M. INITIAL CLINICAL TRIAL AND IMPORT LICENSE APPLICATION UNDER REGULATORY RELIANCE

The CTA is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to conduct a clinical trial of an investigational drug product. On the other hand, the IL is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to allow importation of investigational product and ancillary supplies necessary for the conduct of clinical trial. The Philippine FDA recognizes the other National Regulatory Authority decision in the issuance of CT approval based on the criteria set under FDA Circular 2023-004.

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), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO 50 s. 2001 & FDA Circular No. 2012-007-A : Php 2,500.00 + 1% LRF Fee for External Regulatory Reviewers: Php 60,000.00 Import License for Clinical Study: Php 500.00/importation + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
AO No. 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Table of Contents for Clinical Trial Application 2. Cover Letter for Application 3. Clinical Trial Application Form 4. Investigational Product and Ancillary Supplies Information 5. Import License Application 6. Proof of payment 7. Letter of Authorization 8. Clinical Trial Protocol and amendment(s), where applicable 9. GCP Certificate and Curriculum vitae (CV) for investigators of each trial site 10. Informed Consent Form/Assent Form 11. Investigator's Brochure 12. Pharmaceutical Data 13. GMP Certificate from NRA and/or evidence of GMP compliance	Applicant Company

14. Shipping condition for IP and trial related materials 15. Labelling Materials of the Investigational product Additional requirements based on FDA Circular 2023-004 16. A formal letter written request from the applicant notifying the FDA of its intent to avail of the abridged review, identifying the RDRA. 17. Copy of the clinical trial approval or any equivalent from the identified RDRA. Proof of conduct of the clinical trial in the country of RDRA such as clinical trial registry. 18. A Sworn Assurance duly signed by the Sponsor or the authorized CRO stating the requirements under Section V.A.7.b and A.7.c of the Circular	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	1. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, inform the client of the deficiency/ies.	None		CRS Administrative Staff
2. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section	2. Upon receipt of the proof of payment, the application will be encoded/update in the database.	AO 50 s. 2001 & FDA Circular No. 2012-007-A : Php 2,500.00 + 1% LRF Import License for Clinical	Day 1 1 working day	CRS Administrative Staff

through clinicalresearch@fda.gov.ph		Study: Php 500.00/import ation + 1% LRF		
	2. Decks/Assigns the application to an evaluator.	None	Day 1 1 working day	Food-Drug Regulation Officer (FDRO) III
	3. Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (3 working days to respond to the queries)	None	Day 1 1 working day	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	4. Assigns regulatory reviewer /issuance of regulatory permit	None	Day 2 1 working day	FDRO I/II/III
	5. Forwards documents (Protocol and other documents) to External Regulatory Reviewer	None	Day 2 1 working day	Applicant
	6. Reviews Pharmaceutical data requirements and Import License application	None	Day 3-17 15 working days	FDRO I/II/III
If an electronic notice of deficiencies (E-NOD) was issued by the external regulatory reviewer, submits complete compliance documents to the evaluator.	7. Assesses the application though the FDA CT Assessment Form *Any clarifications/ deficiencies will be communicated to the clients through electronic communication (10 calendar days to respond to the queries)	Fee for External Regulatory Reviewers: Php 60,000.00 (direct to External reviewers) FDA Circular 2012-007-A	Day 3-17 15 working days	External Regulatory reviewer [St. Luke's Medical Center (SLMC),

	*This constitutes a stop clock on the processing time (based on AO 2020-0010, Section VI, Paragraph 5.6)			University of the Philippines – National Institutes of Health (UPNIH), Philippine Heart Center (PHC)]
	8. Reviews the assessment from the Regulatory Reviewer	None	Day 17 1 working day	FDRO I/II/III
	9. Reviews the evaluated application bearing the recommendation of the evaluator	None	Day 18 1 working day	Clinical Research Section Supervisor
	10. Prints the final response and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	Day 19 1 working day	FDRO I/II/III
	11. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 19 1 working day (per batch of applications)	PRSDD Chief
	12. Signs and approves the final decision	None	Day 19 1 working day (per batch of applications)	CDRR Director
	13. Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	Day 20 1 working day (per batch of applications)	CDRR-CRR Unit Personnel

3. Receives the approval	14. Releases the appropriate CT response and IL to the client	None	Day 20 1 working day	AFS Releasing Section Personnel
TOTAL: Service is covered under Administrative Order No. 2020-0010.		**PHP 63,035.00**	**20 Working days**	