

FEDERAL REPUBLIC OF NIGERIA



Application Form for Accreditation of Institution /Organisation to Carry out Genetic Modification/ Genetic Engineering

**Institution /Organisation for which accreditation is sought:
(legal entity name)**

Is this application accompanied by an application for a declaration that certain information be treated as **Confidential Commercial Information (CCI)**?

☐

Yes

☐

No

General instructions

Please print clearly.

All sections, parts and questions must be completed unless otherwise directed on the form.

If the spaces provided are not sufficient to set out the requested information, you should attach additional information and clearly mark on the attachment which

section, part and question the information relates to. You should also indicate against the item that there is additional information attached, noting the attachment title/number and the page number Please keep a photocopy of your application at the time of lodgement.

This form should be forwarded to the **Director General/Chief Executive Officer, National Biosafety Management Agency, National Parks Service, Umaru Musa Yar'adua expressway, Airport Road-Abuja**, on completion:

The completion of this form indicates your Institution/Organisation is applying for accreditation. If the information you provide is incorrect or incomplete the decision about this application may be delayed or may result in not granting the accreditation.

You may be required to provide additional information If necessary.

The information you provide in this application must be true and accurate. There are penalties where a person gives information that he/she knows to be false or misleading under the corresponding law of the Federal Republic of Nigeria.

If the Institution/ organisation is accredited, it will be obliged to comply with the conditions of accreditation.

Indicate if specific information is confidential.

The application must be signed by a person authorised to sign on behalf of the Institution/organisation.

Section 1:

Organisation and Personnel Information

Status/type of Institution/ Organisation

Question 1 Is this application being made by:

- | | |
|---------------------------------|--------------------------|
| (a) a natural person, or | ☐ |
| (b) an Institution/organisation | ☐ |

If the application is by an Institution/ organisation, indicate below which of the following describes your Institution/organisation.

1. A corporation i.e., involving GMO trade, Research and Development GMO import and export

Yes	☐	No	☐
-----	--------------------------	----	--------------------------

2. An International Institution/Organization.

Yes	☐	No	☐
-----	--------------------------	----	--------------------------

3. A Government Agency/Institution:

Yes	☐	No	☐
-----	--------------------------	----	--------------------------

If a Government Agency/Institution, indicate by ticking the appropriate box which of the below best describes your status.

(a) State Government;	☐
(b) Federal Government;	☐

4. A Higher Education Institution:

Yes	☐	No	☐
-----	--------------------------	----	--------------------------

Institution/Organisation Information

Institution/Organisation name: (legal entity name)			
Street number and name:			
Town/City:			
State:		Postcode:	
Country:			
Postal /E-Mail address:			

Telephone No.

Chief Executive Officer (CEO) or Equivalent

Surname:		first name:	
title: (eg Ms/Mr/Dr)		Rank/Designation:	
Phone number:			
Mobile number:		E-mail address:	
Street number and name: (if different from org. address)			
Town/City:		State:	
Postcode:		Country:	
Postal address: (if different)			

Institution/Organisation Contact Person

Surname:		first name:	
Title: (eg Ms/Mr/Dr)		Rank/Designation:	
Phone number:			
Mobile number:		E-mail address:	
Street number and name: (if different from Institution/org.			
Town/City:		State:	
Postcode:		Country:	
Postal address: (if different)			

Section 2:

Accreditation Information

You may copy this application form where multiple copies of certain parts are required. If the same information is relevant to more than one IBC there is no requirement to repeat the information (and attachments) but you must clearly make reference to this in your answer(s) and clearly identify the relevant information (and attachment).

If there is insufficient space in the boxes provided, please include any additional information as an attachment. Note the attachment title/number and the page number(s) in the space provided and mark on the attachment which Section, Part and question the information relates to.

Part A: Suitability

Question 1 Has the organisation previously been accredited by the **National Biosafety Management Agency**

Yes ☐ → Go to question 2 No ☐ → Go to question 3

Question 2 If the answer to question 1 is yes, please state whether the previous accreditation was cancelled, suspended or surrendered, or whether the period for which it was valid has expired.

Cancelled: ☐

Suspended: ☐

Surrendered: ☐

Expired: ☐

If you ticked any of the above, please provide details.

Question 3 Has the Institution/organisation been convicted, within a period of ten years immediately before making this application, of an offence against a law of Nigeria, a State or a foreign country relating to the health and safety of people or the environment which is punishable by a fine

Yes ☐

No ☐

If yes, please provide details.

Question 4 Has the Institution/organisation ever had a licence or permit (however described) under a law of Nigeria, a State or a foreign country relating to the health and safety of people or the environment revoked, suspended or cancelled?

Yes ☐

No ☐

If yes, please provide details.

Question 5 Is there any other information relevant to questions 1 - 4 that may assist in making a decision about accreditation?

Yes ☐

No ☐

If yes, please provide details.

A large, empty rectangular box with a thick gray border, intended for providing details.

PART B: Institutional Biosafety Committee (IBC)

Question 6 Does the organisation:

(a) have an established IBC?

Yes ☐ → Complete Part C ☐ No

(b) have arrangements in place to use an IBC established by another accredited organisation?

Yes ☐ → Complete Part D ☐ No

If you answered 'yes' to more than one of the above options, please complete all relevant parts.

If you answered 'no' to all parts of question 6, please provide an explanation in the space provided below. Note that this Institution/ organisation may not be accredited.

PART C: Established IBC

Access to IBC by Institution/ organisation / Maintaining a properly constituted IBC

Question 7 How many IBCs has the Institution/Organisation established?

Please provide the following information, on pages 10 - 13, for each IBC. If more than one IBC has been established, please complete and attach extra copies. Then answer questions 13 – 18 relating to the established IBC(s).

If individual contact details have been previously provided in this application, you need only complete the surname and first name (and any other information necessary to clearly identify the person).

Name of IBC:

Chair/Biosafety Officer of IBC

Surname:

first name:

Title:

(eg Ms/Mr/Dr)

Rank/Designation:

Phone number:

Mobile number:

E-mail

address:

Street number and name:
(if different from org. address)

Town/City:

State:

Postcode:

Country:

Postal address:
(if different)

Contact Person for the IBC (if different to Chair)

(The person who will receive all correspondence relating to the IBC)

Surname:		first name:	
Title: (eg Ms/Mr/Dr)		Rank/Designation:	
Phone number:			
Mobile number:		E-mail address:	
Street number and name: (if different from org. address)			
Town/City:		State:	
Postcode:		Country:	
Postal address: (if different)			

Question 8 Does the membership of the IBC(s) possess the collective technical scientific expertise necessary to assess all the matters that are likely to be put to it by the accredited Institution/organisation(s)?

Note: Expertise must include skills and experience to competently assess and advise on the identification and management of the risks associated with dealings with GMOs undertaken by the accredited Institution/organisation, and to advise on the containment of GMOs?

Yes ☐ No ☐

If no, please provide reasons.

Question 9 Does the IBC membership include at least one independent member?

Note: an independent member is someone who could be reasonably regarded as being free of any business or other relationship, including a relationship of employment, with the applicant Institution/ organisation that could materially interfere with the exercise of unfettered and independent judgement in contributing to decisions made by the IBC.

Yes ☐

Please describe below why this member is independent to the organisation.

No ☐

Please provide reasons below. (Here you may choose to describe why you believe a person, who does not meet the requirement for independence in the note above, is nevertheless independent).

Indemnification of IBC members

Question 10 Does the organisation have appropriate indemnification for all members of the IBC?

Yes ☐

No ☐

If no, please provide explanation.

Question 11 Do all IBC members consider this indemnification to be acceptable?

Yes ☐

No ☐

If no, please provide explanation.

Question 12 Is there any other information relevant to Questions 7 – 12 that may assist in making a decision about accreditation?

Yes ☐

No ☐

If yes, please provide details.

PART D: Access to IBC Established by Another Accredited Institution/Organisation

Access to IBC by organisation

Question 13 How many IBCs, established by another accredited Institution/organisation, will the Institution/organisation be using?

- a) Please list the IBCs, their IBC registration number with the **National Biosafety Management Agency**, and their parent accredited Institution/ Organisation (ie. the organisation that has established and maintains the IBC).

IBC name	IBC number	Parent accredited organisation (i.e. organisation that established the IBC)

- b) Please provide confirmation that each Institution/ Organisation, whose IBC(s) are proposed to be used, has agreed to the applicant Institution/ Organisation using the IBC(s). This must be done by submitting a completed and signed copy of the declaration (Section 3, Part B) for each IBC.

Please complete Questions 14 – 18 relating to the IBC(s) established by another accredited Institution/ Organisation.

Question 14 Does the membership of the IBC(s) possess the collective technical scientific expertise necessary to assess all the matters that are likely to be put to it by the accredited Institution/ organisation(s)?

Note: Expertise must include skills and experience to competently assess and advise on the identification and management of the risks associated with dealings with GMOs undertaken by the accredited Institution/ Organisation, and to advise on the containment of GMOs?

Yes ☐

No ☐

If no, please provide reasons.

Question 15 Does the IBC membership include at least one independent member?

Note: an independent member is someone who could be reasonably regarded as being free of any business or other relationship, including a relationship of employment, with the applicant organisation that could materially interfere with the exercise of unfettered and independent judgement in contributing to decisions made by the IBC.

Yes ☐

Please describe below why this member is independent to the applicant organisation.

No ☐

Please provide reasons below. (Here you may choose to describe why you believe a person, who does not meet the requirement for independence in the note above, is nevertheless independent).

Indemnification of IBC members

Question 16 Are there appropriate indemnification arrangements for all members of the IBC?

Yes

☐

No

☐

Note: When using an IBC established by another accredited Institution/organisation it may or may not be necessary for the applicant organisation to arrange the indemnification, depending on the indemnity arrangements made by the IBC's parent institution/organisation. If the parent organisation has indemnification arrangements in place to cover the use of the IBC by the applicant Institution/Organisation, or if the applicant Institution/Organisation has agreed to indemnify the IBC members, then tick 'Yes'.

If no, please provide an explanation.

Question 17 Do all IBC members consider this indemnification to be acceptable?

Yes

☐

No

☐

If no, please provide explanation.

Question 18 Is there any other information relevant to questions 13 – 17 that may assist in making a decision about accreditation?

Yes	☐	No	☐
-----	--------------------------	----	--------------------------

If yes, please provide details.

PART E: Capacity to comply with accreditation conditions

Capacity to comply with accreditation conditions

Question 19 Does the organisation have the capacity to comply with the conditions of accreditation that will generally be applied to an accredited organisation?

Yes ☐

No ☐

If no, please advise in what way(s) the Institution/Organisation fails to comply with the *Guidelines*; and what strategies are suggested to enable/maintain accreditation of the Institution/Organisation.

Attachment list

(All attachments to the application form must be listed here).

[illegible]

Section 3: Declarations

Part A - Declaration of the Institution/Organisation submitting application

This declaration must be completed and signed by a person with the authority to sign on behalf of the Institution/Organisation.

I declare that:

- I am duly authorised to sign this declaration;
- the information supplied on this form and any attachment is true and correct; and
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the corresponding law of the Federal Republic of Nigeria.

Name:		Signature:	
Job title:		Date:	

Part B - Declaration of the Institution/organisation responsible for the IBC

This declaration needs to be completed if the organisation for which accreditation is sought intends to rely on the services of an IBC established by **another** Institution/organisation accredited by the Gene Technology Regulator (the other Institution/organisation). The CEO or equivalent of the other Institution/ organisation (or delegate) must make the following declaration.

(1) Name of applicant Institution/organisation for which accreditation is being sought:

.....

(2) I declare that:

- I am authorised to sign on behalf of:

.....,

(other Institution/organisation name)

which is accredited by the **National Biosafety Management Agency** (Accreditation number:.....).

- the information provided regarding the IBC named below (in this form and any relevant attachment[s]) is true and correct;
- the Institution/organisation I represent has agreed that the Institution/organisation, named at (1), may access the IBC named at (3);
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the corresponding law of the Federal Republic of Nigeria.

(3) Name of the IBC to be used:

.....

Name:		Signature:	
Job title:		Date:	