CHONG HUA HOSPITAL
Healing with Passion. Caring with Compassion.

UNEXPECTED ADVERESE EVENT REPORT FORM

Form HRP-IRB-025

Principal Investigator:	Protocol No.:	IRB No: ☐☐☐ - ☐☐☐☐ - ☐☐
Study Title:		
Name of the study medicine/device:	Report Date: ☐ initial ☐ follow-up	Onset date:
	Sponsor:	Date of first use:

Subject's initial/number:	Age:	☐ Male ☐ Female
Subject's history:	Laboratory findings:	
SAE:	Treatment: Outcome: ☐ resolved ☐ on-going	
Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization –○ initial ○ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other	Relation to ○ Drug ○ Device ○ study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown	
Changes to the protocol recommended?	☐ No ☐ Yes , attach proposal	
Changes to the informed consent form recommended?	☐ No ☐ Yes , attach proposal	
Reviewed by:	Date:	
Comment:	Action:	

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CIOMS FORM

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2.a AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7 + 13 DESCRIBE REACTIONS (including relevant tests/lab data)										□ PATIENT DIED □ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION □ INVOLVED PERSISTENCE OF SIGNINFICANT DISABILITY OR INCAPACITY □ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? □ YES □ NO □ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCITON? □ YES □ NO □ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATE (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24A. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE □ STUDY □ LITERATURE □ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE □ INITIAL □ FOLLOWUP	