

**Protocol Amendment Form**

**Research Project Code** Click or tap here to enter text.

**1. Research Project Title** Click or tap here to enter text.

 **COA/COE Approval Date** Click or tap to enter a date.

 **Expiry Date** Click or tap to enter a date.

**2. Current status of the research project**

[ ]  Not yet recruit research participants

 [ ]  In the process of recruiting research participants

 [ ]  Already recruited all research participants and/or undergoing follow-up study

 [ ]  Completed follow-up study of research participants and/or in process of named

 Data analysis only

 [ ]  In the process of data analysis which can connect to research participants information

 [ ]  Analyze anonymous data which unable to connect the research participants information

 **Planned number of research participants**

*(Please specify)*

 **Number of research participants at present**

*(Please specify)*

 **Participants who completed the study**

*(Please specify)*

 **Participants withdrawn during the study**

*(Please specify)*

 **(Please specify the cause)**

*(Please specify)*

**3. Please specify what you want to amend.**

*(Please specify)*

**4. The amendment is**

 [x]  Major changes

 [ ]  Minor changes

**5. Please clarify the type of research protocol.**

(Please note that the final decision of protocol consideration is up to the CMUREC)

 [x]  Exemption

 [x]  Expedited

 [ ]  Full Board

**6. The proposed amendments posed an increased risk to the research participants.**

 [ ]  Less than minimal risk

 [ ]  Over than minimal risk

 If over than minimal risk, please describe the risks of the participants and additional and risk mitigation measures.

*(Please specify)*

**7. Other descriptions (if any)**

*(Please specify)*

\*\* Please submit with Form AF02-12 (Comparison Table of Amendment) and all related documents \*\*