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MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION OF EXEMPTION FROM REGISTRATION OF MEDICAL DEVICES FOR THE PURPOSE OF CLINICAL RESEARCH OR PERFORMANCE EVALUATION

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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NOTIFICATION OF EXEMPTION FROM REGISTRATION OF MEDICAL DEVICES FOR THE PURPOSE OF CLINICAL RESEARCH OR PERFORMANCE EVALUATION

1. Introduction

Placement and supply of a medical device in the Malaysian market requires the device comply with the requirement of the Medical Device Act 2012, (Act 737), including that the device be registered with the Medical Device Authority. The Medical Device (Exemption) Order 2016 however has provided for medical devices to be exempted from the registration requirement if they are to be supplied for investigational or other specific defined purposes.

Prior to supplying a device potentially eligible for exemption, manufacturer or sponsor of the device investigation must submit a notification to Medical Device Authority for an exemption. No Restriction Letter issued by the MDA then permits the device to be supplied lawfully for the specific defined use.

This Guidance document provides guidance to manufacturer or sponsor of clinical investigation of medical device on the notification of exemption. It covers eligibility for exemption, the notification procedures and the use of exempted device including compliance with applicable standards, responsibilities of sponsors and investigators, labelling, records, and reports.

2. Scope and application

This document is applicable to all classes of unregistered medical devices for clinical research or performance evaluation, excluding those used for the in vitro examination of specimens derived from the human body.

3. Term and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 Adverse device effect

Adverse event related to the use of an investigational medical device.

NOTE 1. This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

NOTE 2. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

[Source: MEDDEV 2.7/2 revision 2]

3.2 Clinical data

Safety and/or clinical performance information that are generated from the use of a medical device in humans.

Explanation: Sources of clinical data may include:

(i) Results of pre- and post-market clinical investigation(s) of the device concerned;

(ii) Results of pre- and post-market clinical investigation(s) or other studies reported in the scientific literature of a justifiably comparable device;

(iii) Published and/or unpublished reports on other clinical experience of either the device in question or a justifiably comparable device.

[Source: Global Harmonization Task Force (GHTF) document, SG5/N1R8:2007]

3.3 Clinical evaluation

Review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

[Source: Medical Device Regulations 2012 (MDR 2012)]

3.4 Clinical evaluation report

The documentation of clinical evaluation.

[Source: MEDDEV 2.7/2 revision 2]

3.5 Clinical Evidence

The clinical data and the clinical evaluation report pertaining to a medical device.

Explanation:

Clinical evidence is an important component of the technical documentation of a medical device, which along with other design verification and validation documentation, device description, labelling, risk analysis and manufacturing information, is needed to allow a manufacturer to demonstrate conformity with the Essential Principles. It should be cross-referenced to other relevant parts of the technical documentation that impact on its interpretation.

In accordance with applicable local regulations, clinical evidence, in part or in total, may be submitted to and reviewed by conformity assessment bodies and regulatory authorities. The clinical evidence is used to support the marketing of the device, including any claims made about the clinical safety and performance of the device, and the labelling of the device.

Clinical evidence should be reviewed and updated throughout the product life cycle by the manufacturer as new information relating to clinical safety and performance is obtained from clinical experience during marketing (e.g. adverse event reports, results from any further clinical investigations, formal post market surveillance studies) of the device in question and/or comparable devices.

[Source: GHTF document SG5/N1R8:2007]

3.6 Clinical investigation plan (CIP)

A research study that prospectively document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record keeping of the clinical research.

[Source: ISO 14155]

3.7 Clinical investigator

Individual and/or institution responsible for the conduct of a clinical investigation who and/or which takes clinical responsibility for the well-being of the subjects involved.

[Source: ISO 14155]

3.8 Clinical performance

Behavior of a medical device or response of the subject(s) to that medical device in relation to its intended use, when correctly applied to appropriate subject(s).

[Source: ISO 14155]

3.9 Clinical use

Use of a medical device in or on living human subjects

NOTE. Includes use of a medical device that does not have direct patient contact.

[Source: MEDDEV 2.7/1 revision 4]

3.10 Clinical Safety

Freedom from unacceptable clinical risk, when using the device according to the manufacturer's instruction for use

NOTE. In exceptional cases where an instruction for use is not required, the collection, analysis and assessment are conducted taking into account generally recognized modalities of use.

[Source: MEDDEV 2.7/2 revision 2]

3.11 Ethic Committee (EC)

Independent body whose responsibility it is to review clinical investigation in order to protect the right, safety and wellbeing of human subjects participating in a clinical investigation.

NOTE. For the purposes of this guidance document, ethics committee is synonymous with research ethics committee, independent ethics committee or institutional review board.

3.12 Principal investigator

Qualified person responsible for conducting the clinical investigation at an investigation site

NOTE 1. If a clinical investigation is conducted by a team of individuals at an investigation site, the principal investigator is responsible for leading the team.

NOTE 2. Whether this is the responsibility of an individual or an institution can depend on national regulations.

[Source: ISO 14155]

3.13 Performance evaluation

Review of the performance of a medical device based on upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

[Source: Medical Device Regulations 2012]

3.14 Sponsor

An individual or organization taking responsibility and liability for the initiation or implementation of a clinical research or performance evaluation.

NOTE. When a clinical investigator independently initiates, implements and takes full responsibility for the clinical research and performance evaluation, the clinical investigator also assumes the role of the sponsor.

[Source: ISO 14155]

3.15 Qualified practitioner

A medical practitioner registered under Medical Act 1971 (Act 50) or dental practitioner registered under the Dental Act 1971 (Act 51).

4. Eligibility for notification of exemption from registration of medical devices for the purpose of clinical research or performance evaluation

Three categories of medical device defined by intended use in **Table 1** may be eligible for exemption from registration.

Table 1. Categories of medical device eligible for exemption from registration

No.	Categories of medical device	Description
a)	Clinical investigational use / performance evaluation	The use of an unregistered device in a clinical investigation designed to generate clinical data on the clinical performance and safety of the device required to support the Pre-Market Approval submission for device registration. NOTE**.** Clinical investigational use also includes study of modification to a registered device or new intended use of a registered device, with view to eventually extending the device registration to include the modification or new intended use. If the proposed clinical investigation is designed other than to demonstrate clinical performance and/or safety, e.g. user handling or preference studies, it should not be carried out on an unregistered device. Such studies should only be performed on registered devices unless they form part of a study to investigate safety and performance for registration purposes.

No.	Categories of medical device	Description
b)	Clinical use	The use of an unregistered or registered device to generate clinical experience data that is outside the conduct of a clinical investigation, on the clinical performance and safety of the device required to support the Pre-Market Approval submission for device registration. Clinical use is a particularly useful source of clinical data for low risk devices that are based on long standing, well-characterised technology and, therefore, unlikely to be the subject of either reporting in the scientific literature or clinical investigation.
c)	Research supportive use	The use of an unregistered device in the context of another health research. The device per se is not under investigation but is required to make the research feasible to be conducted in Malaysia. Common examples are: • Companion diagnostic test, unregistered and unavailable in Malaysia, to be used in a proposed clinical trial of novel targeted cancer drugs to be conducted in Malaysia • Screening diagnostic test, unregistered and unavailable in Malaysia, to be used in a health survey to be conducted in Malaysia. • Medical device, unregistered and unavailable in Malaysia, to be used in a proposed clinical trial of a surgical technique to be conducted in Malaysia

5. Notification process

5.1 Notification process for clinical investigational use

5.1.1 Applicant shall submit a Notification of Exemption from Registration of Medical Devices for Clinical Investigational Use using the form in **Annex A** to Medical Device Authority.

5.1.2 Particulars and information/ documents required in the application form are explained as per **Table 2.**

Table 2. Explanation on the particulars

Particulars	Explanation/Requirement
Purpose of notification	i. Whether notification is for importation or supply of the medical device. ii. Notification for supply is applicable for locally manufactured medical device only.
GENERAL INFORMATION	
SECTION A: APPLICANT DETAILS	
i. Applicant can be a local sponsor, manufacturer, an authorised person from a local organisation (in the case of foreign sponsor)/ Contract Research Organisation (CRO) or others. ii. Name, IC/passport, designation, name and address of firm/company, contact number, fax and email.	
SECTION B: SPONSOR DETAILS	
i. If the applicant in Section A is not the sponsor, please fill in details of the sponsor in this section. If the applicant itself is the sponsor, this section is not applicable. ii. Name of contact person of the sponsor, name and address of firm/company, contact number, fax, and email.	
SECTION C: APPLICATION DETAILS	
Application	i. Whether this is your first application or subsequent application. ii. For subsequent, please state the previous MDA identification number and the submission date.
National Medical Research Registry (NMRR) Registration ID	The registration ID under National Medical Research Registry (NMRR).
Title of clinical investigation - as stated in CIP document (please attach a copy of Clinical Investigation Plan (CIP):	State the title of the clinical investigation as stated in CIP and a copy of CIP.
- CIP No.	As stated on the CIP document.
- Estimated duration of the clinical investigation	Estimated duration for completion of the investigation.
- Proposed date of start of clinical investigation	The date of start according to CIP.
- Proposed date of completion of clinical investigation	The date of completion according to CIP.

SECTION D: ENTRY POINT (for importation only)	
Whether the entry point of importation checked as listed. If other than listed, please specify.	
SECTION E: MULTIPLE SHIPMENT	Whether more than one shipment applied, total number of devices per shipment to be specified.
SECTION F: FOR OFFICIAL USE	This Section is only for MDA use
SECTION G: ATTESTATIONS and DECLARATION	The attestations and declaration section shall be signed by applicant, with the company stamp and dated.
SECTION H: INVESTIGATOR BROCHURE: Device Identification	
a. Is this study being conducted in First In Human (FIH) / First In Man (FIM)?	Whether the study being conducted in FIH/FIM or not
b. Does the device contain a drug? (Not applicable for IVDs)	Whether the device contain drug or not.
- Brand/Trade Name of Drug	Unique name given by the manufacturer
- Active Ingredients	Active ingredient of the drug
- Manufacturer	The name of manufacturer that is the brand owner of the drug
- Applicable Drug Identification Number (if any)	The Drug identification Number issued by National Pharmaceutical Regulatory Agency (NPRA) of the drug if any.
c. Device usage category	Whether the device usage is within the category obstetrics & gynaecology, cardiovascular, ophthalmology, orthopaedics, physical medicine, neurology, dental, ear, nose & throat, anaesthesiology, radiology/imaging, gastroenterology & urology, general hospital, general & plastic surgery or others.
d. For IVDs only	Whether the IVDs medical device usage is within the category of chemistry, microbiology, immunology, clinical toxicology, haematology, pathology or others.
e. Will the medical device be marketed in Malaysia?	Whether the medical device will be marketed in Malaysia or not.

f. Medical Device Grouping	Grouping of medical device according to grouping rules as specified in Second Schedule of MDR2012
g. Please provide following supporting document for investigational medical device - A sample of packaging label for the device	Packaging label for investigational medical device. Content of label as prescribed by the Authority.
- Device Identification	Identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.
- Trade Name	Trade name of device given by the manufacturer
- Generic Name	The name given to a medical device that is used to Identify it irrespective of trademark or etc.
- Model Name	The name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer's medical device distinct from those of other manufacturers.
- Model number(s) (if any)	Model number(s) including revision number(s), if any (or reference from apparent).
- Manufacturer name and address	Manufacturer as specified in Section 2, Act 737, and address.
- Device Classification	The rule applied according to classification rules in First Schedule of MDR2012.
- Total Cost of Devices (MYR)	Total cost of devices in Malaysian Ringgit (MYR).
SECTION I: CLINICAL INVESTIGATIONAL PLAN (CIP): General Information	
Name & Address of the investigation site	Name (s), address of the institution (s) in which the clinical investigation (s) will be conducted; identification of the sponsor and other institution playing critical role in the investigation.
Name and professional positions of Principal Investigator	Name, professional position of principle investigator at the time of filing.
Address, contact number and email of Principal Investigator	Address, contact number and email of principle investigator.
Names and professional positions of Coordinating Investigators	Names, professional positions of Coordinating Investigators at the time of filing.

Contact numbers and emails of Coordinating Investigators	Contact numbers and emails of Coordinating Investigators from multicentre clinical investigation at the time of filing.
Name of the Ethics Committee	Specified name of the Ethics Committee.
Authorisation/Opinion of Ethics Committee	Tick the appropriate box
SECTION J: SUPPORTING DOCUMENTS	
Supporting documents required as per stated in Section C, Section H and Section I.	
- Clinical Investigation Plan (CIP)	Synopsis of the clinical investigation plan; reference to GCP standards followed, i.e. Declaration of Helsinki and ISO 14155. Rationale and justification of the clinical investigation; Summary of background to study with reference to important relevant scientific literature (if any) with analysis and bibliography; pre-clinical testing and previous clinical experience overview in support of justification for conducting the clinical investigation; device and investigation risk analysis and risk assessment. A summary of necessary training experience for use of device in question, if applicable. Copy of informed consent or the draft informed consent submitted in parallel to the Ethics Committee.
- Sample of device packaging label	Sample of packaging label of the device.
- EC Approval Letter	Ethics Committee (EC) Approval Letter for each local investigation institution is required.

5.1.3 Investigator Brochure: Other Device Details

a) Description of the intended clinical performance (refer ISO 14155).

b) A description of device including a list of accessories, principles of operation and block or flow diagrams of major components, together with a brief description of other devices designed to be used in combination for purpose of the investigation, if applicable.

c) Identification of any features of design that are different from a previously similar marketed product (if relevant).

d) Details of any new or previously untested features of the device including, where applicable, function and principles of operation.

e) Summary of experience with any similar devices made by same manufacturer including length of time on market and a review of performance related problems, complaints and any actions taken to address. Clinical data on device in question or similar device, if available. Reference should be made as to how experience with previous device models has affected the current iterations of design (if applicable).

f) Benefit/Risk analysis to include identification of hazards and estimated risks associated with the manufacture (including factors relating to device choice, choice of materials, software) and the use of the device, together with the description of what actions have been taken to minimise or eliminate the identified risks (NOTE. may also be included in the clinical investigation plan). Obligation to use ISO 14971.

g) Summary and analysis of pre-clinical testing and experimental data including results of design calculations, mechanical tests, electrical tests, tests for validation of software, reliability checks and any performance and safety tests in animals.

h) Description of materials coming into contact with the body, rationale for choice of materials and which standard apply (if relevant*)*

i) Description of how biocompatibility and biological safety have been addressed including identification of the risks and hazards associated with the use the device and how these have been addressed.

j) Identification of any pharmacological components of device with description of intended purpose and previous experience with the use this substance.

k) Design drawings, if necessary for the understanding of the functioning of the device.

l) Description of software, logic and constraints (if relevant).

m) Method of sterilisation and validation (method, justification, if ETO-residuals) (if applicable) and methods of cleaning, disinfection and sterilisation for reusable devices.

n) Identification of any tissues of animal origin incorporated within the device together with information on the sourcing and collection of animal tissue(s) prior to manufacturing operation; and details with regard to validation of manufacturing procedures employed for the reduction or inactivation of unconventional agents. This is also applicable in circumstances of genetically produced material.

o) Identification of any special manufacturing conditions required and if so, how such requirements have been met.

p) List of relevant Standards applied in full or in part, or description of solutions adapted to meet the essential requirements of the Directive if relevant standards have not been fully applied, using the form List of Standard applied in full or part as per **Annex B.**

q) Instructions for use/labelling including risks, contra indications and warnings (if available).

r) What provisions, if any have been made by the manufacturer for the recovering of the device (if applicable, i.e. implantable devices, multiple use devices) and subsequent prevention of unauthorised use.

5.1.4 Clinical investigation plan (CIP): investigation parameters and design

a) Objectives of clinical investigation.

b) Investigation design, e.g. randomised, controlled, including clear statement of the endpoints corresponding to the objectives of the clinical investigation, variables to be used, methods and timing of the assessments.

c) Numbers of subjects (with justification).

d) Duration of study with estimated start and finishes dates and proposed follow up period (with justification).

e) Criteria for subject selection.

f) Criteria for withdrawal from study

g) Description and justification of hazards caused by invasive procedures that are not medically required (if applicable).

h) Description of general methods of diagnosis or treatment of the medical condition for which the investigation testing is being proposed.

i) Monitoring arrangements during the clinical investigation including request for direct access to source documents including extent of source data verification.

5.1.5 Clinical investigation plan: data collection /analysis/statistics

a) Description of endpoints to demonstrate safety and performance and the data recorded to achieve the endpoints, method of subjects follow up, assessment and monitoring arrangements during investigation.

b) Description and justification of statistical design, method and analytical procedures. Statistical considerations including statistical design and methods describing how to reach endpoints to demonstrate safety and performance. Level of significance and the power of the clinical investigation, any criteria for termination of the clinical investigation (if applicable) with statistical justifications.

c) Procedures for data collection, review, cleaning, and issuing and resolving queries, if appropriate.

d) Recording and reporting procedures of clinical investigation plan deviations, if appropriate.

5.1.6 Clinical investigation plan: other information

a) Ethics and informed consent procedures

b) Procedure for early termination or suspension of the investigation giving criteria and risk analysis.

c) Procedure for clinical investigation plan amendments

d) Final report and publication policy.

5.2 Notification for clinical use and research supportive use

5.2.1 Applicant shall submit a Notification of Exemption from Registration of Medical Devices for Clinical Use and Research Supportive Use using the form in **Annex C** to Medical Device Authority.

5.2.2 For issuance of the Letter of No Restriction from MDA, the applicant shall submit a copy of letter of approval from Ethics Committee.

5.2.3 Particulars and information/ documents required in the application of notification are explained in **Table 3**.

Table 3. Explanation on the particulars

Particulars	Explanation/Requirement
First application	Choose if it is a first application
Subsequent Application, please state the previous notification no.	Choose this if it is a subsequent application and state the Notification number of the previous application.
SECTION A: PURPOSE OF RESEARCH	
Tick whether the purpose of research is for clinical use, clinical trial (for drug study) or for research supportive use.	
SECTION B: APPLICANT DETAILS	
i. Applicant can be a local sponsor, manufacturer, an authorised person from a local organisation (in the case of foreign sponsor)/ Contract Research Organisation (CRO) or others. ii. Provide the name, IC/passport, designation, name and address of firm/company, contact number, fax and email.	
SECTION C: SPONSOR DETAILS	
i. If the applicant in Section A is not the sponsor, please fill in details of the sponsor in this section. If the applicant itself is the sponsor, this section is not applicable. ii. Name of contact person of the sponsor, name and address of firm/company, contact number, fax, and email.	
SECTION D: CLINICAL RESEARCH DETAILS	
1. National Medical Research Registry (NMRR) Registration ID	The registration ID under National Medical Research Registry (NMRR).

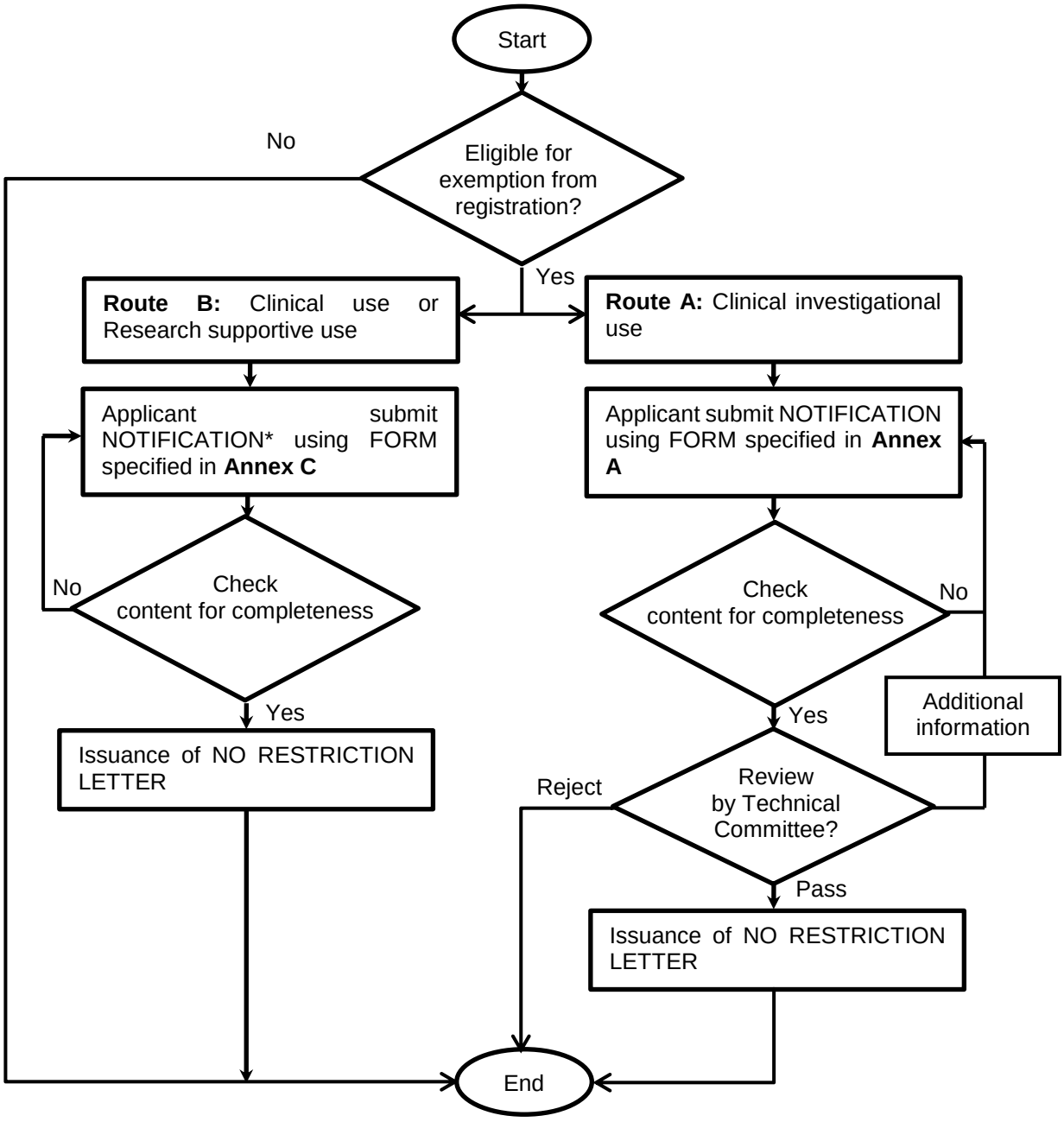
2. Title of Clinical Trial - as stated in Protocol document	State the title of the Clinical Trial as stated in Protocol document.
3. Protocol No.	As stated on the Protocol document.
4. Estimated duration of the clinical trial	Estimated duration for completion of the clinical trial.
5. Proposed date of start of trial	The date of start according to Protocol document.
SECTION E: TRIAL SITE DETAILS For multiple sites in Malaysia, please refer **Appendix A** – Repeat as needed	
1. Name & Address of the trial site	Specified name of location and address of the trial site
2. Name of Principal Investigator	Name of the Principal Investigator of the specified site
3. Name of the Ethics Committee	Specified name of the Ethics Committee
4. Authorisation/Opinion of Ethics Committee (please attach the approval letter)	Whether the approval is to be requested, pending approval or Authorisation accepted/favourable opinion. Approval letter must be attached on the application.
SECTION F: MEDICAL DEVICE DETAILS	
Please provide medical device details according to the following: 1. **Appendix B (Annex C)** for Non-Investigational Medical Devices	
PARTICULARS OF NON-INVESTIGATIONAL MEDICAL DEVICES – (Repeat As Needed)	
Is the packing list for Study-Visits Specific Kits attached as part of the supporting documents?	Whether the packing list for Study-Visits Specific Kits attached as part of the supporting documents or not.
Device Name	The proprietary name and generic name of medical device
Identifier (e.g. Model/ Lot/Batch Number)	Identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.
Description & Intended Purpose (description must be precisely in details)	General description of the device which explains how the device functions, the basic scientific concepts that form the fundamentals for the device,

	the component materials and accessories used in its principles of operation. Intended use of the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device.
Risk Class	According to the Rules of Classification as specified in Appendix 1, Schedule 1 MDR 2012.
Product Owner / Manufacturer	Definition of 'manufacturer' as defined in section 2 of Act 737.
Total Quantity per site (Units)	Total quantity of device per site
Total Quantity (Units)	Total quantity of device
Total Cost of devices (MYR)	Total cost each device in Malaysian Ringgit
SECTION G: ENTRY POINT Tick in the appropriate box from which entry point the device is coming through and specified the location if others location than given.	
SECTION H: MULTIPLE SHIPMENT Whether more than one shipment applied, total number of devices per shipment to be specified.	
SECTION I: ATTESTATIONS and DECLARATION The attestations and declaration section shall be signed by applicant, name, designation, with the company stamp and dated.	
SECTION J: FOR OFFICIAL USE This section is for MDA use	
SECTION K: SUPPORTING DOCUMENTS Supporting documents required as per stated in Section E (or Appendix A) and Appendix B.	
- EC Approval Letter	Ethics Committee (EC) Approval Letter for each local trial institution is required.
- Packing List for Study-Visits Specific Kits	A complete packing list of the items in the Study-Visits Specific Kits can be attached as a supporting document for the submission. Study protocol number should be indicated on the packing list for reference.

5.3 Notification Review

The review involves in the notification of exemption from registration of medical devices for the purpose of clinical research or performance evaluation is summarized in the **Figure 1** below.

Figure 1. Flowchart for notification review



REMARK:
*NOTIFICATION: Applicant is required to provide some information about the Clinical use or Research supportive use of the device in the NOTIFICATION to MDA. This is all that is required by MDA to grant the applicant the exemption from registration. NOTIFICATION process in route B unlike route A is not subject to formal review by MDA.

5.3.1 Table 4 shows necessary preparations before making an application for notification. It also shows certain requirements to be met for each step of the preparation.

Table 4. Particulars for notification review

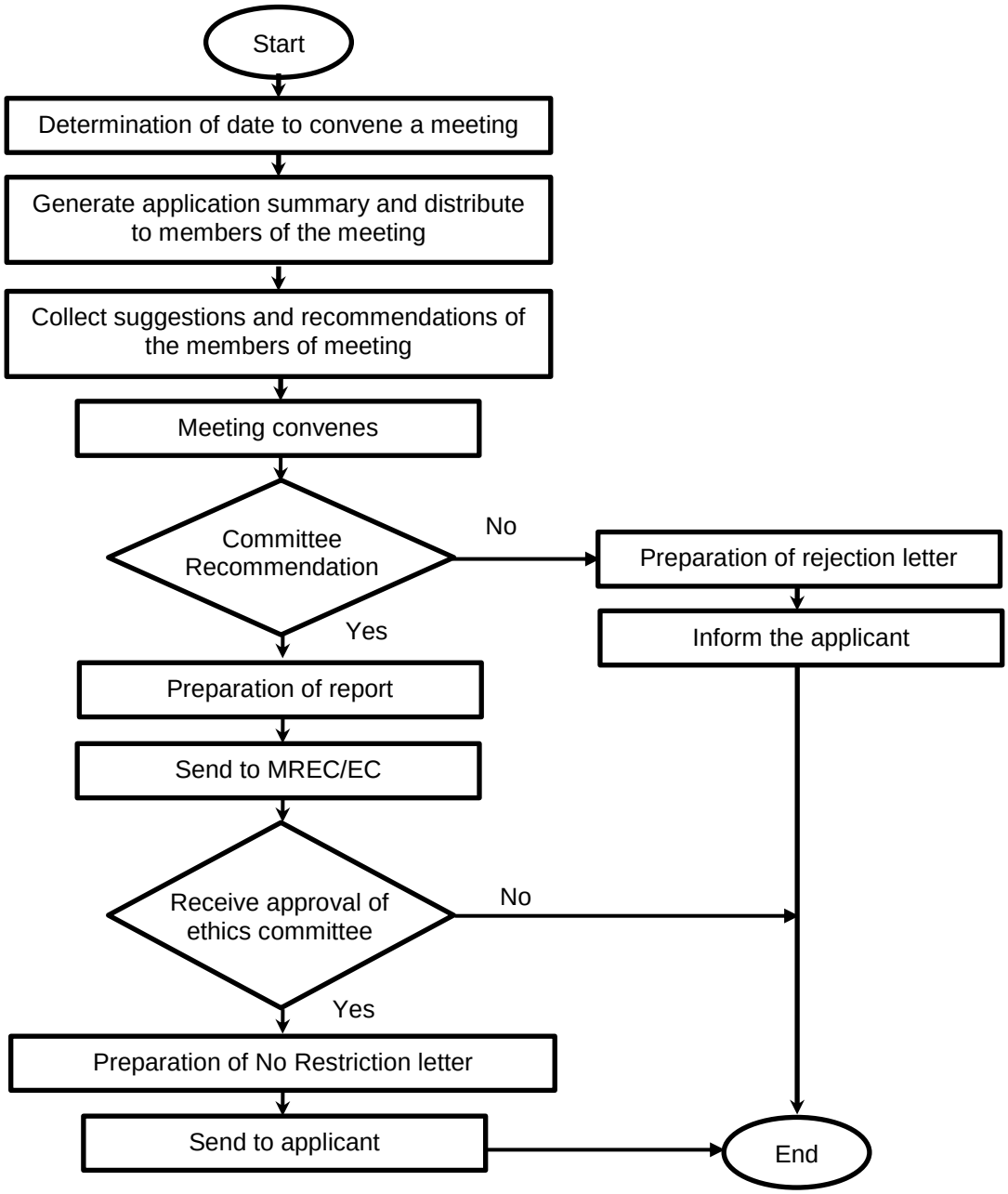
Step	Preparation /criteria
a) Applicant submit notification to MDA	Applicant should submit the form together with National Medical Research Registry (NMRR) identification number (if applicable). To obtain the NMRR number, applicant must submit the clinical investigations to the NMRR system before applying for notification of medical devices for the purpose of clinical research or performance evaluation.
b) MDA check content for completeness	Accepted applications will be screened to ensure the completeness of the application as well as the attached supporting documents as mentioned in the forms. Incomplete applications will be informed and returned to the applicant to make the necessary changes.
c) Review by Technical Committee	The application process will be sorted according to type of notification review: • ROUTE A: Notification for Clinical Investigational Use NOTE. Notification for Clinical Investigational Use will go through the Technical Committee Review as per in **Figure 1** • ROUTE B: Notification for Clinical Use or Research Supportive Use or NOTE. Notification for Clinical Use or Research Supportive Use will not subject to formal review by The Technical Committee.
d) MDA issue No Restriction Letter	A No Restriction Letter will be prepared and sent to the applicant.

5.4 Flowchart for ROUTE A: Notification for Clinical Investigational Use

5.4.1 Notification for Clinical Investigational Use will go through the Technical Committee Review. The process involves in Technical Committee Review is summarized in the **Figure 2** below.

NOTE. Turnaround time for Technical Committee Review is approximately 30 working days.

Figure 2. Flowchart for Technical Committee Review process



5.4.2 Table 5 shows processes involve in the **ROUTE A** and the preparations required for notification of **Clinical Investigational Use**.

Table 5. ROUTE A: Notification for Clinical Investigational Use

Step	Preparation /criteria
a) Determination of date to convene a meeting	The Secretariat of the meeting will determine the date for the meeting to convene, through the agreement of all its members.
b) Generate application summary and distribute to members of the meeting	Summary of the application will be prepare and distribute by the secretariat to the members of the meeting prior to the date of the meeting.
c) Collect suggestions and recommendations of the members of meeting	Suggestion and recommendation received from the members of meeting will be compiled.
d) Meeting convenes	During the meeting, members will review the application, as well as the collected feedbacks and recommendations to make a decision on each and every application.
e) Committee recommendation	The meeting will give recommendation whether the clinical investigation can be conducted in the healthcare facilities. If the clinical investigation is not safe to be conducted, a rejection letter will be prepared to notify the applicant on that matter.
f) Preparation of report	If the clinical investigation meets the safety criteria, a report will be prepared by MDA.
g) Send to Medical Research and Ethics Committee (MREC)	The report to MREC consists of the approval of ethical protocols, rational and safety concern on the clinical investigation.
h) Approval of ethics committee	An approval shall be obtained from the ethics committee before the notification letter of exemption from registration can be issued. If the ethics committee does not approve the clinical investigation, the notification letter of exemption from registration will not be issued to the applicant.
i) Preparation of No Restriction letter	After the approval by MREC/EC, a No Restriction letter will be prepared and sent to the applicant.
j) Send to applicant	The letter will be sent to the applicant.

5.5 Conditions

5.5.1 The notification of exemption from registration of medical devices for the purpose of clinical research or performance evaluation shall be subjected to the following conditions:

a) The unregistered medical devices shall only be permitted for import by the applicant.

b) The applicant shall be responsible for ensuring that the quality, safety and performance of the unregistered medical device are not adversely affected during import, storage and distribution of the medical devices.

c) The applicant shall ensure that medical devices for clinical investigational use is designed, conducted and reported in accordance to ISO 14155, *Clinical research of Medical Devices for Human Subjects – Good Clinical Practice*.

d) The applicant shall ensure the relevant Ethics Committee approval has been obtained for each investigation site.

e) The applicant shall inform Medical Device Authority of any incidents arising from the use of the unregistered medical devices for clinical research /performance evaluation that become known to the applicant as according to **Form SADE in Annex D**. Any adverse consequence that results from the use of the medical device shall be the responsibility of the qualified practitioner and the applicant. The applicant shall report the incident/problem to the Authority. The incident/problem reporting must be reported to Medical Device Authority within 48 hours of the occurrence of the incident. The applicant shall indemnify against all actions, claims or proceedings in respect of any incidents, problems injury to or death of any person whomsoever arising out of or in connection with the use of the unregistered medical device(s).

f) The Applicant shall maintain records on the distribution of the unregistered medical device at the clinical research /performance evaluation sites.

g) Upon completion of the clinical research /performance evaluation, the Applicant shall make a declaration using the form in **Annex E**. This declaration shall be submitted to the Authority within 30 days after the date of completion.

h) Should the clinical research /performance evaluation terminate earlier than the proposed date or temporarily suspended, Medical Device Authority shall be notified of the reasons for termination or suspension within two (2) weeks of the clinical research /performance evaluation being discontinued using the form in **Annex E**.

i) The approved quantity of the unregistered medical devices shall be indicated with “NOT FOR SALE, FOR CLINICAL INVESTIGATION/CLINICAL RESEARCH/PERFORMANCE EVALUATION PURPOSES ONLY”.

j) All remaining unused supplies of the unregistered medical device(s) shall be returned to the Sponsor.

k) All medical devices involved in clinical research except the used disposables shall be returned to Sponsor.

l) Applicant shall submit a progress report every 6 months, following template as per form in **Annex F**.

m) Any other conditions may be requested by the Authority from time to time.

n) The medical devices should be label accordance with labelling requirement specified by the Authority.

NOTE. The 'letter of No Restriction to import the unregistered medical device' may be cancelled by Medical Device Authority by informing the Applicant in writing. If the notification is cancelled, all unsupplied or balance of the unregistered medical devices imported under this letter of No Restriction shall be placed under quarantine by the Applicant in their facility. The Applicant shall not supply or remove medical devices under quarantine until further instruction by Medical Device Authority. Medical Device Authority will provide feedback within 7 working days upon complete documentation.

6. Application for change

Applicant shall inform Authority on the changes on clinical research under clinical research notification using **form in Annex G**.

The changes involved may include:

a) Change to principal investigator;
b) Change in site name;
c) Change in site address;
d) Subsequent notification of additional clinical research notification site;
e) Change to ethic committee;
f) Changes of device (e.g.: quantity of device and type of device used); or
g) Others (e.g.: change in protocol/CIP, protocol title, subject recruitment)

7. Notification of early termination, suspension or completion of clinical research/ performance Evaluation

On completion of the clinical research /performance evaluation approved in the Clinical Research Plan, the Applicant shall be required to submit using **form in Annex E** on the status of medical devices that have been imported and supplied in Malaysia to the Authority.

Annex A
(normative)

NOTIFICATION TO IMPORT AND/OR SUPPLY MEDICAL DEVICES FOR CLINICAL INVESTIGATIONAL USE (In accordance with Medical Device (Exemption) Order 2016)		
All fields are mandatory unless stated otherwise.		
PURPOSE OF NOTIFICATION: ☐ Importation ☐ Supply (Note: for locally manufactured medical device)		
GENERAL INFORMATION		
SECTION A: APPLICANT DETAILS		
1. Please tick the appropriate box:		
☐ Local Sponsor		
☐ Manufacturer		
☐ An authorised person from a local organization (in case of foreign sponsor)/ Contract Research Organisation (CRO) (Note: shall have a permanent address in Malaysia)		
☐ Others (please specify):……..		
2. Name of Applicant:		
3. NRIC No./Passport:	4. Designation:	
5. Name & Address of Organisation:		
6. Telephone No.:	7. Fax No.:	8. Email Address:
SECTION B: SPONSOR DETAILS (to be filled if applicant details above is not sponsor)		
1. Name of Contact Person:		
2. Name & Address of Organisation:		
3. Telephone No.:	4. Fax No.:	5. Email Address:

SECTION C: APPLICATION DETAILS	
1. ☐ First Application	
2. ☐ Subsequent Application, please state: Previous MDA identification no.: …… Previous submission date :……	
3. National Medical Research Registry (NMRR) Registration ID:	
4. Title of clinical investigation - as stated in in Clinical Investigation Plan (CIP) document (please attach a copy of Clinical Investigation Plan (CIP):	5. CIP No.:
	6. Checklist CIP review report (refer to Appendix A for template of checklist):
	7. Estimated duration of the clinical investigation :
	8. Proposed date of start of clinical investigation:
	9. Proposed date of completion of clinical investigation:

SECTION D: ENTRY POINT (Note: For Importation Only)	
Please tick the appropriate box:	
☐ Lapangan Terbang Antarabangsa Kuala Lumpur	☐ Lapangan Sultan Abdul Aziz Shah Subang
☐ Pelabuhan Klang	☐ Pelabuhan Pulau Pinang
☐ Pelabuhan Johor Bahru	☐ Others (please specify): ……

SECTION E: MULTIPLE SHIPMENT *(tick the appropriate box & kindly state the total no. of devices per shipment if this trial requires multiple shipment* – Repeat if necessary*)*
☐ First shipment : Total number of devices _____
☐ Second shipment : Total number of devices _____
☐ Third shipment : Total number of devices _____

SECTION F: FOR OFFICIAL USE		
MDA Identification No.:	**Date:**	**Valid Till:**

SECTION G: ATTESTATIONS & DECLARATION

(In accordance with Medical Device (Exemption) Order 2016)

I, the undersigned, on behalf of the company hereby declare that:

a. This/These medical device (s) indicated on this application:
   i. Conform(s) to all relevant essential principles for safety and performance as set out in the Appendix 1 of Third Schedule of the Medical Device Regulations (MDR) 2012;

   ☐ Fully ☐ Partially

   ii. Has/have met all the labelling requirements determined by the Authority

b. I hereby confirm that/confirm on behalf of the sponsor (delete which is not applicable) that:
   - the information provided is complete
   - the attached documents contain an accurate account of the information available
   - the clinical investigation will be conducted in accordance with the clinical investigation plan
   - serious adverse events and result-related information will be reported, in accordance with the applicable legislation
   - I confirm that the medical device(s) conform(s) to the essential requirements of all applicable directives and regulations except for those which are the scope of this CI
   - I confirm that appropriate safety measures have been taken for study participants/users
   - I accept the applicable fee(s)

c. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of investigation;

d. I am aware this/these medical device(s) is/are permitted for clinical investigation purpose only. Therefore, the medical device(s) shall not be:

   - placed/used at the trial site after the trial has ended;
   - placed in Malaysia;

e. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of Malaysia after the investigation has ended;

I, the undersigned, hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding **RM 500,000.00** or to imprisonment for a term not exceeding **3 years** or to both. (S.76 Act 737 refers).

Signature: Company Stamp:

Name:

Designation: Date:

SECTION H: INVESTIGATOR BROCHURE: Device Identification				
a. Is this study being conducted in First In Human (FIH) / First In Man (FIM)? ☐ Yes ☐ No				
b. Does the device contain a drug? (Note: this question does not apply to IVDs) ☐ Yes ☐ No	If yes,			
	i. Brand/Trade Name of Drug:			
	ii. Active Ingredients:			
	iii. Manufacturer:			
	iv. Applicable Drug Identification Number (if any):			
c. Device usage category (please tick the appropriate box)				
☐ Obstetrics & Gynaecology	☐ Cardiovascular	☐ Ophthalmology	☐ Orthopaedics	☐ Physical Medicine
☐ Neurology	☐ Dental	☐ Ear, Nose & Throat	☐ Anaesthesiology	☐ Radiology/Imaging
☐ Gastroenterology & Urology	☐ General Hospital	☐ General & Plastic Surgery	☐ Others (please specify):……..	
d. For IVDs only (please tick the appropriate box)				
☐ Chemistry	☐ Microbiology	☐ Immunology	☐ Clinical Toxicology	
☐ Haematology	☐ Pathology	☐ Others (please specify):……..		

e. Will the device be marketed in Malaysia? ☐ Yes ☐ No

f. Medical Device Grouping:

☐ Single ☐ Family ☐ Set ☐ System ☐ IVD Test Kit ☐ IVD Cluster

g. Please provide following supporting document for investigational medical device:

☐ Sample of packaging label for the device

No.	Device Identification	Trade Name	Generic Name	Model Name	Model number(s) (if any)	Manufacturer name and address	Device Classification	Total Cost of Devices (MYR)

h. Please provide the Investigator Brochure containing other device details as specified in 5.1.3 in the Guidance Document – Notification of Exemption From Registration of Medical Devices For The Purpose Of Clinical Research or Performance Evaluation

SECTION I: CLINICAL INVESTIGATIONAL PLAN (CIP): General Information							
No.	**Name & address of the investigation site**	**Name and professional position of Principal Investigator**	**Address, contact number and email of Principal Investigator**	**Name and professional positions of Coordinating Investigator**	**Address, contact number and email of Coordinating Investigator**	**Name of the Ethics Committee**	**Authorisation/Opinion of Ethics Committee** (please attach the approval letter)
							☐ To be requested ☐ Pending ☐ Authorisation accepted /favourable opinion
							☐ To be requested ☐ Pending ☐ Authorisation accepted /favourable opinion
							☐ To be requested ☐ Pending ☐ Authorisation accepted /favourable opinion

SECTION J: SUPPORTING DOCUMENTS			
DOCUMENTS	**CHECKLIST** (Please tick if the document is attached)	**REQUIRED FOR**	**REMARKS**
Clinical Investigation Plan (CIP) (Including a copy of informed consent or the draft informed consent submitted in parallel to the Ethics Committee)		Section C	
Sample of device packaging label		Section H	
EC Approval Letter		Section I	Ethics Committee (EC) Approval Letter for each local investigation institution is required.

Note: Additional documents or information may be requested by MDA, if deemed necessary

The form and supporting documents can be sent either via email *(Please convert the form to PDF Format) to* CI@mdb.gov.my OR via posts to:

Pengarah
Bahagian Penilaian Teknikal
Pihak Berkuasa Peranti Perubatan
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA

Appendix A

CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) MEDICAL DEVICE FOR CLINICAL INVESTIGATIONAL USE AND GENERATING DATA INTENDED TO BE SUBMITTED TO REGULATORY AUTHORITY

(Source: Malaysian Standard for Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice (ISO 14155:2011, COR. 1:2011, IDT, ICH harmonized Tripartite Guideline for Good Clinical Practice 1996)

No.	Details	Tick (√) if Submitted	Comments
1.	**GENERAL INFORMATION** **a. <u>Identification of CIP</u>** - Title of clinical investigation - Reference / protocol number identifying the specific clinical investigation, if any - Version or date of the CIP - Summary of the revision history in the case amendments - Version / issue number and reference number, if any, with the page number and the total number of pages on each page of the CIP **b. <u>Sponsor</u>** - Name (contact person) - Address - Contact no. **c. <u>Principal Investigator, Coordinating Investigator & Investigation Site(s)</u>** - Name, address, and professional position of i. Principal investigator(s) ii. Coordinating investigator, if appointed - Name and address of the investigation site(s) in which the clinical investigation will be conducted - Name(s) and address(es) of other institutions involved in the clinical investigation. **d. <u>Overall synopsis of the clinical investigation</u>** - Summary or overview of the clinical investigation regarding the clinical investigation design, i.e i. inclusion / exclusion criteria ii. number of subjects, iii. duration of the clinical investigation iv. follow-up v. objective(s) vi. endpoint(s)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
2.	**BACKGROUND** **a. <u>Identification and description of the investigational device</u>** - Summary		

	i. description of the investigational device and its intended purpose ii. necessary training and experience needed to use the investigational device iii. Findings from nonclinical and clinical studies - Details concerning the manufacturer of the investigational device i. Name & address, phone no. - Name / number of the model / type, including software version and accessories, if any, to permit full identification - Intended purpose of the investigational device in the proposed clinical investigation - The populations and indications for which the investigational device is intended - Description i. investigational device including any materials that will be in contact with tissues or body fluids ii. specific medical or surgical procedures involved in the use of the investigational device iii. how traceability shall be achieved during and after the clinical investigation, for example, by assignment of lot numbers, batch numbers or serial numbers - Acknowledgement to conduct the trial in compliance with GCP & other regulatory requirements - Accountability procedure for investigational device - Literature review	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
3.	**JUSTIFICATION** **a. <u>Justification for the design of the clinical investigation</u>** - Evaluation of the results of the relevant pre-clinical testing / assessment - Evaluation of clinical data, relevant to the proposes clinical investigation	☐ ☐	
4.	**RISKS AND BENEFITS** **a. Risks and benefits of the investigational device and clinical investigation** - Anticipated clinical benefits - Anticipated adverse device effects - Residual risks associated with the investigational device, as identified in the risk analysis report - Risks associated with participation in the clinical investigation - Possible interactions with concomitant medical treatments - Steps that will be taken to control or mitigate the risks	☐ ☐ ☐ ☐ ☐ ☐	

	- Risk-to-benefits rationale	☐	
5.	**OBJECTIVES AND PURPOSE** **a. Objectives and hypotheses of the clinical investigation** - Objectives, primary and secondary - Hypotheses, primary and secondary, to be accepted or rejected by statistical data from the clinical investigation - Claims and intended performance of the investigational device that are to be verified - Risks and anticipated adverse effects that are to be assessed	☐ ☐ ☐ ☐	
6.	**TRIAL DESIGN** **a. General** - Description i. Type of clinical investigation with rationale ii. Measures to be taken to minimize / avoid bias – randomization, blinding / masking - Primary and secondary endpoints - Methods and timing for assessing, recording and analysing variables - Equipment to be used for assessing the clinical investigation variables and arrangements for monitoring maintenance and calibration - Stopping rules / discontinuation for parts or entire trial - Maintenance of randomization codes and procedures for breaking codes - Sequence and duration of all trial periods including follow-up, if any - Identification of data to be directly recorded on CRF **b. Investigational device & comparator(s)** - Description of the exposure to the investigational device(s) or comparator(s), if used - Justification of the choice of comparator(s) - List of any medical device / medication to be used during the clinical investigation - Number of investigational devices to be used, with justification **c. Subjects** - Inclusion criteria for selection - Exclusion criteria for selection - Withdrawal / discontinuation – criteria & procedures - Point of enrolment - Total expected duration of the clinical investigation - Expected duration of each subject's participation	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	

	- Number of subjects required to be included in the clinical investigation - Estimated time needed to select number of subject (enrolment period) - Type and timing of data to be collected from withdrawn subjects - Follow-up on withdrawn subjects - Replacement of subjects – the procedures - Treatment of subjects i. Details on treatments to be administered ii. Permitted and not permitted medications / treatments during trial iii. Rescue medication / procedure iv. Monitoring plan for subject compliance **d. Procedures** - Description i. clinical-investigation-related procedures that subjects undergo during the clinical investigation ii. activities performed by sponsor representatives (excluding monitoring) - any known / foreseeable factors that may compromise the outcome of the clinical investigation or the interpretation results **e. Monitoring Plan** - Follow the general outline including access to source data & extent of source data verification planned	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
7.	**STATISTICAL CONSIDERATIONS** - Description & justification for i. Statistical design, method analytical procedures ii. Sample size – reason & calculation iii. Selection of subjects to be included in analysis iv. Level of significance & power of the clinical investigation v. Expected drop-out rates vi. Pass/fail criteria to be applied to the results of the clinical investigation vii. The provision for an interim analysis, where applicable viii. Criteria for the termination of the clinical investigation on statistical grounds ix. Procedures for reporting any deviation(s) from the original statistical plan x. The specification of subgroups for analysis xi. Procedures that take into account all data	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	

	xii. The treatment of missing, unused or spurious data, including drop-outs and withdrawals xiii. The exclusion of particular information from the testing of the hypotheses, if relevant, xiv. In multicentre clinical investigations, the minimum and maximum number of subjects to be included for each centre (Special reasoning and sample size(s) are applicable for early clinical investigation(s))	☐ ☐	
8	**ASSESSMENT OF EFFICACY** - Specification of efficacy parameters - Methods and timing for assessment, recording and analysis	☐ ☐	
9	**ASSESSMENT OF SAFETY** - Specification for safety parameters - Methods and timing for assessment, recording and analysis - Procedures for getting reports and reporting of adverse events and intercurrent illnesses - Type and duration of follow-up after adverse events	☐ ☐ ☐ ☐	
10.	**DATA MANAGEMENT** - Procedures i. Used for data review, database cleaning, issuing and resolving data queries ii. Verification, validation and securing electronic clinical data systems iii. Data retention - Specific data retention - Other aspects of clinical quality assurance - Direct access to source data / documents - Permit trial related monitoring, audits, IEC review and regulatory inspection by the investigator	☐ ☐ ☐ ☐ ☐	
11.	**AMENDMENTS TO CIP** - Procedures to amend the CIP	☐	
12.	**DEVIATIONS FROM CIP** - Statement to specify that investigator cannot deviate from the CIP - Procedures for recording, reporting and analysing CIP deviations - Notifications requirements and time frames - Corrective and preventive actions and principal investigator disqualification criteria	☐ ☐ ☐ ☐	

13.	**DEVICE ACCOUNTABILITY** - Procedures for the accountability of investigational devices	☐	
14.	**STATEMENTS OF COMPLIANCE** - Clinical investigations shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki - Compliance to International Standard and any regional or national regulations, as appropriate - Clinical investigations shall not begin until the required approval / favourable opinion from the EC or regulatory authority have been obtained - Any additional requirements imposed by the EC or regulatory authority shall be followed - Type of insurance that shall be provided for subjects	☐ ☐ ☐ ☐ ☐	
15.	**INFORMED CONSENT PROCESS** - Description i. General process for obtaining informed consent, including the process for providing subjects with new information ii. Informed consent process in circumstances where the subject is unable to give it; in the case of emergency treatment	☐ ☐	
16.	**ADVERSE EVENTS, ADVERSE DEVICE EVENTS AND DEVICE DEFICIENCIES** - Definitions i. Adverse events and adverse device events ii. Device deficiencies iii. Serious adverse events, serious adverse events and unanticipated serious adverse device events - Time period in which the principal investigator shall report all adverse events and device deficiencies to the sponsor and, where appropriate, to ECs and the regulatory authority - Details i. Process for reporting adverse events a. Date of adverse events b. Treatment c. Resolution d. Assessment of both the seriousness e. Relationship to the investigational device	☐ ☐ ☐ ☐ ☐ ☐	

	ii. Process for reporting device deficiencies - List of foreseeable adverse events and anticipated adverse device events, together with their likely incidence, mitigation and treatment - Emergency contact details for reporting serious adverse events and serious adverse device events - Information regarding DMC	☐ ☐ ☐	
17.	**VULNERABLE POPULATION** - Description i. Vulnerable population ii. Specific informed consent process iii. EC's specific responsibility iv. Medical care provided for subjects after the clinical investigation has been completed	☐ ☐ ☐ ☐	
18.	**SUSPENSION / PREMATURE TERMINATION** - Criteria i. Arrangement for suspension / premature termination of the whole clinical investigation or of the clinical investigation in one or more investigation sites ii. Access to and breaking the blinding / masking code in the case of suspension or premature termination of the clinical investigation, if it involves a blinding / masking technique - Requirements for subject follow-up	☐ ☐ ☐	
19.	**PUBLICATION POLICY** - Statement i. Indication of results of the clinical investigation will be submitted for publication ii. Indication of the conditions under which results of the clinical investigations will be offered for publication	☐ ☐	
20.	**QUALITY CONTROL AND ASSURANCE**	☐	
21.	**ETHICS**	☐	
22.	**DATA HANDLING AND RECORD KEEPING**	☐	
23.	**FINANCE AND INSURANCE**	☐	
24.	**SUPPLEMENTS**	☐	

Annex B
(normative)

List of the Standards Applied in Full or in Part

Investigational Device (Name, Size, Model)
Manufacturer:
Date:

Standard (Identifier and Title)	Version / Year	Compliance (with the exception of clinical requirements that will be assessed during the clinical investigation)		
		Full	Partial	Description of all deviations and of the alternative solutions adopted to meet the essential principles.
		☐	☐	
		☐	☐	
		☐	☐	
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		☐	☐	

Annex C
(normative)

NOTIFICATION TO IMPORT MEDICAL DEVICES FOR CLINICAL RESEARCH USE (In accordance with Medical Device (Exemption) Order 2016)		
All fields are MANDATORY unless stated otherwise.		
☐ First Application		
☐ Subsequent Application, please state the previous **notification no**.: MDA/_____		
SECTION A: PURPOSE OF RESEARCH		
☐ Clinical Use	☐ Clinical Trial (for Drug Study use)	
☐ Research Supportive Use		
SECTION B: APPLICANT DETAILS		
1. Please tick the appropriate box:		
☐ Local Sponsor	☐ Manufacturer	
☐ An authorised person from a local organisation / company / Contract Research Organisation (CRO) (Note: must have a permanent address in Malaysia)		
2. Name of Applicant:		
3. NRIC No./Passport:	4. Designation:	
5. Name & Address of Organisation:		
6. Telephone No.:	7. Fax No.:	8. Email Address:
SECTION C: SPONSOR DETAILS		
1. Name of Contact Person:		
2. Name & Address of Organisation:		
3. Telephone No.:	4. Fax No.:	5. Email Address:
SECTION D: CLINICAL RESEARCH DETAILS		
1. National Medical Research Registry (NMRR) Registration ID:		
2. Title of Clinical Trial - as stated in Protocol document	3. Protocol No.: 4. Estimated duration of the clinical trial: 5. Proposed date of start of trial:	
SECTION E: TRIAL SITE DETAILS		
For multiple sites, please refer **Appendix A**		
1. Name & Address of the trial site:		
2. Name of Principal Investigator:		
3. Name of the Ethics Committee:		

4. Authorisation / Opinion of Ethics Committee (please attach the approval letter):	☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion

SECTION F: MEDICAL DEVICE DETAILS

Please provide medical device details according to the following:
1. **Appendix B** Details of Medical Device

SECTION G: ENTRY POINT

Please tick the appropriate box:

☐ Lapangan Terbang Antarabangsa Kuala Lumpur 1	☐ Lapangan Terbang Sultan Abdul Aziz Shah Subang
☐ Lapangan Terbang Antarabangsa Kuala Lumpur 2	☐ Pelabuhan Pulau Pinang
☐ Pelabuhan Klang	☐ Pelabuhan Pasir Gudang, Johor
☐ Pelabuhan Tanjung Pelepas, Johor	☐ Others (please specify): ……

SECTION H: MULTIPLE SHIPMENT *(tick the appropriate box & kindly state the total no. of devices per shipment if this trial requires multiple shipment* – Repeat if necessary*)*

☐ First shipment : Total number of devices _____

☐ Second shipment : Total number of devices _____

☐ Third shipment : Total number of devices _____

SECTION I: ATTESTATIONS & DECLARATION

I, the undersigned, on behalf of the company hereby declare that :

a. This/These medical device (s) indicated on this application:
   i. Conform(s) to all relevant essential principles for safety and performance as set out in the Appendix 1 of Third Schedule of the Medical Device Regulations (MDR) 2012;
   ii. Has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012;

b. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of trial;

c. I am aware this/these medical device(s) is/are permitted for clinical research purpose only. Therefore, the medical device(s) shall not be:
   - placed/used at the trial site after the trial has ended;
   - placed in Malaysia;

d. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of Malaysia after the trial has ended;

I, the undersigned, hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding RM 500,000.00 or to imprisonment for a term not exceeding 3 years or to both. (S.76 Act 737 refers).

Signature:	Company Stamp:
Name:	
Designation:	Date:

SECTION J: FOR OFFICIAL USE

Notification No.:	**Date:**

APPENDIX A

TRIAL SITE DETAILS (For multiple sites in Malaysia – Repeat as needed)				
No.	**Name & Address of the trial site**	**Name of Principal Investigator**	**Name of the Ethics Committee**	**Authorisation/Opinion of Ethics Committee** (please attach the approval letter)
				☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion
				☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion
				☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion
				☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion

APPENDIX B

DETAILS OF MEDICAL DEVICES – (Kindly list down medical devices ONLY. All fields are mandatory)								
Is the packing list for Study-Visits Specific Kits attached as part of the supporting documents? ☐ Yes ☐ No								
No.	**Device Name**	**Identifier (e.g. Model/ Lot/Batch Number)**	**Description & Intended Purpose** (description must be precisely in details)	**Risk Class**	**Product Owner / Manufacturer**	**Total Quantity per site (Units)**	**Total Quantity (Units)**	**Total Cost of devices (MYR)**

SECTION K: SUPPORTING DOCUMENTS			
DOCUMENTS	**CHECKLIST** (Please tick if the document is attached)	**REQUIRED FOR**	**REMARKS**
IRB / EC Approval Letter		Section E or Appendix A	Institutional Review Board (IRB) / Ethics Committee (EC) Approval Letter for each local trial institution is required.
Packing List for Study-Visits Specific Kits		Appendix B	A complete packing list of the items in the Study-Visits Specific Kits can be attached to facilitate the submission for Appendix B (Non-Investigational Medical Devices). Study protocol number should be indicated on the packing list for reference

Note: Additional documents or information may be requested by MDA, if deemed necessary. Any insufficient / incomplete information provided upon submission will be returned to the applicant.

The form and supporting documents can be sent either via email *(Please convert the form to PDF Format) to* ci@mdb.gov.my OR via posts to:

Pengarah
Bahagian Penilaian Teknikal
Pihak Berkuasa Peranti Perubatan
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA.

Annex D
(normative)

Serious Adverse Device Events (SADE) form

Status:		
Date Sponsor Received Report of SAE (dd/mm/yyyy)		
Country Code		
Study Center		
Patient ID Code		
SAE ID Code		
Date of Procedure / First Use (dd/mm/yyyy)		
Date of Event Onset (dd/mm/yyyy)		
SAE OR Device Defect.		
Description of Event		
Action / Treatment / Patient Outcome		
Relationship to Procedure: Not related OR Unlikely OR Possible OR Probable OR Causal Relationship		
Relationship to Investigational Device: Not related OR Unlikely OR Possible OR Probable OR Causal Relationship		
Unanticipated SADE: Yes OR No		
Treatment Arm: Investigational Device / Control Group / Blinded / N.A		
Event Status: Resolved / Resolved with Sequelae / Ongoing / Death		
Date of Event Resolution: (dd/mm/yyyy)		

Note 1: Submission of this report does not, in itself, represent a conclusion by the sponsor or the competent authority that the content of this report is complete or that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Note 2: If additional columns are added to this form (for instance to include the opinion of the investigators), please add them next to the existing columns on the right. This form may be subjected to automatic analysis and addition of columns in between may interfere with automatic analysis. Widening of columns can be applied without alteration of the order.

Note 3: Serious Adverse Event = SAE

Annex E
(normative)

NOTIFICATION FOR EXPORT /DISPOSAL OF DEVICES UPON COMPLETION /TERMINATION OF CLINICAL INVESTIGATION /DRUG STUDY		
All fields are mandatory unless stated otherwise.		
Please state previous Notification ID to Import and/or Supply Unregistered Medical Devices Used in Clinical Trial: ……		
PURPOSE OF NOTIFICATION: ☐ Export ☐ Dispose locally		
SECTION A: APPLICANT DETAILS		
7. Please tick the appropriate box:		
☐ Local sponsor		
☐ Person or organization authorized by the sponsor to make the application		
☐ Others (please specify): ……		
8. Name of Applicant:		
9. NRIC No.:	10. Designation:	
11. Name & Address of Organisation:		
12. Telephone No.:	7. Fax No.:	8. Email Address:
SECTION B: SPONSOR DETAILS		
1. Name of Contact Person:		
2. Name & Address of Organisation:		
3. Telephone No.:	4. Fax No.:	5. Email Address:
SECTION C: CLINICAL TRIAL DETAILS		
6. Title of Clinical Trial (as stated in Protocol document):		
7. Protocol No.:	8. Date of Study Completion:	
9. Reason for Completion: (please tick)		
☐ Concluded normally	☐ Premature termination – *safety reason**	
☐ Insufficient recruits	☐ Premature termination – *other**	
☐ Directed by Authority/Ministry of Health	☐ Directed by Ethics Committee	

	**Please give details below. Attach additional page if insufficient space.*

SECTION D: MEDICAL DEVICE DETAILS

Please provide medical device details in **Appendix A**

SECTION E: ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that :

1. The information provided on this application form for export of unregistered medical device/s used in clinical trial is accurate, correct and complete;
2. Aware that any supply, other than export, of this medical device/s is/are prohibited;
3. Agree to comply with all relevant rules and regulations in the Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012.

Signature: Name: Designation:	Company Stamp: Date:

SECTION F: EXPORT POINT

☐ Lapangan Terbang Antarabangsa Kuala Lumpur 1	☐ Lapangan Sultan Abdul Aziz Shah Subang
☐ Lapangan Terbang Antarabangsa Kuala Lumpur 2	☐ Pelabuhan Pulau Pinang
☐ Pelabuhan Klang	☐ Pelabuhan Johor Pasir Gudang
☐ Pelabuhan Tanjung Pelepas Johor	☐ Others (please specify): ……

SECTION G: FOR OFFICIAL USE

Notification No.:	**Date:**

APPENDIX A

PARTICULARS OF MEDICAL DEVICES TO BE EXPORTED OUT –T (Repeat As Needed)				
Type of Device: ☐ Investigational Medical Device/s ☐ Non-Investigational Medical Device/s				
No.	**Device Name**	**Identifier (e.g. Model Number)**	**Total Quantity Imported (Units)**	**Total Quantity Exported (Units)**

Attachment 1A

Notification to Import/Supply Medical Devices for Clinical Research Use

Name of Sponsor:		
Address:		
Name of Contact Person & Designation:		
Email Address & Tel. Number:	Clinical research Protocol Reference Number:	
	National Medical Research Registry ID (NMRR):	
Title of Approved Clinical research/Performance Evaluation:	Start Date of Clinical research/Clinical Research/Performance Evaluation	
	End Date of Clinical research/Clinical Research/Performance Evaluation	

S/N	**Name as per Medical Device Label**	**Manufacturer**	**Product Identifier**	**Pre-market Clearance** *[Please state the name (s) of country (s) and provide supporting documents as evidence] if applicable*	**Quantity (UOM)**

* Pease attach separate sheets if more lines are required.
** This form is part of the notification to be submitted together with Attachment A

Date

Signature/Company stamp of Applicant

Annex F
(normative)

<table>
<tr><th colspan="2">INVESTIGATIONAL DEVICE (IDE) PROGRESS REPORT</th></tr>
<tr><td colspan="2">All fields are mandatory unless stated otherwise.</td></tr>
<tr><td colspan="2">IDE NO.:</td></tr>
<tr><td colspan="2">SECTION A – BASIC ELEMENTS</td></tr>
<tr><td colspan="2">1. Device Name:</td></tr>
<tr><td colspan="2">2. Indication(s) for Use:</td></tr>
<tr><td>3. Sponsor’s Name:</td><td rowspan="3">4. Address:</td></tr>
<tr><td>5. Phone No.:</td></tr>
<tr><td>6. Fax No.:</td></tr>
<tr><td>7. Contact Person:</td><td>8. Designation:</td></tr>
<tr><td>9. Phone No. (W):</td><td>10. Email:</td></tr>
<tr><td colspan="2">SECTION B – STUDY PROGRESS
(Data from beginning of the study should be reported, unless otherwise indicated)</td></tr>
<tr><td colspan="2">1. Summary (in relation to investigational plan):</td></tr>
<tr><td>2. No. of devices shipped:</td><td>3. No. of subjects enrolled (indication / model)</td></tr>
<tr><td colspan="2">4. No. of Investigators / Investigational Sites (kindly refer to Appendix A) :</td></tr>
<tr><td colspan="2">5. Summary of results:</td></tr>
<tr><td colspan="2">6. Summary of anticipated & Unanticipated Adverse Effects</td></tr>
<tr><td>i. Anticipated</td><td>ii. Unanticipated</td></tr>
<tr><td colspan="2">7. Description of deviations (if any, since last progress report):</td></tr>
</table>

SECTION C – RISK ANALYSIS	
1. Summary of new adverse information (since last progress report) that may affect the risk analysis – *includes i) pre-clinical data, ii) animal studies, iii) foreign data, iv) clinical studies, etc.*	
2. Reprints of articles published from data collected from this study (supporting documents)	
3. New Risk Analysis *(based on new information & study progress, if any)*:	
SECTION D – OTHER CHANGES	
1. Changes in Manufacturing Practices & Quality Control *(including changes not reported in a supplemental application)* – Summary:	
2. Changes in the Investigational Plan Not Required to be Submitted in a Supplemental Application – Summary:	
SECTION E – FUTURE PLANS	
1. Progress Toward Product Approval *(with projected date of PMA)*:	
2. Plans to change the investigation:	
SECTION F – ATTESTATIONS & DECLARATION	
Signature: Name: Designation:	Company Stamp: Date:
SECTION G – OFFICIAL USE	
Notification No.:	Date:

APPENDIX A

TRIAL SITE DETAILS *(For multiple sites in Malaysia – Repeat as Needed)*				
No.	**Name of Trial Site**	**Name of PI**	**Name of EC**	**Authorisation / Opinion of EC**

SECTION H – SUPPORTING DOCUMENTS			
Documents	**Checklist**	**Required For**	**Remarks**
Published articles		Section C – No. 2	
IRB / EC Approval Letter		Appendix A	

Annex G
(normative)

NOTIFICATION OF CHANGE ON CLINICAL TRIAL FOR MEDICAL DEVICES USE		
All fields are mandatory unless stated otherwise.		
Please state the previous notification ID no. (*as referred to the Notification to Import Medical Device for Clinical Trial Use*): ……..		
SECTION A: APPLICANT DETAILS		
1. Please tick the appropriate box:		
☐ Local Sponsor		
☐ An authorised person from a local organisation / company / Contract Research Organisation (CRO) (Note: must have a permanent address in Malaysia)		
☐ Others (please specify):……..		
2. Name of Applicant:		
3. NRIC No./Passport:	4. Designation:	
5. Name & Address of Organisation:		
6. Telephone No.:	7. Fax No.:	8. Email Address:
SECTION B: SPONSOR DETAILS		
1. Name of Contact Person:		
2. Name & Address of Organisation:		
3. Telephone No.:	4. Fax No.:	5. Email Address:
SECTION C: CLINICAL TRIAL DETAILS		
1. NMRR Registration ID:	2. Protocol No.:	
3. Title of Clinical Trial - as stated in Protocol document:	4. Estimated duration of the clinical trial: 5. Proposed date of start of trial:	
SECTION D: PURPOSE OF CHANGE		
☐ Change of Principal Investigator	☐ Change of Coordinating Investigator	
☐ Change of IRB / EC	☐ Change in Site Name	
☐ Change of device(s)	☐ Change in Site Address	

☐ Subsequent Notification of Additional Clinical Research Notification Site	☐ Others, (change in protocol/clinical investigation plan (CIP) – title, subject recruitment, etc) kindly state the relevant reasons:

Please provide details to the applicable Appendix(ces):

1) **Appendix A (i) – Change in Principal Investigator**
2) **Appendix A (ii) – Change in Coordinating Investigator**
3) **Appendix A (iii) - Change in IRB/EC**
4) **Appendix A (iv) – Change in Site Name**
5) **Appendix A (v) – Change in Site Address**
6) **Appendix A (vi) – Subsequent Notification of Additional Clinical Research Site**
7) **Appendix A (vii) – Change of Device(s)**

SECTION E: ATTESTATIONS & DECLARATION

I, the undersigned, on behalf of the company hereby declare that :

a. This/These medical device (s) indicated on this application:
   i. Conform(s) to all relevant essential principles for safety and performance as set out in the Appendix 1 of Third Schedule of the Medical Device Regulations (MDR) 2012;
   ii. Has/have met all the labeling requirements set out in the Sixth Schedule of the MDR 2012;

b. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of trial;

c. I am aware this/these medical device(s) is/are permitted for clinical research purpose only. Therefore, the medical device(s) shall not be:
   - placed/used at the trial site after the trial has ended;
   - placed in Malaysia;

d. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of Malaysia after the trial has ended;

I, the undersigned, hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date.

Signature: Name: Designation:	Company Stamp: Date:

SECTION F: FOR OFFICIAL USE

Notification No.:	**Date:**

Appendix A (i)

PRINCIPAL INVESTIGATOR DETAILS	
1) Name (former Principal Investigator):	
Site:	Tel. No.:
Dept./Specialties:	Email:
2) Name (new appointed Principal Investigator):	
Site:	Tel. No.:
Dept./Specialties:	Email:

Appendix A (ii)

COORDINATING INVESTIGATOR DETAILS	
1) Name(former Coordinating Investigator):	
Site:	Tel. No.:
Dept./Specialties:	Email:
2) Name (new appointed Coordinating Investigator):	
Site:	Tel. No.:
Dept./Specialties:	Email:

Appendix A (iii)

INSTITUTIONAL REVIEW BOARD / ETHICS COMMITTEE DETAILS (please attach the approval letter)	
Name:	
Address:	☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion
Name (new appointed IRB/EC):	
Address:	☐ To be requested ☐ Pending ☐ Authorisation accepted/favourable opinion

Appendix A (iii)

TRIAL SITE DETAILS (Change of Site Name – please attach relevant document(s))	
1) Name:	
Address:	Tel. No.:
2) Name (new appointed site):	
Address:	Tel. No.:
Site Expected Start Date:	

Appendix A (iv)

TRIAL SITE DETAILS (Change of Site Address – please attach relevant document(s))	
Name:	
Old Address:	Tel. No.:
New Address:	Tel. No.:
Site Expected Start Date:	

Appendix A (v)

SUBSEQUENT NOTIFICATION OF ADDITIONAL CLINICAL RESEARCH SITE (please attach relevant document(s))
Previous Notification ID:

APPENDIX A (vi)

CHANGE OF <u>NON-INVESTIGATIONAL MEDICAL DEVICES</u> – (Repeat As Needed)								
Is the packing list for Study-Visits Specific Kits attached as part of the supporting documents? ☐ Yes ☐ No								
No.	**Device Name**	**Identifier (e.g. Model / Lot / Batch Number)**	**Description & Intended Purpose** (purpose of use must be described in details)	**Risk Class**	**Product Owner / Manufacturer**	**Total Quantity <u>per site</u> (Units)**	**Total Quantity (units)**	**Entry Point**

SECTION G: SUPPORTING DOCUMENTS			
DOCUMENTS	**CHECKLIST** (Please tick if the document is attached)	**REQUIRED FOR**	**REMARKS**
IRB / EC Approval Letter		Section D or Appendix A (ii)	Institutional Review Board (IRB) / Ethics Committee (EC) Approval Letter for each local trial institution is required.
Packing List for Study-Visits Specific Kits		Appendix A (vi)	A complete packing list of the items in the Study-Visits Specific Kits can be attached to facilitate the submission for Appendix A (vi) (Non-Investigational Medical Devices). Study protocol number should be indicated on the packing list for reference
Confirmation / Cover Letter		Appendix i, ii, iv and vi	A cover letter provided by the Sponsor / CRO to briefly inform the change(s) that has been made in the letter.

Note: Additional documents or information may be requested by MDA, if deemed necessary

The form and supporting documents can be sent either via email *(Please convert the form to PDF Format) to* CI@mdb.gov.my OR via posts to:

Pengarah
Bahagian Penilaian Teknikal
Pihak Berkuasa Peranti Perubatan
Aras 6, Prima 9, Prima Avenue II,
Blok 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

Medical Device Authority
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: http://www.mdb.gov.my