Research Proposal Completeness Check Form

Protocol Package Checklist Form

Research Protocol Title	(TH & EN)
Principal Investigator	Name: Affiliation: Email: Phone number:
Research Coordinator	Name: Email: Phone number:

No.	document	have	do not have	Not relevant
Invoice/ Proof of payment ** In the online submission system , documents are on the [Global] side.				
	1) this document is not present, it will be considered incomplete and will not be accepted for this document.			
Submission Letter & List of Documents ** In the online submission system , documents are on the [Global] side.				
	Book / Note for submitting research proposal Description : 1) In the memo section, it can be prepared according to the institution's format. 2) If there is no signed document, the document will be considered incomplete and will not be accepted for this document. 3) Upload documents in both word and pdf file versions.			
	List of Documents (AP08-S04) Description :			

No.	document	have	do not have	Not relevant
	1) this document is not present, it will be considered incomplete and will not be accepted for this document. 2) Upload documents in both word and pdf file versions.			
	AP09-S04_ICF checklist Description : 1) Research Project of the Internal Medicine Board and Pediatrics Board. If this document is missing, it will be considered incomplete and will not be accepted for this document.			
CREC Submission Form ** In the online submission system , documents are on the [Global] side.				
	Proposal for Ethical Consideration for Biomedical Research Projects (AP 04 - S04) or Proposal for Ethical Consideration of Human Research for Social/Behavioral Science Research Projects (AP 05-S04) Description : 1) If there is no signed document, the document will be considered incomplete and will not be accepted for this document. 2) Upload documents in both word and pdf file versions.			
Approval documents : Research protocol ** In the online submission system , documents are on the [Global] side.				
	Complete research outline Description : 1) If this document is not available, it will be considered incomplete and will not be accepted for this document.			
	Brief Thai version of the research outline Description : 1) In the case where the research project has a complete research outline English version: Please provide a brief Thai version of the research outline. In this regard, the			

No.	document	have	do not have	Not relevant
	protocol submission form from the EC of any institution in the research project can be prepared and submitted to CREC for consideration.			
Approval documents : Informed Consent Documents ** In the online submission system , documents are on the [Global] side.				
	Research participant information document / Letter of consent (in the case of English Master) Description : 1) a master English version of the explanatory document/consent letter that is not separated by each institution			
Approval documents : Informed Consent Documents ** In the online submission system , documents are on the [Site Specific] side.				
	Research participant information document / Letter of Intention (documents separated by institution) Description : 1) CREC does not have a form for the Statement of Intent/Consent. We suggest using the FERCIT Template : http://www.fercit.org/template.htm 2) The explanatory documents/intention letters should be arranged in the same order and details for all institutions, with adjustments to specific information for each institution, such as the name of the researcher, the research location, the institution's committee, or other information, such as travel expenses.			
Approval documents : Investigator's Brochure ** In the online submission system , documents are on the [Global] side.				
	Investigational Drug: A Researcher's Guide			
	Investigational Drug: A certificate certifying that the drug has been approved by the FDA.			

No.	document	have	do not have	Not relevant
	Investigational Drug: Drug invoice in the case of drugs that have 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 A prescription invoice must be attached.			
	Medical Device: Technical file for medical device research project (AP 01- S 07)			
	Medical Device: Details and characteristics of medical devices as specified by the manufacturer, results of usage tests, and safety tests in humans and animals, as per the documents attached to the announcement.			
	Medical Device: Medical Device User Manual			
	Document summarizing the details and characteristics of the herbal plant or herbal product, in vitro activity test data , toxicity data (if applicable).			
Approval documents : Case Record Form ** In the online submission system , documents are on the [Global] side.				
	Data recording form			
Approval documents : Research Tools ** In the online submission system , documents are on the [Global] side.				
	Questionnaire or interview			
	notebook			
	Documents for inviting research participation, such as brochures, posters, and public relations scripts.			
	Other documents used with volunteers/research participants			
	Description : 1) In case there are documents that are separated by each research center, upload them in the [Site Specific] section. Put it in the subfolder of each research center.			
Approval documents : Insurance				

No.	document	have	do not have	Not relevant
** In the online submission system , documents are on the [Global] side.				
	Certificate of Insurance			
Approval documents : Acknowledgement Document ** In the online submission system , documents are on the [Global] side.				
	Various documents for notification			
Supporting documents for consideration				
	(Draft) Material transfer agreement (MTA) Description : 1) In the case of sending specimens outside the research institution, please upload a (draft) Material transfer agreement (MTA) according to the form of each institution. 2) In case it is a single project document, upload it into the [Global] section. But if it is separated into each research center, upload it in the [Site Specific] side . Put it in the subfolder of each research center. 3) CREC Board will consider this document but will not endorse it.			
	(Draft) Research Project Budget Description : 1) In case it is a single project document, upload it into the [Global] section. But if it is separated into each research center, upload it in the [Site Specific] side . Put it in the subfolder of each research center. 2) CREC Board will consider this document but will not endorse it. Therefore, please send this document as well.			
Approval documents : Investigators ** In the online submission system , documents are on the [Site Specific] side.				
	CV & Ethics Training Evidence and GCP Description : 1) For uploading documents in the CREC online submission system , the officer will primarily consider documents from			

No.	document	have	do not have	Not relevant
	the “ List of Researchers ” section . If there is a researcher’s name in the “ List of Researchers ” section, No need to add anything else in this section. 2) Ethics training evidence for all researchers in the Biomedical research ethics course and Human subject protection 3) * In the case of projects that are clinical trials and/or interventions , Good Clinical Practice (GCP) training must also be used. ● / GCP training evidence, if an expiration date is specified, will be based on the specified date. If no expiration date is specified, it will be based on 3 years from the date of Certification or as determined by each institution. ● GCP training evidence must be submitted 6 months before the expiration date or as specified by each institution. If less than that, the office will request an updated version.			
	Conflict of Interest Form of Principal Investigator and Co-Investigator **(AP 06-S04)** * (Separate documents by institution) ** In the online submission system , documents are on the [Site Specific] side. Description : 1) If the documents are incomplete during the Initial Submission process , the application can be accepted, but CREC will not certify the researcher until the documents are complete. 2) Upload documents in the [Site Specific] section. Put it in the subfolder of each research center.			

*** Uploading research project documents

1) Please proceed according to the Instructions for submitting new project documents through the online submission system . If the officer checks and finds that it does not comply with the Instructions , it will be sent back for correction.
2) In the case where the research project coordinator is the one who submits documents into the CREC online submission system , every time the documents are to be submitted, the research project leader must confirm the submission of the project documents into the system every time. If the system shows the status of the research project as "Waiting for confirmation from the research project leader", it means that the submission is not complete and the CREC officer has not yet found the submission of that project.

sign ……..……

Auditor

Office staff

date.....