3. POST MARKETING SURVEILLANCE (PHASE IV Clinical Trial) PROTOCOL [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020]

This Approval of Post Marketing Surveillance (Phase IV Clinical Trial) Protocol is issued to applicants as part of the post-approval requirements in the issuance of a Certificate of Product Registration for Monitored-Release/New Chemical Entities applications if additional activity(ies) are necessary based on FDA Circular No. 2021-020.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), and Importers of Pharmaceutical Products Note: This is only applicable if additional PV activity(ies) are determined to be necessary by FDA based on FDA Circular No. 2021-020
Fees to be Paid	:	AO 50 s. 2001Protocol for MR/Post Marketing Surveillance: Php 2,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
FDA Circular No. 2018-012: Rescinding FDA Circular No. 2013-014 and Instituting Post-Marketing Surveillance (PMS) Requirements for New Drugs under Monitored Release **Bureau Circular No. 05 s. 1997: Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products** Post Marketing Surveillance (Phase IV Clinical Trial) Protocol Requirements 1. Application Letter 2. Protocol 2.1 Study Title 2.2 Names of Investigator(s) including supervising investigator, principal investigator, co-investigator(s) 2.3 Funding/Sponsoring Agency	Applicant Company

2.4 Summary of the Proposed Study 2.5 Introduction including an identification of what is being studied, an explanation of why the study is valid or the scientific rationale 2.6 Objective(s) of the study indicating the general objective and specific objective(s). 2.7 Study Design e.g. descriptive study, case control, cohort, randomized concurrent trial. 2.8 Methods including a description of the study subjects, sample size, description of the study procedure, and a description of outcome measurements. 2.9 Data analysis including the criteria for substantive and statistical success, definition of drop-outs, withdrawals, treatment failure, details of statistical strategy to be used, and a specification of data handling, collation and computer use. 2.10 Ethical Consideration including a. Good outweighing harm b. Free informed consent c. Freedom to withdraw from the study at any time d. Confidentiality 2.11 Indemnification Policy which is compensation statement indicating availability payment for treatment or free treatment hospitalization in case of an adverse drug experience. 2.12 Time schedule or duration of clinical trial. 2.13 Duties and responsibilities of research personnel. a. The investigator must conduct the studies in conformance with the "Declaration of Helsinki" or the laws and regulations of the country in which the research is conducted, whichever represent the greater protection of the individual b. The investigator must keep careful records of his study and retain them for at least two years after the new drug application is approved. The records must be available promptly to the drug sponsor (usually the drug manufacturer) and to the drug regulatory agency. Progress reports must be sent to the sponsor at intervals not exceeding one year. c. The investigator must send emergency reports to the sponsor and the regulatory agency when dangerous adverse effects are observed. d. The investigators must observe the regulations regarding consent of human subjects being given an investigational drug.	Applicant Company Applicant Company

2.14 Bibliography 2.15 List of Hospital Resources/Personnel Required. 2.16 List of Basic Sciences Resources 2.17 Appendices including informed consent form, patient/case report form, flowchart of activities, questionnaire, dummy tables and graphs. 2.18 A statement that the protocol was reviewed and approved by the Research Committee and	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits application with complete documents and requirements. The documents should be included in the MR/NCE application.	1. Endorses the PMS (Phase IV Clinical Trial) protocol to the PRSDD.	AO 50 s. 2001 Protocol for MR/Post Marketing Surveillance: Php 2,500.00 +1% LRF	Day 1 1 working day	Licensing and Registration Division (LRD) Quality *Evaluator* and Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2. Receives the application from FDAC and encodes/updates the database	None	Day 2 1 working day	CDRR– CRR (PRSDD) Unit
	3. Decks/Assigns the application to the assigned evaluator	None	Day 3 1 working day	CDRR Director/ CRR Unit
2. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4. Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (5 working days to respond to the queries).	None	Day 4-32 29 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

	5. Reviews the evaluated application bearing the recommendation of the evaluator	None	Day 33-37 5 working days	Clinical Research Section *Supervisor*
	6. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	Day 37 1 working day	*FDRO I/II/III*
	7. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 38 1 working day (per batch of applications)	PRSDD *Chief*
	8. Signs and approves the final decision	None	Day 39 1 working day (per batch of applications)	CDRR *Director*
	9. Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	Day 40 1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*
	10. Releases the appropriate response to the client (if applied separately) or to the LRD Quality Evaluator (if submitted together with the MR application)	None	Day 40 1 working day	AFS Releasing Section *Personnel*
3. Receives the documents		None	Day 40 1 working day	LRD Quality *Evaluator*

TOTAL: (Simultaneously processed with the Monitored-Release Registration application; within the 180-day timeline of Monitored-Release application; or processed as post-approval requirement if additional PV activities will be required based on FDA Circular No. 2021-020; Service is covered under RA 3720 and 7394).	**Php 2,525.00**	**40 Working days**