SUTD Institutional Review Board (IRB)

PROTOCOL AMENDMENT FORM

|  |
| --- |
| Please use this form to request approval for changes to an approved research protocol.Please attach copies of all revised materials (**with tracked changes**) with new version numbers and dates to SUTD-IRB. |
| **Principal Investigator** |  | **IRB Approval No.** |  |
| **Protocol Title \***\*As stated in your original approval letter. |  |
| **Revision or Amendment Description – Check (x) for all that apply** |
| Revision to approved IRB application form |  | New version no. & date |  |
| Revision to approved protocol |  | New version no. & date |  |
| Revision to approved participant information sheet & informed consent form (PIS & CF) |  | New version no. & date |  |
| Revision to list of co-investigator(s) / Change in principal investigator |  | New version no. & date |  |
| Others, please specify: |  | New version no. & date |  |
| Describe changes to the approved protocol/IRB application form. Explain in detail in the space below the reasons for requesting these changes and which part(s) of the approved document will be amended. Please highlight changes in the revised document. |
|  |
| Describe changes to the Participant Information Sheet & Consent Form/assent form/recruitment advertisement, etc. Explain which sections of these items are being changed. Please highlight changes in the revised document.  |
|  |
| Do any of these changes increase the risks to subjects? Are subjects aware of the change in the risk? Will the subjects be re-consented?  |
|  |
| How many subjects how you recruited so far? Are there any adverse events? |
|  |
| **Principal Investigator’s Endorsement** |
| Signature of Principal Investigator |  | Date |  |
| Email |  | Contact Number |  |
| Pillar/Department / Institution |  |
| **Sign below only if there are changes to the list of co-investigator(s).** *Please submit a copy of their 2-page CVs.(Add more lines if necessary)* |
| Signature of Co-Investigator |  | Date |  |
| Name of Co-Investigator |  | Contact Number |  |
| Pillar/Department / Institution |  | Email |  |
| Signature of Co-Investigator |  | Date |  |
| Name of Co-Investigator |  | Contact Number |  |
| Pillar/Department / Institution |  | Email |  |