**Protocol Amendment Form**

1. **Protocol Information**

|  |  |
| --- | --- |
| Protocol number | Click or tap here to enter text. |
| Project Title | Click or tap here to enter text. |
| Principal Investigator | Click or tap here to enter text. |
| Country Research Lead (if different from the PI) | Click or tap here to enter text. |
| Applicant Institution | JPGSPH  BIGD  BIED  Other |
| If other, please specify | Click or tap here to enter text. |
| Sponsoring Centre of Excellence/Hub (Only for BRAC JPGSPH study) | CGSRHR  SISU  CNCDN  HSUHC  UEH  Humanitarian Research Hub |
| Corresponding Person for the IRB (If not the same as the PI or the Country Lead) | Click or tap here to enter text. |
| E-mail of the corresponding person | Click or tap here to enter text. |
| Phone number of the corresponding person | Click or tap here to enter text. |
| Date of IRB approval | Click or tap here to enter text. |
| How many amendments have been made so far? | Click or tap here to enter text. |

1. **Description of proposed modification (check all that are applicable)**

|  |  |
| --- | --- |
| B.1.i Team composition | Yes  No |
| B.1.ii If yes, then specify | Click or tap here to enter text. |
| B.2.i Study objective(s) or hypotheses | Yes  No |
| B.2.ii If yes, then specify | Click or tap here to enter text. |
| B.3.i Study sites | Yes  No |
| B.3.ii If yes, then specify | Click or tap here to enter text. |
| B.4.i Study population | Yes  No |
| B.4.ii If yes, then specify | Click or tap here to enter text. |
| B.5.i Number of participants/Sample size | Yes  No |
| B.5.ii If yes, then specify | Click or tap here to enter text. |
| B.6.i Inclusion and/or exclusion criteria | Yes  No |
| B.6.ii If yes, then specify | Click or tap here to enter text. |
| B.7.i Consent process or forms | Yes  No |
| B.7.ii If yes, then specify | Click or tap here to enter text. |
| B.8.i Data safety monitoring plan (Data Quality Assurance Standards, Data Security and Management, Roles and Responsibilities of Data Collection supervisors etc.) | Yes  No |
| B.8.ii If yes, then specify | Click or tap here to enter text. |
| B.9.i Study tools (questionnaire, FGD guidelines etc.) | Yes  No |
| B.9.ii If yes, then specify | Click or tap here to enter text. |
| B.10.i Data collection process | Yes  No |
| B.10.ii If yes, then specify | Click or tap here to enter text. |
| B.11.i Compensation for participation in research (e.g., increasing/decreasing the amount) | Yes  No |
| B.11.ii If yes, then specify | Click or tap here to enter text. |
| B.12.i Intervention of the study | Yes  No |
| B.12.ii If yes, then specify | Click or tap here to enter text. |
| B.13.i Collection of biological samples (e.g., type, number of tests, amount of sample) | Yes  No |
| B.13.ii If yes, then specify | Click or tap here to enter text. |
| B.14.i Analysis of biological samples (e.g., type, number of tests, amount of sample) | Yes  No |
| B.14.ii If yes, then specify | Click or tap here to enter text. |
| B.15.i Anything else | Yes  No |
| B.15.ii If yes, then specify | Click or tap here to enter text. |

*I understand that I cannot initiate any change in the approved research protocol until my requested change(s)*

*is/are approved by all relevant Committees/bodies.*

|  |  |
| --- | --- |
| Signature of Principal Investigator | Date: Click or tap to enter a date. |
| Signature of Country Lead (if different from the PI) | Date: Click or tap to enter a date. |
| Approved by,    Signature of the Centre Director/Lead of Humanitarian Research Hub (for JPGSPH)/Head of the institution (for BIGD and BIED) | Date: Click or tap to enter a date. |