Research protocol completeness check form

Protocol Package Checklist Form .

Project name	
Head of research project	
Coordinator	

No.	document	have	do not have	Not relevant
Applied Document				
1	Book / notes for submitting research proposal *			
2	Submission form for ethical consideration For biomedical research projects (AP 04 - S04) * - Incomplete, missing last page information “Additional information” list of institutions in research projects and researchers in research centers so that CREC can deliver the Local Issue assessment correctly. - AP04-S04 appl form biomed.docx (sharepoint.com)			
Approval documents : Research protocol				
3	Complete research outline			
4	Brief research outline in Thai			
Approval documents : Informed Consent Documents				
5	Document explaining information about research project participants / Letter of consent (in the case of an English Master)			
6	Document explaining information about research project participants / letter of consent (Separate documents by institution) - CREC does not have a form for Explanatory documents/letter of consent It is proposed to be prepared according to FERCIT 's Template form : http://www.fercit.org/template.htm - Explanatory documents/letter of consent Please ensure that the sequence and details are the same in all institutions. By adjusting			

No.	document	have	do not have	Not relevant
	specific information for each institution, such as the name of the researcher, research location, committee of the institution, or other things such as travel expenses.			
Approval documents : Case Record Form				
7	Data recording form	✓		
Approval documents : Investigator's Brochure				
8	Investigational Drug: Investigator's Guide			
9	Investigational Drug: Certificate that the drug has passed the FDA.			
10	Investigational Drug: Drug invoice in the case of a drug that has already been registered with the FDA. Description : 1) In the case where the research drug is a drug that has already been registered with the FDA. The medicine invoice must also be attached.			
11	Medical Device: Technical file for medical device research project (AP 01-S 07)			
12	Medical Device: Details and characteristics of medical devices as specified by the manufacturer. Usage test results Safety testing in humans and animals according to the documents attached to the announcement.			
13	Medical Device: Manual for using medical equipment			
14	A document summarizing details and characteristics of medicinal plants or medicinal plant products. Test data for in vitro activity , toxicity data (if relevant)			
Approval documents : **Others Document**				
15	Questionnaire or interview		✓	
16	notebook			
17	Documents for inviting participation in research, such as brochures, posters, public relations scripts.			

No.	document	have	do not have	Not relevant
18	Other documents used with volunteers/research participants			
19	Other documents that must be certified			
Approval documents : Acknowledge Document				
20	Insurance documents to compensate for injuries from research			
21	Other documents Any other			
Documents for consideration				
22	(Draft) Material transfer agreement (MTA)			
23	(Draft) Research project budget			
Approval documents : Investigators				
24	CV & evidence of ethics training / GCP (in case there are no researchers in the system)			
25	Conflict of interest form of the principal investigator and co-investigator **(AP 06-S04)** * (Separate documents by institution)			
26	**Evidence of fee payment** *			

*Required documents (Require)

sign.....

inspector

Office staff

date .....