#### 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
	<ul> <li>Complete and submit the relevant ethics approval application forms to the JPF/JPN secretariat: <ol> <li>Application Form for Ethics Approval (REC 2).</li> <li>Research Risk Classification Form (REC 3).</li> <li>Subject Information Sheet (REC 4) and Assent form (REC12) (if applicable).</li> <li>Checklist for Applicants (REC 5).</li> </ol> </li> <li>OR</li> <li>Application of Exemption from Ethical Review (REC 11) (if applicable).</li> </ul>	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 <sup>rd</sup> 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*
	<ul> <li>Full board presentation by applicants to REC committee <ul> <li>i. Approve</li> <li>ii. Conditional Approval:</li> <li>Minor corrections: Amendments within one (1) month.</li> <li>Major corrections: Amendments within three (3) months.</li> </ul> </li> <li>iii. Reject</li> </ul>	Forms REC 2,3,5 and 4/12 or REC 11. Other relevant documents.	Applicants, REC Committee	3 <sup>rd</sup> 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.