

 ภาควิชา ...............Department.............

โทร. ..... Telephone of department...............

วันที่ ……..........Date............................

เรื่อง ขอนำส่งเอกสารการปรับเปลี่ยนโครงการหลังได้รับการรับรอง (COA) แล้ว

เรียน ประธานคณะกรรมการจริยธรรมฯ

 ตามที่**คณะกรรมการจริยธรรมการวิจัยในคนฯ** (MU-DT/PY-IRB) ให้การรับรองโครงการวิจัยเรื่อง “...............Title of Project.....................” หัวหน้าโครงการ........ Principal Investigator’s name............... ภาควิชา/หลักสูตร........ Department/Course................

 ในการนี้ผู้วิจัย มีความประสงค์ของปรับเปลี่ยนรายละเอียดโครงการดังกล่าวตามเอกสารแนบ ดังมีรายการสรุปตามรายการต่อไปนี้

1. แบบฟอร์มการขอปรับเปลี่ยนโครงการวิจัยที่ได้รับการรับรอง

(Protocol Amendment)

1. Submission form 6 (revise) 1 copy
2. Protocol 1 copy or
3. Participant information sheet (revise) 1 copy or
4. Consent form (revise) 1 copy or
5. Questionnaire (revise) 1 copy or

4. Other 1 copy

Please sent file Email: sasitorn.nga@mahidol.ac.th

 จึงเรียนมาเพื่อทราบ และโปรดพิจารณาดำเนินการต่อไปด้วย จักขอบพระคุณยิ่ง

ลงชื่อ .................................................................(…………Principal Investigator’s name..……..……………)

 หัวหน้าโครงการ

ลงชื่อ ...............................................................(…………..Thesis Advisor ……..……………..……..)

 อาจารย์ที่ปรึกษา

Contact researcher
Name.............................................
Tel:................................................

Email:……………………………….

***Note:***

* ***For other issues in protocol amendment, you may delete some none related issues or may delete some significant issue changing including table in case you check*** 🗹 ***no change***
* ***Please specify the reason for amendment Principal investigator /*** ***Co-investigator***

**Protocol Amendment Report Form**

**Protocol Title** ………………………………………..…………………….………….…………………………………………………………………….……..………

**Name of Principal Investigator**……………………………..…………………………….………………………………………………...…..…………….…

**Research Site.**…………………………….……………………………………………………………………………………………………………………….………...

**Protocol No.** ……............................. **No. of COA** *Si* ……………………….……… **Expiry date of COA** …………….……………………

Amendment No. ...................................dated……………….…………………………

**❒ Minor Protocol Amendment ❒Major Protocol Amendment**

**Please fill all the changes from previous protocol which had been previously approved in this table**

**1. Changing of important study design such as adding more numbers of participant for new group, increase/**

 **decrease study arms.**

 ❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

**2. Changing of inclusion/exclusion criteria or changing number of participants**

❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

**3. Data amendment which has direct effects to participants such as invasive intervention or procedures, study visit, frequency or volume of blood collection or money expense for time or travel compensation.**

 ❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

**4. Other protocol amendment (other than in no.1-3) which has effects to risk/ benefit to subjects.**

 ❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

**5. Protocol amendment in other issues**

 ❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

**6. Amendment in patient information sheet / informed consent form**

 ❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

❒ Consent form addendum, issue no. ……………. for reconsent

❒ New consent form, issue no. ……………. for

 ❒ new participant

 ❒ reconsent

**7. Changing of other protocol documents such as case record form/advertisement for recruitment**

 ❒ Yes ❒ None

**Essential issues in changing:**

* .................................................................................................................................................................................
* .................................................................................................................................................................................

**Detail of the adjustment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topic, page, previous message** | **New message** | **Reasons for amendment** | **Impact on participants** |
| 1. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |
| 2. |  |  | ❒ None❒ Yes ………………….………Measure to reduce the impacts................................ |

**Summary: Overall benefit/risk ❒ No change**

 **❒ Change for...............................**

 Signature................................................../ date ............................

 (.........................................................)

Principal Investigator