**CHECKLIST OF LIABILITY AND INDEMNITY PROVISION IN CLINICAL TRIAL AGREEMENTS**

1. Scope of liability by the Institution (UP Manila/PGH) and Principal Investigator
	* Medical negligence
	* Not following protocol unless with the consent of the CRO/Sponsor
	* Violation of laws relating to Clinical Trials
2. Scope of liability of the Sponsor
	* Negligence
	* Product-related injuries and death
	* Violation of laws relating to Clinical Trials
3. Cost and control of defense
	* The sponsor directly or through the CRO shall be notified of any complaint for injuries or death file by a participating person in the clinical trial
	* The sponsor may only participate in the control of the defense only upon providing payment for the cost for the defense
	* After the final judgement, the party at fault shall bear the cost for defense including reasonable attorney’s fees
	* If both parties are liable, the parties shall proportionally bear the cost
	* If the cost for defense is shared by the parties, no party shall enter into a compromise agreement without the written authority of the other party
4. Insurance
	* If both parties are liable, the parties shall proportionately bear the cost
	* Before the commencement of the clinical trial, the sponsor shall provide the Institution certified true copies of the insurance policies for all clinical trial-related injuries or death which shall remain in full force and effect from the commencement of the clinical trial and at least until six (6) months from the termination thereof.
	* The insurance shall not relieve the sponsor of any liability adjudged with finality by the court or administrative tribunal for payment of damages if the amount is in excess of the insurance coverage or it the insurance agent fails or refuses to pay for such liability
	* The CTA shall not be considered valid and binding without presenting to the Institution/Primary Investigator a certified true copy of insurance policy

**CHECKLIST OF DOCUMENTARY SUPPORT FOR THE ENDORSEMENT OF CLINICAL TRIAL AGREEMENTS**

**For Clinical Trials of Investigational New Drug/s**

* FDA-issued License to Operate as a CRO/Sponsor
* FDA clearance/approval for the clinical trial

**For all Clinical Trials**

* Articles of Incorporation or certificate of registration issued by the government where the corporation of the Sponsor is registered
* Articles of Incorporation or certificate of registration issued by the government where the CRO is registered
* Power of Attorney issued by the Sponsor in favor of the CRO to represent is as party to the CTA
* Power of Attorney issued by the CRO in favor of its designated signatory to the CTA
* Protocol
* UPMREB ethics review approval
* Insurance in favor of the study participants in case of injuries or death in relation to their participation in the study or intake of study drugs or being subjected to the study medical devise or equipment
* Usual format for the citation of the University of the Philippines as party to the CTA:

The University of the Philippines, the national university of the Philippines created by virtue of Act No. 1870, as amended and reorganized and operating by virtue of Republic Act No. 9500, through its constituent university, University of the Philippines Manila, with office address at 8/F RCB Building, Philippine General Hospital, Manila, represented herein by its Chancellor, DR. CARMENCITA D. PADILLA, hereinafter referred to as the “UPM,” representing the PHILIPPINE GENERAL HOSPITAL (Site/Institution);