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PUSAT KOMPLIANS DAN KAWALAN KUALITI

CENTRE OF COMPLIANCE AND QUALITY CONTROL

BAHAGIAN REGULATORI FARMASI NEGARA

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

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| LAPORAN TAHUNAN JAWATANKUASA ETIKAETHICS COMMITTEE ANNUAL REPORT |

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

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

1. **Semua jawatankuasa etika yang berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD) perlu melaporkan aktiviti operasi jawatankuasa etika secara tahunan dengan mengisi borang laporan tahunan ini.**

*All ethics committees registered with the Drug Control Authority (DCA) are required to report the operational activities of the ethics committee annually by filling out this annual report form.*

1. **Borang laporan tahunan ini perlu ditaip dan disi dengan lengkap dan dihantar sebelum 31 Disember tahun berikutnya.**

*This annual report form shall be typed, filled out completely, and submitted before 31st December of the following year.*

1. **Borang yang telah lengkap hendaklah dihantar dalam bentuk PDF melalui emel ke: beec@npra.gov.my. Bagi semua makluman dan pertanyaan 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 the ethics committee.* |
| QUERY | Sebarang pertanyaan umum.*Any general enquiries.* |

**Sebagai contoh: ECU – Laporan tahunan jawatankuasa etika ABC.**

*For example: ECU – Annual report 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.*

**BAHAGIAN 1: BUTIRAN JAWATANKUASA ETIKA TERKINI**

*PART 1: LATEST 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 for contact* |  |
| **5.** | **Alamat emel rasmi Jawatankuasa Etika / alamat emel untuk dihubungi** *EC official email address / email for contact* |  |
| **6.** | **Nama pengerusi Jawatankuasa Etika***Name of EC’s chairperson*  |  |
| **7.** | **Alamat emel pengerusi Jawatankuasa Etika***EC chairperson's email address* |  |

**LAPORAN TAHUNAN BAGI TAHUN: YYYY**

***ANNUAL REPORT FOR THE YEAR: YYYY***

Lengkapkan maklumat bagi Bahagian 2 hingga 4 bagi aktiviti operasi jawatankuasa etika bagi tahun yang dinyatakan di atas.

*Complete the information for Parts 2 to 4 regarding the operational activities of the ethics committee for the year mentioned above.*

**BAHAGIAN 2: MAKLUMAT BERKAITAN KEAHLIAN JAWATANKUASA ETIKA**

*PART 2: INFORMATION RELATED TO THE EC MEMBERSHIP*

1. **Senarai keahlian terkini**

*Current List of Membership*

|  |  |  |
| --- | --- | --- |
| Bil. Ahli Saintifik*No. Scientific Member* | : |  |
| Bil. Ahli Bukan Saintifik*No. Non-Scientific Member* | : |  |
| Bil. Ahli Awam*No. Lay Person* | : |  |
| Bil. Ahli Bebas*No. Independent Member* | : |  |
| Bil. Perunding Bebas*No. Independent Consultant* | : |  |

**Lengkapkan senarai penuh keahlian sepanjang tahun yang dilaporkan di Lampiran 1.**

*Complete the full membership list for the reported year in Appendix 1.*

1. **Senarai latihan berkaitan GCP atau jawatankuasa etika yang dihadiri (tahun yang dilaporkan)**

*List of GCP or EC-related training attended (reported year)*

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Tajuk Latihan***Training Title* | **Tarikh***Date* | **Ahli yang hadir***Members who Attended* |
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**BAHAGIAN 3: MAKLUMAT BERKAITAN OPERASI JAWATANKUASA ETIKA**

*PART 3: INFORMATION RELATED TO THE OPERATIONS OF THE EC*

1. **Senarai mesyuarat yang dijalankan dalam tahun yang dilaporkan**

*List of meetings conducted in the reported year*

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **No. Mesyuarat***Meeting No.* | **Tarikh***Date* | **Kehadiran***Attendance* |
|  | Bil 1/2024 | DD/MM/YYYY | Hadir:Tidak hadir:Bil. ahli awam:Bil. ahli bebas: |
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1. **Perakuan konflik berkepentingan**

*Conflict of interest declaration*

|  |  |  |
| --- | --- | --- |
| 1. Sumber pembiayaan untuk kos operasi jawatankuasa etika

*Source of funding for the operational cost of the EC* | : |  |
| 1. Jumlah pembiayaan yang diterima dalam tahun yang dilaporkan

*Total funding received last year* | : |  |
| 1. Jumlah pembayaran untuk ahli

*Total reimbursement for the member* | : |  |
| 1. Adakah mana-mana ahli menerima pembiayaan yang mungkin menimbulkan konflik kepentingan sebagai ahli EC?

*Do any members receive funding that might create a conflict of interest as an EC member?* | : |  |

1. **Senarai permohonan KAJIAN KLINIKAL yang dinilai dalam tahun yang dilaporkan**

*List of CLINICAL TRIAL applications evaluated in the reported year*

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **No. Protokol / Tajuk Kajian***Protocol No. / Study Title* | **Keputusan***Decision* | **Tarikh Keputusan***Decision Date* |
|  | No. protokol:Tajuk kajian:  | Approved / Approved with condition / Reject | DD/MM/YYYY |
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**\*Tambah ruang jika perlu**

\*Add space if necessary

**Lampiran 1**

*Appendix 1*

**AHLI-AHLI JAWATANKUASA ETIKA UNTUK TAHUN YYYY**

*MEMBERS OF ETHICS COMMITTEE FOR YEAR YYYY*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Nama***Name* | **Jawatan***Position* | **Peranana** *Rolea* | **Kaitan dengan Institusi***Affiliation with Institution* | **Tempoh pelantikan***Term of appointment* | **Status Lantikanb***Appointment Statusb* |
| 1. Name
 | Dekan / Pensyarah Kanan | Pengerusi | Ya / Tidak | DD/MM/YYYY – DD/MM/YYYY | Aktif |
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**\*Tambah ruang jika perlu**

\*Add space if necessary

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*
 | b. Status lantikan* Aktif / *Active*
* Digugurkan / *Removed*
* Letak jawatan / *Resigned*
 |

**BAHAGIAN 4: PERAKUAN PEMOHON**

*PART 4: APPLICANT’S DECLARATION*

**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.*

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

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**[Untuk Kegunaan Seksyen Pusat Kajian Bioekuivalens & Jawatankuasa Etika Sahaja]**

*[For Bioequivalence Centre & Ethics Committee Section Use Only]*

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| **Tarikh terima borang:** ***Form receipt date:*** |
| **Ulasan Pegawai Penyelaras***Coordinator’s Comment*  |
| **Ulasan / *Comment:*** |
| **Tandatangan / Signature:** |
| **Tarikh / Date:** |
| **Ulasan Ketua Seksyen** *Head of Section’s Comment* |
| **Ulasan / *Comment:*** |
| **Tandatangan / Signature:** |
| **Tarikh / Date:** |