Research Ethics Committee Universiti Teknologi MARA 40450 SHAH ALAM



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Flowchart II: Research Ethics Approval Application for More than Minimal Risk (MMR) Research

Flow	Process/ Activity	Record/reference	Personnel	Timeline
	 Complete and submit the relevant ethics approval application forms to the JPF/JPN secretariat: Application Form for Ethics Approval (REC 2). Research Risk Classification Form (REC 3). Subject Information Sheet (REC 4) and Assent form (REC12) (if applicable). Checklist for Applicants (REC 5). OR Application of Exemption from Ethical Review (REC 11) (if applicable). 	Forms: REC 2,3,5 and 4/and 12 Form: REC 11 (if applicable)	Applicants	
	Screening of REC 2,3,5 and 4/and 12 or REC 11 forms JPF/JPN secretariat to submit completed forms (softcopy) and related documents to REC secretariat by uploading at the following link: https://forms.gle/KdyiNMNsLT2UR6fL7 or email <u>recuitmsubmit@gmail.com</u> Submission to REC at least two (2) weeks before the subsequent meeting (3 rd Tuesday of each month).	Cover letter from JPF/JPN Forms REC 2,3,5 and 4/and 12 or REC 11 (softcopy). Other relevant documents.	JPF/JPN secretariat	Within 14 working days upon submission*

	Screening of REC 2,3,5 and 4 /and 12 or REC 11 forms	Forms REC 2,3,5 and 4 /and 12 or REC 11. Other relevant documents.	REC Secretariat	7 working days*
	 Full board presentation by applicants to REC committee i. Approve ii. Conditional Approval: Minor corrections: Amendments within one (1) month. Major corrections: Amendments within three (3) months. iii. Reject 	Forms REC 2,3,5 and 4/12 or REC 11. Other relevant documents.	Applicants, REC Committee	3 rd Tuesday of each month
	Notification to the applicants	Notification of decision via email	REC Secretariat	14 working days

*Considering no amendments required

Terms of Submission of Ethics Approval Application

- 1. All incomplete forms will be returned.
- 2. Only approved applications by JPF/JPN will be submitted to REC.
- 3. Any data collection instruments requiring respondent/subject/participant input must be prepared in both Malay and English languages, and other language(s) understood by the respondent/subject/participant (if necessary)
- 4. Submission of Research Completion Report Form (REC 8 form) within 2 months upon completion of research.

Terms of condition for Clinical Trials

1. Submission of Monitoring of Ongoing Studies Form (REC 6 Form) every 6 or 12 months upon approval.