13.1. **Annex 1 FORM- PCT-001.03**: **Clinical Trial Application review checklist**

EFDA ETHIOPIAN FOOD & DRUG AUTHORITY	**Pharmacovigilance & Clinical Trial Lead Executive Office**	**FORM- PCT-001.03** **SOP/ PCT_CT001**
Title	**Clinical Trial Application review checklist**	

Clinical trial application general information				
Clinical trial title				
Trial unique ID number				
Application received No				
Ser. No	**List of documents to be submitted**	**Submitted**	**Not submitted**	**Remark by the screening Expert**
1.	Signed and dated application letter from the sponsor/applicant or CRO			
2.	Filled clinical trial application form			
3.	Clinical trial protocol			
4.	Investigator's brochure			
5.	Preceding study report based on the type and phase of the study			
6.	Non- Clinical Data of the Investigational Product			
7.	Study team (PI, CO-PIs, pharmacists, nurses, laboratory etc) updated and signed CVs with credentials as required			
8.	Study team (PI, CO-PIs, pharmacists, nurses, laboratory etc) current GCP certificates			
9.	Participant information form			
10.	Informed Consent Form (ICF)			

11.	Case report forms (CRFs)			
12.	Adverse Event or safety reporting Forms			
13.	Investigational supplies accountability forms			
14.	Administrative forms to track research funds and expenses			
15.	Signature log or form sample			
16.	Delegation log or form sample			
17.	Forms to disclose information about the investigator's financial, property,or other interests in the product under study			
18.	formats for reports of monitoring visits			
19.	GMP certificate of the IP/IM manufacturer			
20.	COA of the IP/IM			
21.	For registered IP/IM, Summary of Product characteristics, Patient information leaflet/Package insert and Labelling			
22.	Certificate of Accreditation for the central Laboratory if Applicable			
23.	DSMB charter if applicable			
24.	DSMB members CVs and GCP certificates if applicable			

25.	Support letter from Study site or health facility.			
26.	Insurance certificates and/or policy			
27.	Ethical Approval from NRERB or recognized Institutional Ethics review committees.			
28.	Formats for progress reports, annual reports, and final study reports			
29.	Declaration by the Investigators			
30.	Declaration by the sponsor			
31.	Signed agreement between investigator and the sponsor			
32.	Others, if applicable			
Completion date of screening				

Screener summary report and conclusion

Screened By	
Name	
Date	
Signature	
Approved By	
Name	
Date	
Signature	