d. Valid Work permit No/Research Permit (If applicable).....
 - e. Telephone No: Include area codes.....
 - f. Applicants home Organization:
 - (i) Postal address:
 - (ii) Physical Address.....
 - (iii) Fax.....
 - (iv) E-mail.....Website.....
 - g. Official contact person (in case of legal entity).....
- 2. Corporate / Other Organizations
 - a. Name of Corporate/Organization.....
 - i. Postal address.....
 - ii. Physical Address.....
 - iii. Fax.....
 - iv. E-mail.....Website.....

- b. Name of person completing the form.....
- (i) ID No. /Passport No.....PIN No. / Visa No.....
- (ii) Valid Work permit No..... (If applicable)
- c. Telephone No: Include area codes.....
- d. Person to contact (in case of legal matters).....

3. Local Partner/Affiliates (if applicable)

- a. Name.....
- b. Postal address.....
- c. Physical Address.....
- d. ID No. /Passport No/PIN No.....
- e. Tel No.....
- f. Fax. No.....
- g. E-mail.....
- h. Official contact person (Chief executive officer of affiliating institution):
- i. Name.....
- ii. Title.....

4. Project type

- a. Proposed Project (Indicate by placing X in the box provided)

- (i) Educational research

- (ii) Commercial Use
- (iii) Industrial application
- (iv) Bio - prospecting
- (v) Conservation
- (vi) Other (specify).....

b. Genetic resource(s) to be accessed

- (i) Plants
- (ii) Animals
- (iii) Vertebrates
- (iv) Invertebrates'
- (v) Micro-organisms

(vi) Scientific nameCommon name:.....Local name (if known).....

(vii) Status of conservation

- Abundant
- Endemic
- Rare
- Threatened
- Endangered

Type (whole or part) Unit of measurement Quantity Frequency of collection

c. Details about Genetic Resource to be accessed (Indicate by placing X in the box provided)

d. Methodologies of collection (briefly describe how genetic material above will be collected from the organism).
.....

e. Sites/habitat in which collection will be undertaken (County, locality, GPS where possible)
.....

f. Attach documented bio-cultural protocols

g. Duration of material collection activity (Days, Months, Years)

• How long will analysis take

h. Location/ where the analysis and development will take place

i. Further details required in case of applied research

i. Are you aware of any product made of the material you are proposing to access? Yes / No...

ii. Are you aware of any specific uses of the material by the local community where it is found? Yes/ No

iii. Are you aware of any current industrial application of the material Yes/ No

j. Role of local community in the project (provide details on how the community where material is found will participate in the project)

.....Potential Impacts

Describe briefly the potential impacts of accessing the genetic resource(s) on the environment and the socio-economics of the provider community.

(i) Impacts on the environment

-

(ii) Socio-economic impacts

..... Proposed mitigation measures

-

k. Third Party Involvement

Indicate potential involvement of third parties

i.

ii.

iii.

5. Benefit Sharing Arrangements

The benefits derived from accessing genetic resource will be shared in accordance with the Mutually Agreed Terms (MAT) annexed hereto.

6. Communicating project implementation

Provide the ways in which an audit of accrued benefits agreed under MAT will be ensured during and after the project period.

.....

7. Project Budget

Indicate the overall project budget.....

8. Additional Information:

Provide any additional information the provider should know in order to make an informed decision of permitting your access to the genetic resource(s).

.....

PART B (The Persons /Community to be involved)

Details of Genetic Resource Provider

This part shall be filled by the person providing Genetic Resource (GR Provider). The person can either be an individual, corporate, organization or community.

1. Community /Corporate or organization/ Individual

- a) Name
- b) Address.....
- c) Physical Address.....
- d) ID No/Passport No.....
- e) PIN No.....
- f) Tel. No.....Fax No.....
- g) E-mail

Notes on documents to enclose

- a) For community attach authority to act on behalf of the community duly executed by the community’s representatives and or a resolution to that effect in case of the more organized communities e.g. duly signed minutes.
- b) For Corporate/organization above attach authority/resolution to act on behalf of the organization

DECLARATION

Read carefully the information provided in Part A before appending your signature below

I/We a resident
of.....;.....(county; sub-county; location) and of P.O Box.....
..... County hereby declare that:

1. I/we understand the scope, aims, and purposes of this project and the activities that are involved and the expected duration and manner of my/our participation.
2. I/we have received a description of reasonable foreseeable risks associated with this project; I/we have had them explained to me/us, and understand them.
3. I/we have received a description of potential benefits that may accrue from this project and understand how they will be shared
4. I/we understand that the confidentiality of all data, records and IP rights associated with my/our participation in this project must be within the extent of the law.
5. I/we understand my/our obligations as citizen to the state and county governments as pertains to access to and benefit-sharing from genetic resources and associated TK in Kenya.
6. I/we confirm that no coercion or inducements of any kind was used in seeking my participation in this project.
7. I/we understand that if my/our rights as a genetic resource(s) provider are infringed upon, I/we have the right to be given the opportunity to discuss redress with the above named user, failure hitherto I/we have the right to seek redress at the Environment and Land Court of Kenya.
8. I/we understand that any outputs from this project will be associated with me/us.
9. I/We understand that I/we have a duty to cooperate with state organs and other persons to protect and conserve the environment and ensure ecologically sustainable development and use of natural resources.
10. I/We hereby consent to the access of (name (s) of biological resources and/or state the associated knowledge) by (name of the person/institution seeking to access) for the uses stated in Part A, 4 (e)).

Signatures

Genetic Resource Material Provider

Name.....

ID NO-/Passport No...../PIN. No.....

Date.....Signature.....

FIFTH SCHEDULE- (r. 2)

FORM OF MUTUALLY AGREED TERMS

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding is entered BETWEEN

(Insert the name of the provider) AND (Insert the name of user)

IN RELATION TO (Insert appropriate title of the project)

Whereas the sovereign rights over biodiversity are vested in the State; and

Noting that Kenyan Government has put in place various legislative measures for sustainable utilization and conservation of biodiversity such as; the Constitution of Kenya (2010), Environmental Management Co-ordination Act (EMCA) 1999, the Wildlife (conservation and Management) Act, Amendment 1989, the Forest Act of 2005, Industrial Property Act, 2001, Plants and Seed Varieties Act, Cap 326, Kenya Agriculture Research Act, 2012, the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations 2006;

NOW THEREFORE the parties agrees as follows:

1: PARTIES TO THE AGREEMENT

These Mutually Agreed Terms (MAT) hereinafter referred to as ‘the agreement’ is entered into at..... (Insert location) on this day..... of _____ [insert year]: BETWEEN, P. O Box, Physical Address....., Tel., Fax:, E-mail:.....Here in-after referred to as Provider, AND, P. O Box, Physical Address....., Tel....., Fax:, E-mail:.....herein-after referred to as User /recipient.

2: USE OF TERMS

In this Agreement, the expressions set out below are defined as indicated in the glossary of this toolkit.

3: SCOPE AND OBJECTIVES OF THE AGREEMENT

3.1. Scope

This Agreement shall apply to access and benefit sharing of genetic resources for both non-commercial and commercial uses within the scope of the Constitution of Kenya, 2010 and the laws of Kenya.

3.2 The objectives of this Agreement

To facilitate:

- a. Access to genetic resources including derivatives and associated TK,
- b. Sustainable utilization of the genetic resources including derivatives,
- c. Transfer of genetic resources including derivatives to third parties, and
- d. Sharing the benefits resulting from the utilization of genetic resources including derivatives.

4: STATEMENT OF WORK (PROJECT SUMMARY)

4.1 The user shall attach a (1-2 page) description of the project that includes elements in Annex 1 of this Agreement.

4.2 The Genetic resource(s) shall be accessed from (insert exact locality where the resource is to be accessed including the GPS coordinates, L.R. No., e.t.c)

4.3 Title and Objectives of the Project shall be

5: OBLIGATIONS OF PARTIES

5.1. Obligations of the Provider

5.1.1 To allow the user to access the genetic resource and/or associated traditional knowledge – (specify the nature of material or species and the part(s) of the species to be accessed) relating to:

5.1.2 To conserve the genetic resources and preserve any associated traditional knowledge

5.1.3 To collaborate with a relevant lead agency/ies in providing the genetic resource

5.1.4 To facilitate the user(s), designated and competent authorities with information and data pertinent to the utilization of the genetic resources

5.1.5 To meet minor costs incidental to the access, including organizing for community meetings and reporting

5.1.6 To adhere to terms and conditions of this Agreement

5.1.7 To renegotiate for PIC, and MAT (where applicable) during variation of the access permit,

5.1.8 Shall disclose and share information on:

a) Any known use of the accessed material.

b) Any potential use.

5.2. Obligations of the User

5.2.1. Shall ensure that they obtain an access permit from the designated authority prior to accessing genetic resource(s)

5.2.2 Shall collaborate with a relevant lead agency/ies in accessing the genetic resource

5.2.3 Shall facilitate the provider(s), designated and competent authorities with information and data pertinent and resulting from the utilization of the genetic resources including derivatives

5.2.4 Shall meet all costs incidental to the access, including technology transfer and reporting

5.2.5 Shall use the GR and/or associated TK as specified in PIC consent and MAT.

5.2.6 Shall renegotiate the PIC, and MAT (where applicable) and apply for a variation of the access permit, if s/he intends to vary the use of the GR and or its derivatives in the initial PIC and MAT.

5.2.7 Shall disclose and share information on:

a) Any known use of the accessed material.

b) Any potential use.

6: CONFIDENTIALITY

6.1 All parties hereby undertake to treat as confidential any data and information generated by either party during and after access and declares in writing to be confidential and which is not otherwise known or available to the public (hereinafter referred to as 'Confidential Data') The Designated National Authority and/or Competent Authority shall give the user thirty (30) days written notice of its intention to publish data and information provided by the user to a third party in public interest or safety.

6.2 Confidential TK shall not be disclosed without PIC from the original holder.

6.3 TK, information and data disclosed and or generated during access to the GR shall not be disclosed to third parties without consent of the provider .

7: REPORTING

Parties agree that;

7.1. The User shall submit a written quarterly report to the Competent Authority and the Designated National Authority with effect from the date of issuance of access permit.

7.2. The user shall submit a written annual report to the provider from the date of issuance of access permit. Where the provider is a local or indigenous community, a summary of the report shall be adapted to a non-scientific audience and translated into Kiswahili or local language by the Competent Authority using the existing communication mechanism at the cost of the user.

8: BENEFIT SHARING

The Designated National Authority, Competent Authority, Provider, User and Local Community shall work together to share fairly and equitably the benefits arising out of the genetic resource and/or associated traditional knowledge as spelt out in this Agreement and shall have a clear benefit sharing plan indicating both monetary and non-monetary benefits as outlined in Annex 2 of this Agreement.

9: OWNERSHIP OF GENETIC RESOURCES AND ASSOCIATED KNOWLEDGE

9.1 The Government of Kenya shall retain ownership of, and title to the genetic resource accessed by the user on behalf of Kenyan citizens.

9.2 The Government will ensure that special arrangements are made to transmit equitable benefits to the provider including the local community.

10: INTELLECTUAL PROPERTY RIGHTS

10.1. The user shall not file or obtain whether in the country of the user, Kenya or elsewhere any intellectual property rights over any accessed genetic resource under this Agreement including any properties, derivatives or processes including those that may utilize the knowledge of local communities regarding any product or process, even if the process has been modified to a more sophisticated level of commercialization for extracting, isolating or synthesizing the chemical extracted from the genetic resource without prior agreement with the provider.

10.2. In the event that the intellectual property application must be filed urgently and may not have adequate time to notify the provider, the user shall notify the provider and DNA of such filing within fourteen days.

11: TRANSFER TO THIRD PARTIES

The user shall not transfer genetic resources or any component thereof to third parties without first having explicit written consent from provider.

12: TERMINATION OF AGREEMENT

This agreement shall be terminated as follows:

12.1 If the user is in the process of bankruptcy, the lead agency and the provider can immediately terminate the agreement.

12.2 If one of the parties repeatedly fails to fulfill or repeatedly violates its obligations under this agreement, PIC and/or MAT then the aggrieved party may terminate the agreement upon 30 days notice given in writing to the other party (ies).

12.3 Termination of this agreement, except in the case of bankruptcy, will be done through mutual agreement by all parties.

12.4 The termination of this agreement shall not affect the rights and obligations that were due to accrue to any party (ies) prior to the effective date of termination.

12.5 Starting with the day of termination of this Agreement, the user shall stop using the genetic resources. However, the user will continue to use co-owned product upon payment of royalties agreed upon by all parties.

13: HANDLING OF THE GENETIC RESOURCE AFTER TERMINATION

13.1. Upon completion of the project or termination thereof, the genetic resource shall be returned to the provider at the expense of the user or destroyed as may be determined by the DNA and lead agency.

14: FORCE MAJEURE

14.1 Neither party (ies) shall be liable to the other party (ies) for any delay or non-conformance of its obligations under this Agreement arising from any clause beyond its reasonable control, including, but not limited to, any of the following: Act of God, decree, war, fire, drought, explosion, civil commotion or industrial disputes of a third party or impossibility of obtaining gas or electricity or materials.

14.2. The affected party (ies) must promptly notify the other party (ies) in writing, but in no circumstances no later than 14 days, of the cause and likely duration of the cause.

14.3. Such notice having been given, the performance of the affected party's obligations, to the extent affected by the cause, shall be suspended during the period the cause persists.

14.4. Without prejudice to the above, the affected party (ies) must take all reasonable measures to minimize the impact of any force majeure on the performance of its obligations under the Agreement and to ensure, as soon as practicable, the resumption of normal performance of the obligations affected by the force majeure.

15: Applicable Laws

15.1 This agreement is governed by and shall be construed in accordance with the laws of Kenya.

16: DISPUTE RESOLUTION

16.1. Any dispute, difference or question arising out of or in connection with this agreement, including any question regarding its existence, validity or termination shall, to the extent possible, be resolved by negotiation, mediation and/or conciliation.

16.2. In the event that the dispute remains unresolved for more than three (3) months from the date when the dispute is first notified in writing by either party to the other party, the dispute shall be referred to and finally settled through arbitration in accordance with the Arbitration Act No. 4 of 1995 of laws of Kenya as amended from time to time or it shall be submitted to an arbitration body in accordance with the procedure laid down in part 1 of Annex II of the Convention on Biological Diversity.

16.3. If either of the parties fails to comply with the award of the arbitral tribunal, the aggrieved party(ies) may, in accordance with paragraph 16(d) (iv) of the Annex to Section A of Decision VI/24 of the 6th Conference of the Parties of the Convention on Biological Diversity, UNEP/CBD/COP/6/20, the Hague, 7-19 April 2002, ask the Government of Republic of Kenya or the Government of Netherlands to enforce the award given by the arbitral tribunal.

17: NOTICE

17. 1. Any notice or other document to be served under this Agreement must be delivered by hand or sent by registered mail or by international courier service to be served at the addresses below:

The..... the Provider, P. O Box, Physical Address....., Tel., Fax:, E-mail:.....

or

The.....the User, P. O Box, Physical Address....., Tel....., Fax:, E-mail:.....

Copied to:

- a) Competent Authority (Insert the name of the Institution and the address) and
- b) Designated National Authority (Insert the name of the Institution and the address)

17.2. All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.

18: ENTIRE AGREEMENT

18.1 The provisions of this agreement and the contents of Prior Informed Consent constitute the entire agreement between the parties and the parties do not make any representations or warranties except those contained in this agreement and Prior Informed Consent. The agreement shall only be extended or amended by consent in writing and signed by authorized representatives of the parties of this Agreement.

19: NO ASSIGNMENT

19.1 This agreement is specific to the parties and none of the rights or the obligations under this Agreement may be assigned or transferred without the prior informed consent of the other party (ies).

20: NO PARTNERSHIP IN LAW

20.1. Nothing contained in this Agreement shall constitute a partnership in law between the Competent Authority, Provider and User or constitute either of the Agent of the other.

21: MONITORING & EVALUATION

21.1. The parties to this agreement shall put in place and implement appropriate measures for monitoring and evaluation of terms of this Agreement.

22: DISTRIBUTION OF COPIES OF AGREEMENT

22.1 Each of the parties to this Agreement shall receive and keep a copy bearing original signatures. In addition one counterpart of the Agreement shall be submitted to DNA at the time of applying for an access permit.

22.2 The language of this Agreement shall be English. There shall be translation of whole or in part into Kiswahili where necessary.

IN WITNESS WHEREOF the parties hereto, or their duly authorized representatives, have hereunto subscribed their hands and seals on the date and year mentioned above.

Executed as an Agreement

SIGNED on behalf of the

1. PROVIDER

(Insert the name of the provider)

By (insert name of signatory)

(Insert signatory position)

DATED

SIGNED on behalf of the

2. Witnessed by

(insert name of signatory)

(Insert signatory position)

3. USER

(Insert the name of the user).....

By (insert name of signatory)

(Insert signatory position)

DATE

4. Witnessed by

(insert name of signatory)

(Insert signatory position)

5. COMPETENT AUTHORITY

(Insert name of the institution)By..

(insert name of signatory)

(Insert signatory position)

DATED

SIGNED on behalf of the

SIXTH SCHEDULE- (r. 21)

FORM OF MATERIAL TRANSFER AGREEMENT

Article: 1.0 Preamble

Whereas the sovereign rights over biodiversity are vested in the State;

Aware of the letter and the spirit of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the 1992 Convention on Biological Diversity (CBD), Nagoya Protocol (2010), the 2004 International Treaty on Plant Genetic Resources for Food and Agriculture, Biological and Toxins Weapon Convention (BTWC) 1972 UN resolution 1540 (2004),

Recognizing that Kenyan Government has put in place various legislative measures for sustainable utilization and conservation of biodiversity such as; the Constitution of Kenya (2010), Environmental Management Co-ordination Act (EMCA) 1999, the Wildlife (conservation and Management) Act, Amendment 1989, the Forest Act of 2005, Industrial Property Act, 2001, Plants and Seed Varieties Act, Cap 326, Kenya Agriculture Research Act, 2012, the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations 2006.

Noting the diversity, varied origins and inherent value of Kenya's genetic resources and their contribution to environmental health and socio-economic development.

Acknowledging: The rights of local communities to associated traditional knowledge on biological resources and its contribution to science, technology and innovation:

The parties hereby agree as follows:

Article 2.0 –Parties to the Agreement

2.1 This Material Transfer Agreement hereinafter referred to as the agreement is the official document for transfer of biological/genetic materials for Kenya.

The party(ies) to the agreement shall be recognised legal entities.

Private resource owners, international research organizations and nongovernmental organizations shall become party through relevant national agencies.

2.2 This agreement is between;

Provider(insert legal contacts of providing institution, names of authorized officers)

And

Recipient.....(insert legal contacts of receiving institution, names of authorized officers)

Article 3.0 Terms and Conditions of this Agreement

3.1 The purpose and objectives: State the purpose whether: Academic, Research or commercial, taxonomy, collection, and expected outputs; include the title of the project and the abstract

.....

3.1.1 Objectives

.....
.....

Indicate type of material, source and GPS points

.....
.....

3.1.2 Provide documentary evidence of the following (Attach as annex):

- a) Deposition of duplicate specimen in designated repository center
- b) PIC and MAT

3.1.3 Provide associated traditional knowledge and source (if any)

.....
.....

4.0 Rights and obligations of providers and recipients

- a) Both the provider and the recipient shall notify the NEMA and any other relevant lead agency on the MTA implementation, material transfer to Third party, any discoveries and further use of the material through reports
- b) TK, information and data disclosed and or generated during access to the GR shall not be disclosed to third parties without consent of the provider.

c) Confidential or proprietary GR information shall not be disclosed unless the information is in the public domain or is disclosed in public interest.

4.1. Rights and obligations of the provider

- i. The provider retains ownership of the genetic material including any material contained or incorporated in modifications.
- ii. The provider may repatriate genetic resources held by recipient with adequate prior written notice.
- iii. The provider also retains rights to any intellectual property it owns in genetic resource.
- iv. The provider retains the right to access, audit and monitor the use and application of the genetic material provided under this MTA.
- v. No rights under any intellectual property of Kenya or rights in any other material or confidential information provided by the Kenyan to the recipient under this agreement is granted or implied as a result of providing this material to the recipient, other than as expressly set forth herein.

4.2. Rights and obligations of the recipient

- i. The Recipient shall use the genetic resource(s) for the purpose stated in this agreement only
- ii. The Recipient is responsible for ensuring that all permits required for the movement of the material are obtained and that sufficient proof of such permits is provided to the provider whenever required to provide such proof.
- iii. In no circumstances shall the recipient collect materials in such a way that adversely affects the environment or in any way alter the genetic diversity of the source material
- iv. No commercialization shall take place without notice and a negotiated agreement with the provider.
- v. In the event of commercialization whether by the recipient, its servants and or agent or any party acting under it regardless of whether there was an act or omission on the part of the recipient resulting in the use and commercialisation of the GR without re-negotiation for the commercial license agreement the recipient will pay 50% of the gross income arising from the GR. In any case the provider shall become the duly recognised supplier of the genetic resource.
- vi. The Kenya Government shall have unrestricted access to the technologies and processes developed from the access and use of the GR.
- vii. In the event of commercialisation, the recipient and provider are enjoined in ownership of patents of inventions arising from utilization of genetic resources accessed as agreed.

viii. The GR obtained under this agreement shall only be transferred by the recipient to a third party with prior written authorization from the provider and MTA between the recipient and the third party.

ix. The recipient shall indemnify and keep provider indemnified from any claim, action, and damage or cost deriving from or in connection with the recipient's use of the GR.

x. The recipient may file patent application(s) claiming rights over its inventions made by recipient through the use of GR or modifications and in the event of technology transfer to third party or commercialization, the recipient shall negotiate with the provider prior to such use.

Article 5: Repatriation of Genetic Resources from Foreign Depositories

5.1 Due to national interests such as food or environmental security, the Government of Kenya may require the return of the remaining GR as required by the circumstances and recipient shall return such GR, to such institution as may be designated by NEMA without any condition.

5.2 The recipient shall use the genetic resource and/or associated traditional knowledge for the purpose(s) contained in this agreement and/or continue to keep the genetic resource in safe custody in accordance with standard procedures and practice.

Article 6: Termination of Agreement

6.1 This agreement is binding throughout the existence of the accessed GR.

6.2 On termination of this agreement, the recipient shall destroy (unless requested by provider to return the said remaining material) and shall provide proof immediately to the provider

6.3 Any procedurally duplicated GR/biological material shall survive the lifetime of this agreement and should be freely accessible to the Kenya government and the provider upon request.

Article: 7.0 Warranty

a) The Provider makes no warranties as to the safety of or title to the GR material, nor as to the accuracy or correctness of any information provided with the Material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Material being furnished.

b) The phytosanitary condition of the Material is warranted only as described in any attached phytosanitary certificate. The Recipient assumes full responsibility for complying with the recipient nation's quarantine regulations and rules as to import or release of genetic material.

Article 8: Applicable Laws

The applicable law shall be the domesticating national laws of Kenya, the relevant provisions of the Nagoya protocol, and, when necessary for interpretation, the decisions of the NEMA.

Article 9: Dispute Resolution

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

- a) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation.
- b) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed.
- c) Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Act No. 4 of 1995 of laws of Kenya and in accordance with the procedure laid down in part 1 of Annex II of the Convention on Biological Diversity.

Article 10: Force majeure

10.1 Neither party(ies) shall be liable to the other party(ies) for any delay or non-conformance of its obligations under this Agreement arising from any clause beyond its reasonable control, including, but not limited to, any of the following: government Act, war, fire, drought, explosion, civil commotion or industrial disputes of a third party or impossibility of obtaining gas or electricity or materials.

10.2 The affected party(ies) must promptly notify the other party(ies) in writing, but in no circumstances no later than fourteen (30) days, of the cause and likely duration of the cause.

10.3 Such notice having been given, the performance of the affected party's obligations, to the extent affected by the cause, shall be suspended during the period the cause persists.

10.4 Without prejudice to the above, the affected party(ies) must take all reasonable measures to minimize the impact of any force majeure on the performance of its obligations under the Agreement and to ensure, as soon as practicable, the resumption of normal performance of the obligations affected by the force majeure.

Article 11: Notices

Any notice or other document to be served under this Agreement must be delivered by hand or sent by registered mail or by international courier service to be served at the addresses below:

Designated National Authority

Insert the name of the Institution and the address

Competent Authority

Insert the name of the Institution and the address

Provider

Insert the name of the Provider(s) and the address

Recipient

Insert the name of the Institution and the address

All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.

Signature/Acceptance

For provider

Name and Signature of Head of institution-----

Name and signature of Authorizing officer:-----

For recipient:

Name and Signature of authorized official-----

Name and signature of principal investigator-----

Witnessed by-----