*Please complete each section of this application form electronically as a Word Document and as a scanned signed PDF file, ensure that the electronic and the printed versions of the completed form accompany your submission.*

# **Application details**

## Clinical Trial Application Number: *e.g. CTA 0015………………………………………*

## Other identifier number: *e.g* PACTR, EUDRA, DAIDS, UNCST etc………………….

## Details of the approved original protocol: ………………………………………………

|  |  |
| --- | --- |
| * + 1. Date of approval of original protocol (dd/mm/yyyy)
 | REC:UNCST:NDA: |
| * + 1. Principal Investigator approved for the clinical trial
 |   |
| * + 1. Number and names of sites approved for the clinical trial
 |   |
| * + 1. Number of participants approved for the clinical trial
 |   |
| * + 1. Number of participants accrued at time of application for renewal
 |  |

## Applicant details

|  |  |
| --- | --- |
| * + 1. **Applicant[[1]](#footnote-1)**

**(Sponsor or Principal Investigator)**  |  |

|  |  |
| --- | --- |
| * + 1. **Contact person responsible for this application**
 | First name: Surname name: Email:Telephone: |
| * + 1. **Sponsor Details**
 | Sponsor:Physical address:Email:Fax:Telephone: |

# **Summary of study activities in the approval period**

## CTA title, Version number and date:

## Details of regulatory approvals

|  |  |
| --- | --- |
| Dates of most recent approval period by Research Ethics Committee  |   |
| Date of most recent approval period by UNCST  |   |
| Dates of most recent approval period by NDA |  |

## Summary of amendments during report period (if any)

|  |  |  |
| --- | --- | --- |
| **Type of amendment** | **Brief summary of amendment** | **Date of approval by** |
| *e.g. Increase in sample size* |  | **REC;****NDA**; |
|  |  |  |
|  |  |  |
|  |  |  |

## List any clarification memos and/or letters of amendment during report period (if any)

## Has the study been extended beyond the initial approval period? (Yes/No)

## Outline any regulatory lapses during the report period (if any)

|  |  |  |
| --- | --- | --- |
| Regulatory Lapse | Dates of Occurrence | Reason |
|  |  |  |
|  |  |  |

## List any halts to the study conduct during the report period (if any)

|  |  |  |
| --- | --- | --- |
| Halt to Study conduct | Dates of Occurrence | Reason |
|  |  |  |
|  |  |  |

## Have you submitted a line listing of Serious Adverse Events (SAEs) during the report period? (*Provide an attachment)*

## Provide an outline of deviations during the reporting period (if any)

|  |  |  |
| --- | --- | --- |
| Deviation | Date of Occurrence | CAPA |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Outline any audits/ inspections by regulatory bodies (*e.g.* RECs, UNCST) during the reporting period as well as the outcome/s

|  |  |  |
| --- | --- | --- |
| **Regulatory body** | **Date of Inspection** | **Outcome** |
|  |  |  |
|  |  |  |
|  |  |  |

# **Documentation** checklist

The following documents have been submitted together with this application form:

|  |
| --- |
| *Note: All documents must be provided for this application to be valid.*  |
| Signed Cover letter clearly indicating protocol title |

|  |
| --- |
|  |

 *Yes*

|  |
| --- |
|  |

 *No* |
| Valid ethical approval of the study |

|  |
| --- |
|   |

 *Yes*

|  |
| --- |
|  |

 *No* |
| Annual progress report clearly indicating reporting period |

|  |
| --- |
|   |

 *Yes*

|  |
| --- |
|  |

 *No*  |
| DSMB report /Interim Analysis |

|  |
| --- |
|   |

 *Yes*

|  |
| --- |
|  |

 *No*  |
| Investigational Product Accountability for the reporting period and projected need for the next period *(Attach IMP Accountability table)* |

|  |
| --- |
|   |

 *Yes*

|  |
| --- |
|  |

 *No* |

# **Declaration *(by Applicant)****.*

I declare that:

|  |
| --- |
|   |

 The information submitted is true and correct.

Principal Investigator’s Name: ………………………. Signature: ………………..

Date: ………………………………

1. Applicant

An applicant is the Sponsor or Principal Investigator who was issued a Clinical Trial Certificate. The applicant shall therefore be responsible for signing the application form. Regulation 4 of National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014 [↑](#footnote-ref-1)