

PUSAT KOMPLIANS DAN KAWALAN KUALITI

CENTRE OF COMPLIANCE AND QUALITY CONTROL

BAHAGIAN REGULATORI FARMASI NEGARA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

|  |
| --- |
| PERMOHONAN PENDAFTARAN DAN PEMERIKSAAN JAWATANKUASA ETIKAREGISTRATION AND INSPECTION APPLICATION FOR ETHICS COMMITTEE |

**Sila baca arahan berikut sebelum mengisi borang.**

*Please read the following instructions before completing this form.*

1. **Borang permohonan perlu ditaip dan disi dengan lengkap.**

*The application form shall be typed and filled out completely.*

1. **Borang yang telah lengkap hendaklah dihantar dalam bentuk PDF melalui emel ke: beec@npra.gov.my. Bagi semua koresponden melalui emel, sila gunakan awalan seperti di bawah pada permulaan tajuk di ruang ”PERKARA” emel.**

*Please submit the completed application form in PDF format to beec@npra.gov.my.* *Please use the following prefixes in the ”SUBJECT” for all correspondence through email.*

|  |  |
| --- | --- |
| **Awalan***Prefixes* | **Tujuan***Purpose* |
| ECU | Sebarang makluman terkini berkaitan jawatankuasa etika yang berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD) seperti senarai ahli jawatankuasa yang telah dikemaskini atau laporan tahunan.*Any updates related to the ethics committees registered with the Drug Controlled Authority (DCA), such as an updated list of memberships or an annual report.* |
| ECI | Berkaitan dengan permohonan pendaftaran dan pemeriksaan jawatankuasa etika*Related to registration and inspection application for ethics committee* |
| QUERY | Sebarang pertanyaan umum*Any general enquiries* |

**Sebagai contoh: ECI - Permohonan pendaftaran jawatankuasa etika ABC.**

*For example: ECI - Inspection application for EC ABC.*

1. **Sila rujuk *Malaysian Guideline for Independent Ethics Committee Registration and Inspection* untuk maklumat lanjut.**

*Please refer to the Malaysian Guideline for Independent Ethics Committee Registration and Inspection for more information.*

1. **Nota tambahan /** *Additional Information*
* **Borang ini digunakan oleh Jawatankuasa Etika yang menilai percubaan klinikal berkaitan ubat yang dikawal di bawah tanggungjawab NPRA. Permohonan ini tidak merangkumi percubaan klinikal bukan ubat.**

*This form is used by EC, which reviews drug-related clinical trials that relate to areas of responsibility of NPRA. This application does not cover non-drug-related clinical trials.*

**BAHAGIAN 1: BUTIRAN JAWATANKUASA ETIKA**

*PART 1: DETAILS OF ETHICS COMMITTEE (EC)*

|  |  |  |
| --- | --- | --- |
| **1.** | **Nama Jawatankuasa Etika***EC Name* |  |
| **2.** | **Alamat surat-menyurat** *Mailing Address* |  |
| **3.** | **Nombor telefon***Telephone Number* |  |
| **4.** | **Nama setiausaha / sekretariat Jawatankuasa Etika untuk dihubungi***EC secretary / secretariat to contact* |  |
| **5.** | **Alamat emel rasmi Jawatankuasa Etika / alamat emel untuk dihubungi** *EC official email address / email to contact* |  |
| **6.** | **Nama pengerusi Jawatankuasa Etika***Name of EC’s chairperson*  |  |
| **7.** | **Alamat emel pengerusi Jawatankuasa Etika***EC chairperson's email address* |  |

***\*Maklumat ini akan dipapar dalam laman sesawang NPRA sekiranya Jawatankuasa Etika berjaya berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).***

*The above information will be published on the NPRA website once the Ethics Committee is successfully registered with the Drug Control Authority (DCA).*

**BAHAGIAN 2: DOKUMEN SOKONGAN YANG PERLU DISERTAKAN**

*PART 2: SUPPORTING DOCUMENTS TO BE SUBMITTED*

|  |  |
| --- | --- |
| 1. | **Surat Iringan***Cover Letter* |[ ]
| 2. | **Surat Kelulusan National Committee for Clinical Research (NCCR)***Approval letter from the National Committee for Clinical Research (NCCR)* |[ ]
| 3. | **Pihak berkuasa di mana Jawatankuasa Etika ditubuhkan.***The authority under which the EC was established.* |[ ]
| 4. | **Butiran ahli-ahli jawatankuasa etika. Format seperti di lampiran 1.***Details of ethics committee members. The format is as per Appendix 1.* |[ ]
| 5. | ***CV* bagi semua ahlidan semua perunding bebas (jika ada)***CV for all members*and *all independent consultants/experts (if any)* |[ ]
| 6. | ***Standard operating procedures (SOPs)*****a. Senarai induk SOPs***a. Master list of SOPs***b. Semua SOP bertulis seperti yang disenaraikan dalam senarai induk.***b. All written SOPs as listed in the master list.* |[ ]
| 7. | **Bilangan permohonan yang dinilai sepanjang 2 tahun kebelakangan, terutamanya kajian klinikal yang melibatkan LIPK\****Number of application reviewed during the last 2 years,* *specifically drug-related trials and drug-related trials that involve CTIL\** |[ ]
| 8. | **Senarai organisasi/institut yang akan menggunakan Jawatankuasa Etika bagi mendapatkan kelulusan etika***Which organisation/institute is covered by EC for ethical approval of trials?* |[ ]

**\*LIPK: Lesen Import Percubaan Klinikal, lesen yang dikeluarkan untuk mengimport produk tidak berdaftar untuk tujuan percubaan klinikal**

*\*CTIL: Clinical Trial Import License which is a license issued to import non-registered drug for the purpose of clinical trial.*

**BAHAGIAN 3: PERAKUAN PEMOHON**

*PART 3: APPLICANT’S DECLARATION*

1. **Saya dengan ini, mengaku bahawa semua kenyataan di atas dan dalam lampiran yang disertakan adalah benar.**

*I hereby declare that all information provided and contained in this form and its annexes are true and accurate.*

1. **Saya dengan ini, mengaku bahawa Jawatankuasa Etika membenarkan inspektor-inspektor dari NPRA untuk mengakses segala dokumen dan fasiliti-fasiliti yang berkaitan.**

*I hereby declare that the Ethics Committee agrees to permit NPRA inspectors to access any relevant documents and facilities.*

|  |  |
| --- | --- |
| **Tandatangan Pengerusi Jawatankuasa Etika***Signature of EC’s Chairperson* |  |
| **Nama Penuh** *Full Name* |  |
| **Cop Rasmi (jika berkaitan)***Official Stamp (if applicable)* |  |
| **Tarikh (HH/BB/TT)***Date (DD/MM/YY)* |  |

**Lampiran 1**

*Appendix 1*

**BUTIRAN AHLI-AHLI JAWATANKUASA ETIKA**

*DETAILS OF ETHICS COMMITTEE MEMBERS*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Nama***Name* | **Jawatan***Position* | **Peranana** *Rolea* | **Kaitan dengan Institusi***Affiliation with Institution* | **Tempoh pelantikan***Term of appointment* |
| 1. Name
 | Dekan / Pensyarah Kanan | Pengerusi | Ya / Tidak | DD/MM/YYYY – DD/MM/YYYY |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Nota kaki / Footnote:

|  |
| --- |
| a. Peranan* Pengerusi / *Chairperson*
* Timbalan Pengerusi / *Vice Chairperson*
* Setiausaha / *Secretary*
* Sekretariat / *Secretariat*
* Ahli saintifik / *Scientific Member*
* Ahli bukan saintifik / *Non-scientific Member*
* Ahli awam / *Lay Person*
* Ahli bebas / *Independent Member*
* Perunding Bebas / *Independent Consultant*
 |