**ARAHAN:**

INSTRUCTION:

1. **Borang permohonan hendaklah ditaip dan dicetak atas kertas A4 putih depan dan belakang kecuali lampiran I dan II dicetak berasingan (muka depan sahaja).**

Application form should be typed and printed on both sides using white A4 size paper except Appendix I and II to be printed separately (single sided only).

1. **Lampiran variasi yang berkaitan sahaja perlu dicetak.**

Only applicable appendix of variation should be printed.

1. **Setiap jenis permohonan variasi perlu dikemukakan secara berasingan.**

Each variation application should be submitted as a separate application.

1. **Borang permohonan yang dikemukakan hendaklah dalam salinan asal.**

The submitted application form should be in original copy.

1. **Sila rujuk *Malaysian* *Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption* edisi terkini untuk maklumat lanjut.**

Please refer to latest edition of Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption for more information.

**BAHAGIAN 1 BUTIRAN PEMOHON**

PART 1 APPLICANT’S DETAILS

|  |  |  |
| --- | --- | --- |
| **1.1** | **Sila tanda pada kotak yang berkaitan:**  Please tick the appropriate box: | |
|  | **Penaja**  Sponsor |
|  | **Orang atau organisasi yang diberi kuasa oleh penaja untuk memohon**  Person or organisation authorised by the sponsor to make the application |

|  |  |  |
| --- | --- | --- |
| **1.2** | **Nama pemohon**  Name of applicant |  |
| **1.3** | **Nombor kad pengenalan**  Identity card number |  |
| **1.4** | **Nama organisasi**  Name of organisation |  |
| **1.5** | **Alamat organisasi**  Address of organisation |  |
| **1.6** | **Nombor telefon**  Telephone number |  |
| **1.7** | **Alamat emel**  Email address |  |

**Sila isikan butiran individu kedua untuk dihubungi, sekiranya ada.**

Please fill in the details of the second contact person, if necessary.

|  |  |  |
| --- | --- | --- |
| **1.8** | **Nama individu untuk dihubungi**  Name of contact person |  |
| **1.9** | **Nombor telefon**  Telephone number |  |
| **1.10** | **Alamat emel**  Email address |  |

**BAHAGIAN 2 BUTIRAN KAJIAN KLINIKAL**

PART 2 CLINICAL TRIAL’S DETAILS

|  |  |  |
| --- | --- | --- |
| **2.1** | **Nombor pendaftaran National Medical Research Registry (NMRR)**  National Medical Research Registry (NMRR) Registration ID | **NMRR-** |
| **2.2** | **Tajuk penuh kajian klinikal**  Full title of the clinical trial |  |
| **2.3** | **Nombor protokol**  Protocol number |  |

**BAHAGIAN 3 PERMOHOHAN VARIASI**

PART 3 APPLICATION OF VARIATION

**3.1 MAKLUMAT KELULUSAN VARIASI TERDAHULU**

INFORMATION OF PREVIOUS VARIATION APPROVAL

**(Sila tambah ruang sekiranya diperlukan)**

(Please add more lines if appropriate)

|  |  |  |  |
| --- | --- | --- | --- |
| **Bil.**  No. | **Tarikh kelulusan**  Approval date  **(dd/mm/yyyy) 1** | **Nombor rujukan dokumen kelulusan2**  Approval document**2** reference number | **Jenis permohonan variasi**  Type of variation application |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

**1 Tarikh yang dinyatakan pada dokumen kelulusan permohonan variasi yang berkaitan.**

**1** Date as stated in the relevant variation application approval document.

**2 Dokumen kelulusan: surat kelulusan dan/atau Lampiran A**

2 Approval document: approval letter and/or Lampiran A

**3.2 MAKLUMAT PERMOHONAN VARIASI TERKINI**

INFORMATION OF CURRENT VARIATION APPLICATION

**ARAHAN:**

INSTRUCTION:

1. **Sila isi dan cetak lampiran bagi permohonan variasi yang berkenaan sahaja.**

Please fill up and print the appendix for the applicable variation application only.

1. **Bagi permohonan variasi yang sama tetapi melibatkan lebih daripada satu produk kajian/tapak kajian/penyelidik, sila isikan lampiran yang berasingan bagi setiap produk kajian/tapak kajian/penyelidik.**

For the same variation application but for more than one investigational product (IP)/ trial site/investigator, please fill the appendix separately for each IP/trial site/investigator.

|  |  |  |  |
| --- | --- | --- | --- |
| **Bil.**  No. | **Lampiran**  Appendix | **Permohonan Variasi**  Variation Application | **Sila tandakan (√) pada kotak yang berkenaan**  Please tick (√) at the appropriate box |
| **1.** | **Lampiran V1** | **Penambahan kuantiti produk**  Additional quantity of product |  |
| **2.** | **Lampiran V2** | **Penambahan/Penukaran tapak kajian**  Additional/Change of trial site |  |
| **3.** | **Lampiran V3** | **i) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK)/Kebenaran Mengilang dalam syarikat yang sama**  Change of Clinical Trial Import Licence (CTIL)/Clinical Trial Exemption (CTX) holder within the same company |  |
| **ii) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK)/Kebenaran Mengilang kepada syarikat yang berlainan**  Change of Clinical Trial Import Licence (CTIL)/Clinical Trial Exemption (CTX) holder to a different company |  |
| **4.** | **Lampiran V4** | **Penambahan produk kajian**  Additional investigational product (IP) |  |
| **5.** | **Lampiran V5** | **i) Penambahan tapak pengilang**  Additional manufacturer |  |
| **ii) Penukaran tapak pengilang**  Change of manufacturer |  |
| **6.** | **Lampiran V6** | **Penambahan kuantiti bagi protokol baru**  Additional quantity for new protocol |  |
| **7.** | **Lampiran V7** | **Pembaharuan Lesen Import Percubaan Klinikal (LIPK)/ Kebenaran Mengilang**  Clinical Trial Import Licence (CTIL)/Clinical Trial Exemption (CTX) Renewal |  |
| **8.** | **Lampiran V8** | **Lain-lain (cth: perubahan saiz pek/jenis bungkusan)**  Others (e.g. change in pack size/type of packaging) |  |

**PERAKUAN PEMOHON**

APPLICANT DECLARATION

**Saya, yang bernama dan beralamat di bawah sebagai wakil syarikat yang memohon, mengaku bahawa:**

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

1. **Segala maklumat yang dibekalkan adalah lengkap.**

The information provided is complete.

1. **Segala maklumat dalam borang permohonan ini dan dokumen-dokumen dibekalkan adalah benar dan tepat.**

All details contained in this form and attached documents are true and accurate.

1. **Saya akan bertanggungjawab sepenuhnya terhadap kualiti, efikasi dan keselamatan produk ini.**

I will be fully responsible towards the quality, efficacy and safety of this product(s).

1. **Saya akan mematuhi semua peruntukan dalam Akta Jualan Dadah 1952 (Disemak 1989), Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984 serta lain-lain keperluan regulatori/ garispanduan.**

I will comply with all the relevant rules and regulations in Sale of Drugs Act 1952 (Revised 1989), Control of Drugs and Cosmetics Regulations 1984 together with other regulatory requirements/ guidelines.

|  |  |  |  |
| --- | --- | --- | --- |
| **Nama Penuh**  Full Name |  | **Jawatan**  Position |  |
| **No. Kad Pengenalan**  Identity Card No. |  | **Cop Rasmi Syarikat**  Official Stamp of the Company |  |
| **Tandatangan Pemohon**  Signature of applicant |  |
| **Tarikh (DD/MM/YY):**  Date (DD/MM/YY): |  |

**Lampiran V1**

|  |  |
| --- | --- |
| **Penambahan kuantiti produk**  Additional quantity of product | |
| **Nama produk**  Product name |  |
| **Nama tapak kajian**  Name of trial site |  |
| **Tambahan kuantiti diperlukan bagi semua tapak kajian**  Additional quantity required for all trial sites |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Justifikasi penambahan kuantiti**  Justification of additional quantity  🞎 **Pengiraan kuantiti**  Calculation of quantity  🞎 **Lampiran I, jika berkenaan**  *Lampiran I*, if applicable |

**Lampiran V2**

|  |  |
| --- | --- |
| **Penambahan/Penukaran tapak kajian**  Additional/Change of trial site | |
| **Nama tapak kajian baru**  Name of new trial site |  |
| **Alamat tapak kajian baru**  Address of new trial site |  |
| **Nama tapak kajian asal1**  Name of initial trial site1 |  |
| **Alamat tapak kajian asal1**  Address of initial trial site1 |  |
| **Nama penyelidik utama**  Name of principal investigator (PI) |  |
| **Nombor kad pengenalan/pasport2**  Identity card/passport number2 |  |
| **Profil penyelidik utama**  Profile of PI | 🞎 Declaration of PI: (dd/mm/yyyy)  🞎 Curriculum vitae: (dd/mm/yyyy)  🞎 Good Clinical Practice (GCP) Certificate:  GCP Course Organiser :  Course Date : (dd/mm/yyyy) |
| **Maklumat perhubungan penyelidik utama**  Contact details of PI | |
| **Nombor telefon**  Telephone number |  |
| **Alamat emel**  E-mail address |  |
| **Jumlah subjek yang dijangka**  Total number of subjects planned |  |
| **Nama jawatankuasa etika**  Name of ethics committee |  |
| **Status kelulusan daripada jawatankuasa etika**  Ethics committee approval status | 🞎 To be requested  🞎 Pending  🞎 Given  If given, please specifiy:  Date of authorisation/opinion (dd/mm/yyyy):\_ \_/\_ \_/\_ \_ \_ \_  🞎 Authorisation accepted/ favourable opinion  🞎 Not accepted/ not favourable  The reasons:­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Pengakuan asal daripada penyelidik utama bagi setiap tapak kajian**  Originaldeclaration by PI for each trial site  🞎 **Sijil GCP bagi penyelidik utama**  GCP certificate for PI  🞎 ***Vitae* kurikulumbagi penyelidik utama**  *Curriculum Vitae* (CV) for PI  🞎 **Surat kelulusan/pendapat jawatankuasa etika**  Letter of approval/opinion of ethics committee  🞎 **Lampiran I, jika berkenaan**  *Lampiran I*, if applicable |

**1Untuk penukaran tapak kajian sahaja**

**1**For change of site only

2**Untuk kajian klinikal yang dijalankan di Malaysia sahaja**

2For clinical trial conducted in Malaysia only

**Lampiran V3**

|  |  |
| --- | --- |
| **i) Penukaran pemegang LIPK/ Kebenaran Mengilang dalam syarikat yang sama**  Change of CTIL/CTX holder within the same company | |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang asal**  Name of current CTIL/CTX holder |  |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang baru**  Name of new CTIL/CTX holder |  |
| **Nombor kad pengenalan**  Identity card number |  |
| **Nombor telefon**  Telephone number |  |
| **Alamat emel**  Email address |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Alasan bagi penukaran pemegang LIPK/ Kebenaran Mengilang**  Reason for the change of CTIL/CTX holder  🞎 **Lesen Racun Jenis A/Perakuan Pengekalan Tahunan**  Type A Poison Licence/Annual Retention Certificate (ARC) |
| **ii) Penukaran pemegang LIPK/ Kebenaran Mengilang kepada syarikat yang berlainan**  Change of CTIL/CTX holder to a different company | |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang asal**  Name of current CTIL/CTX holder |  |
| **Nama syarikat pemegang LIPK/ Kebenaran Mengilang yang asal**  Company’s name of current CTIL/CTX holder |  |
| **Alamat syarikat pemegang LIPK/ Kebenaran Mengilang yang asal**  Company address of current CTIL/CTX holder |  |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang baru**  Name of new CTIL/CTX holder |  |
| **Nombor kad pengenalan**  Identity card number |  |
| **Nama syarikat pemegang LIPK/ Kebenaran Mengilang yang baru**  Company name of new CTIL/CTX holder |  |
| **Alamat syarikat pemegang LIPK/ Kebenaran Mengilang yang baru**  Company address of new CTIL/CTX holder |  |
| **Nombor telefon**  Telephone number |  |
| **Alamat emel**  Email address |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Alasan bagi penukaran pemegang LIPK/ Kebenaran Mengilang**  Reason for the change of CTIL/CTX holder  🞎 **Lesen Racun Jenis A/Perakuan Pengekalan Tahunan**  Type A Poison Licence/Annual Retention Certificate (ARC)  🞎 **Sijil pendaftaran syarikat bagi pemegang LIPK/ Kebenaran Mengilang yang baru**  Company registration certificate of the new CTIL/CTX holder  🞎 **Surat kebenaran penukaran pemegang LIPK/ Kebenaran Mengilang**  Letter of authorisation for the transfer of CTIL/CTX holder  🞎 **Kenyataan penerimaan**  Statement of acceptance |

**Lampiran V4**

|  |  |  |  |
| --- | --- | --- | --- |
| **Penambahan produk kajian**  Additional investigational product (IP) | | | |
| **Nama produk kajian yang telah diluluskan bagi protokol ini (seperti di dalam LIPK/Kebenaran Mengilang)**  Name of current approved IP for this protocol (as per CTIL/CTX) | 1.  2.  3. | | |
| **Deskripsi produk kajian tambahan**  Description of additional IP | | | |
| **Kegunaan produk kajian**  Use of IP | | 🞎 **Produk kajian yang diuji**  IP being tested  🞎 **Produk kajian yang digunakan sebagai *comparator***  IP used as a comparator  🞎 ***Placebo***  Placebo  🞎 ***Standard-of-care***  Standard-of-care | |
| **Nama produk**  Name of product | |  | |
| **Kekuatan dan unit kepekatan (nyatakan semua kekuatan yang akan digunakan serta saiz vial/isipadu akhir sekiranya ada)**  Strength and concentration unit (specify all strengths to be used and vial size/finalvolume if applicable) | |  | |
| **Bentuk dosej**  Dosage form (use standard  terms) | |  | |
| **Nama produk dicetak pada LIPK/Kebenaran Mengilang (termasuk nama, bentuk dos dan kekuatan)**  Product’s name to be printed on CTIL/CTX (include name, dosage form and strength) | |  | |
| **Adakah bentuk dos dan bahan aktif yang digunakan mengandungi sumber yang dianggap `culturally unacceptable’?**  Does the dosage form or active ingredient contains source/origin that may be culturally unacceptable? | | yes 🞎 no 🞎 | |
| **Sekiranya ada, sila nyatakan**  If yes, please specify the source | |  | |
| **Laluan pemberian ubat**  Route of administration | |  | |
| **Data Stabiliti *Representative Batch* (*Condition* & Tempoh)**  Stability Data Representative Batch (Condition & Duration) | | Real Time Data  \_\_\_\_\_\_ °C  \_\_\_\_\_\_\_ months | Accelerated Data  \_\_\_\_\_\_ °C  \_\_\_\_\_\_\_ months |
| **Tempoh penyimpanan yang dicadang**  Proposed shelf life | |  | |
| **Keadaan Penyimpanan**  Storage condition | |  | |
| **Nama dan alamat pengilang**  Name and address of manufacturer | | Name and address of manufacturer:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Repeat this information for all manufacturers | |
| **Status pendaftaran produk**  Product registration status | | | |
| **Adakah produk kajian yang digunakan adalah produk berdaftar dengan PBKD?**  Is this IP to be used in the trial a registered product with DCA? | | yes  no | |
| **Sekiranya ada, sila nyatakan nama dagangan dan nombor pendaftaran produk**  If yes, please specify the trade name and product registration number | |  | |
| **Adakah produk kajian akan didaftarkan di Malaysia?**  Is this product going to be registered in Malaysia? | | yes  no | |
| **Adakah produk kajian yang digunakan adalah produk berdaftar di luar negara?**  Is this IP to be used in the trial a registered product overseas? | | yes  no | |
| **Sekiranya ada, sila nyatakan nama negara serta nama dagangan produk**  If yes, please specify the country name and product’s trade name | |  | |
| **Adakah produk kajian berbeza daripada yang telah berdaftar?**  Is the IP modified compared to the registered form? | | yes  no | |
| **Jika ya, sila nyatakan**  If yes, please specify | |  | |
| **Dokumen disertakan**  Document included | | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Justifikasi penambahan produk kajian**  Justification for additional IP  🞎 **Pengiraan kuantiti**  Calculation of quantity  🞎 **Data farmaseutikal**  Pharmaceutical data  🞎 **Sijil analisa**  Certificate of analysis  🞎 **Label produk kajian**  IP label  🞎 **Bukti Komplians Amalan Perkilangan Baik (APB)**  Evidence of Good Manufacturing Practice (GMP) compliance  🞎 **Salinan penyerahan yuran pemprosesan (Lampiran II)**  Copy of processing fee form (Lampiran II)  🞎 **Salinan resit rasmi** **yuran pemprosesan**  Copy of official receipt of payment  🞎 **Lampiran I, jika berkenaan**  *Lampiran I,* if applicable | |

**Lampiran V5**

|  |  |
| --- | --- |
| **i) Penambahan tapak pengilang**  Additional manufacturer | |
| **Nama produk**  Product name |  |
| **Nama pengilang baru**  Name of the new manufacturer |  |
| **Alamat pengilang baru**  Address of the new manufacturer |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎**Bukti komplians Amalan Perkilangan Baik (APB)**  Evidence of Good Manufacturing Practice (GMP) compliance |
| **ii) Penukaran tapak pengilang**  Change of manufacturer | |
| **Nama produk**  Product name |  |
| **Nama pengilang asal**  Name of initial manufacturer |  |
| **Alamat pengilang asal**  Address of initial manufacturer |  |
| **Nama pengilang baru**  Name of new manufacturer |  |
| **Alamat pengilang baru**  Address of new manufacturer |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Bukti komplians Amalan Perkilangan Baik (APB)**  Evidence of Good Manufacturing Practice (GMP) compliance |

**Lampiran V6**

|  |  |
| --- | --- |
| **Penambahan kuantiti bagi protokol baru**  Additional quantity for new protocol | |
| **Nombor protokol asal yang telah diluluskan**  Initially approved protocol number |  |
| **Nombor protokol baru**  New protocol number |  |
| **Senarai produk kajian yang terlibat dalam protokol baru**  **(Nama seperti yang dicetak dalam LIPK/ Kebenaran Mengilang)**  List of IP involved in the new protocol (Name as printed on CTIL/CTX) | 1.  2.  3. |
| **Nombor pendaftaran National Medical Research Registry (NMRR)**  NMRR registration ID | **NMRR-** |
| **Tajuk penuh kajian klinikal**  Full title of the clinical trial |  |
| **Tajuk singkatan kajian klinikal, jika ada**  Abbreviated title of the trial, where available |  |
| **Fasa**  Phase | 🞎 Human Pharmacology (Phase I)  🞎 First-in Human  🞎 Bioequivalence study  🞎 Other, please specify:  🞎 Therapeutic exploratory (Phase II)  🞎 Therapeutic confirmatory (Phase III)  🞎 Therapeutic use (Phase IV) |
| **Anggaran jangkamasa kajian klinikal**  Estimated duration of the clinical trial |  |
| **Cadangan tarikh kajian bermula**  Proposed date of start of recruitment |  |
| **Tapak Kajian di Malaysia**  Trial Site(s) in Malaysia  (repeat as needed for multiple sites in Malaysia) | |
| **Nama tapak kajian**  Name of trial site |  |
| **Alamat tapak kajian**  Address of trial site |  |
| **Nama penyelidik utama**  Name of principal investigator (PI) |  |
| **1Nombor kad pengenalan/pasport**  1Identity card/passport number |  |
| **Profil penyelidik utama**  Profile of the PI | 🞎 Declaration of PI: (dd/mm/yyyy)  🞎 Curriculum vitae: (dd/mm/yyyy)  🞎 Good Clinical Practice (GCP) Certificate:  GCP Course Organiser :  Course Date : (dd/mm/yyyy) |
| **Maklumat penyelidik**  Contact details of investigator | |
| **Nombor telefon**  Telephone number |  |
| **Alamat emel**  E-mail address |  |
| **Jumlah subjek yang dijangka**  Total number of subjects planned |  |
| **Nama jawatankuasa etika**  Name of the ethics committee |  |
| **Status kelulusan daripada**  **jawatankuasa etika**  Ethics committe approval status | 🞎To be requested  🞎Pending  🞎 Given  If given, please specify:  Date of authorisation/opinion (dd/mm/yyyy):\_ \_/\_ \_/\_ \_ \_ \_  🞎Authorisation accepted/ favourable opinion  🞎Not accepted/ not favourable  Reasons:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2Status permohonan kepada badan regulatori (bagi kajian klinikal dijalankan di luar negara)**  2Regulatory authority application status (for clinical study conducted outside of Malaysia) | 🞎To be requested  🞎Pending  🞎 Given  If given, please specify:  Date of authorisation/opinion (dd/mm/yyyy):\_ \_/\_ \_/\_ \_ \_ \_  🞎Authorisation accepted/ favourable opinion  🞎Not accepted/ not favourable  Reasons:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Status permohonan kajian klinikal di negara-negara lain**  Clinical trial application status in the other countries | |
| **Belum dikemukakan**  Pending submission |  |
| **Dikemukakan**  Submitted |  |
| **Lulus**  Approved |  |
| **Ditolak**  Refused |  |
| **Penambahan kuantiti produk**  Additional quantity of product | |
| **Nama tapak kajian**  Name of trial site |  |
| **Nama produk**  Product name |  |
| **Tambahan kuantiti diperlukan**  Additional quantity required |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 ***Letter of Authorisation, if applicable***  *Letter of Authorisation,* jika berkaitan  🞎 **Protokol kajian klinikal**  Clinical trial protocol  🞎 **Pengakuan asal daripada penyelidik utama bagi setiap tapak penyelidikan**  Original declaration by PI for each trial site  🞎 **Sijil GCP bagi penyelidik utama**  GCP certificate for the PI  🞎 ***Vitae* kurikulumbagi penyelidik utama**  *Curriculum Vitae (*CV) for the PI  🞎 **Pengiraan kuantiti**  Calculation of quantity  🞎 **Borang persetujuan termaklum (versi asal sahaja)**  Informed consent form (ICF) (initial version only)  🞎 **Label produk kajian**  IP label  🞎 ***Overall risk and benefit assessment***  🞎 **Surat kelulusan/pendapat jawatankuasa etika**  Letter of approval/opinion of ethics committee |

**1Untuk kajian klinikal yang dijalankan di Malaysia sahaja.**

1For clinical trial conducted in Malaysia only.

**2 Untuk permohonan Kebenaran Mengilang sahaja**

**2** For CTX application only.

**Lampiran V7**

|  |  |
| --- | --- |
| **Pembaharuan LIPK/Kebenaran Mengilang**  CTIL/CTX renewal | |
| **Nama produk kajian untuk pembaharuan (seperti di dalam LIPK/Kebenaran Mengilang)**  Investigational product name for renewal (as per CTIL/CTX) | 1.  2.  3. |
| **Nombor LIPK/Kebenaran Mengilang**CTIL/CTX number | 1. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_/ CTX\_\_ \_\_ \_\_ \_\_ \_\_ \_\_  2. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_/ CTX\_\_ \_\_ \_\_ \_\_ \_\_ \_\_  3. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_/ CTX\_\_ \_\_ \_\_ \_\_ \_\_ \_\_ |
| **Tarikh luput CTIL/Kebenaran Mengilang**  CTIL/CTX expiry date  **(dd/mm/yyyy)** | 1. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  2. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  3. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
| **Senarai protokol yang menggunakan LIPK/Kebenaran Mengilang yang sama**  List of protocol using the same CTIL/CTX | 1.  2.  3. |
| **1Nama dan alamat pengilang produk kajian dan/atau *final/batch releaser* sahaja**  1Name and address of manufacturer for drug product and/or final/ batch releaser only |  |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Lampiran I, jika berkenaan**  Lampiran I, if applicable  🞎 **Salinan borang penyerahan yuran pemprosesan (Lampiran L)**  Copy of processing fee form (Lampiran L)  🞎 **Salinan resit rasmi** **yuran pemprosesan**  Copy of official receipt of payment  🞎 **Justifikasi penambahan kuantiti, jika berkaitan**  Justification of additional quantity, if applicable  🞎 **Pengiraan kuantiti, jika berkaitan**  Calculation of quantity, if applicable |

**1Sila pastikan nama dan alamat pengilang produk kajian dan/atau *final/batch releaser* adalah berdasarkan LIPK/ Kebenaran Mengilang dan variasi yang telah diluluskan.**

1Please ensure name and address of manufacturer for drug product and/or final/ batch releaser are based on the approved CTIL/CTX and variation.

**Lampiran V8**

|  |  |
| --- | --- |
| **Lain-lain (cth. perubahan saiz pek/ jenis bungkusan)**  Others (e.g. change in pack size/ type of packaging) | |
| **Dokumen disertakan**  Document included | 🞎 **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**  Copy of all CTIL/CTX for this protocol  🞎 **Salinan Lampiran A untuk protokol ini**  Copy of *Lampiran A* for this protocol  🞎 **Justifikasi variasi**  Justification of variation  🞎 **Dokumen sokongan**  Supporting document  **SIla senaraikan dokumen sokongan:**  Please list all supporting documents: |

**Lampiran I**

**MAKLUMAT KUANTITI PRODUK KAJIAN YANG DILULUSKAN TERDAHULU**

INFORMATION OF PREVIOUSLY APPROVED QUANTITY FOR THE INVESTIGATIONAL PRODUCT (IP)

**(Satu lampiran untuk setiap produk berdasarkan dokumen kelulusan2)**

(One attachment for each product based on approval document2)

**i) Kuantiti yang diluluskan pada kelulusan asal**

Quantity approved in the initial application

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Bil.**  No. | **Tarikh kelulusan**  Approval date  **(dd/mm/yyyy)1** | **Nombor rujukan dokumen kelulusan2**  Approval document reference number2 | **Tapak kajian**  Trial site | **Jumlah produk kajian yang diluluskan3**  Quantity approved3 |
| 1. |  |  |  |  |

**1Tarikh yang dinyatakan pada dokumen kelulusan yang berkaitan.**

**1**Date as stated in the relevant approval document.

**2 Dokumen kelulusan: surat kelulusan dan/atau Lampiran A**

2 Approval document: approval letter and/or Lampiran A

3**Jumlah produk kajian yang dinyatakan pada dokumen kelulusan yang berkaitan.**

3Quantity of investigational product stated on relevant approval document.

**ii) Kuantiti yang diluluskan bagi permohonan variasi yang melibatkan pertambahan kuantiti**

Quantity approved in variation application that involves additional quantity of product (eg. Additional quantity, Additional quantity for new protocol, Additional IP with quantity, Additional trial site with quantiy etc.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Bil.**  No. | **Tarikh kelulusan**  Approval date  **(dd/mm/yyyy)1** | **Nombor rujukan dokumen kelulusan2**  Approval document2 reference number | **Tapak kajian**  Trial site | **Jumlah produk kajian yang diluluskan3**  Quantity approved3 |
| 1. |  |  |  |  |
| 2. |  |  |  |  |

**1Tarikh yang dinyatakan pada dokumen kelulusan yang berkaitan.**

**1**Date as stated in the relevant approval document.

**2 Dokumen kelulusan: surat kelulusan dan/atau Lampiran A**

2 Approval document: approval letter and/or Lampiran A

3**Jumlah produk yang dinyatakan pada dokumen kelulusan yang berkaitan.**

3Quantity of investigational product stated on relevant approval document.

**Lampiran II**

# BORANG PENYERAHAN YURAN PEMPROSESAN

|  |  |
| --- | --- |
| **Nama Pemohon** |  |
| **Nama dan Alamat Syarikat Pemohon** |  |
| **Nombor Protokol** |  |

|  |  |  |
| --- | --- | --- |
| **Bil** | Nama Produk | Nombor DerafBank/ Wang Pos/ Kiriman Wang |
|
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

### Nota (Untuk Kegunaan Pejabat Sahaja):

### Sila jelaskan bayaran di kaunter Seksyen Kewangan, Akaun dan Hasil sebelum mengemukakan permohonan ke PPPK

### Permohonan variasi hanya akan diterima setelah resit rasmi dikemukakan

1. Segala pembayaran yang telah dibuat tidak akan dikembalikan
2. Jumlah yuran pemprosesan bagi permohonan variasi ini adalah sebanyak \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tandatangan dan cop