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

# **1. Application details**

**1.1 Amendment category: (tick all applicable options)**

|  |  |  |
| --- | --- | --- |
|  | Major amendment |  |

Immediate notification

|  |  |  |
| --- | --- | --- |
|  | Minor amendment |  |

Letter of Amendment (LoA)

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

**1.3 Details of the approved original protocol:**

|  |  |
| --- | --- |
| Date of approval of original protocol (dd/mm/yyyy) |  |
| Principal Investigator approved for the clinical trial |  |
| Number of sites approved for the clinical trial |  |
| Number of subjects approved for the clinical trial |  |

## 1.4 Applicant details

|  |  |
| --- | --- |
| **Applicant[[1]](#footnote-1)**  **(Sponsor or Principal Investigator)** |  |

Application Form for Amendment of Conditions of a Clinical Trial

|  |  |
| --- | --- |
| Contact person responsible for this application | Title/Designation:  First name:  Surname name: |
| Contact person's job title |  |
| Contact person's postal address |  |
| Contact person's email address |  |
| Contact person's phone number |  |

# **2. Summary of proposed changes**

*For multiple amendments reproduce this section and provide separate summaries for each proposed amendment.*

## 2.1 Amendment title, number and nature of supporting documentation

e.g. *Major amendment # 1:*

*Change in the shelf life of the investigational medicinal product from 12 months to 24 months— stability data to support the change is attached*

*Major amendment #2: To change the dose or regimen of the investigational medicinal product- Amended Informed Consent Form and Updated Investigator Brochure attached; 5 peer-reviewed publications and pre-clinical/clinical data to support the change attached*

**2.2 Summary of current and proposed details:**

|  |  |
| --- | --- |
| **Current details** | **Proposed details** |

Application Form for Amendment of Conditions of a Clinical Trial

|  |  |
| --- | --- |
| e.g Current shelf life 6 to 12 months Current sample size: 100 infants  Current Protocol version and date | Proposed: 12 to 24 months  Proposed sample size: 150 infants  Amended Protocol version and date |

**2.3 Reason/rationale for change(s):** *Please itemize the rationale for each change if more than one*.

**2.4 Multi-centre trials:** Will this amendment apply to all approved site(s)?If No: Specify the sites for which the amendment will apply

**2.5 Date of implementation** (*for Immediate Notifications only*)

**2.6 Additional investigators or Change of Principal Investigator:**

|  |  |
| --- | --- |
| Name of additional or new Principal Investigator |  |
| Physical address and contact information of Investigator |  |
| Proof of ICH-GCP training attached | Yes/No: |
| Summary of on-going or planned studies at the site involving the Investigator: | Provide details of studies, including numbers of participants of the clinical trial, whether the investigator is involved in research on a full-time or part-time basis, and any other details that may affect the capacity of the site at any one time |
| Date of approval by IRB |  |
| Date of approval by UNCST |  |

*Please attach an up to date curriculum vitae of additional investigator(s) or new Principal Investigator and a signed declaration of intent.*

# Application Form for Amendment of Conditions of a Clinical Trial

## 3. 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.* |  |
| Valid ethical approval of the proposed change(s) | |  | | --- | |  |   *Yes*     |  | | --- | |  |   *No* |
| Evidence of payment of amendment fees (NDA receipt) | |  | | --- | |  |   *Yes* |
| Supporting documentation (Detail the kind of documents submitted e.g Stability data, Curriculum vitae, Memorandum of Understanding/Contractual agreement, Certificate of accreditation of laboratory X, Budget for FY 2017/2018 ) | |  | | --- | |  |   *Yes* |

**4. Declaration *(by Applicant)****.*

I declare that:

|  |
| --- |
|  |

For each change all conditions as stipulated in the ***NDA Guidelines on Amendments to Conditions of a Clinical Trial*** for the change(s) requested are fulfilled.

|  |
| --- |
|  |

There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.

|  |
| --- |
|  |

The information submitted is true and correct.

# Application Form for Amendment of Conditions of a Clinical Trial

Name:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tilte/Designation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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.

   [↑](#footnote-ref-1)