**HUMAN RESEARCH SUBJECTS AMENDMENT FORM (UPSI/PPPI/UPP/BE04)**

**HUMAN RESEARCH SUBJECT AMENDMENT FORM**

**1. Details of Principle Investigator**

|  |  |
| --- | --- |
| Name: |  |
| Address of institution: |  |
| Telephone: |  |
| E-mail: |  |

**2. Details of approved application**

|  |  |
| --- | --- |
| Title of study: |  |
| Ethical approval reference number: |  |
| Date of ethical approval: |  |

**3. Description of amendment (Fill in related amendment only. Please attach an amended version with all changes tracked or highlighted)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Criteria** | | **Description before amendment** | **Description after amendment** | **Justification** |
| **Title** | |  |  |  |
| **Objective** | |  |  |  |
| **Participant selection criteria** | **Inclusion criteria** |  |  |  |
| **Exclusion criteria** |  |  |  |
| **Data collection method** | **Location** |  |  |  |
| **Design** |  |  |  |
| **Sample** |  |  |  |
| **Instrument** |  |  |  |
| **Method of dosage formulation** |  |  |  |
| **Dosage amounts** |  |  |  |
| **Informed consent form** | |  |  |  |
| **Others** | |  |  |  |

**5. Declaration**

**I confirm that the above information is true.**

|  |  |
| --- | --- |
| Signature of Principal Investigator: |  |
| Name: |  |
| Date of submission: |  |

**6. Endorsement by Human Ethics Review Committee**

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| **Comments:**  **Approve**  **Require amendment**  **Not approve**    **( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Human Ethics Review Committee** |
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