**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🞎 GivenIf given, please specifiyDate 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 favourableThe 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**

|  |  |
| --- | --- |
| **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**  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **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