



**PUSAT KAJIAN PRODUK BARU**  
*CENTRE FOR INVESTIGATIONAL NEW PRODUCT*

**AGENSI 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.*

- i. **Borang permohonan yang dikemukakan hendaklah dalam salinan asal**  
*The submitted application form should be in original copy*
- ii. **Borang permohonan hendaklah ditaip dan dicetak atas kertas A4 putih depan dan belakang.**  
*Application form shall be typed and printed on both sides using white A4 size paper.*
- iii. **Borang yang telah lengkap hendaklah dihantar kepada Pengarah, Agensi Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Malaysia. (u.p.: Timbalan Pengarah, PUSAT KAJIAN PRODUK BARU)**  
*Please submit the completed application form to: Director, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Malaysia (attn.: Deputy Director, CENTRE FOR INVESTIGATIONAL NEW PRODUCT).*
- iv. **Sila rujuk *Malaysian Guideline for Independent Ethics Committee Registration and Inspection* edisi pertama untuk maklumat lanjut**  
*Please refer *Malaysian Guideline for Independent Ethics Committee Registration and Inspection* first edition for more information*
- v. **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 IEC 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.*
  - **Borang ini digunakan untuk tujuan yang berikut:**
    - (a) **Memohon untuk pendaftaran dan pemeriksaan bagi Jawatankuasa Etika yang baru**
    - (b) **Mengemaskini atau menyemak semula maklumat berkaitan Jawatankuasa Etika***This form is to be used for the following purposes:*
    - (a) *To apply for registration and inspection for a new IEC*
    - (b) *To update or revise the registration information of an IEC*

**BAHAGIAN 1: BUTIRAN AM****PART 1: GENERAL INFORMATION****1. Tujuan permohonan / The purpose of this application:**

[ ]	<b>Permohonan baru pendaftaran dan pemeriksaan Jawatankuasa Etika</b> New application for IEC registration and inspection
[ ]	<b>Mengemaskini-maklumat pendaftaran Jawatankuasa Etika</b> Update or revise registration information

**BAHAGIAN 2: BUTIRAN JAWATANKUASA ETIKA****PART 2: DETAILS OF INDEPENDENT ETHICS COMMITTEE (IEC)**

1.	<b>Nama Jawatankuasa Etika</b> <i>IEC Name</i>	
2.	<b>Alamat</b> <i>Address</i>	
3.	<b>Alamat surat-menyurat (jika berbeza daripada atas)</b> <i>Mailing Address (if different from above)</i>	
4.	<b>Nombor Telefon</b> <i>Telephone Number</i>	
5.	<b>Nombor Faks</b> <i>Facsimile Number</i>	
6.	<b>Alamat Emel</b> <i>Email address</i>	

**BAHAGIAN 3: BUTIRAN PENERUSI JAWATANKUASA ETIKA****PART 3: DETAILS OF INDEPENDENT ETHICS COMMITTEE CHAIRPERSON**

1.	<b>Nama</b> <i>Name</i>	
2.	<b>Nombor Telefon</b> <i>Telephone Number</i>	
3.	<b>Nombor Faks</b> <i>Facsimile Number</i>	
4.	<b>Alamat Emel</b> <i>Email address</i>	

**BAHAGIAN 4: BUTIRAN AHLI-AHLI JAWATANKUASA ETIKA****PART 4: DETAILS OF INDEPENDENT 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)
<b>1. Chairperson</b>						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
<b>Secretary / Secretariat</b>						
1.						
2.						
3.						
4.						
5.						
<b>Independent Consultant / Non-Voting Member</b>						
1.						
2.						
3.						
4.						
5.						

**BAHAGIAN 5: DOKUMEN SOKONGAN YANG PERLU DISERTAKAN**  
**PART 5: SUPPORTING DOCUMENTS TO BE SUBMITTED**

**Bagi tujuan permohonan baru untuk pendaftaran dan pemeriksaan sahaja**  
*For new application of IEC registration and inspection only*

- |   |                          |
|---|--------------------------|
| <b>1. Surat Iringan</b><br><i>Cover Letter</i>  | <input type="checkbox"/> |
| <b>2. Surat Kelulusan National Committee for Clinical Research (NCCR)</b><br><i>Approval letter from National Committee for Clinical Research (NCCR)</i>          | <input type="checkbox"/> |
| <b>3. Dokumen berkaitan penubuhan Jawatankuasa Etika</b><br><i>Documents referring to the establishment of the IEC</i>  | <input type="checkbox"/> |
| <b>4. Ahli-ahli Jawatankuasa Etika</b><br><i>IEC memberships</i><br><i>a. CV for all members</i><br><i>b. CV for all independent consultants/experts (if any)</i> | <input type="checkbox"/> |
| <b>5. Standard operating procedures (SOPs)</b><br><i>a. Master list of SOPs</i><br><i>b. All written SOPs as listed in the master list.</i>                       | <input type="checkbox"/> |

**BAHAGIAN 6: PERAKUAN PEMOHON**  
**PART 6: 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.*
2. 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 Independent Ethic Committee agrees to permit NPRA inspectors to access any relevant documents and facilities.*

**Tandatangan Pengerusi Jawatankuasa Etika***Signature of IEC's Chairperson* \_\_\_\_\_**Nama Penuh (Huruf Besar)***Full Name (Block Letter)* \_\_\_\_\_**No. Kad Pengenalan***Identity Card No.* \_\_\_\_\_**Cop Rasmi (Jika berkaitan):***Official Stamp (if applicable):***Tarikh (HH/BB/TT):***Date (DD/MM/YY):*

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