AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Guidelines for Institutional Biosafety Committees (IBCs)

West Africa Integrated Vector Management Programme

Technical Working Group on Biosafety

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About The AU, AUDA-NEPAD and WAHO

The African Union (AU)

The African Union (AU) is a body of 55 member states that make up the countries of the African Continent. It was officially launched in 2002 as a successor to the Organization of African Unity (OAU), which ran from 1963 to1999. The decision to re-launch Africa's pan-African organisation was the outcome of a consensus by African leaders that in order to realise Africa's potential, there was a need to re-focus attention from the fight for decolonisation and ridding the continent of apartheid hitherto pursued under the OAU, towards increased cooperation and integration of African states to drive Africa's growth and economic development. The AU is guided by its vision of *An integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in the global arena [1].*

To realise this vision, the Africa Union developed and adopted a 50-year strategic plan called Agenda 2063 [2]. Agenda 2063 is the continent's strategic framework that aims to deliver on its goal for inclusive and sustainable development and is a concrete manifestation of the pan-African drive for unity, self-determination, freedom, progress and collective prosperity pursued under Pan-Africanism and African Renaissance.

The AU has been steadfast in proposing more enabling and science-based approaches to the challenges of the continent. Its report on gene drives clearly embraces the technology as a realistic option for effective disease control. A constructive development along this path was witnessed at the 29th Ordinary Session of Heads of State and Government of the African Union in Addis Ababa, where pursuant to Decision *Assembly/AU/Dec.649 (XXIX),* the session embraced the gene drive technology as a realistic option for malaria control. The session, in its decision, requested the African Union Commission (AUC), West African Health Organization (WAHO) and African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD) to collectively support the initiative [3].

In 2018, through recommendations of the African ministers responsible for science and technology *EX.CL/Dec. 987(XXXII),* the Executive Council of the African Union encouraged member states to harness emerging technologies, including gene drive, in their development initiatives [4].

The decisions above have offered solid policy statements for the continent regarding gene drives for human health purposes, which have impacted discussions in AU member states. It is a basis for a harmonised approach for Africa in the development of policy regulations and guidelines such as this to facilitate the responsible and safe application of the technologies for research and subsequent deployment.

The African Union Development Agency - NEPAD (AUDA-NEPAD)

At the 31st Ordinary Session of the Assembly of African Union Heads of State and Government held in Nouakchott, Mauritania from 25th June to 2nd July 2018, the Heads of State and Government approved the transformation of the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency into the African Union Development Agency (AUDA) as the technical body of the African Union with its own legal identity, defined by its own statute [6]. The objectives of AUDA-NEPAD are to: a) coordinate and execute priority regional and continental projects to promote regional integration towards the accelerated realisation of Agenda 2063; b) strengthen capacity of African Union Member States and regional bodies; c) advance knowledge-based advisory support; d) undertake the full range of resource mobilisation; and e) serve as the continent's technical interface with all Africa's development stakeholders and development partners.

The West African Health Organization (WAHO)

The West African Health Organization (WAHO) was established in 1987 when the Heads of State and Government from all fifteen countries in the Economic Community of West African States (ECOWAS) adopted and thereafter ratified the protocol for its creation. WAHO has transcended linguistic borders and hurdles in the sub-region to serve all fifteen ECOWAS Member States. The protocol grants WAHO the status of a specialised agency of ECOWAS and, as guided by its mission statement, 'the attainment of the highest possible standard and protection."

The regional agency is charged with the responsibility of safeguarding the health of the peoples in the sub-region through initiation and harmonisation of relevant policies of Member States, pooling of resources, and in cooperation with one another, maintaining a collective and strategic focus on important health problems of the sub-region.

WAHO has, through its strategic programmes, undertaken measures to combat malaria, malnutrition, HIV/AIDS as well as maternal and infant mortality. It has also spearheaded the prevention of blindness, increased access to medicines and vaccines, epidemiological surveillance as well as training and health information management in the sub-region.

Through its second strategic plan, WAHO is currently implementing various cutting-edge programmes in the sub-region to improve the overall health systems, ensure high-quality health services, develop sustainable financing of health and support institutional development within WAHO itself.

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Acronyms

APET	African Union High Level panel on Emerging Technologies
AU	African Union
AUDA	African Union Development Agency
BSO	Biosafety Officer
CRISPR-CAS9	Clustered regularly interspaced short palindromic repeats- CRISPR-associated protein 9
DNA	Deoxyribonucleic acid
ECOWAS	Economic Community of West African States
GM	Genetically Modified
GMOs	Genetically Modified Organisms
IBCs	Institutional Biosafety Committees
LMOs	Living Modified Organisms
NBA	National Biosafety Authority
NBC	National Biosafety Committee
NEPAD	New Partnership for Africa's Development
IBC	Institutional Biosafety Committee
PI	Principal Investigator
rDNA	Recombinant Deoxyribonucleic Acid
SOPs	Standard Operating Procedures
WAHO	West African Health Organization

Foreword

Like for many other genetically modified organisms, the testing and use of genetically modified mosquitoes are subject to regulations that are premised on national legislative frameworks. Functional regulatory systems, therefore, need to be in place in countries that contemplate harnessing the potential benefits of genetic engineering for the benefit of their public health, increased agricultural productivity and environmental sustainability.

In a number of countries, Institutional Biosafety Committees (IBC) are required to complement national regulatory agencies in ensuring that genetically modified organisms and products are developed and used in full compliance with the national rules and regulations.

IBCs are creatures of existing regulatory frameworks with an oversight mandate over genetic engineering research activities and related product development at the institutional level. In doing so, IBCs contribute to augmenting the overall regulatory compliance within a territorial jurisdiction, which is essential to ensure the safety of the processes and products while building public trust that will facilitate acceptance of the end products.

As such, it is of a priority for AUDA-NEPAD to support the establishment and operationalisation of IBCs in countries that have made provisions for it. It is crucial that research scientists and other relevant stakeholders fully comply with the legislation of their country, taking into account provisions of relevant multilateral agreements, regional cooperation and international best practices.

The purpose of the current IBC guidelines is to guide research institutions and similar organisations within the African Union Members States that are engaged in genetic engineering work.

The roles and responsibilities of IBC members, as well as the principles and operating procedures of the committees that are described here, are characteristic of any IBCs mandated by existing legal frameworks to perform biosafety functions for genetically modified organisms.

Taking into account the fast-evolving developments in genetic engineering, especially with the advent of innovative tools such as CRISPR-CAS9 and gene drive, AUDA-NEPAD will make sure that these guidelines are revised timely and adapted in order to keep pace with these developments. To that end and to better serve the purpose of supporting the establishment of enabling regulatory environment for the safe use of proven technologies, AUDA-NEPAD greatly welcomes feedback on the utilisation of the guidelines by stakeholders at various levels of the national regulatory systems.

Glossary

Biosafety Officer - the designated officer appointed within the IBC to advise the head of the organisation involved in genetically modified organisms (GMOs)/living modified organisms (LMOs)/recombinant Deoxyribonucleic acid (rDNA) activities on matters relating to the safe handling of biological materials and perform other functions defined by law.

Containment - used to describe all safety measures used to ensure "contained use" of GMOs/LMOs/rDNA

Contained use - any operation undertaken within a facility, installation, or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit contact with, and impact on, the external environment.

Gene Drive (three dimensions in its definition) - a process that promotes or favours the biased inheritance of certain genes from generation to generation - any genetic element able to bias its inheritance within a population. - a tool to effect certain changes in a population

> *Phenomenon or Process:* A gene drive is a phenomenon of biased inheritance in which the prevalence of a genetic element (natural or synthetic) or specific alternate form of a gene (allele) is increased, even in the presence of some fitness cost. This leads to the preferential increase of a specific genotype that may determine a specific phenotype from one generation to the next and potentially spread throughout a population. In other words, a gene drive is a process that promotes or favours the biased inheritance of certain genes from generation to generation.
>
> *Material Object:* A gene drive is composed of one or more genetic elements that can cause the process of biased inheritance in its favour. A gene drive is any genetic element able to bias its inheritance within a population.
>
> *Intention:* A gene drive may be intended as a management tool to effect certain changes in a population. A gene drive may include additional "cargo" elements, in addition to the drive components, that are intended to introduce new trait(s) into an interbreeding population so as to effect a change in the characteristics of the population. A gene drive also may cause effects directly, for example, by inserting into and disrupting a target gene. www.pnas.org/cgi/doi/10.1073/pnas.2020417117

Genetic engineering - the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, is generated outside the organism or the cell is inserted into the said cell or organism. It also refers to forming new combinations of genetic material by incorporating a cell into a host cell, where they occur naturally (self-cloning), or modification of an organism or in a cell by deletion and removal of parts of the heritable material.

Head - Head of an organisation involved in modern biotechnology.

IBC - The Institutional Biosafety Committee (IBC) is a statutory committee of an organisation undertaking modern biotechnology and chaired by the Head of the organisation or his designate (a suitable senior officer) to have oversight for research involving rDNA at the institutional level.

Incident - This means unintended release, breach of containment, spill, or occupational exposure to GMOs/LMOs/rDNA materials.

Principal Investigator - The Principal Investigator (PI) is the lead Investigator involved in conducting the research in an organisation. The PI is accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety

Recombinant DNA (rDNA) - a form of DNA generated after in vitro introduction of different segments of DNA (one being the vector and the others normally unrelated sequences) that are capable of replication in a host cell either autonomously or as an integral part of the host's genome and maintenance of their continued propagation.

Engineered gene drive - refers to gene drives that are designed and introduced in organisms using genetic engineering techniques.

Executive Summary

As part of their national regulatory frameworks, countries may require the establishment of IBCs within any organisation working in modern biotechnology, including research institutions and universities. Therefore, IBCs are meant to complement the work done by national regulatory agencies or national biosafety committees in ensuring full compliance with the national rules and regulations governing the development and use of modern biotechnology and products.

These guidelines provide indications for the constitution, composition, roles, and functions of IBCs as well as the basic compliance requirements, based on national regulations, international agreements, and best practices.

IBCs are certified by the national biosafety agencies or relevant committees and comprise members selected from within and outside of the organisation. Members comprising a chairperson, a secretary, a biosafety officer, and others are appointed by the Head of the organisation for a 3-year term renewable option. In the discharge of its function, the IBC may choose to engage consultants where it deems it appropriate.

IBCs are responsible for the review and recommendations for approval of project proposals, the monitoring of research facilities and procedures and for providing information to the National Competent Authority and to the Principal Investigator of projects.

Conduct of business of IBCs includes holding regular and extraordinary meetings, physically or virtually, to deliberate on research projects and all aspects of compliance pertaining to research facilities and to terms and conditions of regulatory approvals.

Reporting by IBCs includes submission of annual reports to the national biosafety agencies or committees reporting on incidents and records. An IBC receives copies of inspection reports from the biosafety inspectors mandated by the national biosafety agency or committee.

As part of their guiding core values, IBC members sign a no conflict-of-interest statement when required and observe confidentiality at all levels of their work.

Adequate training is critical for IBC members to continuously build their capacity and their recommendations are implemented with guidance from the national biosafety agencies or committees.

Introduction

Modern biotechnology has the potential to help tackle several development issues, e.g., in agricultural, health and environmental sectors. For example, the use of gene drives to suppress or modify mosquito populations could significantly improve and accelerate ongoing efforts to control and eliminate malaria, a disease that still affects and kills hundreds of millions of people, most of them in African children [4]. However, there are some concerns regarding the potential adverse impact of these technologies, which must be properly assessed and addressed. Therefore, research programmes and all relevant activities related to modern biotechnology should be monitored to ensure the safe use of the technology.

As part of the regulatory systems in different countries, biosafety regulations may require the constitution of an IBC by every organisation engaged in any research or production activities involving genetically modified organisms.

Based on the co-evolutionary approach recommended by the African Union High Level Panel on modern biotechnology in their 2007 "Freedom to Innovate" report and reiterated by the African Union High Level Panel on Emerging Technologies (APET) in 2017, where the two reports overly emphasised that technology adoption and regulation should co-evolve, AUDA-NEPAD endeavours to provide the necessary support towards ensuring the adoption of science-based approaches to deliver science-based decisions in the AU Member States.

As part of that effort, AUDA-NEPAD has developed the present guidelines to assist African Union Member States to complement their national regulatory systems by establishing institutional biosafety committees where they are needed.

The guidelines describe the procedures to establish an IBC, the roles, and responsibilities of its members, as well as the conduct of business. Templates forms for registration and renewal of the operations of an IBC, among others, are proposed to practically guide the institutions that decide to establish and operationalise IBCs at their establishments. These guidelines will be reviewed as and when the need may arise and be adapted based on the feedback received from the users and taking into account the fast-evolving science and regulatory practices in the area of modern biotechnology.

Purpose

The purpose of these Guidelines is to provide recommendations to organisations that conduct research or other activities involving modern biotechnology that intend to set up and manage IBCs in compliance with their country's biosafety laws or regulations.

Scope

This document describes the guidelines for the constitution, composition, role, and functions of IBCs. It provides essential information for compliance requirements by IBCs and processes that must be followed when dealing with genetically modified organisms and associated technologies in compliance with national regulations, international agreements, and best practices.

Setting Up an IBC

Constitution and tenure of IBC

Any organisation, which undertakes research involving modern biotechnology, shall establish an IBC in accordance with the provisions of the national law and regulations governing biosafety and in compliance with international best practices. The IBC shall be certified as provided for by law.

Where the critical mass or the expertise to constitute an IBC is not available, one or two organisations may jointly form one IBC to serve the organisations involved. Such organisations may also opt to rely on the IBC of other organisations. These arrangements must receive prior approval from the National Competent Authority, which may be a Department in a Government Ministry, a semi-autonomous Biosafety Authority/Agency, or the National Biosafety Committee (NBC).

Without prejudice to existing legislation, IBCs may be certified for a period of three years. This certification must be renewed every three years. Request for renewal shall be submitted before the expiry of the term of the IBC and as determined by organisational policies and national laws or regulations

Organisation of IBC

IBCs comprise at least five members selected based on their experience and expertise in genetic modification technologies and appointed by the Head of the institution. An additional two members who are from the organisation should be appointed. IBC members should collectively have the capability to assess the safety of the research work involving genetic modification technologies and to identify any associated potential risks to public health and/or to the environment.

Typically, an IBC comprises:

- five members selected from the organisation,
- two members not affiliated with the organisation but knowledgeable in modern biotechnology or related fields, and representing government agencies responsible for the environment, public health, and food safety and
- other persons or industry representatives that are active in these fields.

IBC membership

Typically, an IBC has the following:

1. a chairperson,
2. a secretary,
3. a biosafety officer and
4. other members

IBCs may comprise as many members as the organisation deems necessary. There is no upper limit to the membership, but big committees may be difficult to manage.

Membership profile

BC Chairperson

- The Head of the organisation or any person appointed by the Head of the organisation shall chair the IBC.
- The Chairperson must have knowledge and experience in scientific research pertaining to genetic modification technologies and to the activities being conducted by the organisation

The Biosafety Officer

- The organisation shall appoint the Biosafety Officer.
- The Biosafety Officer is also a member of the IBC and shall act as a technical liaison between the researchers and the IBC.
- The Biosafety Officer must be adequately trained to be able to offer advice on biosafety requirements.
- The Biosafety Officer should have experience in working with biological agents in a containment laboratory and, where applicable, working knowledge of the assessment of risks for work with genetically modified organisms.
- The Biosafety Officer must be conversant with the host organisation's policies and guidance, national laws, as well as international laws and best practices on work with biological agents, including genetically modified organisms.

- In particular, the Biosafety officer must be capable of assisting scientists and the developer(s) in developing emergency plans for containment and clean-up of accidental spills. He/she must also be capable of investigating and reviewing recombinant DNA lab accidents to ensure that measures are in place to prevent the accidental escape of regulated GMOs/LMOs and rDNA materials by undertaking a periodic review to ensure the suitability of the laboratory facility and the control procedures.
- In addition, the Biosafety Officer must be sufficiently independent to exercise authority as related to the responsibilities of this office.
- Regarding the work on organisms with gene drive, in particular, the Biosafety officer must be able to offer advice on specialised containment requirements.

The Secretary

The Secretary must be an in-house scientist.

The Secretary is crucial to the smooth running of an IBC meeting. This involves activities before, during and after Committee meetings. The Secretary may be the Biosafety Officer, or any other suitable person appointed by the Head of the Organization

Other Members

These are other individuals whom the organisation finds relevant in relation to the work on genetic modification and are appointed to the committee. They should be people with expertise in the management of GMOs and associated safety requirements.

The members should include a layperson and an independent member working or living in the testing area but is not directly affiliated with the organisation.

Appointment of IBC Members

- IBC members are appointed by the Head of the organisation and will usually serve a 3-year term unless they are appointed to complete the term of any member who can no longer serve on the IBC due to reasons such as resignation, retirement, transfer, suspension, or death.
- Members may be reappointed at the end of the 3-year term. In principle, there is no limit to the number of terms for an IBC member. However, membership can be reviewed annually by the IBC Chairperson and the Head of the organisation and appropriately revised to ensure effective participation and to extend the group's knowledge to emerging topics.

Changes in IBC Membership

- The IBC Chairperson or the Secretary must notify the NBA/NBC of any changes in the IBC membership or composition within two weeks of the new appointment or discontinuation.
- The notice from the IBC Chairperson or the Secretary must include the revised list of members, contact details and background information for each of the new members.

Use of Experts/Consultants

- An IBC may use qualified experts or consultants from within or outside the organisation. These experts will provide the IBC with advice and information on specific projects or topics as and when required.
- An IBC may invite any PI or representative of NBA/NBC or any other person to its meetings.
- The participation of such external experts, consultants or observers in the meeting must be recorded in the minutes of the meetings.

Registration/Certification and renewal of IBCs

To register an IBC,

- The organisation shall prepare a request using a standardised form (Annex1) and submit the same to the National Biosafety Authority, along with an overview of the institution and brief biodata of the proposed members, including their qualifications, affiliation, and relevant experience. If approved by the NBA, the IBC of the organisation is registered.

To renew an IBC

- The organisation shall follow the same procedures as for the registration, using Form 2 (Annex 2).
- The organisation shall provide the same requirements regarding the list and background of proposed members as for the IBC registration.

Responsibilities and Functions of IBCs

The responsibilities of the IBC shall include but not be limited to the following:

- Review and recommend approval of project proposals pertaining to or employing genetic modification in line with national laws and regulations.
- Assess and monitor the research facilities and procedures utilised in the genetic modification research work.
- Inform the Principal Investigator about IBC review, approval, or rejection of their projects.
- Inform the National Competent Authority or NBC about ongoing and new activities on genetic modification in the organisation.
- Ensure that the information provided in the application form is complete and understandable.
- Provide guidance to the Principal Investigator on the issues related to biosafety while dealing with genetic engineering, including the safety of all persons working in or visiting the research facilities or associated with the research activities.
- Monitor field experiments to ensure that the proposed risk management measures and emergency plans are in place and adhered to.
- Review the emergency plan submitted by the Investigator for responding to an accidental release of a GMO and all other plans proposed to meet any emergency. Copies of the site emergency plan are to be submitted to the biosafety authority.
- Review and report to the Head of the organisation and to the national biosafety authority any problems or non-compliance with the relevant guidelines
- Identify areas where additional resources, training or competencies are needed to fulfil these responsibilities.

Roles and Responsibilities of IBC Chairperson

Roles and responsibilities of the IBC Chairperson shall include but not limited to the following:

- Preside over the IBC meetings and serve as the contact person to liaise the IBC with other regulatory agencies.
- Co-sign the minutes of the IBC meetings, together with the IBC Secretary.
- Designate a member of the IBC to serve as Acting Chair in his/her absence.
- Ensure that all requirements regarding compliance with the national regulations and any related regulations and specific terms and conditions of permits associated with genetically modified materials and all the biosafety guidelines linked to these are followed in his organisation.
- Ensure that the facilities at the organisation are sufficient to meet the containment levels stipulated for genetically modified products and processes, as prescribed by relevant guidelines.
- Ensure that regular meetings of IBC are organised to review genetic modification research projects being

conducted within the organisation; ensure that open discussions take place amongst the members during the meetings and that the views of external members are recorded sincerely.

- Provide leadership and support to ensure that the laboratory personnel receive appropriate training prior to the initiation of research projects.
- Submit annual reports of IBC to the National Biosafety Authority on behalf of the organisation.

Roles and Responsibilities of IBC Secretary

Roles and responsibilities of the IBC Secretary shall include but not limited to the following:

- Be responsible for all reporting and communication regarding the functioning of the IBC.
- Maintain documents, agenda of minutes of meetings and other related documentation for proper record keeping.
- Organise IBC meetings in the appropriate format, either in-person or virtual or combined, taking into account new safety challenges.
- Co-sign the minutes of IBC meetings, together with the IBC Chairperson.

Roles and Responsibilities of the Biosafety Officer

Roles and responsibilities of the Biosafety Officer shall include but not limited to the following:

- Act as a focal point for compliance with safety guidelines, good laboratory practices, biological containment, and other relevant requirements.
- Review measures proposed by the PI to prevent accidental escape of regulated organisms.
- Undertake periodic reviews for laboratory suitability.
- Assist the Principal Investigator in developing emergency plans for containment and confinement and cleaning up accidental spills.
- Investigate and review any laboratory accident or failure to comply with associated genetic modification work.
- Submit a report that is included as part of the IBC annual report.

Conduct of the business of an IBC

The IBC meetings

- The IBC shall hold two types of meetings. These are:
  - » regular or ordinary meetings and
  - » emergency or extraordinary meetings, as necessary.
- IBC meetings shall be conducted in-person or online, taking into account safety measures as and when necessary.

Regular meetings

- The IBC shall meet at least twice a year to review and make recommendations on the relevant research projects being implemented within the organisation.
- The IBC Chairperson and the Secretary shall ensure that regular meetings take place.
- During regular meetings, IBC members shall deliberate on the following points:
  - » Appraisal of compliance to terms and conditions of approved projects

  - » Implementation of decisions of earlier IBC meetings
  - » Assessment of work practices, policies, and procedures
  - » Evaluation of research projects
  - » Monitoring for suitability and compliance of containment and field facilities
  - » Reporting on compliance and incident management
  - » Preparation of reports for regulatory agencies
  - » Review of the medical reports of employees working on approved projects
  - » Procedures and other approval requirements.
- Prior to any regular meeting, the Secretary must share the relevant documents to review along with any other relevant working document.

Extraordinary meetings

- IBC Chairperson shall call extraordinary meetings of the IBC to address special and/or urgent issues. These may include non-compliance or unexpected events involving the regulated work within the institution.

Attendance and quorum

- All IBC members should endeavour to attend IBC meetings.
- Members who are unable to attend an IBC meeting must inform the IBC Chairperson and provide a written summary of their review and comment they might have on issues scheduled to be discussed.
- The attendance sheet must be signed by all attendees and annexed as part of the minutes of the meeting. Electronic signatures are used in case of online meetings.
- At least 50% of the IBC members must be present to conduct in-person meetings or at least 30% for online meetings, taking into account challenges specific to an online format
- Final approval or refusal of projects requires a majority vote by IBC members. Any dissenting views should be explained and recorded in the minutes, albeit without revealing individual member names or how they voted.
- IBC meeting must be adjourned in case there is no quorum at any time during the meeting. No further action should be taken by the IBC until a quorum is re-established or a new meeting is appropriately convened.

Minutes of IBC meetings

- Minutes of IBC meetings must provide sufficient details about IBC discussions and document the rationale behind any particular decision made by the meeting.
- The Chairperson and the Secretary of the IBC must sign to validate the minutes.
- Minutes of the IBC meetings should include the following information elements:
  - » Attendance of members and invitees, if any.
  - » Brief description and details of the project(s) reviewed.
  - » Decisions on all applications considered in the meeting, including modifications to project proposals, if any.
  - » Observations and remarks on the suitability of the facilities based on the containment requirements.

Reporting by the IBC

Submission of annual reports

- The IBC shall submit an annual report to the NBC / NBA regarding the observance of the safety requirements and the status of the research projects being conducted within the organisation.

Reporting of incidents

- The PI shall report to the IBC Chairperson within 24 hours any incident resulting from a breach of biosafety requirements or any significant research-related accidents and illnesses.
- A similar report should be submitted to the Head of the organisation.
- The PI shall also report the same case to NBC/NBA within 48 hours after the Chairperson of the IBC has signed the reporting form.
- If the situation requires more urgent action, the PI, Biosafety Officer, or Chairperson of the IBC may proceed to contact the relevant authorities at the same time as notifying the IBC.
- If deemed necessary, NBC/ NBA may also recommend that the IBC reports the incident to other relevant agencies such as the local public health departments.
- In case of emergencies, the PI may immediately contact the relevant agencies in a manner consistent with legal reporting requirements.

IBC records

The IBC shall maintain the following records in hard and soft copies for future references.

- Incident forms
- Approved and duly signed minutes of IBC meetings, including attendance sheets.
- Annual report of all ongoing relevant research projects.
- Information about projects approved by IBC and related enclosures/attachments.
- Applications forwarded to NBC / NBA.
- Other documents such as statements regarding conflict-of-interest confidentiality agreements with NBC / NBA nominee and/ external experts.

Monitoring for compliance and suitability of containment procedures and facilities

- The IBC shall monitor activities in laboratories and field sites to ensure compliance with terms and conditions of the approval, relevant guidelines, standard operating procedures (SOPs) and international best practices.
- The IBC shall maintain on file copies of the inspection reports produced by inspectors duly mandated by the regulatory authorities.
- IBC members and other relevant inspectors duly mandated by the regulatory authorities must be allowed access to laboratories and other infrastructure used for the regulated research activities.

Ensuring the security of genetically modified materials and personnel involved in the genetic modification work

- The PI and all associated personnel must ensure control of research materials and be held accountable for them.
- Access to biological materials shall be limited to authorised personnel only.
- The PI shall develop a plan to ensure the security of relevant materials.
- SOPs must be in place for all relevant operations and security management, including routine cleaning, maintenance, and repairs, restricting unauthorised persons, addressing the loss of keys, passwords and any other secured information and material.
- Personnel protective measures should be in place.

Packaging and transportation of genetically engineered materials

- All regulated materials must be packaged and transported in a manner compliant with organisational procedures and guidelines, as well as national and international regulations.
- Reference should be made to the guidelines for transportation, importation and import of genetically modified mosquitoes for malaria vector control.

Disposal

- The IBC shall consider genetically engineered materials that are no longer needed as regulated waste.
- The IBC shall, therefore, take necessary measures to appropriately dispose of the regulated waste in a manner consistent with national regulations and related safety guidelines.

IBCs Core Value Considerations

Conflict of interest

Any conflict of interest by the IBC members should be declared and confirmed before the start of each IBC meeting. IBC members shall sign a no conflict-of-interest statement and review any conflicts that may have arisen before the meeting. The IBC should document how the conflict of interest is handled.

Conflict of interest may arise from:

- own proposal
- a proposal in which the member is a co-investigator.
- a proposal in which the member or a family member has a financial interest.

A member involved in a conflict-of-interest situation must be excused from the meeting when the project they are involved in is being discussed. Minutes should record the information on such members who have declared a conflict of interest.

Confidentiality

- The IBC Chairperson must request IBC members and other external experts to sign a confidentiality agreement.
- IBC members, as well as external experts, must maintain confidentially of the proposals and other related information made available to them for review, reference, or discussion.
- IBC members must not divulge any confidential information or Intellectual Property (IP), or Confidential Business Information (CBI) made available to them.
- IBC members must respect the confidential nature of the opinions of other IBC members or invited experts expressed during discussions or provided in written form and must not divulge to any person, press or media.

Compliance

Persons responsible for compliance

- The Head of the organisation and PI are responsible for biosafety compliance within the organisation.
- The IBC provides guidance to ensure biosafety compliance.
- Any possession and/ or use of regulated materials within the organisation must be in compliance with biosafety requirements.

Head of the organisation

- The head of the organisation is responsible for compliance with the national regulations for biosafety.
- The head of the organisation maintains ultimate responsibility for the safe conduct of activities pertaining to the regulated research project as far as biosafety requirements are concerned.

Principal Investigator (PI)

The roles and responsibilities of the Principal Investigator shall include but are not limited to the following:

- Inform the IBC, seek permission from the IBC before starting the experiments or seek permission from the NBC / NBA through the IBC.
- Perform risk assessment and select appropriate Biosafety levels.
- Determine the required levels of physical and biological containment in accordance with the relevant guidelines.
- Submit the initial research protocol and any subsequent changes, such as changes in the source of DNA or host-vector system, to the IBC for review and approval.
- Ensure that no work commences before the research project has been approved by the IBC and has met all requirements of NBC / NBA guidelines.
- Communicate with IBC throughout the conduct of the project.
- Ensure safe conduct of the experiments in his laboratory.
- Make available the protocols that describe the potential hazards and the precautions to be taken by all laboratory staff.
- Instruct laboratory staff about the practices and techniques required to ensure safety and the procedures for dealing with accidents, including the reasons and provisions for any precautionary medical practises advised or requested (e.g., vaccinations or serum collection).
- Supervise the performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- Undertake corrective measures promptly for any work errors and conditions that may result in the release of recombinant DNA materials.
- Be responsible for the preparation of biosafety applications for consideration by the IBC
- Respond to all queries from IBC and attend relevant meetings when invited by IBC
- Comply with the appropriate research guidelines and all applicable regulations related to biosafety.
- Be accountable to the IBC with respect to biosafety requirements.
- Ensure that the Laboratory personnel:
  - » follow all safety guidelines and established good laboratory practices.
  - » work within the assigned biological safety containment level
  - » use personal protective equipment as recommended by the PI,
  - » immediately notify the PI or Biosafety Officer (BSO) of any health condition that may be due to their work in the laboratory or any health condition that may be compromised prior to the initiation of a research project (i.e., pregnancy, immunosuppression).
  - » follow all practices and procedures as provided by the PI and BSO,
  - » ensure strict compliance with all required biosafety regulations and guidelines.
  - » report to the PI and, if necessary, to the BSO, any problem, procedural mistakes, spills, etc., that are deemed a significant breach of risk management measures as soon as they occur.
  - » reports to the PI, BSO or IBC on non-compliance of biosafety guidelines or policies.

Addressing non-compliance

Non-compliance by the Principal Investigator (PI)/ Organisation

- The IBC shall address non-compliance to the regulations or to the organisation's policies and procedures and any other relevant legal requirements.
- The IBC shall take the following actions in case of non-compliance:
- Report the case of non-compliance to the NBA/NBC for action to be taken. Such actions may include:
  - » suspension of the use of the regulated materials,
  - » confiscation and/or destruction of the regulated materials,
  - » any other action necessary to protect the public and/or the organisation, including suspension of the relevant research activity.
- Report to the NBA/NBC of the corrective actions taken on the non-compliance.

Non-compliance by IBCs

The NBC/NBA shall withdraw the certification of an IBC in case the IBC does not comply with the relevant regulations and/or stipulated guidelines, including reporting requirements.

If the annual report of an IBC is not received for two consecutive years, the registration will automatically lapse, and the organisation shall have to re-initiate the process of registration of its IBC.

IBC Capacity Building

Training of IBC Members

- The IBC Chairperson is responsible for confirmation that relevant training of IBC members is achieved.
- The IBC Chairperson shall ensure that the training of IBC members is organised with guidance from the NBA/NBC.
- IBC Chairperson shall ensure that:
- IBC members receive initial and refresher training on the basics of biosafety, national regulations, including relevant institutional policies and guidelines and procedures for reviewing applications.
- IBC members receive refresher training on any changes to national guidelines.
- IBC members may propose specific types of training in line with their experiences and observations on current and upcoming applications.

Training of the Biosafety Officer

- The BSO shall attend appropriate biosafety training organised with guidance from the national biosafety authority or a recognised training organisation.
- The BSO must properly document the training that he/she attended, what the training entailed and any indication of successful completion for the training.

Training of laboratory personnel

The IBC Chairperson is responsible for confirmation of that:

- PI ensures all persons involved in regulated project activities receive training on general principles of biosafety, including handling, management and reporting of laboratory incidents and accidents.
- PI ensures individual researchers report to the IBC on their training.

Conclusion

These guidelines have been developed with the benefit of numerous literature available and several national guidelines that are best suited for our African setting and fit for purpose in use by specific organisations working on modern biotechnology in general on the continent. They are expected to serve as a template to be adapted on a case-by-case basis by research institutions, universities and other relevant organisations based on their country's regulations and their areas of focus in modern biotechnology. While the core principles and procedures for the conduct of business of IBCs are described herein, the guidelines are not expected to significantly vary between countries. The details of information required on activities and research facilities through the forms suggested in the annexures, for instance, may call for necessary adaptation, qualifications and modifications based on the technologies of focus and the fast-evolving developments in emerging technologies. Feedback to be received from the users of these guidelines will guide AUDA-NEPAD to timely initiate reviews to ensure continuous improvement of the document for the benefit of scientists, regulators and other stakeholders engaged in safely advancing science, technology, and innovation in the African Union Member States across the continent.

References

1. African Union. An Integrated, *Prosperous and Peaceful Africa, driven by its own citizens and representing a dynamic force in the global arena.* 2021 [cited 2021 January 2021]; Available from: https://au.int/en/overview.
2. African Union, *Agenda 2063 The Africa we want in 2063 - Report of the commission on the African Union*. 2015.
3. AUDA-NEPAD. *Who We Are; Our Mandate*. 2021 [cited 2021; Available from: https://nepad.org/who-we-are.
4. World Health Organization, *World Malaria Report 2020*. WHO, 2020.

Annexes

Annex 1 - IBC Registration Form

FORM 1 - APPLICATION FOR REGISTRATION OF AN INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

1. Name of the Institution
2. Head of the Institution
3. Complete address of the Institution
4. Proposed activities/projects to be undertaken:
5. Indicate the list of organisms/genetically engineered organisms to be used:
6. Category of biosafety level as per the national regulations:
7. Containment facilities available for regulated activities:
   - Laboratory set up
   - Greenhouse / cages / malaria spheres (Details include structure, size, size of the mesh etc.):
   - Any other specialized facility
8. Proposed composition of IBC:
   - Chairperson
   - Secretary
   - Biosafety officer
   - Members – Indicate members who are part of the institution and members from outside the institution
   - Provide copies of CVs of members
9. Provide a brief summary about the institution including details of infrastructural facilities available to carry out the proposed activities

Date .....

Signature of the Head of the Organisation .....

Annex 2 - IBC Renewal Form

FORM 2 - APPLICATION FOR RENEWAL OF AN INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

1. Name of the Institution:
2. Head of Institution:
3. Complete address of the institution:
4. Date of constitution of the IBC:
5. Provide a copy of the certificate of approval issued by the NBA/NBC
6. Provide the composition of the term ending IBC:
   - Chairperson
   - Secretary
   - Members - Indicate members who are part of the institution and members from outside the institution
   - Biosafety officer
7. Brief overview of activities undertaken the last three years including applications reviewed, meetings held, minutes effectively submitted to the NBA/NBC
8. Composition of proposed renewed IBC:
   - Name
   - Chairperson
   - Secretary
   - Members - Indicate members who are part of the institution and members from outside the institution
   - Provide copies of CVs of members
9. Updated status of containment facilities:
   - Laboratory set up
   - Greenhouse/cages / malaria spheres (Details include structure, size, size of the mesh etc.):
   - Any other specialized facility
10. Provide a brief summary about your institution including details on the infrastructural facilities available to carry out the proposed activities:

Date ……

Signature of the Head of the Organisation …….....

Annex 3 - Declaration of Confidentiality Report

FORM 3: CONFIDENTIALITY AGREEMENT FOR MEMBERS OF IBC

As a member of the Institutional Biosafety Committee (IBC) constituted by the

Name of Organisation ....., as per provisions of regulations .....

I hereby declare that I am aware of my obligations to respect confidentiality of applications, issues and other matters placed before the IBC and discussed thereupon, during my entire tenure of membership of IBC.

I hereby solemnly agree and undertake to maintain the confidentially of the proposals and other related information made available to me for review, reference, or discussion.

I hereby further agree and undertake not to divulge any confidential or Intellectual Property (IP) or confidential business information (CBI) of the organisation/institute acquired as a result of my review of such proposals and subsequent discussions arising there from.

I shall also respect the confidential nature of the opinions expressed by other IBC members or experts during discussions in meetings or provided in written form and would not divulge the same to any person, press or media.

I also agree that I would avoid any conflict of interest such as relationship with any applicant, financial interest and providing any consultancy, advice, services as an individual/scientist to any applicant except of the academic, scientific, and intellectual nature.

Executed at (Place) .....on (Date) .....

Signature……

Name & Address.....

Annex 4 - IBC Annual Report Form

FORM 4 - ANNUAL REPORT OF THE INSTITUTIONAL BIOSAFETY COMMITTEE TO NBA / NBC

1. Name of the Organisation:
2. NBA / NBC Memorandum No.:
3. Date of IBC constitution:
4. Composition of IBC:
    - Chairperson:
    - Member Secretary:
    - Members
    - Outside Experts
    - Biosafety Officer
5. Changes in IBC composition during the year, if any:
6. Details of IBC meetings during the year:

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