**ARAHAN:**

INSTRUCTION:

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

Application form should be typed written and printed on both sides using white A4 size paper except Appendix N 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 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 untuk memohon**  Person or organization 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** | **Nombor faksimili**  Fax number |  |
| **1.8** | **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.

|  |  |  |
| --- | --- | --- |
| **1.9** | **Nama individu untuk dihubungi**  Name of contact person |  |
| **1.10** | **Nombor telefon**  Telephone number |  |
| **1.11** | **Nombor faksimili**  Fax number |  |
| **1.12** | **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 penyelidikan klinikal**  Full title of the clinical trial |  |
| **2.3** | **Nombor protokol**  Protocol number |  |
| **2.4** | **Anggaran jangkamasa kajian klinikal**  Estimated duration of the clinical trial |  |

**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) \*** | **Nombor Rujukan Surat kelulusan**  Approval Letter Reference Number | **Jenis Permohonan Variasi**  Type of VariationApplication |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

**\* Tarikh yang dinyatakan pada surat kelulusan variasi yang berkaitan.**

**\*** Date as stated in the relevant variation approval letter.

**3.2 MAKLUMAT PERMOHONAN VARIASI TERKINI**

INFORMATION OF CURRENT VARIATION APPLICATION

**ARAHAN:**

INSTRUCTION:

1. **Sila isikan 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 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 | **Bilangan lampiran yang dIsertakan**  Number of appendix enclosed |
| **1.** | **Lampiran A** | **Penukaran penyelidik utama**  Change of principal investigator |  |  |
| **2.** | **Lampiran B** | **Penambahan kuantiti produk**  Additional quantity of product |  |  |
| **3.** | **Lampiran C** | **Penambahan kuantiti produk bagi kegunaan *compassionate***  Additional quantity of product for compassionate use |  |  |
| **4.** | **Lampiran D** | **Penambahan tapak kajian**  Additional trial site |  |  |
| **5.** | **Lampiran E** | **Penambahan pintu masuk pengimportan**  Additional entry point |  |  |
| **6.** | **Lampiran F** | **(i) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK) syarikat yang sama**  Change of CTIL holder within the same company |  |  |
| **(ii) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK) syarikat yang  berlainan**  Change of CTIL holder of different company |  |  |
| **7.** | **Lampiran G** | **Penambahan produk kajian**  Additional investigational product |  |  |
| **8.** | **Lampiran H** | **i) Penambahan tapak *\**pengilang/ ‘repacker’**  Additional \*manufacturer/ repacker site |  |  |
| **ii) Penukaran tapak\*pengilang/ ‘repacker’**  Change of \*manufacturer/ repacker site |  |  |
| **9.** | **Lampiran I** | **Penambahan kuantiti bagi protokol baru**  Additional quantity for new protocol |  |  |
| **10.** | **Lampiran J** | **Pembaharuan Lesen Import Percubaan Klinikal**  Clinical Trial Import Licence Renewal |  |  |
| **11.** | **Lampiran K** | **Perubahan bungkusan**  Change in packaging |  |  |
| **12.** | **Lampiran L** | **Penukaran tempoh luput**  Change of shelf life |  |  |
| **13.** | **Lampiran M** | **Lain-lain**  Others |  |  |

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

**Lampiran A**

|  |  |  |
| --- | --- | --- |
| **3.2.1** | **Penukaran penyelidik utama**  Change of principal investigator | |
|  | **Nama Tapak Kajian:**  Name of Trial Site: |  |
| **Nama Penyelidik Baru:**  Name of New Principal Investigator: |  |
| **Nama Penyelidik Asal:**  Name of Current Principal Investigator: |  |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Pengakuan asal daripada penyelidik bagi tapak kajian**  Original Declaration by investigator/ PI for trial site  🞎 **Sijil GCP bagi penyelidik utama**  GCP certificate for principal investigator  🞎 **Vitae kurikulum bagi penyelidik utama**  CV for principal investigator  🞎 **Surat Kelulusan/Pendapat Jawatankuasa Etika**  Letter of Authorisation/Opinion of Ethic Committee |

**Lampiran B**

|  |  |  |
| --- | --- | --- |
| **3.2.2** | **Penambahan kuantiti produk**  Additional quantity of product | |
|  | **Nama produk:**  Product name: |  |
|  | **Nama Tapak Kajian:**  Name of Trial Site: |  |
| **Tambahan kuantiti diperlukan bagi setiap tapak kajian:**  Additional quantity required for each trial site: |  |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Justifikasi penambahan kuantiti**  Justification of additional quantity  🞎 **Pengiraan kuantiti**  Calculation page |

**Lampiran C**

|  |  |  |
| --- | --- | --- |
| **3.2.3** | **Penambahan kuantiti produk bagi kegunaan *compassionate***  Additional quantity of product for compassionate use | |
|  | **Nama produk:**  Product name: |  |
| **ID subjek:**  Subject ID: |  |
| **Nama Tapak Kajian:**  Name of Trial Site: |  |
| **Tambahan kuantiti diperlukan:**  Additional quantity required: |  |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Justifikasi penambahan kuantiti dengan ID subjek**  Justification of additional quantity with subject ID  🞎 **Pengiraan kuantiti**  Calculation page |

**Lampiran D**

|  |  |  |
| --- | --- | --- |
| **3.2.4** | **Penambahan tapak kajian**  Additional trial site | |
|  | **Nama pusat kajian**  Name of trial site |  |
| **Alamat pusat kajian**  Address of trial site |  |
| **Nama penyelidik utama**  Name of principal investigator |  |
| **Maklumat perhubungan penyelidik**  Contact details of Investigator | |
| **Nombor telefon**  Telephone number |  |
| **Nombor faksimili**  Fax number |  |
| **Alamat emel**  E-mail address |  |
| **Jumlah subjek yang dijangka**  Total number of subjects planned |  |
| **Nama Jawatankuasa Etika**  Name of the Ethics Committee |  |
| **Keputusan dari Jawatankuasa Etika**  Authorisation/ Opinion of Ethics Committee | 🞎 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 LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Pengakuan asal daripada penyelidik bagi tapak kajian**  OriginalDeclaration by investigator/ PI for trial site  🞎 **Sijil GCP bagi penyelidik utama**  GCP certificate for investigator/ PI  🞎 ***Vitae* kurikulumbagi penyelidik utama**  CV for investigator/ PI  🞎 **Surat Kelulusan/Pendapat Jawatankuasa Etika**  Letter of Authorisation/ Opinion of Ethic Committee |

**Lampiran E**

|  |  |  |
| --- | --- | --- |
| **3.2.5** | **Penambahan pintu masuk pengimportan**  Additional entry point | |
|  | **Pintu masuk asal:**  Current Entry Point: |  |
| **Sila tandakan(** √ **) pintu masuk pengimportan yang baru.**  Please tick ( √ ) new entry point for investigational product importion. | 🞎 **Lapangan Terbang Antarabangsa Kuala Lumpur(KLIA)**  🞎 **Lapangan Sultan Abdul Aziz Shah**  🞎 **Pelabuhan Klang**  🞎 **Pelabuhan Johor Bahru**  🞎 **Pelabuhan Pulau Pinang**  🞎 **Lain-lain(sila nyatakan): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Others (Please specify): *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| **Dokumen disertakan :**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX |

**Lampiran F**

|  |  |  |
| --- | --- | --- |
| **3.2.6** | **(i) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK) syarikat yang sama**  Change of CTIL holder within the same company | |
|  | **Nama Pemegang LIPK Asal:**  Name of current CTIL holder: |  |
| **Nama Pemegang LIPK Baru:**  Name of new CTIL holder: |  |
| **Dokumen disertakan :**  Document included: | 🞎 **Salinan LIPK**  Copy of CTIL  🞎 **Lesen Racun Jenis A/ Perakuan Pengekalan Tahunan**  Type A Poison Licence / Annual Retention Certificate (ARC) |
| **(ii) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK) syarikat yang berlainan**  Change of CTIL holder of different company | |
| **Nama Pemegang LIPK Asal:**  Name of current CTIL holder: |  |
| **Nama Syarikat Pemegang LIPK Baru**  Company name of current CTIL holder: |  |
| **Alamat Syarikat Pemegang LIPK Baru**  Company address of current CTIL holder: |  |
| **Nama Pemegang LIPK Baru:**  Name of new CTIL holder: |  |
| **Nama Syarikat Pemegang LIPK Baru**  Company name of new CTIL holder: |  |
| **Alamat Syarikat Pemegang LIPK Baru**  Company address of new CTIL holder: |  |
| **Dokumen disertakan :**  Document included: | 🞎 **Salinan LIPK**  Copy of CTIL  🞎 **Alasan bagi penukaran pemegang LIPK**  Reason for the change of CTIL holder  🞎 **Lesen Racun Jenis A/ Perakuan Pengekalan Tahunan**  Type A Poison Licence/ Annual Retention Certificate (ARC)  🞎 **Sijil Pendaftaran Syarikat bagi pemegang lesen yang baru**  Company Registration Certificate of the new CTIL holder  🞎 **Surat kebenaran penukaran pemegang LIPK**  Letter of Authorisation for transfer of CTIL Holder  🞎 **Kenyataan penerimaan**  Statement of Acceptance |

**Lampiran G**

|  |  |  |
| --- | --- | --- |
| **3.2.7** | **Penambahan produk kajian**  Additional investigational product | |
|  | **A) Pengenalan Produk Kajian**  Identification of 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 |
| **Nama Produk Kajian Asal (seperti di dalam LIPK)**  Current Investigational Product Name (as per CTIL) | 1.  2.  3. |
| **Nombor Lesen Import  Percubaan Klinikal (LIPK)**  Clinical Trial Import Licence (CTIL) Number | 1. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_  2. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_  3. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ |
| **Tarikh Luput Lesen**  Licence Expiry Date  **(dd/mm/yyyy)** | 1. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  2. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  3. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
| **Penambahan produk kajian berlainan \*kekuatan/ bentuk dosej/ saiz vial/ isipadu akhir**  Additional investigational product of different \***s**trength, dosage form, vial size and final volume |  |
| **B) Deskripsi Produk Kajian**  Description of IP | |
| **Nama Produk Kajian**  IP name |  |
| **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 name to be printed on CTIL/ CTX  (includes 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 |  |
| **Tempoh penyimpanan yang dicadang**  Proposed shelf life |  |
| **Keadaan Penyimpanan**  Storage condition |  |
| **Nama dan alamat pengilang**  Name and address of manufacturer |  |
| **Nama dan alamat repacker1**  Name and address of repacker1 |  |
| **C) 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**  If yes, please specify the trade name |  |
| **Nombor Pendaftaran Produk, sekiranya telah berdaftar dengan PBKD**  Product Registration number, if registered with DCA |  |
| **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 LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Justifikasi penambahan produk kajian**  Justification for additional investigational   product  🞎 **Pengiraan kuantiti**  Calculation page  🞎 **Data Farmaseutikal**  Pharmaceutical Data  🞎 **Sijil Analisa**  Certificate of Analysis  🞎 **Label produk kajian**  Trial Product Label  🞎 **Sijil Amalan Perkilangan Baik**  GMP Certificate   Statement  🞎 **Dua salinan Borang BPFK-001.3 (Lampiran N)**  Two copies of BPFK-001.3 Form  🞎 **Resit Rasmi** **Yuran Pemprosesan** |

**1Terhad kepada 5 repacker untuk setiap produk.**

1Limited to 5 repackers for each product.

**Lampiran H**

|  |  |  |
| --- | --- | --- |
| **3.2.8** | **i) Penambahan tapak *\**pengilang/ repacker1**  Additional \*manufacturer/ repacker site | |
|  | **Nama produk:**  Product name: |  |
| **Nama \*Pengilang/ Repacker Baru:**  Name of the \*New Manufacturer/ Repacker Site: |  |
| **Alamat \*Pengilang/ Repacker Baru:**  Address of the\*New Manufacturer/ Repacker Site: |  |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Sijil Amalan Perkilangan Baik**  GMP Certificate |
| **ii) Penukaran tapak\*pengilang/ repacker1**  Change of \*manufacturer/ repacker site | |
| **Nama produk:**  Product name: |  |
| **Nama \*Pengilang/ Repacker asal:**  Name of current \*Manufacturer/ Repacker Site: |  |
| **Alamat \*Pengilang/ Repacker asal:**  Address of current \*Manufacturer/ Repacker Site: |  |
| **Nama \*Pengilang/ Repacker baru1:**  Name of new \*Manufacturer/ Repacker Site1: |  |
| **Alamat \*Pengilang/ ‘Repacker’ baru:**  Address of new \*Manufacturer/ Repacker Site: |  |
| **Dokumen disertaka:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Sijil Amalan Perkilangan Baik**  GMP Certificate |

**1Terhad kepada 5 repacker untuk setiap produk.**

1Limited to 5 repackers for each product.

**Lampiran I**

|  |  |  |
| --- | --- | --- |
| **3.2.9** | **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 |  |
| **Nama Produk Kajian (seperti di dalam LIPK)**  Investigational Product Name (as per CTIL) | 1.  2.  3. |
| **Nombor Lesen Import  Percubaan Klinikal (LIPK)**  Clinical Trial Import Licence (CTIL) Number | 1. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_  2. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_  3. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ |
| **Tarikh Luput Lesen**  Licence Expiry Date  **(dd/mm/yyyy)** | 1. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  2. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  3. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
| **Nombor Pendaftaran National Medical Research Registry (NMRR)**  National Medical Research Registry (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 administration to humans  🞎 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 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 |  |
| **Maklumat perhubungan penyelidik**  Contact details of investigator |  |
| **Nombor telefon**  Telephone number |  |
| **Nombor Faks**  Fax number |  |
| **Alamat Emel**  E-mail address |  |
| **Jumlah subjek yang dijangka**  Total number of subjects planned |  |
| **Nama Jawatankuasa Etika**  Name of the Ethics Committee |  |
| **Keputusan dari Jawatankuasa Etika**  Authorisation/ Opinion of Ethics Committee | 🞎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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **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 LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Protokol kajian klinikal**  Clinical trial protocol  🞎 **Pengakuan asal daripada penyelidik bagi tapak   penyelidikan**  Original Declaration by Investigator/ PI for trial site  🞎 **Sijil GCP bagi penyelidik utama**  GCP certificate for investigator/ PI  🞎 ***Vitae* kurikulumbagi penyelidik utama**  CV for investigator/PI  🞎 **Surat Kelulusan/Pendapat Jawatankuasa Etika**  Letter of Authorisation/Opinion of Ethic Committee  🞎 **Pengiraan kuantiti**  Calculation page  🞎 **Label produk kajian**  Trial Product Label  🞎 **Letter of Authorisation**  🞎 **Overall Risk and Benefit Assessment** |

**Lampiran J**

|  |  |  |
| --- | --- | --- |
| **3.2.10** | **Pembaharuan Lesen Import Percubaan Klinikal**  Clinical Trial Import Licence Renewal | |
|  | **Senarai protokol yang menggunakan LIPK yang sama**  List of protocol using the same CTIL | 1.  2.  3. |
|  | **Nama Produk Kajian (seperti di dalam LIPK)**  Investigational Product Name (as per CTIL) | 1.  2.  3. |
| **Nombor Lesen Import  Percubaan Klinikal (LIPK)**  Clinical Trial Import Licence  (CTIL) Number | 1. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_  2. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_  3. PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ |
| **Tarikh Luput Lesen**  Licence Expiry Date  **(dd/mm/yyyy)** | 1. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  2. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_  3. \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK**  Copy of CTIL  🞎 **Dua salinan Borang BPFK-001.3 (Lampiran N)**  Two copies of BPFK-001.3 Form  🞎 **Resit Rasmi** **Yuran Pemprosesan** |

**Lampiran K**

|  |  |  |
| --- | --- | --- |
| **3.2.11** | **Perubahan bungkusan**  Change in packaging | |
|  | **Nama Produk Kajian**  Investigational Product Name |  |
| **Saiz Bungkusan Asal**  Current pack size |  |
| **Saiz Bungkusan Baru**  New pack size |  |
| **Tambahan kuantiti produk (sekiranya perlu)**  Additional quantity of product (if required) |  |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Justifikasi perubahan saiz bungkusan**  Justification of change in pack size  🞎 **Pengiraan kuantiti**  Calculation page  🞎 **Label produk kajian**  Trial Product Label  🞎 **Data Stabiliti**  Stability data (for change of primary packaging only) |

**Lampiran L**

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| --- | --- | --- |
| **3.2.12** | **Penukaran tempoh luput**  Change of shelf life | |
|  | **Nama Produk Kajian**  Investigational Product Name |  |
| **Tempoh Simpanan Asal**  Previous proposed shelf life |  |
| **Tempoh Simpanan Baru**  New proposed shelf life |  |
| **Keadaan Penyimpanan**  Storage condition |  |
| **Dokumen disertakan:**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Data Stabiliti**  Stability data |

**Lampiran M**

|  |  |  |
| --- | --- | --- |
| **3.2.13** | **Lain-lain variasi**  Other variation | |
|  | **Dokumen disertakan :**  Document included: | 🞎 **Salinan LIPK/Kebenaran Mengilang**  Copy of CTIL/CTX  🞎 **Justifikasi variasi**  Justification of variation  🞎 **Dokumen sokongan**  Supporting document  **SIla senaraikan dokumen sokongan:**  Please list all supporting documents: |

**Lampiran N**

**BORANG BPFK-001.3**

# BORANG PENYERAHAN YURAN PEMPROSESAN

|  |  |
| --- | --- |
| **Nama Pemohon** |  |
| **Nama and Alamat Syarikat Pemohon** |  |
| **Tarikh Penyerahan** |  |

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| --- | --- | --- | --- | --- |
| **Bil** | Nama Produk | NomborDerafBank/ Wang Pos/ Kiriman Wang | Untuk Kegunaan Pejabat Sahaja | |
| No. RujukanLIPK | Nombor Resit |
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### Nota:

### Sila menjelaskan pembayaran di kaunter Seksyen Kewangan, Akaun dan Hasil sebelum mengemukan permohonan ke PKPB

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

1. Segala pembayaran yang telah dibuat tidak akan dikembalikan