## **Research Ethics Committee** Universiti Teknologi MARA

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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/JEK secretariat:  1. Research Ethics Depository (RED) System  • PART A: Project Details  • PART B: Member (s)  • PART C: Research Risk  • PART D: Participation Form  • PART E: Supporting Documents  • PART F: Endorsement  OR	RED System: PART A – E	Applicants	
	Application of Exemption from Ethical Review (REC 11) (if applicable).	manual application – not via RED system		
	Screening of application through RED (PART A – E) or REC 11 forms  JPF/JPN/JEK secretariat to verify the application through RED (PART A – E)  Note: To verify after all necessary corrections are done by applicants  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  RED System (PART A – E) or REC 11 (softcopy). Other relevant documents.	JPF/JPN/ JEK secretariat	Within 14 working days upon submission*

Screening of (PART A – E) in RED System	RED System (PART A – E)  Other relevant documents.	REC Secretariat	14 working days*
Reviewing process and feedback by the primary reviewer:	RED System (PART A – E) or REC 11 (softcopy).  Other relevant documents.	REC Members/ Associate Members	14 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	RED System (PART A – E) or REC 11 (softcopy).  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

<sup>\*</sup>Considering no amendments required

## **Terms of Submission of Ethics Approval Application**

- 1. All incomplete forms will be returned.
- Only approved applications by JPF/JPN will be submitted to REC.
   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. Please keep in mind that required amendments will need additional processing time.
- 5. The timeline of each process is subjected to the application workload of the month.
- 6. 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.