SERIOUS ADVERSE EVENT REPORT FORM (FORM 18)

Whenever there is any SAE event in any research approved by the CGHMC RERB, it has to be reported by the principal investigator (PI) to the RERB. Section 1 of this form should be filled up by the PI.

SECTION 1

<table>
<tr><td colspan="4">Principal Investigator: (Name)</td></tr>
<tr><td colspan="2">CGHMC RERB Protocol No.</td><td colspan="2">Sponsor Protocol No.</td></tr>
<tr><td colspan="2">Date Submitted</td><td colspan="2">Signature</td></tr>
<tr><td colspan="4">Study Title:</td></tr>
<tr><td colspan="2" rowspan="3">Name of the study medicine/device:</td><td colspan="2">Report Date:</td></tr>
<tr><td colspan="2">☐ Initial ☐ Follow-up</td></tr>
<tr><td colspan="2">Onset Date:</td></tr>
<tr><td colspan="2">Sponsor:</td><td colspan="2">Date of first use of drug/device:</td></tr>
<tr><td colspan="4">Title of the Report</td></tr>
<tr><td colspan="2">Subject's Number:</td><td>Age:</td><td>☐Male ☐ Female</td></tr>
<tr><td colspan="2">Subject's history:</td><td colspan="2">Laboratory findings:</td></tr>
<tr><td colspan="2">SAE:</td><td colspan="2">Treatment Outcome:
☐ Resolved
☐ On-going</td></tr>
<tr><td colspan="2">Seriousness:
☐ Death ☐ Life Threatening
Hospitalization:
☐Short-stay ☐ Prolonged
☐Disability/Incapacitated
☐ Congenital Anomaly
☐ Others</td><td colspan="2">Relation to
☐ Drug ☐ Device Study
☐ Not related
☐ Possibly
☐ Probably
☐ Definitely related
☐ Unknown</td></tr>
</table>

Note: PI should attach standard SAE report form to this RERB form.

SECTION 2 (to be filled up by the designated SAE Subcommittee reviewer)

Document received by the RERB Secretariat	Signature	Date
Reviewer's Name/Signature:		Date: (dd/mm/yyyy)

Changes to the protocol recommended? Comments:	☐ Yes	☐ No
Changes to the informed consent form recommended? Comments:	☐ Yes	☐ No

RERB Final Action:

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Take note and no further action
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting

_____

Name of RERB Reviewer:	Signature	Date (dd/mm/yyyy)