

Definition of Data elements required for submission to NMRR

\* Indicates data is required for submission

#	Fields	*	Definition
	<i>Title, Identification and Study organization</i>		
1.	Research Title	*	Research official title
2.	Abbreviated research title	*	Abbreviated project title, limited to 50 characters
3.	Purpose of submission on NMRR	*	Select purpose of submission, may be for one or more of the following : <ul style="list-style-type: none"> <li>• Research registration (this is mandatory as required by current MOH guideline)</li> <li>• Research submission to NIH for approval</li> <li>• Research submission to NIH for MREC review &amp; approval</li> <li>• Research submission to NIH for MRG application</li> <li>• Research publication submission to NIH for DG approval</li> <li>• Research notification to IRB/IECs</li> <li>• Research notification to Clinical Trials &amp; Compliance Section NPCB</li> </ul>
4.	Sponsor(s)	*	Research sponsoring organization(s)
5.	Sponsor type	*	May be either Industry sponsored or Investigator initiated study
6.	Funding sources	*	The sources of funding for research . May be <ul style="list-style-type: none"> <li>• Industry grant</li> <li>• International grant</li> <li>• MOH grant</li> <li>• Government(non MoH ) grant</li> <li>• University research grant</li> <li>• Self funding</li> <li>• MOSTI grant (any type)</li> <li>• others</li> </ul>
7.	Investigator(s)	*	Name of participating investigator(s) and their institutions
8.	Project team		Name of project staff, such project manger, CRA/monitor, statistician, data manager, safety surveillance associate, IT support staff etc
9.	NIH Institute(s)	*	This is applicable only if the research is supported or is to be conducted in collaboration with one or more of the research organizations (IMR, CRC, IPH, IHSR, IHM, and IHP) under the NIH MOH that is supporting or collaborating in this research.
	<i>Research details</i>		
10.	Student Academic Project (university/collage)	*	Indicate whether the proposed research constitute part of a student's academic work leading to an academic degree such as Bachelor , Master, or PhD
11.	Type of Research	*	Type of research maybe: 1. Biomedical research: research conducted primarily in lab setting

			<p>involving use of animals or biological specimen</p> <p>2. Clinical research: research conducted primarily in clinical setting involving patients or human volunteers as research subjects</p> <p>3. Community research: research conducted primarily in community setting involving patients or human volunteers as research subjects</p> <p>4. Health Economics research</p> <p>5. Health Social science/ Behavioral research</p> <p>6. Health management or system research</p> <p>9.Others</p>
12.	Subtype of Research	*	<p>Sub-Type of research.</p> <p>For Clinical research:</p> <p>7. Interventional: studies in human beings in which individuals are assigned to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed</p> <p>8. Observational: studies in human beings in which biomedical and/or health outcomes are assessed in a pre-defined group of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study</p> <p>9.Others</p>
13.	Research purpose	*	Brief description of research purpose
14.	Research description	*	Brief description of research design and method
15.	URL		<p>A Web site directly relevant to the research may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services.</p> <p>Links to educational, research, government, and other non-profit Web pages are acceptable.</p> <p>Provide complete URL, including http://</p>
16.	Keywords		<p>Words or phrases that best describe the research. Keywords help users find studies in the database.</p> <p>Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate.</p> <p>Be as specific and precise as possible. Avoid acronyms and abbreviations</p>
17.	Date start	*	Expected or actual date that enrollment to the research begins
18.	Date completed	*	Expected or actual date that analysis is concluded for the research
19.	Ministry of Health 9MP Health Research Priority Areas		<p>Please refer to the Ministry of Health Research Priorities for the 9th Malaysia Plan as in <a href="http://www.nih.gov.my">www.nih.gov.my</a></p> <p>CAM Disease / Cross Cutting Group</p> <p>Research Scope</p>

	being addressed		Relative rank
21.	Potential benefits of the project :		Please identify clearly, the potential customers / beneficiaries of the research findings and provide details of their relevance to the health services. If this is a directed / requested research, please name the health service provider involved
23.	Risks of the project		Please describe the factors that may cause delays in, or prevent implementation, of the project as proposed above; estimate the degree of risk
25.	Anticipated project duration		Indicate the planned starting date of the project and the elapsed time, in months, to complete the project. Do not include time for preparation of publication
27.	Research background of the project		Please indicate if the project is new, modification, or extension. Give a summary of your literature review and related research to indicate originality and feasibility of proposed research. If modification, indicate why modification is required. If extension, indicate findings of previous research project and why extension is required).
29.	Costing Details		worksheet
31.	Title of Publication		Publication official title
33.	Title of Presentation		Presentation official title
35.	Potential users of research findings, please check one or more :		Targeted users or readers for recommend the publication.
37.	Author List		Name of authors and their institution
<i>Additional details for Clinical research only</i>			
39.	Recruitment status	*	Overall research accrual activity for the research. Select one. 1. Not yet recruiting: participants are not yet being recruited or enrolled 2. Recruiting: participants are currently being recruited and enrolled 3. No longer recruiting: participants are no longer being recruited or enrolled 4. Completed: participants are no longer being recruited; data analysis is complete 5. Suspended: recruiting or enrolling participants has been halted but potentially will resume 6. Terminated: recruiting or enrolling participants has been halted and will not resume
40.	Condition	*	Primary disease or condition being studied, using the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary. The condition field is used to index studies in the register

41.	Eligibility	*	Summary criteria for participant selection Copy and paste Inclusion and Exclusion criteria of the research here
42.	Gender	*	Physical gender of individuals who may participate in the research. Select one. 1. Both: both female and male participants are being studied 2. Female: only female participants are being studied 3. Male: only male participants are being studied
43.	Age limit	*	Minimum Age Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no minimum age is indicated.  Maximum Age Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no maximum age is indicated.
44.	Acceptable Participant	*	Accepts Healthy Volunteers? Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.
45.	Target Number of Subject	*	Estimated number of participants to be studied
46.	Target Number of Subject in Malaysia	*	Estimated number of participants to be studied from Malaysia
<i>Research details for Clinical trial only</i>			
47.	Intervention	*	Specific name of intervention under investigation
48.	Intervention Type	*	Intervention Type. Select one per intervention studied 1. Drug 2. Gene Transfer - including gene transfer and recombinant DNA (e.g., Human nerve growth factor) 3. Vaccine 4. Behavior (e.g., Protein and calorie controlled diet; Self-hypnotic relaxation) 5. Device (e.g., Defibrillators, implantable; Electronic medication reminder system) 6. Procedure (e.g., Adenoidectomy; Bronchoalveolar lavage)
49.	Therapy Area	*	Therapeutic area of trial Example: Nephrology, Neurology etc.
50.	Study Phase	*	Phase of clinical trial. Select only one. 1. Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients

			<ol style="list-style-type: none"> <li>2. Phase 1/Phase 2: for trials that are a combination of phases 1 and 2</li> <li>3. Phase 2: includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks</li> <li>4. Phase 2/Phase 3: for trials that are a combination of phases 2 and 3</li> <li>5. Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling</li> <li>6. Phase 4: post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use</li> <li>7. N/A: or trials without phases, such as expanded access trials or registries. Used rarely</li> </ol>
51.	Purpose of Clinical trial	*	<p>Purpose of trial. Select one.</p> <ol style="list-style-type: none"> <li>1. Treatment: research designed to evaluate one or more interventions for treating a disease, syndrome, or condition</li> <li>2. Prevention: research designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition</li> <li>3. Diagnosis: research designed to evaluate one or more interventions aimed at identifying a disease or health condition</li> <li>4. Educational/Counseling/Training: research designed to assess one or more interventions in an educational, counseling, or training environment</li> </ol>
52.	Allocation	*	<p>Participant selection. Select one.</p> <ol style="list-style-type: none"> <li>1. Randomized Controlled Trial: participants are assigned to intervention groups by chance</li> <li>2. Nonrandomized Trial: participants are expressly assigned to intervention groups</li> </ol>
53.	Masking	*	<p>Knowledge of intervention assignments. Select one.</p> <ol style="list-style-type: none"> <li>1. Open: no masking is used. All participants involved know the identity of the intervention assignment.</li> <li>2. Single Blind: participants are unaware of the intervention assignment; investigators are aware.</li> <li>3. Double Blind: both participants and investigators are unaware of the intervention assignment</li> </ol>
54.	Control treatment	*	<p>Nature of the intervention control. Select one.</p> <ol style="list-style-type: none"> <li>1. Placebo: participants may receive only placebo throughout the course of the research</li> <li>2. Active: participants may receive some form of treatment (e.g.,</li> </ol>

			<p>standard treatment) in place of the intervention under investigation</p> <ol style="list-style-type: none"> <li>3. Uncontrolled: no controls are used</li> <li>4. Historical: the control consists of results from past studies</li> <li>5. Dose Comparison: participants may receive one of several doses of the intervention</li> </ol>
55.	Assignments	*	<p>Study configuration and intervention assignments. Select one.</p> <ol style="list-style-type: none"> <li>1. Single Group: all participants receive the same intervention throughout the research</li> <li>2. Parallel: participants receive an intervention throughout the research</li> <li>3. Cross-over: participants may receive different interventions sequentially during the research</li> <li>4. Factorial: participants may receive no intervention, some intervention, or multiple interventions simultaneously</li> <li>5. Expanded Access: includes treatment IND research</li> </ol>
56.	Endpoint	*	<p>Overall outcome that the research is designed to evaluate. Select one.</p> <ol style="list-style-type: none"> <li>1. Safety: show if the drug is safe under conditions of proposed use</li> <li>2. Efficacy: measure of an intervention's influence on a disease or health condition</li> <li>3. Safety/Efficacy</li> <li>4. Bio-equivalence: scientific basis for comparing generic and brand name drugs</li> <li>5. Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body</li> <li>6. Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound</li> <li>7. Pharmacodynamics: action of drugs in living systems</li> <li>8. Pharmacokinetics/dynamics</li> </ol>
57.	Outcome measure	*	<p>Specific measurements or observations used to measure the effect of experimental variables in a study.</p> <p><b>Primary Outcome Measures</b>  The specific measure that will be used to determine the effect of the intervention(s). The description should include the time at which the measure will be taken.  Examples: all causes of mortality at one year; score on a depression rating scale at 6 weeks</p> <p><b>Secondary Outcome Measures</b>  Other measures that will be used to evaluate the intervention(s), and that are specified in the research. The description should include the</p>

			time at which the measures will be taken. Examples: cardiovascular mortality at 6 months; functional status at 4 weeks
<i>Research details for observational research only</i>			
58.	Disease area	*	Choose one disease area of research being studied. Select most relevant one from list provided
59.	Purpose	*	Reason for the research. Select one 1. Natural History: research designed to investigate a disease or condition through observation under natural conditions (i.e., without intervention) 2. Screening: research designed to assess or examine persons or groups in a systematic way to identify specific markers or characteristics (e.g., for eligibility for further evaluation) 3. Psychosocial: research designed to observe the psychosocial impact of natural events
60.	Sample selection	*	Sampling design or sample selection 1. Convenience Sample: participants or populations are selected due to ease of recruitment 2. Defined Population: participants or populations are selected based on predefined criteria 3. Random Sample: participants or populations are selected by chance 4. Case Control: participants or populations are selected to match the control participants or populations in all relevant factors except for the disease; only the case participants or populations have the disease
61.	Length of study	*	Length of research. Select one. 1. Longitudinal: studies in which participants are evaluated over long periods of time, typically months or years 2. Cross-sectional: studies in which participants are evaluated at one point in time or over short periods of time
62.	Timing of study		Time of research 1. Retrospective: a research that observes events in the past 2. Prospective: a research that observes events in real time (may occur in the future) Both: a research that combines retrospective and prospective observation
<i>Research documents</i>			
65.	Covering Letter		A letter accompanying a submission to explain the purpose of the Submission
67.	Covering Letter to MREC		This is a formal signed cover letter from the Principal Investigator to the MREC Secretariat with list of all Investigators and their roles, participating sites and all documents for MREC approval. Please state reasons if any waiver is requested

69.	Study Proposal	A brief document that describes the rationale, objective(s), design, methodology, statistical considerations, and organization of a proposed research. Required if no protocol is submitted
71.	Study Protocol	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. Required for all research submitted to MREC.
73.	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) Required for clinical trial only.
75.	Informed Consent Form	Form to document subject's consent to participate in the research. Required in English, Bahasa Malaysia and Mandarin languages Required for all human subject research
77.	Study CRF	Clinical Report form is a document used to record protocol-required information for each subject in the study
79.	Patient's diary	A patient takes the medication according to the treatment schedule will measure treatment compliance.
81.	Questionnaire	Questionnaire that will be distributed to respondents or patients during trial
83.	Advertisement	Advertisement for subject recruitment Required for clinical trial only.
85.	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. Required for clinical trial only.
87.	Research Agreement / Clinical Trial Agreement (CTA)	A written, dated, and signed agreement between a non-MOH party (such as industry sponsor, university and other collaborators) on the one hand, and the MOH investigator and authorized MOH signatory on the other, that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters Required where applicable only.
89.	Draft of research report, manuscript or abstract	Rresearch report, journal article or abstract for scientific meeting by MOH personnel or research funded by MOH research grant. Required for publications
91.	Research Grant:	Research Grant: Costing worksheet (in EXCEL). Alternatively,

	Costing worksheet		attach the completed JTP-KKM3 ver1.1 form
93.	Project Activity		Project activities (include Project activities list, Gantt chart, key milestone, project schedule)
	<i>Investigator's documents</i>		
96.	Curriculum Vitae		Investigator is required to submit his or her CV
98.	GCP certificate		Required for Clinical Trial only. Investigator is required to submit his or her GCP certificate unless he or she qualifies for "grandfather" status. The MREC will check the validity of this claim.
100.	IA-HOD-IA		Submit scanned copy of the signed and dated "Investigator's agreement, Head of Department's and Institutional approval" document (IA-HOD-IA) (Persetujuan Penyelidik, Pengesahan Ketua Jabatan dan Institutsi)
102.	Prof. Indem.		Submit valid professional indemnity certificate. Required for clinical trial only This refers to Insurance or letter from investigators or SMO to indemnify (legal and financial coverage) the sponsor and institution against claims arising from the trial due to professional malpractice and/or negligence