

**PUSAT KOMPLIANS DAN KAWALAN KUALITI**

*CENTRE OF COMPLIANCE AND QUALITY CONTROL*

**BAHAGIAN REGULATORI FARMASI NEGARA**

*NATIONAL PHARMACEUTICAL REGULATORY AGENCY*

**KEMENTERIAN KESIHATAN MALAYSIA**

*MINISTRY OF HEALTH MALAYSIA*

**PENDAFTARAN DAN PEMERIKSAAN**

**JAWATANKUASA ETIKA**

*INDEPENDENT ETHICS COMMITTEE*

*REGISTRATION AND INSPECTION*

**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.**

*Application form shall be typed and filled completely.*

1. **Borang yang telah lengkap hendaklah dihantar dalam bentuk *pdf* dengan fungsi ”search” 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 with the serach function enabled to* *beec@npra.gov.my**.* *Please use the following prefixes in the ”SUBJECT” for all correspondence through email.*

|  |  |
| --- | --- |
| **Awalan***Prefixes* | **Tujuan***Purpose* |
| BEDN | Berkaitan dengan permohonan pemeriksaan BE dalam negara*Related to inspection application for local BE*  |
| BELN | Berkaitan dengan permohonan pemeriksaan BE luar negara*Related to inspection application for foreign BE* |
| BEDE | Berkaitan dengan permohonan penilaian penentuan keperluan pemeriksaan kajian BE *Related to application for evaluation to determine the need for BE study inspection* |
| 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 ethics committee registered with Drug Controlled Authority (DCA) such as updated list of membership or 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.**

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

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

*Please refer 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 that review drug related clinical trials that relates to areas of responsibility of NPRA. This application does not cover for 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.** | **Nombor Faks (jika ada)***Facsimile Number (if available)* |  |
| **5.** | **Alamat Emel** *Email Address* |  |

**BAHAGIAN 2: BUTIRAN PENGERUSI JAWATANKUASA ETIKA**

*PART 2: DETAILS OF ETHICS COMMITTEE CHAIRPERSON*

|  |  |  |
| --- | --- | --- |
| **1.** | **Nama***Name* |  |
| **2.** | **Nombor Telefon** *Telephone Number* |  |
| **3.** | **Nombor Faks (jika ada)***Facsimile Number (if available)* |  |
| **4.** | **Alamat Emel** *Email Address* |  |

**BAHAGIAN 3: BUTIRAN AHLI-AHLI JAWATANKUASA ETIKA**

*PART 3: DETAILS OF ETHICS COMMITTEE MEMBERS*

**Sertakan lampiran jika ruang tambahan diperlukan**

*Attach additional pages if necessary*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Member Name** | **Gender****M/F** | **Earned Degree** | **Scientist or Non-scientist** | **Primary Specialty** | **Affiliation with Institution****Yes/No** | **Note****(e.g., paediatric population representative)**  |
| **1. Chairperson**  |  |  |  |  |  |  |
| **2.** |  |  |  |  |  |  |
| **3.** |  |  |  |  |  |  |
| **4.** |  |  |  |  |  |  |
| **5.** |  |  |  |  |  |  |
| **6.** |  |  |  |  |  |  |
| **7.** |  |  |  |  |  |  |
| **8.** |  |  |  |  |  |  |
| **9.** |  |  |  |  |  |  |
| **10.** |  |  |  |  |  |  |
| **11.** |  |  |  |  |  |  |
| **12.** |  |  |  |  |  |  |
| **13.** |  |  |  |  |  |  |
| **14.** |  |  |  |  |  |  |
| **15.** |  |  |  |  |  |  |
| **Secretary / Secretariat**  |
| **1.** |  |  |  |  |  |  |
| **2.** |  |  |  |  |  |  |
| **3.** |  |  |  |  |  |  |
| **4.** |  |  |  |  |  |  |
| **5.** |  |  |  |  |  |  |
| **Independent Consultant / Non-Voting Member** |
| **1.** |  |  |  |  |  |  |
| **2.** |  |  |  |  |  |  |
| **3.** |  |  |  |  |  |  |
| **4.** |  |  |  |  |  |  |
| **5.** |  |  |  |  |  |  |

**BAHAGIAN 4: DOKUMEN SOKONGAN YANG PERLU DISERTAKAN**

*PART 4: SUPPORTING DOCUMENTS TO BE SUBMITTED*

|  |  |
| --- | --- |
| **1.** | **Surat Iringan***Cover Letter* |[ ]
| **2** | **Surat Kelulusan National Committee for Clinical Research (NCCR)***Approval letter from National Committee for Clinical Research (NCCR)* |[ ]
| **3** | **Pihak berkuasa di mana Jawatankuasa Etika ditubuhkan.***The authority under which the EC was established.* |[ ]
| **4** | **Ahli-ahli Jawatankuasa Etika***EC Membership****a. CV* bagi semua ahli***a. CV for all members****b. CV* bagi semua perunding bebas (jika ada)***b. CV for all independent consultants/experts (if any)* |[ ]
| **5** | ***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.* |[ ]
| **6** | **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\** |[ ]
| **7** | **Senarai organisasi/institut yang akan menggunakan Jawatankuasa Etika bagi mendapatkan kelulusan etika***Which organisation/institute 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 5: PERAKUAN PEMOHON**

*PART 5: 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 tempat-tempat yang berkaitan.

*I hereby, declare that the Ethic 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* |  |
| **No. Kad Pengenalan***Identity Card No.* |  |
| **Cop Rasmi (jika berkaitan)***Official Stamp (if applicable)* |  |
| **Tarikh (HH/BB/TT)***Date (DD/MM/YY)* |  |