PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mdb.gov.my
Email: mdb@mdb.gov.my

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 in Site Address
☐ Change of IRB / EC	☐ Change of device(s)
☐ Change in Site Name	☐ Others, (change in protocol/clinical investigation plan (CIP) – title, subject recruitment, etc) kindly state the relevant reasons:

Please provide details to the applicable Appendix(es):

1) **Appendix A (i) – Change in Principal Investigator**
2) **Appendix A (ii) – Change in IRB/EC**
3) **Appendix A (iii) – Change of Site Name**
4) **Appendix A (iv) – Change of Site Address**
5) **Appendix A (v) – Change of Device(s)**
6) **Appendix A (vi) – Other change(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 labelling 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)

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)

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**

Appendix A (vi)

OTHER CHANGE(S) (e.g.: change in protocol/CIP, protocol title, subject recruitment- please attach relevant document(s))

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 (i), (ii),(iii), (iv).	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 (v)	A complete packing list of the items in the Study-Visits Specific Kits can be attached to facilitate the submission for Appendix A (v) (Non-Investigational Medical Devices). Study protocol number should be indicated on the packing list for reference.
Confirmation / Cover Letter		Section D	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
Level 5, Menara Prisma,
Persiaran Perdana, Presint 3
62675 Putrajaya.