Responsible	activity	related form
Person Researcher/Research Coordinato	r 1. Check the qualifications of the research projects to apply for accreditation from CREC at	1.AO 01-S04
	https://crecthailand.org/Guide.php	2.AO 02-S04
	2. Research Project Document	3.AP 04-S04
	Preparation a.	4.AP 05-S04
	Complementing the certification from CREC in the form AO 01-S04 or AO 02-	5.AP 06-S04
	S04 (Only for IHRP-accredited research projects) b. List	6.AP 01-S07
	of documents Submitted in accordance with Form AO 01-S04.	7.AP02-S04 for PI
	c. For a clinical trial phase I / II, the preparation of	
	Additional Fo <mark>rm AP02-S04 for P</mark> I	
	3. Determining the date of submitting	
	documents a. Since CREC has 5 committees (panel) to consider projects that are	
	different expertise The committee in each panel has already set a fixed	
	meeting date for each month. Submitting project documents must submit	
	complete documents to the staff at least 20 days before the scheduled	
	meeting . want at https://crecthailand.org/schudule.php	
	4. How to submit project documents	
	a. Submission via the CREC Submission online system:	
	https://crec.submission-online.com/ b.	
	Submitting the documents as detailed below	
	5. Preparation of hard copy documents	

			_
	a. In some cases, hard copies may be requested by the officer, provided that the number		
	COPy of additional hard copies requested is subject to the Reviewer's		
	requirements. b. One hard copy document consisting of a project file and a CD containing		
	Project information in the amount of 1 sheet and request that the documents be placed		
	in the file properly. Sending documents to the office without putting a file Officers		
	must bring documents to put in. c. If the Local EC has a require, provide a hard copy		
	for evaluation.		
	Local Issue CREC will prepare the introduction letter and assessment form.		
	Local Issue will be sent to every Local EC by e-mail, which will be CCed to the researcher/		
	coordinator. The researcher/coordinator will bring the lead letter and the Local Issue		
	assessment form that has been attached with		
	package hard copy 6 <b>Fees</b>		
	a. Proof of fee payment must be attached with the project documentation. otherwise		
	Considered that the project documentation is incomplete. Learn more about the fees at		
	https://crecthailand.org/fee.php b. Fees		
	are in accordance with research funding sources. (government/private) and submission		
	type (Initial Submission / Amendment / Research Project Renewal).		
CREC office	Project Document Checker If the documents are incomplete Notify researchers/people	Processed within 2	1
	Coordinate research to request corrections or submit additional	business days (excluding t	the
	documents. 2. If complete, submit the project to the secretary team for consideration.	submit documents)	
	a. panel responsible for the project		

	b. Type of review (Full Board Review / Expedited Review /	
	Exemption Review), and	
	c. Reviewer committee	
	After consideration, proceed as follows:	
	a. Issuing the project code and	
	notifying the investigator b. Sending documents to the	
	Local EC for assessment of the Local Issue c.	
Researcher/Research Coordinator	Coordinating with the Reviewer and submitting the documents for	
	consideration Projects and types of consideration (Full Board Review / Expedited Review /	
	Exemption	
	Review) 2. Coordinate with the Local ECs requesting approval from	
	CREC to pay the fees or follow the procedures at each institution.	
	set	
	3. In the case that the project is considered as a Full Board Review, the round	
	Meeting to consider the project at https://crecthailand.org/schudule.php	

related form	
1. AO 01-S04	research proposal completeness check form
2. AO 02-S04	Research Proposal Completeness Check Form, in case of transfer from IHRP
3.AP 04-S04	Proposal for Ethical Consideration of Human Research for Biomedical Research Projects

4.AP 05-S04	Proposal for Ethical Consideration of Human Research for Social/Behavioral Science Research Projects
5.AP 06-S04	Conflict of Interest Form
6.AP 01-S07	Investigator's Brochure for Medical Device Study
7. AP02-S04 for PI	Local issues from institutions conducting clinical trial phase I, II for Head of Medical Device Study. research projects of each institution

#### Relevant

**Documents** 1. CREC 04 / v.4.0 Management of Protocol Submission 3. Announcement of the Foundation for the Promotion of Human Research in Thailand No. KMUTT 013/2564 regarding the submission of documents for consideration by the Central Committee. Research Ethics in Humans (2nd Edition)

## **Applied Document**

1

Books/records for submitting research proposals\*

#### Description:

- 1) In the part of the memorandum can be prepared according to the format of the institution But in the part of the list of documents, please sort by

  "Attachments (List of documents to be considered) Attached documents The agent will send back to ask to provide a list of documents according
  to the attached documents.
- 2) In the CREC submission online system, specify this item as "require", so if there is no document uploaded in the system in This item, the office will not be able to issue a project code.
- 3) If there is no signed document It will be considered that the documents are incomplete, and not allowed for this list of documents
- 4) Upload documents both word and pdf versions, 2 forms proposed for

ethical consideration. For biomedical research projects (AP 04-S04)\*

## Description:

- 1) In the part of the memorandum can be prepared according to the format of the institution But request that the content be complete according to the template as an example on the CREC website
- 2) In the CREC submission online system, specify this item as "require", so if there is no document uploaded in the system in This item, the office will not be able to issue a project code.
- 3) If there is no signed document It will be considered that the documents are incomplete, and not allowed for this list of documents
- 4) Upload both word and pdf versions of documents 3 letter of approval

#### from the primary supervisor\* (separate documents by institution)

#### Description:

- 1) Information in "Additional Information (*Please specify in Thai language*)", please complete, especially "Name of researcher at the institute All data repositories in Thailand", which must be a list of all researchers in the research project. including a list of researchers in Institutions that have not submitted through CREC as well, so that officials can acknowledge that Are there any researchers in the research project? They will not be contacted as a reviewer to consider the project. If there is no information in this section It will be considered that the documents are incomplete. and not allowed for This document
- 2) In the CREC submission online system, specify this item as "require". Therefore, if there is no document uploaded in the system in this list, the office will not be able to issue the project code (if there is none, please upload an empty file). completed in the Initial Submission process can be allowed But it must be prepared and submitted before the research project.

Get "Certified"

### Approval documents: Research protocol 4 Complete research

## protocol\*

#### Description:

1) In the CREC submission online system, specify this item as "require", so if there is no document uploaded in the system in This item, the office will not be able to issue a project code. 5 Thai abbreviated research outlines Description: 1) In case the research project has research outline English complete version Please provide a brief research outline. Thai language as well. The protocol submission form can be used from the EC of one of the institutions in the research project, to prepare and submit to CREC for consideration **Approval documents:** Informed Consent Documents 6 Documents explaining information about research participants / letter of consent (in the case of Master in English) Description: 1) In case the research project has Explanation document / letter of consent, master version in English, not separated according to each institution 7 Research Participant Information Document / Consent Letter (separate documents by institution) Description: 1) CREC does not have a form for Explanation document / Letter of consent It is proposed to be prepared according to the form. FERCIT Template: http://www.fercit.org/template.htm 2) Explanation document / Letter of consent Ask them to have the same order and details in all institutions. By adjusting the specific information of each institution, such as the name of the researcher, research place, committee of the institution or others such as travel expenses Approval documents: Case Record Form 8 data recording forms Approval documents: Investigator's Brochure 9 Investigational Drug: Researcher's Guide 10 Investigational Drug: Certification that the drug has passed the FDA 11 Investigational Drug: Invoice in case it is a drug that has been registered with the FDA. Description: 1) In case the research drug is a drug that has been registered with the FDA, the invoice must also be attached. 12 Medical Device: Technical file for medical device research projects (AP 01-S07). 13 Medical Device: Details and characteristics of the medical device as specified by the manufacturer. Usability test results

Safe in humans and animals according to the attachment attached to the announcement.

14 Medical Device: Manual for using medical devices

15 Dbcuments outlining details and characteristics of medicinal plants or medicinal plant products Ex vivo activity test data (in vitro), toxicity data (if applicable) **Approval documents: Others Document** 16 questionnaire or interview 17 Notebooks 18 Solicitation documents such as brochures, posters, publicity scripts 19 Other documents used by subjects/ participants 20 Other documents requiring certification **Approval documents:** Acknowledge Document 21 Research Injury Compensation Insurance Documents 22 other documents supporting documents 23 (Draft) Material transfer agreement (MTA) Description: 1) In case the specimen is exported outside the research institute, it is requested to upload (draft) Material transfer agreement (MTA) according to Forms for each institution 2) The CREC Committee will use this document for its consideration. but did not endorse this document 24 (Draft) Research Project Budget Description: 1) The CREC Committee will use this document for its consideration. but did not endorse this document, so please send this document as well **Approval documents:** Investigators 25 CV & Evidence of Ethics Training / GCP (If there is no researcher in the system) Description: 1) For uploading documents in the CREC submission online system, the officer will consider the documents from the section There is no รายชื่อผู้ร่วมวิจัย If there is a list of researchers in 2) a รายชื่อผู้ร่วมวิจัย need to add more to this section. clinical trial and/or an intervention, the Good Clinical Practice training course is required. (GCP) only 3) Evidence of Ethics Training / GCP if expiration date is specified will be based on the specified date If no expiration date is specified, 3 years from the date of certification 4) Evidence of ethics training / GCP must be submitted before the expiration of 6 months, if less than that, the office will request to send a copy. update

26 C	26 Conflict of Interest Form of the principal investigator and co-investigator (AP 06-S04)* (separate documents by institution).					
	Description:					
	1) In the CREC submission online system, specify this item as "require". Therefore, if there is no document uploaded in the system in this					
	list, the office will not be able to proceed with issuing the project code (if there is none, please upload an empty file 2). In					
	the Initial Submission stage, permission is allowed, but CREC will not certify that researcher.					
	until the documents are complete					
27 Ev	ridence of payment of fees*					
	Description:					
	1) In the CREC submission online system, specify this item as "require", so if there is no document uploaded in the system in					
	For this item, the Office will not be able to issue a project code. 2) Please					
	Tot this term, the office will not be able to issue a project code. 2) Thouse					
	complete the details of issuing receipt and delivery address. 3) If there is no evidence of					
	payment of fees. Please make a clarification letter and upload it.					
28. (	checking the completeness of research proposal AO 01-S04					
<b>29.</b> Al	P02-S04 for PI for clinical trial phase I / II					
	Description:					
	1) Added information in the part of PI's experience in clinical trial and study site personnel were trained in protocol.					
	training					
	PI's experience in clinical trial Number of clinical trials per year:					
	(ระบุชื่อหัวหน้าโครงการวิจัยประจำสถาบัน) Type of clinical trial: (phase 1-4 ระบุจำนวนที่ทำในแผ่ละ phase)					
	Phase I,					
	Phase II,					
	Phase III,					
	Phase IV,					
	Study site personnel มีการอบรม protocol training					
	2) Study site personnel protocol training – protocol training is provided to researchers in research projects. Institution or when, so that all					
	researchers have an understanding of the research project. and carry out research projects					
	the same way					
	3) The project leader's signature is not required. The office will use the information in this section to send to the Local EC for local assessment.					
	Issue					

1) Please follow the Instructions for submitting new project documents through the submission online system from pages 10 – 18. If the officer inspects and finds that the instructions are not in accordance with the Instructions, they will be sent back for corrective action.

<sup>\*</sup>Required documents (Require)

<sup>\*\*\*</sup>Uploading research project documents

(https://crecthailand.org/download/(Draft)Handout%20Submission%20online-Rerearcher\_V.1-

01122021.pdf)

2) In case that the research project coordinator submits documents to the CREC submission online system, every time the document is submitted,

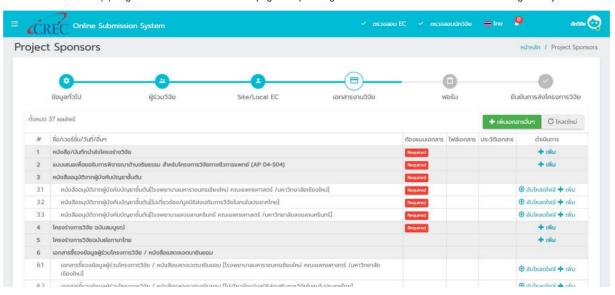
the research project leader Must press to confirm submitting project documents in the system every time. If in the system, the

status of the research project "Awaiting Confirmation from Research Project Leader" indicates that the submission is not complete.

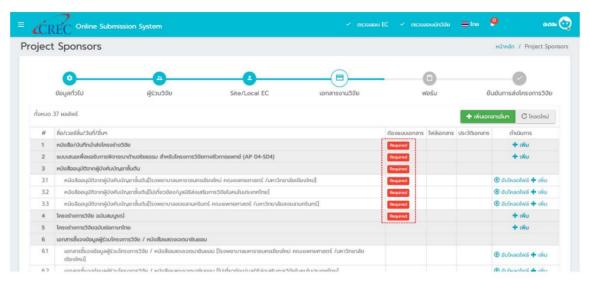
CREC has not found any submissions for that project.

Uploading research project documents in the CREC Submission online system

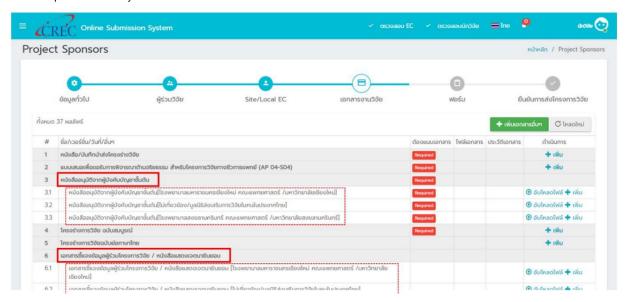
(1) Page "Research Documents" is a page for uploading documents that need to be submitted through the system.



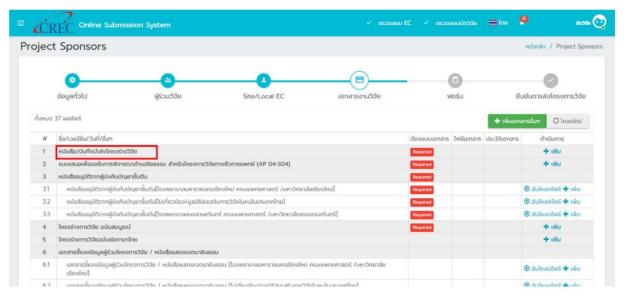
1. Require means documents that must be uploaded in that topic. If there is no system, it will be considered that the document is incomplete. Even if there is a push to submit the document, the CREC staff will not be able to press pass to issue the project code, which is considered complete documents



2. Documents on certain topics, such as approval letters from primary supervisors information sheet research project participants Letter of consent will be displayed by default for each site automatically. Please upload documents to match the site specified in the system.

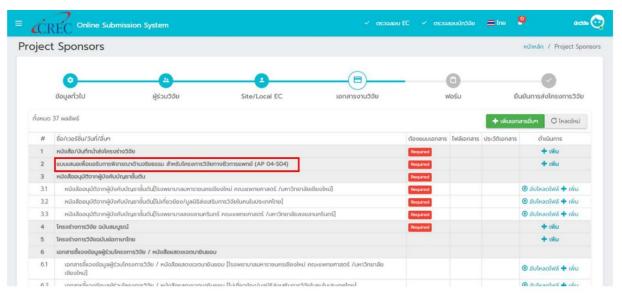


3. Item 1, "Research Project Submitted Book/Record", request to provide a list of documents according to the template, both in word file and PDF format.

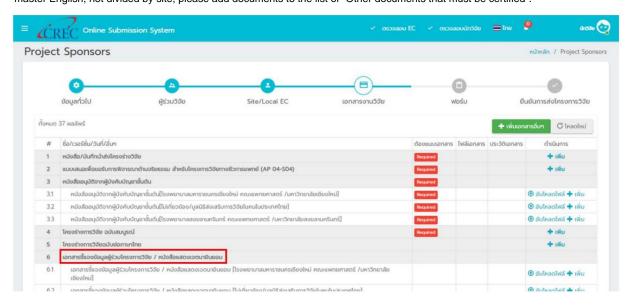


4. Item 2 "Proposal Form for Ethics Consideration For Biomedical Research Program (AP 04-S04)" Please

upload both word and PDF files.

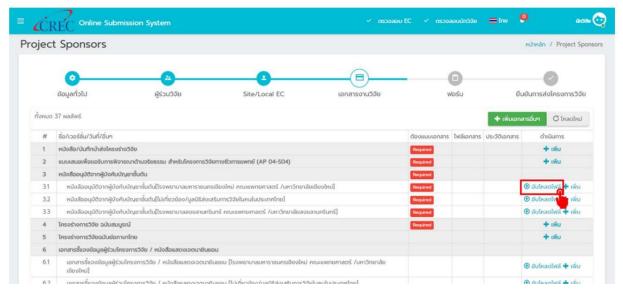


5. In the event that the research participant information clarification document/consent letter has a version that is master English, not divided by site, please add documents to the list of "Other documents that must be certified".

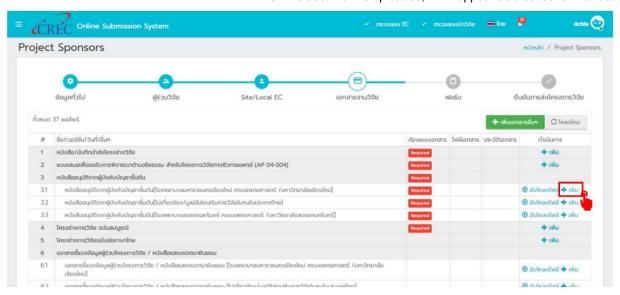


#### 6. Adding documents to each list

document list, with the document name as specified by default.

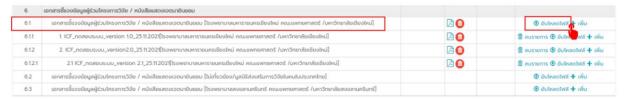


2) Click + 📆 When the document is uploaded, it will appear as a subset of that document. ...

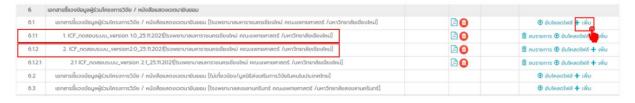


#### Example of a list of documents attached through the system

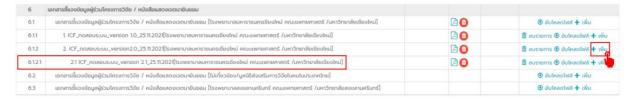
1. When click o julisaciwa In item 6.1, the document appears in item 6.1.



2. When Click • wu In item 6.1, the document appears in tabs 6.1.1 and 6.1.2.



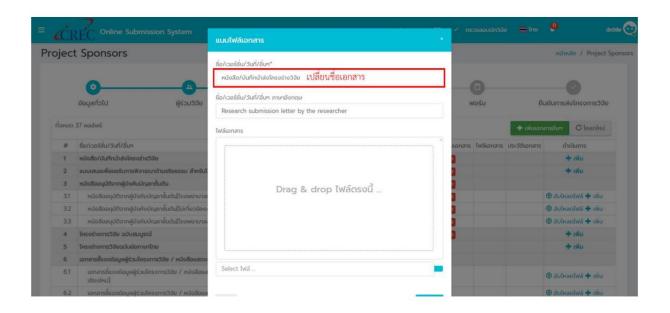
3. When Click + www In item 6.1.2, the document appears in item 6.1.2.1.



7. Attaching documents for 🔸 🛍 Ask to change the name in the box. "Name/Version/

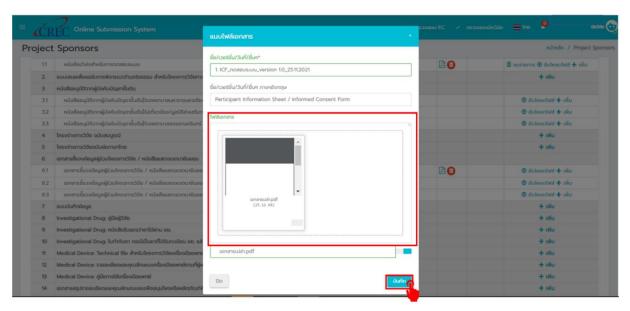
Date/Other" to appear in the system. In order to know which document is which document is

because Submit information will be forwarded to the Local EC and the review committee.

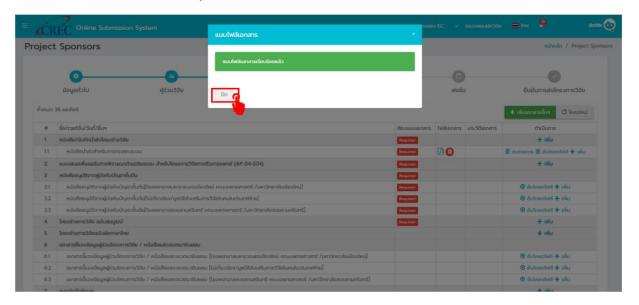


Upload the document in the box "Drag & Drop the file here" when uploading the document Click

"record"

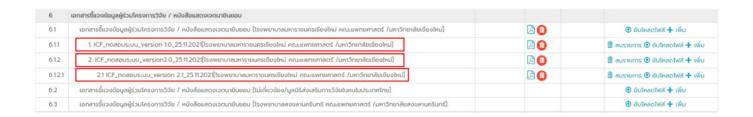


window system "Attach a document file" click "Close"



#### Example of a list of documents uploaded through the

system 1. Example of changing the name of the document in the box "Name/Version/Date/Other"



2. Example of not changing the name of the document in the box "Name/Version/Date/Other"

