

SENARAI SEMAK DOKUMEN (PROJEK PERCUBAAN KLINIKAL (SPONSOR))
(Document Submission Checklist (Clinical Trial (Sponsored)))

Sila sertakan dokumen yang disenaraikan dibawah dalam format MS. word. Tandakan dengan (√) bagi dokumen yang disertakan. Mohon mengemukakan semua dokumen berkaitan dalam salinan lembut ke:

Please enclose the following documents belowin MS. Word format. Indicate with a (√) if enclosed. Please submit documents in soft copy to: sepukm@ukm.edu.my

Research Title			
Principal Investigator	Name	Contact Number	Email

Investigator's documents	Explanatory notes	Total document			
		Investigator		RECUKM	
1. Curriculum Vitae	A summary of the investigator's education, professional history, and job qualifications or other documentation evidencing the investigator's qualifications. (Updated CV)	State Number of Curriculum Vitae			
2. GCP certificate	The certificate indicating successful participation in a Malaysian GCP workshop. The certificate is issued upon successful completion of the workshop exit exam Investigator is required to submit his or her GCP certificate unless he or she qualifies for "grandfather" status. The RECUKM will check the validity this claim.	State Number of GCP certificate			
Research documents	Explanatory notes	Tick (√)		Tick (√)	
3. Checklist	<i>UKM-JEP-SS02_Senarai Semak dokumen (projek percubaan klinikal_sponsor)</i>				
4. Covering letter	A letter accompanying a submission to explain the purpose of the submission				
5. UKM-JEP-BO01	UKM-JEP-BO01 - UKM Research Ethics Committee Application Form				
6. UKM-JEP-BO02	UKM-JEP-BO02 - UKM Research Ethics Committee Review Form (In Ms. Word Format)				
7. UKM-JEP-BO08	UKM-JEP-BO08 - UKM Research Ethics Committee Conflict of Interest Form				
8. Study Protocol / Proposal	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a research. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.				
9. Study Summary/ Synopsis	<i>A brief document that describes the rationale, objective(s), design, methodology, statistical considerations, and organization of a proposed research.</i> <i>Refer: Proposal format_checklist item that should include in the Proposal</i>				
10. Investigator's brochure	A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (ICH GCP 1.36)				
11. Information sheet	Document containing information about research intended for prospective research subject. Required in English and Bahasa Malaysia languages	English		English	
		Malay		Malay	
		Chinese		Chinese	
		Tamil		Tamil	
		Others		Others	
12. Informed Consent Form	Form to document subject's consent to participate in the research. Required in English and Bahasa Malaysia languages.	English		English	
		Malay		Malay	
		Chinese		Chinese	
		Tamil		Tamil	
		Others		Others	

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13.	Trial indemnification: Insurance / Letter of indemnity	Insurance or letter from sponsor to indemnify (legal and financial coverage) the investigator and institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.						
14.	CRF/e-CRF	Case report forms contain data obtained during the patient participation in the clinical trial.						
15.	Questionnaires	<i>Questionnaires contain data obtained during the patient participation.</i>						
16.	Clinical Trial Agreement (CTA)	A Clinical Trial Agreement (CTA) is a legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.						
17.	NMRR Registration	Proof of registration (e-mail or letter) with NMRR registration number is required.						
18.	*Diary card	<i>Subject Diary contain data obtained during the patient participation in the clinical trial.</i>						
19.	*Advertisement	Advertisement for subject recruitment						
20.	*Approval other EC	<i>Approval from other EC contain decision and comment about the research.</i>						
21.	*A Clinical Trial Import License	<i>Clinical Trial Import License (CTIL) / Clinical Trial Exemption (CTX)</i>						
22.	Hard copies all the above documents	<i>Hard copies for all document listed above. To be submit when received feedback email from the RECUKM.</i>						
23.	A copy proof of payment for application RECUKM approval	<p><i>Payment to CIMB ISLAMIC BERHAD account no: 8600081140 (UNIVERSITI KEBANGSAAN MALAYSIA)</i></p> <table border="1"> <thead> <tr> <th>Jenis Permohonan</th> <th>Kadar (RM)</th> </tr> </thead> <tbody> <tr> <td>Industri (Sponsor) (Percubaan Klinikal - Sponsor luar UKM)</td> <td>1,000.00</td> </tr> </tbody> </table> <p><i>Jenis permohonan bagi Pegawai / Pelajar adalah termasuk warga dan bukan warga UKM</i></p> <p><i>*Refer Guidelines UKM-JEP-GP02_Garis Panduan Mengisi Borang Permohonan (Attachment B) at JEPUKM website: https://www.ukm.my/jepukm/</i></p>	Jenis Permohonan	Kadar (RM)	Industri (Sponsor) (Percubaan Klinikal - Sponsor luar UKM)	1,000.00		
Jenis Permohonan	Kadar (RM)							
Industri (Sponsor) (Percubaan Klinikal - Sponsor luar UKM)	1,000.00							

*If Applicable

Receiver:

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Name:

Date: