

Biological Authorization Procedures

Kenya is among the mega diverse biodiversity countries in the world. The country is a home to rich and unique diverse flora and fauna represented by diverse habitats. In addition rich traditional knowledge associated with the biological resources. The Country has diverse habitats, ranging from protected area system (that comprises of approximately 12 percent of the Kenyan territory, classified as national parks, national reserves, marine reserves and forest reserves), private, public and community lands. These areas have varied ecosystems and habitats ranging from marine, inland wetlands, fresh and salty water lakes, rivers, volcanoes, hot springs, savannahs, forests, Mountains, caves, rangelands, drylands among others. The rich biodiversity, serve as the country's biodiversity treasure trove that contributes to both National and global economy, which has an invaluable and extensive potential for innovative products and processes that is still widely untapped. The valuable biological resources and associated traditional knowledge and derivatives continue to attract huge number of diverse stakeholders ranging from academicians, bioprospectors, naturalists and tourists among others.

Management, utilization and conservation of the country's biological resources is governed by various laws. The country has ratified the Convention on biological diversity (CBD), Nagoya Protocol 2010, ITPGRFA, CITES, Cartagena Protocols, Intellectual Property Treaty among others which govern access and use of genetic resources. In addition the country has put in domestic mechanism, that is the Constitution, legislations such as EMCA 1999, subsidiary legislation legal Notice 160, Wildlife Conservation and management Act 2013, Forest Act 2005, NACOSTI 2012 among others to regulate access and use of biological resources.

It is important for anyone seeking to access the country's biological resources for various user rights to obtain appropriate permits/licenses. It is illegal to access Kenya's biological resources without valid authorizations/permits.

Key elements for accessing the country's Genetic resources include:

1. Prior Informed consent from competent resources providers as defined by the law (both Genetic resources and associated Knowledge) and the communities.
2. Research Permits from Competent institution.
3. Work permits from Immigration Service Department
4. Access permit from NEMA.
5. Export permits from competent institutions.

It is recommended that all individuals seeking to access the indigenous biological resources to read carefully the procedures. This will assist one in planning including developing the proposal/projects/funding/ work plans. It is also important to consider the country's priority areas in Research and development.

However, in the recent past, it has been noted that the individuals/organizations experience difficulty while seeking to access the biological/genetic resources or the associated knowledge for research or commercial purposes due to various licenses/permits issued in the country by various government institutions. In most instances one does not know where to start and where to move to next and finally where to end or information on requirements of obtaining such licenses/permits. It is recommended that all individuals seeking to access the indigenous biological resources to read carefully the procedures. This will assist one in planning including developing the proposal/projects/funding/ work plans. It is also important to consider the country's priority areas in Research and development.

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The key notable licenses/permit/consent one should consider acquiring when pursuing access to biological/genetic and associated knowledge in Kenya is:

1. Prior informed Consent (PIC)

Prior informed consent is basic requirement that set a stage for obtaining Access permit. Resource providers (Biological resources and or associated Knowledge) grant the prior informed consent. It is important to know which resources one wants to access and seek prior informed consent from the providers.

For example those seeking to undertake research on wildlife biological resources will seek PIC from the Wildlife Management Authority.

Procedures for obtaining PIC/research authorization on the Country's Wildlife resources

Issuance of prior informed consent /research authorization on wildlife biological resources is governed by the Wildlife Conservation and Management act 2013. This is applicable to both foreign and local users. Where wildlife as defined in Wildlife Act 2013 (microorganism, plants and animals) and scope which include within and outside protected areas

Requirements:

- I. Any person or institution either local or foreign desirous to conduct Research and development on Kenya's wildlife shall have a Prior informed consent (PIC) from the Wildlife management Authority. And where the wildlife is outside protected areas the PIC will be issued jointly with the landowner or communities.
- II. The PIC shall be based on the applicant disclosures that will inform mutually agreed terms (MAT) and Material transfer agreements.
- III. Any person or institution either local or foreign desirous of conducting research in wildlife in Kenya shall apply to the Director-General, KWS for research authorization in prescribed application forms and payment of requisite research fees, whose details are available in the KWS website: www.kws.go.ke
- IV. All wildlife research requests shall be submitted to the Director-General, Kenya Wildlife Service for clearance before application for research clearance with the National Commission for Science Technology and Innovation (NACOSTI) and for Access permit to genetic resources from the National Environment Management Authority (NEMA).
- V. All applications for wildlife research shall be submitted 3 months prior to the intended commencement of the research project.
- VI. All applications will be accompanied by the following documents: a) Comprehensive research project proposal b) Letter of support from the institution of affiliation/sponsorship c) Curriculum Vitae (CV)
- VII. Kenya wildlife service is a joint partner on research and development on wildlife biological resources on behalf of the government.
- VIII. Where the research involves collection of samples/specimens from the field, the applicant must adhere to Kenya wildlife Service scientific specimen collection/depository procedures.

IX. Permission by the Wildlife Authority to undertake research will depend on grant of Access Permit by NEMA.

X. For foreign researchers and institutions, they must submit copies of a) Valid Passport, b) Visa or resident permit from the Immigration Service Department and any other relevant documents.

XI. All seeking to export wildlife material both In-situ and ex-situ should obtain export from the Wildlife Management Authority licensing Department.

2. Research Permit

Research permit to conduct research on the country's biological resources are issued by National Commission for Science, Technology and Innovation (NACOSTI). Issuance of research permit will depend on approved Prior informed consent by the genetic/biological provider as defined in the law. The National Commission for Science, Technology and Innovation (NACOSTI) is an advisory institution of the Government of Kenya on matters of national science, technology, innovation and research.

Research, which is a major tool for generating new knowledge and turning it into new products and services, is crucial for the advancement of the national socio-economic growth and for mankind as a whole.

For this reason the Science and Technology Act, Chapter 250 of the Laws of Kenya, under Section 4, established the NACOSTI to advise and regulate matters of research among other functions in the country.

Guidelines for Online Application of Research Permit

1: Definition of Research

Research is any systematic investigation or activity undertaken for the purpose of acquiring novel facts, solve new or existing problems, prove new ideas, or develop new theories or increase the stock of scientific and technical knowledge.

Research is defined as any creative systematic activity undertaken to increase the stock of scientific and technical knowledge and to devise new applications and includes fundamental research, applied research in such fields as agriculture, medicine, natural and physical sciences etc; and experimental development work leading to new devices, products or processes.

For purposes of research clearance in Kenya, this includes general purpose data collection; bioprospecting as well as geological and genetic resources; and information in the fields of agriculture, medical sciences, physical sciences, ICT, biological sciences etc, or any activity of research related to economic, social and political nature that involves obtaining information through collecting data including interviews or questionnaires. It also includes routine data collection activities such as routine statistical surveys, censuses, market studies; and experimental development work leading to new devices, products or processes.

Scientific expedition is defined as an organized tour of facilities of scientific interest, usually for short periods.

2: Objective of Research Permit

The objectives of research procedures and guidelines and issuance of permit are:-

- a. To facilitate coordination of research as provided for in the Science and Technology Act, Chapter 250 of the Laws of Kenya;
- b. To encourage quality research that will directly benefit Kenya and increase the body of scientific knowledge as a whole;
- c. To secure the data and results of research work undertaken in Kenya;
- d. To document and monitor all research work going on in the Country and have a data base of centrally available information on such work;

e. To facilitate useful research work and discourage projects which are not in the National interest;
f. To ensure maximum benefits and dissemination of knowledge and technologies from research activities to end users;

g. To eliminate the unauthorised collection and transfer of research information and materials;
h. To ensure that research in Kenya is conducted according to professional ethics;
i. To ensure that relevant National Institutions are informed of the intended and on-going research in their mandated areas and that they are given an opportunity to influence the course of the research being undertaken in their areas of interest;
j. To discourage unnecessary duplication of data collection for on- going research projects or research already undertaken or research about to be undertaken; and
k. Generally, to protect national interests and, as far as possible, discourage clandestine activities which may be undertaken under the cover of research.

3: Who Should Apply?

The following are to apply:-

- a. All Non-Kenyans intending to do research in Kenya;
- b. Foreign students intending to come for study tours or undergraduate students coming for a short duration;
- c. All Kenyans who are studying abroad and intend to do research in the Country;
- d. Private institutions either Kenyan or Non-Kenyan intending to do research in the country;
- e. All Kenyans except employees of Government Research Institutions/ Ministries /Departments whose mandate is to do research or as part of their duties or have a Standing Research Clearance; and
- f. In all cases where the research involves acquiring information/data from the Country or Public and Government organizations.

4: Issuance of Research Permit

Research Permit will be issued in the name of the applicant who is the project leader, or the expedition leader or the leader of the institution in the case of Standing Research Clearance. It is a must that, each researcher pays appropriate fee for each research project. The number of researchers for institutional/company permit should not exceed three researchers per permit. The holder of the research permit will be held responsible for making sure that the regulations governing the permit are observed.

5: Research Clearance and Authorization Process:

The process involves the following steps:-

1. Complete appropriate application through online by logging in to oris.NCSTi.go.ke and follow the instructions and note that registration is free.
2. Submit the fully completed application together with research proposal, CV, copy of ID/passport, and others as appropriate (see checklist at the end) and upload as one file.
3. Applications are received by the Research Coordination Division which will forward to relevant experts of the Sciences Scheduled for assessment and advice.
4. Research Coordination Division on receipt of the comments of the relevant science schedule will deal appropriately by issuing Research Permit, or inform applicant in case a further information are required.
5. On completion and finalization of research work the researcher must submit two copies of research reports to NACOSTI and upload a pdf copy into the system. No Research Permit will be issued for subsequent research work if the reports of previous research work were not submitted.
(NB: see below for other requirements on ethical approval, materials transfer, standing research clearance, protected areas and affiliation institutions).

6: Application Fee Structure

Current research application fee structure is:-

(a) Kenya Citizens and Institutions

Student/Attachment/Undergraduate/Diploma.... Ksh.100

Research (Academic) Masters Ksh.1,000

Research (Academic) PhD.... Ksh.2,000

Research (Individual/Post Doctoral) Ksh.5,000

Research (Public/Private Institutions).... Ksh.10,000

Research (Private Companies).... Ksh. 20,000

Extensions Half of the rate concerned.

(b) Non-Kenyan citizens and institutions*

Student Attachment/Undergraduate/Diploma US\$150

Research (Academic) Masters US\$350

Research (Academic) PhD US\$400

Research (Individual/Post-Doctoral) US\$500

Research (Foreign Public/Private Institutions).... US\$ 1,000

Research (Private Companies).... US\$ 10,000

Extensions Half of the rate concerned.

*NB: the fees for citizens from African Union member countries will be twice the amount for Kenyans for each category except for East African citizens whose fees are same as for Kenyan researchers.

7: Affiliation Institution

Non-Kenyan researchers who intend to do research in the Country must be affiliated with a relevant Kenyan Public research institution. A list of institutions approved for affiliation purposes is found online under 'institutions'. Private and foreign institutions can have special collaborative arrangement with Kenya public institutions. In such case the Kenyan institutions will be required to submit to the NACOSTI details of the nature of collaboration.

8: Ethical requirements

All research projects that involve human beings as research participants (e.g. clinical investigations, drugs, social behavioral studies, biological studies involving human organs or specimen) should satisfy the ethical standards for research as provided for in the Guidelines for Ethical Conduct of Biomedical Research involving Human Subjects in Kenya (2004) which is downloadable from NACOSTI website, and any other applicable internationally recognized ethics guidance guidelines. Letter of ethical approval from recognized local ethical research committees must be attached to the applications.

9: Field Research by College Students

Students registered in an educational institution in Kenya and intend to conduct field research should be introduced to the NACOSTI by their head of college/institution. The head of college/institution should provide to the NACOSTI information on name(s) of student(s), subject of research assignments, area in which research is to be done and duration of the research.

10: Research in Protected Areas

Researchers intending to conduct research in protected areas (e.g. wildlife and forest reserves or other conservation sites) are required to obtain approval letter(s) access permits from those

institutions or agencies in charge of the said areas prior to submitting their research project applications to the NACOSTI for approval and clearance.

11: Access to and exchange/Transfer of Materials for Research

All experimental tests, analyses and investigational procedures of materials should be undertaken within Kenya, but where it is proven that no capacity for a particular tests, analysis and investigation of a material exists in Kenya, or where exchange is needed for quality assurance purposes, the researcher wishing to transfer or export samples abroad for research purposes shall be required to obtain approval from relevant Government agency that regulates the export of the materials that researcher intends to export/transfer. Where there is no Government agency that regulates export/transfer of such material is not there, and then the researcher shall write a letter of request for the exchange, transfer, acquisition or export to the Secretary, NACOSTI. The request letter should be accompanied by a Material Transfer Agreement (MTA) document signed by the researcher and the recipient institution abroad and accompanied by a certificate from the affiliation institution in Kenya indicating that the tests or analysis cannot be done in Kenya due to lack of the relevant capacity.

12: Monitoring and Evaluation of Authorized Projects

NACOSTI shall have access to data and the research premises of the project and it may from time to time visit the research projects to familiarize with the work going on and make appropriate recommendations on the project. The affiliating institutions may give to the NACOSTI an evaluation of the preliminary or progress report and to indicate areas that need further action if necessary.

13: Training and Research Assistants

Research projects that will take over 3 years should have a training component for local personnel depending on the duration, nature and scale of the project. It is generally disapproved to have non-Kenyan research assistants particularly where it is obvious that Kenyans can be recruited for such tasks.

14: Work Permit/Visa

Granting of a research permit does not in any way absolve the researcher from the requirement of a work permit or visa. It is up to the researcher to secure the necessary work permit or visa before or upon arrival in Kenya.

15: Extension of Research Permit

A researcher who wishes to continue with the research project, beyond the expiry date of the research permit, is required to make a request by filling the Research Authorization Extension Request Form (Form C) for an extension or renewal to the Secretary, NACOSTI. The request should be made at least two (2) months before the expiry of the Permit.

16: Acknowledgement of Institution

Researchers are required to acknowledge Kenyan collaborators and/or participants on all papers, documentaries and books written/produced out of the research. Kenyan Government research permit must also be acknowledged. The affiliating institution must be acknowledged and the address of the affiliating institution must be shown as the second address for the researcher for the specific research project.

17: Standing Research Clearance

Standing research clearance is given to public institutions to conduct research within its own mandate without having to submit an application for research clearance for each individual projects. The research projects should be reported to the NACOSTI, by means of submission of annual reports

and / or final project report. Public institutions include government ministries, public research institutions and foundations; universities and international UN organizations.

18: How to Apply for Standing Research Clearance

Institutions should apply to the NACOSTI by providing information on the names and nationalities of directors/board members of the institution; mandate and core functions; institution's source of funds; justification for requiring a standing research clearance; the planned research projects/programs; details of research or professional personnel including their curriculum vitae and role in specific research project; and indication of any existing research collaborative arrangement with Kenyan or Non-Kenyan research institutions.

19: Termination of Research Clearance

The NACOSTI reserves the right to terminate, suspend or revoke a research permit in the event of gross misconduct or violation of the provision of these Guidelines or when necessary in the prevailing circumstance. The purpose for research clearance to ensure that research is for public good and for the benefit of mankind; and where the contrary is found to be the case then the research authorization can be discontinued by NACOSTI without any compensation.

20: Review and Termination of Standing Research Clearance

The Standing research clearance will be reviewed from time to time so as to assess the standing research clearance for possible termination where necessary.

Application Checklist:

- a. Complete application (all).
- b. Photographs (all).
- c. Payment receipt for appropriate fee (all).
- d. Identity/passport).
- e. Letter from sponsor if not self-sponsored.
- f. Letter of affiliation (all)..
- g. Letter from host institution abroad (Non-Kenyan).
- h. Letter of ethical approvals (see guideline).
- i. Research proposal..
- j. Company/institution registration & profile (see guideline).
- k. MTA (see guideline).

3. Researchers Pass

The Kenya citizenship and immigration Act (2011), provides for the issuance of Kenya Intern or Researcher's pass to applicants who wish to enter or remain in Kenya for a period not exceeding twelve months for the purposes of internship or conducting research. This pass is issued by Department of Immigration Services.

The following conditions apply:

- a. The intern or researcher should have been accepted as a researcher or intern in an institution within Kenya
- b. The intern or researcher shall remain in Kenya for a period not exceeding twelve months
- c. The intern or researcher must attach approval and or permission from relevant Kenyan authority to undertake these activities

Requirements for Intern or Researcher's Pass

To enable processing of the applications expeditiously, the applicant should provide the following:

- a. Application form (form 30) duly completed
- b. Cover letter from the institution under which internship or research is to be undertaken addressed to:

The Director of Immigration Services
P.O. Box 30191-00100
Nairobi

- c. Valid copy of National passport(the bio-data page and the current immigration status)
 - d. Two passport size photographs.
 - e. Copies of previous academic/professional certificates(translated and certified academic certificates for non-English speaking countries by Public Notary or Embassy) along with CV
 - f. Copy of Research Permit from the National Council for Science, Technology and Innovation
- Fees
Kshs. 15,000 per year or part thereof.

Caution:

It is an offence:

- a) To undertake internship or any research activity without requisite Kenya Intern or Researcher's pass
- b) While in possession of a Kenya Intern or Researcher's pass, to engage in any form of employment without requisite work permit.

4. Access Permit

All accessing Kenya's biological resources for research and development are required to obtain an access permit from NEMA. This is governed by EMCA 1999, the "Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006

How can one apply for Access Permit?

Individual or organizations wishing to access genetic resources and/or associated information in Kenya are required to make an application through online by logging in to www.nema.go.ke and then 'click' on 'licensing portal' and follow the instructions as indicated in the guide.

The applicant is required to submit a fully completed application online with the requirements indicated below in form of attachments.

Requirements

The following is a guiding list but an applicant may be requested for more;

- (1) Bank slip (application fees to be deposited to the bank named below)

Bank Details

- a) Name: Kenya Commercial Bank, KICC Branch
- b) Account Name: NEMA Revenue Account,
- c) Account No.:1102298158,
- d) Bank Code: 01104
- e) Swift Code: KCBLKENX
- (2) Copy of ID if Kenyan or Passport if foreigner
- (3) PIN if the applicant is corporate/organization
- (4) Copies of curriculum vitae for all personnel to be involved in the project
- (5) Evidence of financial sources e.g. letter of commitment if the project will be sponsored.
- (6) A signed Prior Informed Consent (PIC) with written Mutually Agreed Terms
- (7) A signed Material Transfer Agreement (MTA) executed with relevant government institution if the genetic resource will be taken outside Kenya.
- (8) A copy of research permit from National Council for Science and Technology which should be valid

- (9) A copy of Memorandum of Understanding (collaborative agreements) if the applicant is in collaboration with other partners
- (10) Letter of affiliation to a local competent research/academic institution for both Kenyans and foreigners and for Kenyan applicant intending to export genetic materials outside Kenya must show letter from hosting institution abroad and collaborative agreement
- (11) Substantive research proposal and the proposal should have the following:
- a) Project title
 - b) Description of candidate species and its conservation status including its distribution
 - c) Background information and justification
 - d) Clear and detailed methodology of the genetic resource collection
 - e) Specimen analysis
 - f) Expected results and dissemination of results.

Determination of Access Permit Application:

All applications will be processed based on the Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006, other sectoral laws and international conventions/agreements. The decision on the application will be communicated to the applicant within sixty days.

Caution:

Violation of the new access and benefit-sharing Regulations, for example, by persons conducting unauthorized collection activities, can result in fines, imprisonment, and the denial of future visits. Violation may also increase the transaction time needed to obtain a formal access permit. Therefore, it is essential not only to know the relevant policies, principles and laws, but also to have a practical understanding of the various and the agreements, documents, applications, and other required procedural steps necessary for full compliance.

5. Export Licenses

Export licenses are issued either by Kenya Wildlife Service for wildlife related items while KEPHIS issues export certification in form of phytosanitary certificate.

- a) Export Permit Issued by Kenya Wildlife Service In accordance with Wildlife Conservation and Management Act, 2013

Export/Re-export permits

All applications for export or re-export permits will be processed on the basis of their conformity to wildlife (Conservation and Management) Act 2013 and where applicable, relevant international conservation conventions, such as CITES. Depending on their nature, applications may be directed to the Scientific Authority both within and outside KWS and /or other divisions within KWS for inspections, investigation, consultation and recommendations.

Individuals or organization wishing the export wildlife specimens will be required to make an application to the Director General, KWS using official applications forms. Applications will take 21 working days to process.

Export/re-export guidelines

The following will apply to requests to export specimens for the stated purposes:

- i) Scientific specimens
 - The applicants who wish to export scientific specimens will be required to attach the following documents to their application forms
 - Research permits from NACOSTI
 - Research/project proposal
 - Valid PIC from genetic/biological provider.
 - Access permit from NEMA

- Other relevant approvals such as phytosanitary for plant material from KEPHIS and biosafety from Biosafety Authority.
- Approved Material Transfer Agreement (MTA) with Wildlife Management Authority for wildlife biological resources/ approved/verified list of specimen as per the MTA being exported.
- Preliminary study findings (for –on going research)

ii) Personal effects

Applicants who wish to export personal effects will be required to attach to the application form original certificates for ownership/legal possession of or in case of re-export, import permit for the specimen they wish to export

iii) Export of wildlife products from commercial breeding/planting operations

The planting/breeding operation should initially have been authorized by KWS. The applicant will be required to apply for the export permit using official forms. The applications will be subjected to a field inspection by KWS officers and the scientific Authority for recommendation before issuance of the export permit.

Fees- Export/re-export permits

CITES Import/Export/re-export permit Ksh. 2000

Non-CITES Import/Export/re-export permit Ksh. 1000

Other than the export permits KWS issues authorization for persons to enter into conservation areas and the details is below.

b) Phytosanitary Certificate

KEPHIS as the Kenyan's National Plant Protection Organization (NPPO) is mandated to undertake operational responsibilities in relation to export certification, including sampling and inspection of plants, plant products and other regulated articles; detection and identification of pests; surveillance of crops; performance of treatments; and establishing and maintaining a record-keeping system. Export certification is crucial to ensure that consignments meet specified Phytosanitary requirements of the importing country at the time of inspection. An export inspection of a consignment may result in the issuance of a phytosanitary certificate for the consignment or notification of non compliance if the consignment does not meet requirements.

Certification Process:

i) Plant and Plant Products:

All plants and plant products exported from country are inspected to ensure they are free from pest and any pest before a phytosanitary certificate is issued. Inspection is usually done during active growth of plants destined for export market and at exit points where inspection of all material for export is done to ensure compliance to the recommended quality standards and freedom from pests or any foreign material. Usually samples are inspected according to the type and volume of the commodity and inspection levels are determined by the assessed risk of the commodity. Several steps are followed during inspection which includes: Document verification (i.e. invoice, plant import permit (detailing condition for importation, quantity allowed, validity of the permit, plant species allowed for export), produce presentation for inspection in the ware house, sampling, inspection and documentation (issuance of phytosanitary certificate).

When inspecting at the exit points, the following standards are checked:

- Freedom from pests/pest damage
- Freedom from diseases/disease damage
- Maximum Residue Levels compliance
- Has no physiological disorders
- Properly graded (size, color, shape etc.)
- Has no excessive moisture

- Whole (No mechanical damage)
- Packaging (clearly labeled, clean and well ventilated)

ii) Biological control organisms:

KEPHIS issues Phytosanitary certificates for exportation of biological control agent or products of biological nature from the country mainly intended for research purposes. The applicant is required to provide a material transfer agreement (MTA) form the importing country. An annual audit of facilities multiplying or producing such materials is usually conducted to ensure compliance to quality standards.

Electronic Phytosanitary Certification System (ECS)

In recent years, it was noted that the number of Phytosanitary certificates issued annually by KEPHIS continued rising and the much time spent processing the certificates manually led to delayed consignment clearance. Electronic Phytosanitary Certification System (ECS) was thus conceptualised in order to introduce a certification process that would take less time, enhance convenience and cost effectiveness. The concept was actualised by customising and implementing an e-certification system referred to as Client Tool in the Netherlands. After successful development and testing, the Electronic Phytosanitary Certification System under CLIENT Kenya was officially launched on 19th April 2011. The system is in use currently.