

PUSAT KOMPLIANS DAN KAWALAN KUALITI

CENTRE OF COMPLIANCE AND QUALITY CONTROL

BAHAGIAN REGULATORI FARMASI NEGARA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

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| PERMOHONAN PENDAFTARAN DAN PEMERIKSAAN JAWATANKUASA ETIKA  REGISTRATION 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](mailto: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](mailto:beec@npra.gov.my).* *Please use the following prefixes in the ”SUBJECT” for all correspondence through email.*

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| **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)*

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

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| 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.*

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| **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*

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| --- | --- | --- | --- | --- |
| **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 |
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Nota kaki / Footnote:

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| 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* |