Definition of Data elements required for submission to NMRR

* Indicates data is required for submission

*/- Indicates data or documents may be/ may be not required for submission (depending on research types or certain circumstances)

#	Fields	*	Definition
			General Study Information
1.	Submission Type	*	ISR: Industry Sponsored Research IIR: Investigator Initiated Research
2.	Research Title	*	Research official title
3.	Public Title	*	Research title intended for the lay public in easily understood language
4.	Research Title Abbreviation	*	Abbreviated Research title (Acronym or Abbreviation)
5.	Protocol ID		Identification no assigned to a protocol document (eg : For IIR, it should be stated as Version 'x' , dd/mm/yy)
6.	Research Scope	*	• Basic Science/Biomedical • Clinical • Health Management • Health Economic • Health Governance /Policy • Public Health/Epidemiology • Social Science /Behavioral Science

7.	Research Type	*	• Interventional
			  ○ Bioavailability/ Bioequivalent Study
			  ○ Clinical Trial (MGCP definition)
			  ○ Interventional Study (Other than clinical trial)
			  ○ Quasi Experimental/ Pilot Project/ Feasibility Study
			• Observational
			  ○ Case Study/Case Series
			  ○ Cross Sectional
			  ○ Cohort
			  ○ Case Control
			  ○ Case Cross-Over
			  ○ Ecological/Community
			  ○ Family Based
			  ○ Others
			• Qualitative
			• Mixed Method (Both Observational & Qualitative)
			• Proof of Concept/Theoretical Research
			• Applied Research (Biology, Cell-Based, Animal Study, Genetic, Physiology and etc2)
			• Registry/Biobanking/Clinical Database
			• Clinical Audit*/ Quality Assurance/Quality Control (Clinical Audit is defined as systematic critical analysis of

			the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome. **It measures against standards clinical care / practice**)
			• Systematic Review/ Scoping Review/Rapid review/Meta-Analysis/Meta-Synthesis
			• Special Write Up
			  ○ Article
			  ○ Journal Review
			  ○ Book/Chapter

Additional Information for Interventional			
8.	Research Sub-type	*	• Bioavailability/ Bioequivalent Study • Clinical Trial (MGCP definition) • Interventional Study (Other than clinical trial) • Quasi Experimental/ Pilot Project/ Feasibility Study
9.	Secondary ID	*	An identifier(s) other than the organization's Unique Protocol Identification Number that is assigned to the clinical trial. This includes any unique clinical study identifiers assigned by other publicly available clinical trial registries. (e.g.: Universal Trail Number UTN, Primary Registry of ICTRP, ISRCTN, Clinicaltrials.gov NCT and etc2)
10.	Study Phase	*	Phase of clinical trial. Select only one. • Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effectsassociated with increasing doses, and to gain early evidence ofeffectiveness; may include healthy participants and/or patients • Phase 1/Phase 2: for trials that are a combination of phases 1 and 2 • 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 • Phase 2/Phase 3: for trials that are a combination of phases 2 and 3 • 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 • Phase 4: post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use • N/A: or trials without phases, such as expanded access trials or registries. Used rarely

11.	Interventional Allocation	*	Participant selection: • Randomized Controlled Trial (RCT): participants are assigned to intervention groups by chance • Nonrandomized Trial (Non-RCT): participants are expressly assigned to intervention groups • N/A: Not Applicable
12.	Study Assignment	*	Study configuration and intervention assignments: • Single Group: all participants receive the same intervention throughout the research • Parallel Group: participants receive an intervention throughout the research • Cross-over Group: participants may switch to a different intervention at a time point (phase) during the research • Factorial: participants may receive no intervention, some intervention, or multiple interventions simultaneously • Sequential: participants may receive different interventions sequentially (on prior milestones being reached) during the research

13.	Study Arm	*	Description of group or nature of interventions
			• Type of Arm
			  ○ Experimental
			  ○ Active Comparator
			  ○ Placebo Comparator
			  ○ Sham Comparator
			  ○ No intervention

14.	Masking/Blinding	*	Description of the party(ies) involved in the research who are being prevented from having knowledge of the interventions assigned to individual participants: • Open Label • Single Blinded • Double Blinded • Triple Blinded • Others (to specify)
15.	Study Purpose	*	The main objective of the intervention(s) is being evaluated by the research. • Treatment: interventions are being evaluated for treating a disease, syndrome, or condition. • Prevention: interventions are being assessed for preventing the development of a specific disease or health condition. • Diagnostic: interventions are being evaluated for identifying a disease or health condition. • Supportive Care: interventions are evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the participant's health or function. • Screening: interventions are assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor.

			• Health Services Research: interventions for evaluating the delivery, processes, management, organization, or financing of healthcare. • Basic Science: interventions for examining the basic mechanism of action (for example, physiology or biomechanics of an intervention). • Device Feasibility: An intervention of a device product is being evaluated in a small numbers to determine the feasibility of the product; or a trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. • Others (to specify)
16.	Investigational Product (s) (IP)	*	Description of the intervention(s) studied in each arm of research.
17.	IP Type	*	The general type of intervention: • Drug: Including placebo • Device: Including sham, MDA approved, non-MDA approved • Biological/Vaccine • Procedure/Surgery • Radiation • Behavioral: For example, psychotherapy, lifestyle counseling • Genetic: Including gene transfer, stem cell and recombinant DNA • Dietary Supplement: For example, vitamins, minerals • Combination Product: Combining a drug and device, a biological product and device; a drug and biological product; or a drug, biological product, and device • Diagnostic Test: For example, imaging, in-vitro • Questionnaire • Qualitative Method • Others (to spcify)
18.	IP Name	*	The name given to the intervention(s). A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.
Additional Information for Observational			
19.	Study Model	*	• Case Study/Case Series • Cross Sectional • Cohort • Case Control • Case Cross-Over • Ecological/Community • Family Based • Others

20.	Sampling Method	*	How the sample is selected from the population • Simple Random • Systematic Random • Clustered Random • Convenient • Purposive • Others
21.	Time Perspective	*	Timeframe of the data collection • Retrospective • Prospective • Cross-sectional (one particular time) • Others
			Additional Information for Qualitative
22.	Qualitative Model	*	• Phenomenological Model • Narrative Model • Case Study • Historical Model • Ethnography Model • Grounded Theory Model
23.	Qualitative Method	*	How the qualitative research is conducted • Individual Interview in Depth • Focus Group Discussion • Participant Observation • Content Analysis • Others
			Study Information
24.	RMK Priority Area	*	*Rancangan Malaysia* Health Priority Area • Communicable Disease • Non-Communicable Disease • Elderly • Sustainable Environment & Climate Changes • Mental Health • Nutrition & Food Safety • Health Governance Delivery • Oral Health
25.	Research level	*	Indicate whether the proposed research constitute part of a student's academic work leading to an academic degree such as Bachelor, Master, or PhD or a research conducted during routine work

			• Clinical Practice (routine work) • Undergrad Study • Postgrad Study • Fellowship / Subspeciality Study
26.	Research Objective	*	Description of research Objective (Primary, Secondary, Tertiaty)
27.	Research Description	*	Brief description of research purpose, design and method
28.	Research Keyword	*	Words or phrases that best describe the research. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlledvocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations
29.	Disease Area	*	Choose one Primary and Specific disease area of research being studied (based on the ICD-11 Classification). To select the Select most relevant one from list provided – if not related to any disease, to select as 'Not Relevant'
30.	Research Area	*	Choose one Disease area of research being studied. If the research area is not in the list, to select others and specify.
31.	Inclusion Criteria	*	Inclusion criteria for participant selection
32.	Exclusion Criteria	*	Exclusion criteria for participant selection
33.	Study Timeline	*	Information on the research date; • Expected Starting Date: Date of the first subject recruitment/ first data collection • Expected Date of Study Completion: Date of the research complete (with results of the research and the analysis is completed) • Expected Duration of Study Enrollment / Data Collection: Period from the first subject enrollment/data collection until the last subject is enrolled/ data is collected – in week, month or years
34.	Subject (Sample Size) Description	*	Description of research sample size • Overall Number of Subject Expected to be Enrolled (Worldwide) – only for Interventional Research Type • Number of Subject Trial has Enrolled Elsewhere (Outside of Malaysia – only for Interventional Research Type • No of Subject Expected to be Enrolled/ Data to be Collected
35.	Gender Involvement	*	Physical gender of individuals who may participate in the research. Select one • Male: only male participants are being studied • Female: only female participants are being studied • Others: Gender other than male and female are being studied

			• Involve all gender: all participants regardless of gender are being studied • Not applicable: if no physical gender is involved or not relevant
36.	Age Range	*/-	Minimum Age Minimum age of participants. Maximum Age Maximum age of participants.
37.	Involvement of Minor	*/-	If research involves subject less than 18 years old
38.	Site Description	*	Description of Study Site • Other Country Site Involvement – only for Interventional Research Type • Number of sites involved in Malaysia
39.	Current Study Recruitment Status / Study Status	*/-	Overall research accrual activity for the research. To be updated and selected after NMRR registration or after receiving the ethical approval • For Interventional Research Type ○ Not Yet Recruiting (auto select during initial submission) ○ Recruiting /Active Enrolment ○ Enrolling by Invitation ○ Active, not recruiting /Closed Enrolment ○ Completed follow up ○ Study Complete ○ Suspended ○ Terminated ○ Withdrawn Submission • For Other Research Type ○ Not yet Started (auto select during initial submission) ○ Ongoing Data Collection/Sampling ○ Completed Data Collection/Sampling ○ Study Completed ○ Suspended ○ Terminated ○ Withdrawn Submission
40.	Outcome Measure	*	Specific measurements or observations used to measure the effect of experimental variables in a study. • Type ○ Primary: The specific measure that will be used to determine the effect of theintervention(s). ○ Secondary: Other measures that will be used to evaluate the intervention(s), andthat are specified in the research)

			• Name: Description of the outcome • Measurement /method used (eg: functional status, questionnaire, data collection, blood investigation and etc2) • Time points measurement (or endpoint): Time at which the measure will be taken (eg: death of subject , after 1 year, at week 6 and etc2)
41.	Biospecimen Collection / Archiving (only for Interventional & Biobanking Research Type)	*	Description Research biospecimen collection or archiving • Status (Not Retained, Retained for Future Use, Not Applicable) • With/ without DNA • Expected total no of biospecimen collected & archiving • Expected collection per subject
42.	Ethical Application Status	*	Requirement for ethical approval • Ethical Application Submission: submission to ethics approval is required if research involves a living individual about whom an investigator obtains either data through intervention (e.g.: clinical trial) or interaction (e.g.: questionnaire, interview) with the individual, or investigator has access to identifiable private information (e.g.: medical record, personal data)
43.	Study URL	*	A web site directly relevant to the research (e.g.: link to the research questionnaire or site with the information regarding the research that will be conducted). Do not include sites whose primary goal is to advertise orsell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. Provide complete URL, including http://
44.	Individual Clinical Trial Participant-level Data of Individual Participant Data (IPD) Sharing (only for Interventional & Biobanking Research Type)	*	The term IPD sharing refers to the practice of making clinical trial data at the individual level available to researchers who were not part of the original study team Research is required to declare & descript , if any, their plans to share individual participant data (IPD) and related study documents for secondary research purposes .
45.	Sponsor(s)	*	Research sponsoring organization(s)

46.	Funding sources	*	The sources of funding for research . May be
			• Self-Funding
			  ○ Self-Budget
			  ○ Departmental/Institutional Operating Budget
			• Grant Funding
			  ○ MOH Research Grant
			  ○ MOSTI Research Grant
			  ○ University Research Grant
			  ○ Corporate / Industry Grant
			  ○ Government Grant
			  ○ International Grant
			  ○ Others, Specify
			• Full Industry Sponsored
			• Hybrid Sponsored Research (Industry Funding partially + additional source of funding, either self-funding or grant funding)

47.	Study Team	*	Name of participating investigator(s)
48.	Investigator Role	*	Role assigned to each of study • Principal / Coordinating Investigator • Principal Investigator at Site • Sub / Co- Investigator • Expert Opinion
Research documents for Scientific Review & Ethical Approval			
49.	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
50.	Declaration of Conflict of Interest (COI form)	*	A form signed by the Principal Investigator (PI) to disclose any potential circumstances by an individual or study teams that could give rise to a potential conflict of interest as a result of participating the research.
51.	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. A brief document describing the rationale, objective(s), design, methodology, statistical considerations, and organization of a proposed research should be submitted for study that is exempted from MREC review. Required for all research submitted to MREC.

52.	Study Protocol Checklist	*	Checklist for the completeness of information required for the research protocol - only for Interventional Research Type
53.	Participant Information Sheet (PIS) & Informed Consent Form (ICF)	*/-	Form to document subject's consent to participate in the research. Required in English, Bahasa Malaysia and other languages. Required for all human subject research Some research type will require additional PIS &ICF to be submitted: • Information Sheet & Assent Form, 7-12 years • Information Sheet & Assent Form, 13 to less than 18 years • Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for genetic, pharmacodynamic / pharmacogenomic / other studies • Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research other studies • Pregnant Partner Information Sheet & Informed Consent Form
54.	Participant Information Sheet (PIS) & Informed Consent Form (ICF) checklist	*	Checklist for the completeness of information required for Participant Information Sheet (PIS) & Informed Consent Form (ICF) - only for Interventional Research Type (if applicable).
55.	Research on Stem Cell & Cell Based Therapy, National Stem Cell Research and Ethics Subcommittee (NSCERT) Checklist	*	Checklist for the completeness of documents and information required for research involving stem cell & cell-based therapy. To be submitted together during the initial submission - only for Interventional Research Type (if applicable).
56.	Checklist for First in Human Research Protocol	*	Checklist for the completeness of documents and information required for research involving First In Human. To be submitted together during the initial submission - only for Interventional Research Type (if applicable).

57.	Clinical Report Form (CRF) / Data Collection Form	*/-	Clinical report or data collection form is a document used to record protocol required information for each subject in the study
58.	Questionnaire	*/-	Questionnaire that will be distributed to respondents or patients during trial
59.	Interview Guideline	*/-	An interview guide is a document that enables organizations to structure the way of researchers conduct their interview session. It usually contains question or topic to be interviewed or discussed during the session
60.	Project Gantt's Chart	*	Project activities (include Project activities list, chart, key milestone, project schedule)
61.	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. – only for Interventional Research Type (if applicable).
62.	Advertisement		Advertisement for subject recruitment - only for Interventional Research Type (if applicable).
63.	Patient's diary		A patient takes the medication according to the treatment schedule will measure treatment compliance.
64.	Insurance indemnity:	*	Insurance or letter from sponsor to indemnify (legal and financial coverage) the investigator and institution against claims arising from the research and coverage protection of the subject involved - only for Interventional Research Type.
65.	Memorandum of Understanding / 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) and the MOH investigator and authorized MOH signatory , that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters, subject data ownership, distribution and used of data and Intellectual Property(ies)
66.	Letter from Other Ethical Committee/ Approval Committee		Letter of Approval from Other Ethical Committee & Approval Body (e.g.: NSCERT, NRDHM, MDA, First-In Human Committee and etc2)

Investigator's documents			
67.	Curriculum Vitae	*	Investigator is required to submit his or her CV – Compulsory for Submission of all Research Type
68.	GCP certificate	*/-	Investigator is required to submit his or her GCP certificate – Compulsory for all investigators involve in Interventional Research Type The MREC will check thevalidity of this claim.
69.	IA-HOD-IA Form	*/-	Submit scanned copy of the signed and dated "Investigator's agreement, Head of Departments and Institutional approval" document (IA-HOD-IA) (Persetujuan Penyelidik, Pengesahan Ketua Jabatan dan Institutsi) – Required for Submission of all Research Types
70.	Professional Indemnity		Submit valid professional indemnity certificate. - only for Interventional Research Type (if applicable). This refers to Insurance or letter from investigators or CRO to indemnify (legal and financial coverage) the investigator(s) against claims arising from the trial due to professional malpractice and/or negligence