SANGATH INSTITUTIONAL REVIEW BOARD

**APPLICATION FOR AMENDMENT OF PROPOSAL**

An amendment of the proposal is requested to IRB in case of any permanent deviation from the approved protocol (e.g. sample size, analysis method, ways of obtaining consent)[[1]](#footnote-1)

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| **1. Details of study** | |
| **1.1 Project Title** |  |
| **1.2 Sangath IRB reference number** |  |
| **1.3 Name of Principal Investigator** |  |
| **1.4 Date of submission** |  |

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| **2. Summary of the original research study, including key objectives and methods**  Please ensure that you do not exceed a maximum of 200 words. | | |
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| **3. Summary of the specific amendment requested.**  Please summarise each amendment being made to the original study by including a description of and justification for each amendment, and any new ethical implications. Sufficient detail must be given to allow the Committee to make an informed decision. Please list the pages on which changes to the main protocol have been made due to the proposed amendment. | | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | No. | Existing provision | Proposed amendment | Justification | New ethical implication and mitigation plan | | 1. |  |  |  |  | | 2. |  |  |  |  | | 3. |  |  |  |  | | 4. |  |  |  |  | | | |
| **4. Please attach the amended study documents to this amendment application.** | | |
| **Documentation name** | **Version number** | **Last revised date** |
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| **5. Please give details of any other ethical/regulatory approval obtained or that are required to approve the proposed amendment if applicable.**  Please attach copies of approval letter(s) where this has already been obtained. If the letter is not available, please explain why. | | |
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1. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva.

   Council for International Organizations of Medical Sciences (CIOMS); 2016 [↑](#footnote-ref-1)