Effective Date: 22nd October 2021
Review Date: 21st October 2026

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

APPLICATION FORM TO CONDUCT CLINICAL TRIALS IN NIGERIA

Effective Date: 22nd October 2021
Review Date: 21st October 2026

TO ALL APPLICANTS

APPLICATION TO CONDUCT CLINICAL TRIAL

The following are the requirements when submitting a clinical trial application.

1. Covering letter.
2. Cover sheet.
3. Checklist.
4. Completed Application form.
5. All documents to be submitted in triplicate with two electronic copies.
6. Additional copies of the application form may be requested.
7. Protocol
8. Patient Information leaflet (PILs) and Informed consent form
9. Standardized Regulatory Authority's contact details/wording to beadded to PILs
10. Investigators Brochure (IB)/Package insert.
11. Signed investigator(s) CV(s) in Regulatory Authority's CVs format.
12. Signed Declaration by Principal investigator(s).
13. Signed joint declaration by Sponsor/National Principal investigator.
14. Signed Provisional declaration by Co- or Sub-investigators
15. Signed Declaration by regional (local) monitor
16. Indemnity and Insurance Certificate and/or
17. Proof of Malpractice insurance of study investigators.
18. Ethics committee(s) approval or
19. Copy of letter submitted to Ethics committee(s).
20. CD to be submitted in MS Word.
21. Financial declaration

Effective Date: 22nd October 2021
Review Date: 21st October 2026

CLINICAL TRIAL APPLICATION (CTA)

PART 1 – COVER SHEET, CHECKLIST AND DECLARATION:

To be completed by Applicants for all Clinical Trials

COVER SHEET

Study Title:

Protocol No:

Version No: **Date of Protocol:**

PACTR No:

Study Drug (s):

NAFDAC Reg. Number (if applicable):

NAFDAC Reg. Number(s) of comparator drug(s) (if applicable):

NAFDAC Reg. Number(s) of concomitant drug(s) (if applicable):

Date(s) of NAFDAC approval of previous protocol(s) (if applicable) :

Sponsor:

Applicant:

Contact Person:

Address:

Telephone Number: **Fax Number:**

Cell Number:

E-mail address:

For official use only:

Date original application received:

Tracking No:

Proposed Clinical Trials Committee Meeting Date if applicable:

Signature: **Date:**

Effective Date: 22nd October 2021
Review Date: 21st October 2026

ACKNOWLEDGEMENT OF RECEIPT OF CTA (Contact details to be completed by the applicant). Whole cover sheet to be faxed to applicant once details in block above are completed.

Contact Details: Name: **Fax No.:**

Receipt of new application is hereby acknowledged. **Date:**

Signature (of NAFDAC recipient): **Name:**

CHECKLIST

Applicant's Check list		NAFDAC Double-check
☐	**COVERING LETTER**	☐
☐	**CLINICAL PACTR (www.pactr.samrc.ac.za) APPLICATION NO:**	☐
☐	**FULLY COMPLETED APPLICATION FORM**	☐
☐	**PROTOCOL (INCLUDING RELEVANT APPENDICES/QUESTIONNAIRES ETC.)**	☐
☐	**PATIENT INFORMATION LEAFLET(S) AND INFORMED CONSENT(S)**	☐
☐	**INVESTIGATORS BROCHURE AND ALL RELEVANT PACKAGE INSERT(s)**	☐
☐	**INVESTIGATOR'S CV(s) IN NAFDAC FORMAT**	☐
☐	**SIGNED DECLARATION(s) BY INVESTIGATOR(s)**	☐
☐	**REGIONAL (LOCAL) MONITOR'S CV AND DECLARATION**	☐
☐	**CERTIFICATE(S) OF ANALYSIS (Can be submitted with application for importation and release of investigational medicinal products)**	☐
☐	**INSURANCE CERTIFICATE *(PREFERABLY LOCAL INSURANCE COMPANY)***	☐
☐	**ETHICS APPROVAL (IRB/NHREC)**	☐
☐	**COPY/IES OF RECRUITMENT ADVERTISMENT(s) (IF APPLICABLE)**	☐
☐	**FINANCIAL DECLARATION (SPONSOR AND NATIONAL PRINCIPAL INVESTIGATOR (NPI)**	☐

Effective Date: 22nd October 2021
Review Date: 21st October 2026

Electronic versions of the application form (Sections 1 –2), the protocol, the investigator's brochure and/or other relevant documents:

☐ **LABELLED CD-ROM (MS WORD OR RICH TEXT FORMAT)** ☐

List of files submitted on CD-ROM:

NB: DO NOT SUBMIT THE APPLICATION IF AT LEAST 70% DOCUMENTATION IS NOT MET : IT WILL NOT BE PROCESSED

Effective Date: 22nd October 2021
Review Date: 21st October 2026

Declaration by applicant:

We, the undersigned have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application.

We, the undersigned, agree to ensure that if the above-said clinical trial is approved, it will be conducted according to the submitted protocol and National legal, ethical and regulatory requirements.

Applicant (local contact)	Date
National Principal Investigator	Date

Effective Date: 22nd October 2021
Review Date: 21st October 2026

PART 2 – ADMINISTRATIVE AND SUPPLEMENTARY DETAILS

Title:

Protocol Number/identification:

Date of protocol:

Version number:

PACTR number:

2.1 Contact details (name/address/tel/cell/fax/e-mail)

2.1.1 Applicant: (as in Section 1)

2.1.2 Sponsor: (as in Section 1)

2.1.3 If no sponsor – person or organization initiating, managing, and / or funding the clinical trial:

2.1.4 Local Contact Person for correspondence:

2.1.5 National Principal Investigator/Coordinator: (or equivalent person)

2.1.6 International Principal Investigator: (if applicable)

2.1.7 Regional Monitor: (as in Section 1)

2.1.8 Medical monitor:

PART 3: DETAILS OF INVESTIGATIONAL PRODUCT(S)

3.1 Name(s) and details of investigational product(s) to be used in trial: [Formulation(s) and strength(s) (e.g. 10 mg/ml–10ml amp.)] Include NAFDAC registration number and date of registration if applicable.

3.2 Name(s) and details (as above) of comparator product(s) and NAFDAC registration number(s) and date(s) of registration if applicable: [Ensure package inserts or complete pharmacological information been included (Section 1).]

3.3 Name(s) and details (as above) of concomitant medication(s) including rescue medications which are required in the protocol, and NAFDAC registration number(s) if applicable: [Ensure package inserts or complete pharmacological information has been included with application (Section 1).]

3.4 Estimated Quantity of Trial Material (each drug detailed separately) for which exemption will be required:

3.5 If any of the above drugs are available in this country, give an explanation for not using what is available in country.

3.6 Details of receiving of drugs from supplier, storage, dispensing, packaging of drugs:

3.7 Date NAFDAC registration applied for – or envisaged date of application for trial medication. Explain if registration is **not** envisaged:

3.8 Registration status of entity, for the indication to be tested in this trial, in other countries: (i.e. Country: date registered / date applied for / date registration refused / date registration withdrawn by applicant / date registration cancelled by regulatory authority) [Attach as an appendix if necessary.]

Part 4: DETAILS OF INVESTIGATOR(s) AND SITE(s)

4.1 Details of Investigator(s): [designation, title: (i.e. principal investigators / investigators) Include Name/Address/Tel/Cell/Fax/E-Mail]

4.2 Current work-load of Investigator(s): (Number of studies currently undertaken by study investigator(s) as principal and/or co- or sub-investigator, and the total number of patients represented by these studies. Time-commitments of researcher(s) in relation to clinical trial work *and* non-trial work.)

Recommended format for response:

Investigator (Name and designation):			
Total number of current studies (all stages) on specified date	Number	Date	
Total number of patients / participants for which responsible on specified date	Number	Date	
ESTIMATED TIME PER WEEK [168 hours denominator]		**Hours**	**%**
Clinical trials	Clinical work (patient contact)		
	Administrative work		
Organization (Practice / university / employer)	Clinical work		
	Administrative work		
Teaching	Preparation / evaluation		
	Lectures / tutorials		
Writing up work for publication / presentation			
Reading / sourcing information (e.g. internet searches)			
Other (specify)			

4.3 Details of Site(s) (Name of site, physical address, contact details, contact person, etc.)

4.4 Capacity of each Site(s): (Number of staff, names, qualifications, experience -- including study co-ordinators, site facilities, emergency facilities, other relevant infrastructure, commitment to clinical/medical oversight of participants)

Part 5: STUDY PARTICIPANTS *(SUBJECTS)*

5.1 Number of participants in the country:

5.2 Total worldwide:

5.3 Total enrollment in each (country-specific) centre: (if competitive enrollment, state minimum and maximum number per site.)

5.4 Eligibility and enrollment: (Inclusion and exclusion criteria listed and justified)

5.5 Volunteer base from which the country's participants will be drawn:

5.6 Retrospective data indicating potential of each site to recruit required number of patients within envisaged duration of trial. *(to check the relevant section in the NAFDAC/ ICH guidelines)*

Part 6: OTHER DETAILS

6.1 If the trial is to be conducted in the country and not in the host country of the applicant / sponsor, provide an explanation:

6.2 Estimated duration of trial:

6.3 Name other Regulatory Authorities to which applications to do this trial have been submitted, with respective recommendations, positive and negative must be included. Include date(s) of application:

6.4 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities:

6.5 Details if this trial is being undertaken in any other country in Africa, or any country where there is no regulatory control of clinical trials:

6.6 Previous studies using this agent which have been approved by NAFDAC:

NAFDAC approval number:

Study title:

Protocol number:

Date of approval:

National PI / Principal Investigator:

Date(s) Progress report(s):

Date Final report:

6.7 If any sub studies are proposed as part of this protocol, indicate whether or not they will also be done in the country. If not, please explain.

Part 7: ETHICS

7.1 Ethics Committee/IRB responsible for each site, date of approval or date of application:

7.2 Attach copy of response(s) (positive and negative) made by, and/or conditions required by ethics committee(s) if available. Ensure that date of EC response is legible.

7.3 State which Good Clinical Practice (GCP) guidelines are being followed. *(Particular reference to the country-specific guidelines required):*

7.4 Details of capacity building component of the trial, if any (scientific, technical and resource-wise including community upliftment):

7.5 Details of the training of investigators, monitors, study co-ordinators in terms of carrying out this trial and in terms of GCP:

7.6 Detailed monitoring plan for each site: [May be attached. Label as 'Section 2 Item 6.6']

7.7 Details of trial insurance certificate: (e.g. title, protocol-specific, dates, policy #, amount, clarification on whether it is a "No-Fault" policy)

7.8 Details of possible conflict of interest of any person(s)/organisation(s) who/which will be involved in the trial:

7.9 Remuneration/compensation to be received in local currency: (Investigators), (Trial participants), (Others). Indicate broad breakdown of costs to be covered by this amount (The amount should compensate the travel expenses, meals and time of the participant without being a perverse incentive.In international trials, if there is a difference in the compensation amount between developed and developing countries, then the difference should be implemented as projects in the community of the participant)

7.10 Comment on choice of investigators (refer to current NAFDAC Clinical Trials Guidelines)

7.11 Comment on resources of sites and sponsor

7.12 Indicate how additional staff (monitors, pharmacists, nursing staff, etc.) will maintain patient confidentiality, follow the protocol, and abide by ethical and regulatory requirements

7.13 Comment on Patient Information Leaflet and Informed Consent. (NB: inclusion of appropriate level of education; possible benefits / risks ; ensuring patient rights; contact names and numbers of the PI, as well as NAFDAC contact person and contact details, included)

7.14 Comment on availability and completeness of separate PILs and informed consent forms for any proposed archiving of biological specimens for later research or for genetics research.

7.15 Comment on ethics of the publication policy

7.16 Comment on treatment and/or management of participants and their disease condition(s) after completion of trial

7.17 Comment on ethics committee capacity to monitor site.

PART 8: TRIAL/PROTOCOL DETAILS:

Title:

Protocol Number/identification:

Date of protocol:

Version number:

8.1 Summary of the study Rationale: (Why this trial should be done at all?) Include statement about country-specific contribution, if any, to the development of this protocol.

8.2: Background information (essential points that apply to this trial) [1-2 sentences max for each point]:
Disease / problem
National (country-specific) context (e.g. local epidemiology)
Properties of Drug / Entity; hypotheses about mechanism of action, etc.
Pre-clinical findings: (e.g. laboratory / animal / toxicity / mutagenicity)
Clinical findings (e.g. phases; PK; PD; dose-finding; ADRs, others)

8.3 Objectives of study:

8.4 Study design (clearly described and each component justified)
[includes phase, use of placebo, dosages, randomization, blinding, duration, etc.]

8.5 Treatment modalities and regimens, pharmacy plan (e.g. drug accountability clearly explained and justified for all participant groups/arms)

8.6 Outcome measurements/variables (each clearly stated and justified)

8.7 Safety Monitoring:
8.7.1 Adverse events (prevention, definitions – including causality assignment, recording, reporting, time-lines, action to be taken, all clearly described)
8.7.2 Data Safety Monitoring Board (DSMB) - Terms of reference, CV's, declaration of no conflict of interest, stopping rules, local expert representation.

8.8 Statistical measures:
8.8.1 Determination of sample size corrects, clear and justified (with and/or without stratification)
8.8.2 Statistical method(s) and analysis of quantitative measures appropriate, clear and justified
8.8.3 Statistical method(s) and analysis of qualitative measures appropriate, clear and justified
8.8.4 Data processing (how, where, when, who) clearly described and justified. If a country-specific person will be involved in data processing, please identify that person
8.8.5 Interim analysis envisaged or not (justify) and stopping rules if applicable (explain)

9. OTHER RELEVANT INFORMATION NOT INCLUDED ABOVE

E.g. Are references adequate and dates of references current?
Are there discrepancies between protocol and IB or package inserts? Are there specific explanation(s) for these discrepancies?
Are the explanations for not following the country-specific 'GCP guidelines acceptable?

Other comments on this trial.