DATA ELEMENTS & PARAMETERS FOR NMRR SUBMISSION

This document is to be used as a reference during a research submission in NMRR system.

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

#	Fields/ Elements		Definition
			General Study Information
1.	Submission Type	*	• ISR: Industry Sponsored Research • IIR: Investigator Initiated Research *Choose either one of the selections based on the appropriate type of submission*
2.	Research Title	*	Official Research/Submission Title *Insert the research /submission title appropriately (no word limit)*
3.	Public Title	*	Research title written in simple language intended for the public in an easily understood language *Insert the public title appropriately (50-word limit)* *If technical terms or medical jargon are used, they should either be replaced with terms easily understood by the public or the title should be explained or described in brief in layman's language.*
4.	Research Title Abbreviation	*	A shortened forms of words and phrases for a more concise and easier reference, especially in a lengthy research title. It can be an acronym or abbreviation (e.g., Some Research Title Study = " SoRT Study “) *Insert the research title abbreviation appropriately. (no character limit)*
5.	Protocol ID	*/-	The unique identification of the research protocol used to identify the document and its update as assigned by the sponsor or investigator (The simplest ID for a protocol can be the version and version date e.g., Version 2.1 dated 20/03/2023.) *Insert the protocol ID appropriately (no character limit). Submission with the purpose of scientific review and ethical approval is mandatory to have a protocol ID.*

6.	Research Scope	*	• Basic Science/Biomedical • Clinical • Health Management • Health Economic • Health Governance /Policy • Public Health/Epidemiology • Social Science /Behavioral Science *Choose either one of the selections based on the appropriate type of research scope.*

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 (specify)
			• Qualitative
			• Mixed Method (Both Observational & Qualitative)
			• Proof of Concept/Theoretical Research
			• Applied Research
			• Registry/Biobanking/Clinical Database
			• Clinical Audit/ Quality Assurance/Quality Control
			• Systematic Review/ Scoping Review/Rapid review/Meta-Analysis/Meta-Synthesis
			• Special Write Up
			  ○ Article
			  ○ Journal Review
			  ○ Book/Chapter
			
			Choose either one of the selections based on the appropriate research type definition

Additional Information for Research Type (Definition)			
7.1	Interventional		A type of research in which subjects are prospectively assigned to one or more groups (e.g., experimental and control arms) to receive an intervention(s) or a placebo/no interventions/active comparator so that investigators can evaluate the effects of the interventions on biomedical or health-related outcomes.
7.2	Observational		A type of research in which data and information is collected by investigators through observation or measuring specific

			characteristics effect or factor (exposure) and the outcomes at a particular time of interest and its changes over time. However, no attempt is made throughout the research to interfere or change any outcomes that are measured. This can be done through collection of data prospectively or retrospectively.
7.3	Qualitative		A type of research involving collection and analysing of non-numerical data (e.g., text, video, or audio) through means like in-depth interviews, focus groups, or observations in order to understand a concepts, opinions, or experiences. This can be used to gather in-depth insights, subject(s) perspective of certain problem of interest, people's experiences and perception on a particular topic.
7.4	Mixed Method		A type of research that use both observational (also known as quantitative method) & qualitative method in a single or series of research to help answer research question(s) of interest.
7.5	Proof of Concept (POC) /Theoretical Research		Also known as basic research which aims at expanding the fundamental knowledge and comprehension of underlying health conditions, life processes or health related issue. The approaches are less directed to provide a treatment or solution to a particular health-related problem. The results generated is used to enhance and improve the fundamental knowledge and understanding of a particular process or condition and this can be used to develop methods to support other types of research such as applied research and clinical research. (e.g., research in genetic and gene sequencing, microbiology research, physiology research, biochemistry research, animal research and etc.) ***POC in clinical trial setting meanwhile is considered as interventional research due to the nature of the research which intervention is given to subject to evaluate the efficacy and its effect on human body.*
7.6	Applied Research		This is a type of research conducted with the goals to solve a health-related problem in the real-world setting and is likely directed towards specific objectives such as the development of a new drug, therapy, or surgical procedure and providing evidence and solution to a health-related problem and issues. Research can be conducted using animals, tissue culture or even non-living model alternatives such as computer models or artificial intelligence and complex machine learnings. (e.g, toxicology research on drug, biomechanics research, regenerative medicine research, health costing projection, disease analysis modelling, artificial simulation and etc.)
7.7	Registry/ Biobanking/ Clinical		A type of research involving the usage of data from a registry, a biobank or a clinical database to answer a research question of interest. The timelines of this research are driven by the time

	Database		needed to collect or extract data relevant to the given study objective(s) and the time to complete the analyses. The analysis of the data is rather limited to the planned statistical analysis described in the protocol rather than interval or routine based.
7.8	Clinical Audit/ Quality Assurance/ Quality Control		A type of research that seeks to improve medical care and delivery in place (either the services, diagnostic, treatment, resources and etc.) and the outcomes through a systematic data collection and analysis. It measures a criterion (or set of criteria) against the implementation of change or standard clinical care /practice /guideline. In quality control and quality assurance research, aspects of structures, processes and outcomes of care are selected and systematically evaluated against explicit criteria. If indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery. ** *In quality assurance/quality control research that has a certain intervention involving human subjects in place during the conduct and the effects of the intervention are measured before and/or after the implementation, research submissions should be made under the interventional research type.*
7.9	Systematic Review/Scoping Review/Rapid review/Meta-Analysis/Meta-Synthesis		Systematic Review: A type of research and knowledge synthesis that attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a specific research question. Researchers conducting systematic reviews use explicit, systematic methods that are selected with a view aimed at minimizing bias, to produce more reliable findings to inform decision making. This includes a systematic strategies and methods for extracting and interpreting data from published studies on the subject or research question, as well as analysing, describing, critically evaluating, and summarising interpretations into a refined evidence-based conclusion. Scoping review: A preliminary assessment of potential size and scope of available research literature which has not yet been comprehensively reviewed, or exhibits a large, complex, or heterogeneous nature not amenable to a more precise systematic review, or to map existing literature in terms of nature, features, volume or to clarify working definitions and conceptual boundaries of a topic or field and to identify gaps in existing literature/research identify nature and extent of research evidence (usually including ongoing research. Rapid Review: A form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner. Rapid reviews are especially popular among decision-makers in health care settings. Rapid reviews can be distinguished by their

			ability to be conducted within a limited time frame. Meta-Analysis: It is an overall statistic used to combine or pool the individual studies. Many Systematic Reviews measure benefits and harms by collecting data from more than one trial, and combining them to generate an average result. This aims to provide a more precise estimate of the effects of an intervention/exposure and to reduce uncertainty
7.10	Special Write-Up		This is a type of submission outside of the scope of the research type mentioned above for the submission of scientific dissemination approval by the Director General of Health. Among the submissions under this group are, for example, journal review articles, books or chapters, technical reports, and others.
Additional Information for Interventional Research			
8.	Research Sub-type	*/-	• Bioavailability/ Bioequivalent Study • Clinical Trial (MGCP definition) • Interventional Study (Other than clinical trial) • Quasi Experimental/ Pilot Project/ Feasibility Study *Choose either one of the selections based on the appropriate interventional research subtype definition.*
Additional Information for Interventional Research Subtype (Definition)			
8.1	Bioavailability/ Bioequivalent Study		A type of research to evaluate the rate and extent of absorption of a particular drug from a test formulation and to evaluate whether the drug product is achieving a rate of absorption that are not statistically significantly different from those of the reference product when administered at the same molar dose. This usually will compare two or more formulation containing the same active ingredient.
8.2	Clinical Trial - based on Malaysia's Good Clinical Practice (MGCP) definition		Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
8.3	Interventional Study (Other than clinical trial)		Any investigation in which an intervention (other than the definition of clinical trial by MCGP) is assigned to one or more groups of human subjects. This can be either a procedure, behavioral intervention, device and others.
8.4	Quasi Experimental /Pilot Project /Feasibility		Any investigation uses to estimate the causal impact of an intervention on target population without a random assignment. In this type of research, participants are not randomly assigned to conditions or orders of the conditions.

	Study		
Additional Study Information for Interventional Research			
9.	Secondary ID Availability	*/-	An identifier(s) other than the organisation'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) *Choose either one of the selections based on the availability of the secondary ID,* *If available - Insert the secondary ID source, number and description appropriately (no word limit).*
10.	Study Phase	*/-	Phase of clinical trial • Phase 1: includes initial studies to determine the metabolism and pharmacological actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of the drug effectiveness; this 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 trial 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: For trials without phases, such as expanded access trials, feasibility study, registries and etc. *Choose either one of the selections based on the appropriate interventional study phase definition.*
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 *Choose either one of the selections based on the appropriate interventional allocation definition*
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 following the group assignment. • 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 *Choose either one of the selections based on the appropriate interventional study assignment definition*
13.	Study Arm	*/-	Description of each groups/arm assigned in the research. • Type of Arm: nature of the intervention o Experimental: The group that receives the intervention/process/product that is the focus of the clinical trial. o Active Comparator: The group that receives therapy(s) /drug(s)/product(s)/process(s) that is considered effective in which currently in used and considered the acceptable in standard practice/guideline/usage. o Placebo Comparator: The group that receives therapy(s) or drug(s) that appear to be the same as the actual therapy or drugs but does not contain active ingredient and no therapeutic effect o Sham Comparator: The group that receives inactive procedure(s) or process(es) that appears to be the same as the actual procedure or process being studied but does not contain active process or component o No intervention: The group that receives no intervention/product/process *Describe briefly each of the groups/arm involved in the research assignment (100-word limit). All groups/arms should be listed individually.* *Choose either one of the selections for each study arm listed based on the appropriate interventional nature (type of arms)*

14.	Masking/Blinding	*/-	Description of the parties involved in the research who are being prevented from having knowledge of the interventions assigned to individual participants: • Open Label: subject will be in the know of type of intervention he/she will be assigned to • Single Blinded: subject will be blinded of the interventional assignment. • Double Blinded: subject and investigator will be blinded of the interventional assignment • Triple Blinded: subject, investigator and accessor/sponsor will be blinded • Others (to specify the number of blinding) *Choose either one of the selections based on the appropriate interventional masking/blinding definition*
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 number 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) *Choose either one of the selections based on the appropriate interventional purpose definition*

16.	Investigational Product (s) (IP)	*/-	Information regarding the intervention(s) studied in each arm of the research. Each of the IP should be listed individually and separated even for different dosage, frequency, route of administration, process, procedure by the same IP. *Insert all investigational product (s) (IP) involved in each of the assignment groups/arms appropriately. Each IP should be listed individually.*
Additional Information for Investigational Product(s) (IP)			
16.1	Product/Process/ Intervention 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 specify) *Choose either one of the selections based on the appropriate interventional product (IP) type*
16.2	Product/Process/ Intervention 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. *Insert the investigational product (IP) name appropriately (50-word limit)*
16.3	Product/Process/ Intervention Description	*/-	Description of the investigational product (IP) in details. This includes background information, ingredients, dosage, route of administration, frequency, procedure and other relevant information. *Insert the investigational product (IP) description appropriately (300-word limit)*

16.3	Arm Group / Intervention Cross-Reference	*/-	Cross-reference for each of the investigational product (IP) listed with the Arm Group listed in Study Arm Description. *Select and cross-match the IP with one of the Study Arm descriptions appropriately. Each study arm should have at least one or more IP matched between each other.*
Additional Study Information for Observational Research			
17.	Study Model	*/-	Study design for observational research: • Case Study/Case Series • Cross Sectional • Cohort • Case Control • Case Cross-Over • Ecological/Community • Family Based • Others (specify) *Choose either one of the selections based on the appropriate study model definition*
Additional Information for Observational Study Model (Definition)			
17.1	Case Study/Case Series		An in-depth or an intensive description of a single or more individual or group which display or have a certain characteristic, outcome, or exposure within the period of observation.
17.2	Cross Sectional		A type of observational research that analyses data from a certain population of interest or representative subset of a group at a specific point in time.
17.3	Cohort		A type of observational research in which a group of individuals with one or more common characteristics (cohort) is recruited and followed over a certain period of time (also known as longitudinal study). The group is exposed to a certain specific risk factor of interest and the outcome occurrence over the observation period is evaluate and analyses for its association with the exposure. (Exposure → Outcome)
17.4	Case Control		A type of observational research involves a group of individuals of certain characteristics with a certain outcome of interest (cases) and another group of individuals that share the same characteristic like the cases but do not have the outcome of interest. Both group (the case and the control) will be evaluated historically to identify factor(s) and exposure that might have contributed or causing the outcome of interest observed in the case group. (Outcome → Exposure)

17.5	Case Cross Over		A type of observational research involves only group with a certain outcome of interest (cases) and comparing individual to themselves at different times. Timeline of each individual subject is evaluated historically for the exposure event(s) /it's time window (a period where the level of the exposure (event) is elevated before it goes back to the baseline – also known as case days). The history preceding the event is used as the control – known as controls day.
17.6	Ecological/ Community		A type of observational research that analyses data that is represented by group (rather than individual) as the unit of observation. It measures the correlation between aggregated (group level) exposure and the outcomes. (e.g., country, region, geographic, environmental and global)
17.7	Family Based		A type of observational research used to study the presence or absence of familial aggregation for certain trait or disease. This can used to estimate the penetrance for a given genotype of interest and helps in determining the genetic association, its interaction with the environmental factor and its modifier among individual at risk. Usually common in genetic epidemiological research.
18.	Sampling Method	*/-	How the sample is selected from the population • Simple Random • Systematic Random • Clustered Random • Convenient • Purposive • Others *Choose either one of the selections based on the appropriate sampling method*
19.	Time Perspective	*/-	Timeframe of the data collected in the research • Retrospective • Prospective • Cross-sectional (one particular time) • Others (specify) *Choose either one of the selections based on the appropriate time perspective*
Additional Study Information for Qualitative Research			
20.	Qualitative Model	*/-	Study design/model/method used for the qualitative research:

			• Exploratory Model • Phenomenological Model • Narrative Model • Case Study • Historical Model • Ethnography Model • Grounded Theory Model *Choose one or more of the selections based on the appropriate qualitative model definition*
Additional Information for Qualitative Model (Definition)			
20.1	Exploratory Model	*/-	This method/design (also known as Exploratory Descriptive Qualitative (EDQ) Research) involves exploring a topic, particularly related to an event, phenomenon, process or activity that has a limited coverage within the literature. This provides an opportunity for a systematic discovery of knowledge generalisation for the description and fundamental understanding of a particular topics, phenomenon, event or process of interest which may not be possible previously as a result of paucity in literature and inability/ inappropriateness to use other types of model/method/design.
20.2	Phenomenological Model	*/-	A method/design uses to describe how human beings perceive or experience a certain phenomenon or event of interest. These may include individual's perception, thought, memory, imagination, emotion and feeling. The description is usually referred to as *lived experience*.
20.3	Narrative Model	*/-	A method/design in which the experiences or perspective of an individual or a small group of people is recorded and arrange into a chronological narrative. This will usually reveal the lived experience of an individual or community that is represented primarily as a biography, memoir, chronicles, oral history and others
20.4	Case Study(ies)	*/-	This method/design involves in depth description of the experience of a single person or a group of individuals, a family, a community or even an organization intended to highlight a specific issue(s), story(ies) or event(s). Using content analysis involving careful examination and identifying of particular pattern(s) and theme(s), hypotheses can be generated relevant to the research question.
20.5	Historical Model	*/-	A method/design involves describing, identifying, evaluating and examining the past event(s) or phenomenon(a) in order to

			not only discover and to appreciate the past, but also to relate and to gain a deeper understanding of the link with the present and sometime it can be used to anticipate any potential effects for the future. The source of data can come from either a *primary source*, *secondary source* and even tertiary and more.
20.6	Ethnography Model	*/-	A method/design use to explore and describe the attributes or characteristics of a particular group in a society and their culture, values, belief and practice. Observation and data collection can be performed from within the culture (*emic approach*) or from outside through external looking (*etic approach*) where the key informants are usually interviewed during the process.
20.7	Grounded Theory Model	*/-	A method/design characterises by a theory development made through careful observation of event(s) or phenomenon(a) experienced by individual. A process known as *constant comparison* is used in which the collection of data and its analysis is done simultaneously. This is a preferable if the event is repetitive and the data collection is cyclical and reflective in nature.
21.	Qualitative Method	*/-	How the qualitative research is conducted: • Individual Interview in Depth • Focus Group Discussion • Participant Observation • Content Analysis • Others *Choose one or more of the selections based on the appropriate qualitative method*
Study Information *(for All Research Type Submission excluding Special Write Up – only for Research Level & Research Keyword)*			
22.	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 • Not Relevant *Choose either one of the selections based on the appropriate RMK Area*

23.	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 and others or research conducted during routine work • Clinical Practice (during routine work) • Undergrad Study • Postgrad Study • Fellowship / Subspeciality Study *Choose either one of the selections based on the appropriate research level*
24.	Research Objective	*	Description of research Objective (Primary/General, Secondary/Specific, and Tertiary if any) *Describe and list out the objectives for the research. This should include at least General/Primary and Secondary/Specific Objectives.* *Each objective should be listed individually.*
25.	Research Description	*	This is a brief summary or description of the research. The description should include a clear overview or brief introduction on the research topics, hypothesis and/ or objectives of research, methodology and study design, description of the study population, description of the study sites, and duration of the entire research *Insert the research description appropriately (500-1000 words limit)*
26.	Research Keyword	*	Words or phrases that best describe the research. Keywords help user find studies in the database/directory. NLM's Medical Subject Heading (MeSH) is preferable or any controlled vocabulary terms where appropriate. *Insert the research keyword appropriately. Be as specific and precise as possible. Avoid acronyms and abbreviation.*
Disease and/or Research Area (for All Research Type Submission)			
27.	Disease Area	*	Area of disease most relevant to the research and condition studied. Consist of a primary and specific disease area. The list is based on the ICD-11 Disease Classification. *Choose either one of the selections based on the appropriate disease area* *If not related to any disease, to choose the Primary Disease Area as "Not Relevant"*

28.	Research Area	*	Area of knowledge or topic that is being studied. Consist of Primary Research Area. *Choose either one of the selections based on the appropriate research area* *To choose "Others" and to specify if the list is not available on selection.*
Inclusion/ Exclusion Criteria *(for All Research Type Submission excluding Special Write Up)*			
29.	Inclusion Criteria	*	Inclusion criteria for participant/data selection *List out all the inclusion criteria for the research. Each criterion should be listed individually*. *If there are no any inclusion criteria (e.g., in Case Study/Case Series submission), to insert as "Not Applicable" / "NA"*
30.	Exclusion Criteria	*	Exclusion criteria for participant/data selection *List out all the inclusion criteria for the research. Each criterion should be listed individually* *If there are no any inclusion criteria (e.g., in Case Study/Case Series submission), to insert as "Not Applicable" / "NA"*
Study Timeline *(for All Research Type Submission)*			
31.	Study Timeline	*	Information on the research conduct timeline and dates; • 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 *Insert the study timeline information appropriately*
Subject (Sample Size) Description *(for All Research Type Submission excluding Special Write Up)*			
32.	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 *Insert the subject (sample size) description appropriately*
33.	Gender Involvement	*	Physical gender identified for individuals who may participate or from which the data will be collected in the research. • Male: only male participants are being studied /collected • Female: only female participants are being studied/ collected • Others: Gender other than male and female are being studied/ collected • Involve all gender: all participants regardless of gender are being studied/collected • Not applicable: if no physical gender is involved or not relevant (non – human subject) *Choose either one of the selections based on the appropriate gender involvement*
34.	Age Range	*/-	Minimum Age Minimum age of participants/subjects. Maximum Age Maximum age of participants/subjects. *Insert the age range information appropriately. (in years)*
35.	Involvement of Minor	*/-	If research involves subject less than 18 years old *Choose either one of the selections based on the involvement of minor in the research.*
Sites Description *(for All Research Type Submission)*			
36.	Site Description	*	Description of Study Site • Other Country Site Involvement (only for Interventional Research Type) • Number of sites involved in Malaysia *Insert the site description (number of site) involved appropriately.* *Number of sites involved in Malaysia should correspond to the site listed in the Study Site section*
Current Study Recruitment Status / Study Status *(for All Research Type Submission)*			
37.	Current Study Recruitment	*	Overall accrual activity for the research. To be updated and selected post-NMRR registration or after research has received the ethical approval.

	Status/ Study Status		• 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
			
			• For Other Research Types
			  ○ Not yet Started (auto select during initial submission)
			  ○ Ongoing Data Collection/Sampling
			  ○ Completed Data Collection/Sampling
			  ○ Study Completed
			  ○ Suspended
			  ○ Terminated
			
			The selection will be auto selected as "Not Yet Recruiting" or "Not Yet Started"

Outcome Measures *(for All Research Type Submission Excluding Special Write Up)*			

38.	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)
			• Description: Description of the variable or outcome (*no character limit)*
			• Measurement/ method used: Tools/ measurements/ methods that will be used during data analysis or data collection for the intended outcome measure: (e.g.: functional status, questionnaire, data collection, blood investigation and etc2) (*255 characters limit*)
			• Time points measurement (or endpoint): Time frame where the outcome is measured (e.g., after week 2/ one point interval/ end of data collection / end of follow up 1 and etc2) (*255 characters limit*)
			
			Describe and list out all relevant Primary and Secondary outcome measure for the research appropriately. This should include both Primary and at least one Secondary outcome.

Biospecimen Collection / Archiving *(only for Interventional & Biobanking Research Type)*			
39.	Biospecimen Collection/ Archiving	*/-	Description related to biospecimen collection or archiving, its collection status, procedure, number of collection and also its archiving plan (only for Interventional & Biobanking Research Type) • Status: Not Retained, Retained for Future Use, Not Applicable) • With/ without DNA • Expected total no of biospecimen collected & archiving • Expected collection per subject *Choose either one of the selections based on the appropriate planning of the biospecimen collection and DNA collection status.* *Insert information on the expected total no (overall numbers of collection for entire research) of collection & archiving as well as the expected individual number of collection (per subject) appropriately.*
Ethical Application Status *(for All Research Type Submission)*			
40.	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, clinic record and etc.) • MREC, MOH ethical application submission Status • Other Local Other Local Institutional Review Board (IRB)/ Independent Ethic Committee (IEC Submission Status) *Choose either one of the selections based on the appropriate ethical requirement for the research.* *Choose the current status of submission to MREC, MOH for ethical review and approval and status of submission to any relevant local IRC/IEC accredited by NPRA (if any).*

Study URL *(for All Research Type Submission)*			
41.	Study URL	*	A website 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:// *Choose either one of the selections based on the availability of the URL for the research.* *If available, insert the URL address appropriately - if any*
Individual Clinical Trial Participant-level Data of Individual Participant Data (IPD) Sharing *(only for Interventional & Biobanking Research Type)*			
42.	Individual Clinical Trial Participant - level Data of Individual Participant Data (IPD) Sharing	*/-	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 & describe, if any, their plans to share individual participant data (IPD) and related study documents for secondary research purposes. (only for Interventional & Biobanking Research Type) *Choose either one of the selections based on the availability of the IPD Sharing Plan for the research.* *If available, insert the IPD Sharing Plan appropriately- if any*
Study Site *(for All Research Type Submission)*			
43.	Study Site	*	Description of the study site lists involve in the research. Selection is made based on the database search on the establishment registered in the system. *Insert all the study sites involved in the research appropriately* *Searching for the site establishment priorities the use of English Language (e.g.; Radiology Department…. instead of Jabatan Radiologi…) However proper nouns in Malaysian Language will still be retained (e.g.; Hospital Tuanku Ja'afar, Hospital Tunku Azizah and etc2)* *If the search made in Malaysian Language does not result in any listing displayed, kindly try to search the establishment in English Language.*

Study Team *(for All Research Type Submission)*			
44.	Study Team	*	Name of participating investigator(s). Each investigator should be assigned to at least one site listed in the Study Site section. *Insert the study team information for the research. To list all investigator and assign each one with a role and at least one study site.* *Investigator role should be the same across different site (if he/she has been assigned with more than 1 site)* *All study site should have at least one investigator assigned to it. Each investigator should have a CV uploaded.*
45.	Investigator Role	*	Role assigned to each of study team member • Principal / Coordinating Investigator (PI) • Principal Investigator at Site (PI at Site) • Sub / Co- Investigator (Sub-I/ Co-I) • Expert Opinion *Choose either one of the selections for each investigator listed in the study team based on the role definition and assignment appropriately.* *IAHODIA form is mandatory to be uploaded by PI and PI at Site.*
Corresponding Person *(for All Research Type Submission)*			
46.	Corresponding Person (CP)	*	Individual (other than Principal Investigator) who will be granted the access directly to a particular submission following the assignment for editing and any response required during processing and review. CP is consisting of the following: • Main Corresponding Person (Main CP) – This individual will have the access for editing of the submission (if required) once it has been submitted for processing and for submission of all Post Ethical Approval Research Activity Submission after research has been granted the ethical approval. • Backup Corresponding Person (Backup CP) – This individual will have the access for editing of the submission (if required) once it has been submitted for processing and for submission of all Post Ethical Approval Research Activity Submission after research has been granted the ethical approval. • Corresponding Person – PD: individual in-charge for the submission and editing of Protocol Deviation (PD) for a particular site following the assignment (only for Interventional & Observational Research Type) • Corresponding Person – SAE: individual in-charge for the submission and editing of Serious Adverse Event

			(SAE) for a particular site following the assignment (only for Interventional & Observational Research Type) *Insert the corresponding person information for the research appropriately.* *Each study site should be assigned with at least one CP for PD and SAE. (only for interventional & observational research type)*
47.	Coordinator	*/-	Individual assigned by the Sponsor or PI that will be in-charge of the entire submission (for all sites) for any report related to the research. Coordinator is consisting of the following: • Global SUSAR Coordinator - – This individual will have the access for the submission of Global SUSAR Reporting (only for Interventional Research Type) • SAE Coordinator (only for Interventional & Observational Research Type) • PD Coordinator (only for Interventional & Observational Research Type) *Insert the coordinator information responsible for each of the report type appropriately.*
48.	Contact for Public Queries	*/-	Individual assigned by the Sponsor or PI that is related to the research and will be contactable by the public in case there are any queries related to that particular research. PI can be the one listed as the contact person as well (recommended). (only for Interventional Research Type) **Information displayed will be taken from the database of registered user (affiliation address, office contact number and email) and it will be publicly displayed in the research directory. *Insert the contact for public queries information for the research appropriately.*
Sponsor *(for All Research Type Submission)*			
49.	Sponsor(s)	*	Description of the research sponsoring organisation(s) • Sponsor Establishment: Address of sponsor • Sponsor Contact Person: Person that can be contacted regarding the sponsorship information for the research. This can be either sponsor representative or Principal Investigator (PI) that act on behalf of the sponsor in case of IIR Submission. *Insert the Sponsor information for the research appropriately.*

			This includes all primary/main sponsor and secondary sponsor information together with their establishment – if any (for the Interventional Research Type Submission). *For other Research Type, all sponsors should be listed as 2 or more separate listing (more than 1 primary sponsor can be added) for research receiving more than one source monetary support or sponsorship (e.g.: in Hybrid Sponsored Research)* *Insert the Sponsor establishment & Sponsor Contact Person information for the research appropriately.* *The sponsor information for the Self-Funding > Self-Budgeting should be listed the same as the PI affiliation or "PTJ-Centers of Responsibility" establishment.* *For Sponsor without any contact person or grant representative that has an account created in NMRR, Principal Investigator can be listed as the Sponsor Contact Person*.

50.	Funding sources	*	The sources of funding for research.
			• 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 (research that receives sponsorship/funding partially from the Industry Funding, with additional sources of funding coming from either self-funding or grant funding as well.)
			
			Choose either one of the selections based on the source of funding for the research appropriately

Contract Research Organization - CRO (for All Research Type Submission)			
51.	Contract Research Organization (CRO)	*/-	Description for the involvement of a Contract Research Organisation (CRO) for the research. • Status of Involvement • CRO establishment • CRO Contact Person

			Choose either one of the selections based on the status of the CRO involvement. *Insert the CRO establishment & CRO Contact Person information for the research appropriately, if the selection for the Status of Involvement is "Involving CRO"* *Choose the selection as "Not Involving CRO" for All Research Type other than Interventional (if applicable)*
Documents Required for NMRR Registration			
52.	IAHODIA Form (a prefilled form is available for download for each investigator listed in the Study Team subsection.)	*	Investigator Agreement Head of Department Institutional Agreement (IAHODIA) form. This is an approval to conduct research submitted by investigator following the approval to conduct research by the investigator's affiliated HOD and institutional/facility Director. Each individual (investigator, HOD & institutional/facility director) is required to sign, stamp and date the relevant section on the form. This is mandatory to be submitted by Principal Investigator (PI) and Principal Investigator at Site (PI at site). Submission by Sub-Investigator is not mandatory. However, it is recommended for at least one Sub-I to submit the form for the site without a PI/PI at site as a representative for any of the affiliated site *Mandatory to be uploaded for all Research Registration submission.* *Investigator with the role of Principal Investigator (PI) and PI at site is required to submit the form.* *Signatory for the Head of Department (HOD) & Institutional/ Director Agreement (IA) is supposedly from the Investigator's site of origin or affiliation or place of work/study.*
53.	Curriculum Vitae (CV)	*	CV is a comprehensive document of investigator's educational background, position, and research experience. A recent and up to date CV should be uploaded by each of the study team members for verification of investigator's credential and background review by relevant committee during the processing of the submission. *Mandatory to be uploaded for all Research Registration submission.* *All investigator listed in the study team is required to upload/ submit their CV* *CV can either be uploaded by the CP during research registration submission or it will be auto displayed if the file is present in the Investigator's Profile*
Research documents for Scientific Review & Ethical Approval			

54.	Covering Letter to MREC	*	This is a formal letter signed by the Principal Investigator (PI). The content of the letter should include information such as the study title, purpose of submission to MREC, list of all Investigators and their roles, list of participating sites and the list of all documents with version and version date submitted for MREC review and approval. Investigator is also required to state and justify the reasons if any waiver of consent is requested. *Mandatory to be uploaded for MREC Ethical Approvals submission – all type of research submission.* *The document and any of its update should be assigned with a version and a version date.*
55.	Declaration of Conflict of Interest (COI form) (*a prefilled form is available for download*.)	*	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. *Mandatory to be uploaded for MREC Ethical Approvals submission – all type of research submission.* *Study Team subsection should be completed first during the NMRR registration before the COI form can be downloaded.* *The document and any of its update should be assigned with a version and a version date.*
56.	Study Protocol/ Proposal	*	A document that describes the objective(s), design, methodology, statistical considerations, organisation and relevant information related to the research. Protocol: A detail document that describes in details the background, rationale and justification, study design and its action plan analysis and all relevant information for the research. For Interventional Research, the background for the products could be provided in other protocol referenced documents. Submission for ethical review and approval should be in protocol-type document. Proposal: A brief document that contains all the key elements involved in the research process including description of the rationale, objective(s), design, methodology, statistical considerations, and organisation of a proposed research. This document should be submitted for study that can be exempted from MREC review (in case where submission to MREC is required in order to obtain the Letter of Exemption). For Case Study/Case Series submission, draft template of the manuscript can be submitted as the proposal.

			Mandatory to be uploaded for MREC Ethical Approvals submission – all type of research submission. *The document and any of its update should be assigned with a version and a version date.*
57.	Study Protocol Checklist	*/-	A checklist for the completeness of information required for the research protocol - only for Interventional Research Type *The document and any of its update should be assigned with a version and a version date.*
58.	Participant Information Sheet (PIS) & Informed Consent Form (ICF)	*/-	A form to document subject's consent to participate in research. Required in English, Bahasa Malaysia and other languages (if any). Some research type will require additional PIS &ICF to be submitted for MREC review and approval such as: • Information Sheet & Assent Form (for research involving minors between 7-12 years old) • Information Sheet & Assent Form (for research involving minors between 13 to less than 18 years old) • Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for genetic, pharmacodynamic / pharmacogenomic / other studies (for research with any kind of genetic study(ies) and investigation(s) that are not part of the main primary objective of the research.) • Optional Patient Information Sheet (PIS) & Informed Consent Form (ICF) for future research other studies (for research with the collection of samples or biospecimen that might be archived and used for future research) • Pregnant Partner Information Sheet & Informed Consent Form (for research that female subject of reproductive age) *Mandatory to be uploaded for MREC Ethical Approvals submission – for research involving human subject with any kind of interaction and the recruitment / data collection is done prospectively* *It is a requirement by MREC that the submission of PIS&ICF should be at least in 2 languages (Malay & English translation)* *The document and any of its update should be assigned with a version and a version date.*

59.	Participant Information Sheet (PIS) & Informed Consent Form (ICF) checklist	*/-	A checklist for the completeness of information required for Participant Information Sheet (PIS) & Informed Consent Form (ICF) - only for Interventional Research Type (if applicable). *The document and any of its update should be assigned with a version and a version date.*
60.	Research on Stem Cell & Cell Based Therapy, National Stem Cell Research and Ethics Subcommittee (NSCERT) Checklist	*/-	A 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 for registration - only for Interventional Research Type (if applicable). *Mandatory to be uploaded for MREC Ethical Approvals submission – for research involving stem cell & cell-based therapy* *The document and any of its update should be assigned with a version and a version date.*
61.	Checklist for First in Human Research Protocol	*/-	A 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). *Mandatory to be uploaded for MREC Ethical Approvals submission – for research involving First- In Human (phase 1 clinical trial).* *The document and any of its update should be assigned with a version and a version date.*
62.	Clinical Report Form (CRF) / Data Collection Form	*/-	A document used to record the protocol required information for each subject in the study to be used for the analysis. *The document and any of its update should be assigned with a version and a version date.*
63.	Questionnaire	*/-	A document that will be distributed to respondents or patients during trial or research. A validated questionnaire should be submitted for the submission (except for the validation of questionnaire type of research) *The document and any of its update should be assigned with a version and a version date.*
64.	Interview Guideline	*/-	A document that enables organisations to structure the way of investigator conduct their interview session. It usually contains question or topic to be interviewed or discussed during the session.

			Mandatory to be uploaded for MREC Ethical Approvals submission – for research involving the process of interviewing subject or participant. *The document and any of its update should be assigned with a version and a version date.*
65.	Project Gantt's Chart	*	A document that describes and the planned project activities (include Project activities list, chart, key milestone, project schedule) *Mandatory to be uploaded for MREC Ethical Approvals submission – all type of research submission.* *The document and any of its update should be assigned with a version and a version date.*
66.	Investigator's Brochure	*/-	A compilation of the background and detail information related to clinical and non-clinical data on investigational product(s) (IP). This is relevant for research related to the use of the investigational product(s) and device(s) in human subjects. (only for Interventional Research Type - if applicable) *The document and any of its update should be assigned with a version and a version date.*
67.	Advertisement	*/-	Advertisement for subject recruitment - (only for Interventional Research Type - if applicable) *The document and any of its update should be assigned with a version and a version date.*
68.	Patient's diary		A document in which patient or subject use for self-monitoring or taking notes during the consumption of the investigational product(s) (IP) or undergoing the procedure according to the treatment schedule. This document will be used to measure the compliances of participant by the investigator and monitoring of any adverse event. *The document and any of its update should be assigned with a version and a version date.*
69.	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 - if applicable) *The document and any of its update should be assigned with a version and a version date.*

70.	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) with the MOH investigator and authorized MOH signatory. This document 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). *Mandatory to be uploaded for MREC Ethical Approvals submission – for research involving collaboration between MOH and external party(ies) or organisation(s).* *The document and any of its update should be assigned with a version and a version date.*
71.	Letter from Other Ethical Committee/ Approval Committee		Letter of Ethical Approval from Other Ethical Committee or Approval Body (e.g.: NSCERT, NRDHM, MDA, First-In Human Committee and etc2) *The document and any of its update should be assigned with a version and a version date.*
Other Relevant Investigator's Document			
72.	GCP certificate	*/-	Investigator is required to submit his or her Good Clinical Practice (GCP) certificate. This document can be uploaded in the Study Team subsection during investigator selection *Mandatory to be uploaded by all investigator for the purpose of Research Registration and MREC Ethical Approvals submission – especially for submission involving Interventional Research type. For other research types, it is recommended for at least one of the study team members (preferably PI) to upload the GCP certificate.*
73.	Professional Indemnity	*/-	This document refers to an insurance coverage or letter from investigators or CRO or sponsor to indemnify (legal and financial coverage) the investigator(s) against claims arising from the trial due to professional malpractice and/or negligence. It is required for investigator to have a valid professional indemnity certificate especially investigator from private practices. This document can be uploaded in the Study Team Subsection (only for Interventional Research Type - if applicable).

			The document is a necessary especially for a non- MOH investigator working at private facilities planning to conduct Interventional research. It is always recommended for MOH investigator to upload a personal professional indemnity – if any. *Professional indemnity should not be confused with the Insurance Indemnity (under the Scientific Review & Ethical Approval section) which is 2 different documents*
Information for Grant (MOH Research Grant – MRG) Submission			
74.	Costing Details	*/-	A detailed breakdown of the expected costs and expenses associated with the proposed research. The information required includes: • Overall Total Costing (this will be automatically calculated by the system which will combine the total cost of all three years.) • Details Justification (by category) • Amount of cost (per category) • Total costing (per year) (this will be automatically calculated by the system which will combine the costing of all categories) *Insert the information on the justification and detail breakdown of the expected cost and expenses for any relevant category involved. Details should include the description of activities, item, services required, the cost per individual item or per person and total cost as a whole.* *A PDF document of the costing details is available to be downloaded once all information is saved.*
MOH Research Grant (MRG) Cost Category Definition			
75.	Travel Transportation		Expenses on all domestic travels and transportations related to the research (any means of transportation accessible) *Details breakdown and justification for this category should include the origin and targeted final destination, estimated distance travelled between those destination, estimated fair/cost per individual and per ride/journey and other relevant information* *Insert the information on the category appropriately – if any*
76.	Rental		Rental for equipment, transportation and other items related to research activities *Details breakdown and justification for this category should include listing and name of the item/ equipment/ transportation required, cost/price per item, amount of item/ equipment/*

			transportation and other relevant information. *Insert the information on the category appropriately – if any*
77.	Raw Material		Expenses on gases and petrol as well as for purchasing food and beverages for research purposes *Details breakdown and justification for this category should include estimated distance travel and current sell price of the gases/petrol and other relevant information.* *Insert the information on the category appropriately – if any*
78.	Research Material Supplies		Expenses related to research-related supplies and materials (such as reagents, kits, consumables, animal bedding, stationeries, and others) *Details breakdown and justification for this category should include listing and name of the item/ material required, cost/price per item, amount of item/ equipment/ transportation and other relevant information.* *Insert the information on the category appropriately – if any*
79.	Special Service		Expenses covering printing, hospitality, honorarium, reimbursement to the research participants or subjects, service-based input, and others; training costs related to research, such as workshops, and others. *Details breakdown and justification for this category should include listing and name of the services or activities planned for the research, cost/price per service or activity per individual, estimated numbers of services/ activities required, number of individuals involved and other relevant information.* *Insert the information on the category appropriately – if any*
80.	Temporary Personnel		Salary and allowance for short-term personnel, which will be hired based on the research, *Details breakdown and justification for this category should include number of personnel required, expected salary according to the qualification, listing of job scope, duration of contract service and other relevant information.* *Insert the information on the category appropriately – if any*

81.	Special Equipment Accessories		Expenses for minor repairs and modifications of equipment, vehicles, or other items related to research activities. *** The amount allocated for this category should not exceed 40% of the approved total budget. Should any application exceed this limit, PI must provide strong justifications, specifications, quotations, and estimations for the purchase to the grant review committee (JPP-NIH).* *Details breakdown and justification for this category should include listing and name of the services/ modifications proposed, duration of the services/ modifications, estimated cost/price of the services/ modifications and other relevant information.* *Insert the information on the category appropriately – if any*
82.	Other (specify)		Other relevant cost and expenses outside of the above-mentioned category. e.g.; ***Utilities**: All charges related to postage, telephone, telex, telegraph, cables and others* ***Food and Beverages**: Expenses for purchasing food and beverages for research purposes* ***Minor Repair and Modifications**: Expenses for minor repair, maintaining and modifications of equipment, vehicles or other items related to research activities* *Insert the information on the category appropriately – if any*

History of Updates

No.	Update Version	Date of Update	Description of Updates	Prepared by (Checked by)	Endorsement Signature
1.	Version 1.0 (pre NMRR V2 update)	N. A	Taken from previous NMRR V1	NMRR Secretariat	
2.	Version 2.0	10 April 2021	All data element for submission in version 2, specific parameter according to specific research types (interventional research, observational research, qualitative research, mixed method research and biobanking)	NMRR Secretariat	
3.	Version 2.1	19 October 2023	Updates on element related to submission pre- and post-ethical submission, Grant MRG Submission, additional on description and requirement for the parameter/item involved.	NMRR Secretariat	
4.					
5.					
6.					