

**Form: BMRR II-CTA**

**APPLICATION FOR CLINICAL TRIAL AUTHORIZATION**

**Part I: Details of the Trial Applicant**

|                 |  |
|-----------------|--|
| a. Name         |  |
| b. Organization |  |
| c. Address      |  |
| d. Phone Number |  |
| e. E-mail       |  |

**Part II: Details of the Trial Sponsor** *(Skip this section if trial sponsor and applicant are same)*

|   |  |
|---|--|
| a. Name   |  |
| b. Organization   |  |
| c. Address  |  |
| d. Phone Number   |  |
| e. E-mail   |  |
| f. Status of the sponsor<br>(Commercial or Noncommercial) |  |

**Part III: Details of the Trial**

|  |  |
|--|--|
| a. Full Title of the Trial:                                    |  |
| b. Objectives of the trial:                                    |  |
| c. Trial Type (Phase I, Phase II, Phase III, Phase IV):        |  |
| d. Design of the Trial:  |  |
| e. Group of Trial Subjects:                                    |  |
| f. Planned Number of subjects to be included:                  |  |
| g. Age Range of Trial Subjects:                                |  |
| h. Gender of Trial Subjects:                                   |  |
| i. Investigational Medical Product(IMP) to be tested:          |  |
| j. Investigational Medical Product (IMP) used as a comparator: |  |
| k. Clinical Trial Site:  |  |
| l. Expected Duration of the Trial:                             |  |

The prescribed fee has been deposited to the Royal Government of Bhutan  
(Please submit a copy)

In support of this application, following documents are enclosed:

1. *Clinical Trial Protocol as per Good Clinical Trial Practice Guideline prescribed by the Authority.*
2. *Ethical Clearance from independent ethical committee identified by the Authority.*

**Applicant Declaration (please tick the boxes):**

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant:  
Name, address, contact no.:

Date: .....