Application Format for CRO Approval

(Application has to be submitted in organization official Pad)

Dated:

To

The Director General

Directorate General of Drug Administration,

Mohakhali, Dhaka-1212.

Subject: Application for the approval of CRO "Name of the proposed CRO".

Dear Sir

Enclosed: (As per the attached requirements)

Name of the applicant

Designation

Organization.

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-1

Title: Requirements for CRO/Clinical Trial Centre

Form No.	Revision No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-CTO-003/F01-01	00	OCT' 17	OCT' 22		26.10.17	01 of 02

Requirements for CRO/Clinical Trial Centre

SI. No.	Types of document	Availability of Documents			Remarks
		Yes	No	NA	
01	CRO Profile to be submitted				
02	Organogram with name of key personnel				
03	CV of Researchers and members				
04	Job Description				
05	Whether every person involved in the clinical trial has each got GCP training records.				
06	Whether the Clinical Trial Center/CRO has Bio-analytical Lab a. If not, they have got any contract with any Bio-analytical/analytical Lab having Biological Sample Analytical Facility. b. Biological Sample storage & carrying facility. c. Whether the Analytical Laboratory got any accreditation; operates under GCP Compliance (training record)				
08	Whether any chief investigator designated or contracted to the CRO or Clinical Trial Center.				
09	Whether the CRO got IRB/IEC				
10	Storage Facility of IP a. Whether Temperature Sensitive Product Storage Facility				
11	SOP for Handling of IP				
12	Archive Facility a. Is the Archive Facility has Controlled Access b. Is the Archive Storage Area Fire Proof & Pest Control				
13	Does the CRO/Clinical Trial Center has hospital facility/ in-house subject area / pool of subject.				
14	Whether they have emergency handling facility such as, Intensive Care Facility in the Hospital or has contract with any nearby intensive care unit.				

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15	Emergency Trolley & Ambulance Facility				
16	Quality Management Systems and SOPs for each activity / practice.				
17	Contractual / Sub-contractual agreement with third parties e.g. hospitals, university, analytical control lab etc.				
18	Subject recruitment, handling, compensation, confidentiality.				
19	Ethical clearance.				
20	Does the CRO/CT Centre has own IRB/IEC?				
21	Does the CRO/CT Centre has DSMB?				
22	Main products CRO will include in studies (Drug Group)				
23	Estimated cost categories / by molecules				
24	Estimated time to perform study.				
25	Bio-statistical software.				
26	Others if any:				

Note: The above listing is not intended to be exclusive or exhaustive. The contents will vary depending on the requirement of GCP to meet international standard.

	WRITTEN BY	CHECKED BY	APPROVED BY	AUTHORIZED BY
NAME	Dr.Aysha Siddiqua	Md. Salahuddin	Dr. Khandaker Sagir Ahmed	Major General Md. Mustafizur Rahman
DESIGNATION	Pharmacologist	Asstt. Director	Deputy Director	Director General
SIGN/DATE		26.10.17	26.10.17	26.10.17