B I C O L U N I V E R S I T Y
C o l l e g e o f M e d i c i n e
Institutional Review Board
Telefax: (052) 742-0076
URL: http://www.bicol-u.edu.ph/bucm/
Email: bucm_irb@bicol_u.edu.ph

SERIOUS ADVERSE EVENT REPORT FORM (FORM 3.1)

Whenever there is any SAE event in any research approved by the **Bicol University College of Medicine** IRB, it has to be reported by the principal investigator (PI) to the IRB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator:	
Study Title:	Protocol No.:
Name of the study medicine/device:	Report Date: ☐ Initial ☐ Follow-up Onset Date:
Sponsor:	Date of first use:
Title of the Report	Date of the report

Subject's initial/number: _____ Age: _____ ☐ Male ☐ Female

Subject's history:	Laboratory findings:
SAE:	Treatment: Outcome: ☐ Resolved ☐ On-going

Seriousness:	Relation to
☐ Death ☐ Life Threatening	☐ Drug ☐ Device ☐ Study
☐ Hospitalization:	☐ Not related
☐ Initial ☐ Prolonged	☐ Possibly
☐ Disability/Incapacity	☐ Probably
☐ Congenital Anomaly	☐ Definitely related
☐ Others	☐ Unknown

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

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SECTION 2 (to be filled up by the designated IRB representative)
Document receipt by the IRB

Name (IRB Secretariat)	Signature	Date

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended ☐ No ☐ Yes
Comments:

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

IRB 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 is needed.
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting _____

Name of Member- Secretary:	Signature	Date