



L. CLINICAL TRIAL AMENDMENT APPROVAL

The CTA Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the protocol and other related documents on the conduct of clinical trial has been approved.

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 Php 1,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No. 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Clinical Trial Amendment Requirements <ol style="list-style-type: none"> 1. Cover Letter (FDA-CRS Form 2.0) 2. Application Form (Appendix D1) 3. Original Version, corresponding amendments/s and rationale in a tabulated format 4. Supporting Data 5. Proof of Payment 	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC <i>Personnel</i>



<p>2. E-mail submission: Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph</p> <p>For COVID-19 related applications, sends through clinicalresearch@fda.gov.ph</p>	<p>2. Pre-assesses the completeness of the application.</p> <p>If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment.</p> <p>If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).</p>	None		CDRR <i>Personnel</i>
<p>3. For accepted applications, pays the required fee through any of the following:</p> <ul style="list-style-type: none"> • FDA Cashier • BANCNET • Landbank OnColl <p>Sends proof of payment to the FDAC.</p>	<p>3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.</p>	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC <i>Personnel</i>
	<p>4. Receives the application from FDAC and encodes/updates the database</p>	None	Day <u>2</u> <u>1</u> working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	<p>5. Decks/Assigns the application to the assigned evaluator</p>	None	Day <u>2</u> <u>1</u> working day	<i>CDRR Director/ CRR Unit Personnel</i>



<p>If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator</p>	<p>6. Evaluates the application according to requirements and prescribed standards</p> <p>*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication</p>	<p>None</p>	<p>Day <u>3-15</u> <u>13</u> working days</p>	<p><i>Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)</i></p>
	<p>7. Reviews the evaluated application bearing the recommendation of the evaluator</p>	<p>None</p>	<p>Day <u>16-17</u> <u>2</u> working days</p>	<p>Clinical Research Section Supervisor</p>
	<p>8. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief</p>	<p>None</p>	<p>Day <u>17</u> <u>1</u> working day</p>	<p><i>FDRO I/II/III</i></p>
	<p>9. Checks and recommends the decision of the evaluator/s by affixing initial/signature</p>	<p>None</p>	<p>Day <u>18</u> <u>1</u> working day (per batch of applications)</p>	<p><i>PRSDD Chief</i></p>
	<p>10. Signs and approves the final decision</p>	<p>None</p>	<p>Day <u>19</u> <u>1</u> working day (per batch of</p>	<p><i>CDDR Director</i></p>
	<p>11. Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section</p>	<p>None</p>	<p>Day <u>20</u> <u>1</u> working day (per batch of applications)</p>	<p><i>CDDR-CRR Unit Personnel</i></p>



4. Receives the letter	12. Releases the letter to the client	None	Day <u>20</u> <u>1</u> working day	FDAC Releasing Section <i>Personnel</i>
TOTAL:		PHP 1,010.00	20 working days	