**Human Subjects Incident Report Form**

1. **Protocol Information**

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| Protocol number | Click here to enter text. |
| Project Title | Click here to enter text. |
| Principal Investigator | Click here to enter text. |
| Country Research Lead (if different from the PI) | Click 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 here to enter text. |
| E-mail of the corresponding person | Click here to enter text. |
| Phone number of the corresponding person | Click here to enter text. |

*Researchers are required to file a report, using this form within 10 days for any incidents occurring in the course of IRB approved human subjects’ research.  A report should be filed with the IRB for any unanticipated problem, data breach, departure from an approved procedure or for any event resulting in or having the potential to result in physical injury, psychological distress, or other events that introduce the potential for harm into the research process. Events should be reported if the injury, distress, or other event was directly related to participating in the research. In addition to reporting the event, the researcher has the responsibility of informing the participant(s) of the contact information for the chair for the IRB.*

1. Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident.

(*The description must contain: The incident/violation date, time and location, whether actions were taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event. If yes, what actions, any medical surveillance provided or recommended after the incident, any injury or illness associated with the incident*

*Equipment failures (if applicable), does the incident meet the criteria for an unanticipated problem? Was the incident a result of protocol violation or noncompliance? Did the incident involve a data breach? Name(s) of people present during the event (please mention their position if they belong to an organization, their role in the activity, the purpose of their presence, were they outsider, etc*).

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| Click here to enter text. |

If applicable attach supporting documentation (revised protocols, increased monitoring plan, changes to informed consent document or IRB application, etc.)

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| Signature of Principal Investigator | Date: Click here to enter a date. |
| Signature of Country Lead (if different from the PI) | Date: Click here 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 here to enter a date. |