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## PROTOKOL ETIK PENELITIAN KOMISI ETIK PENELITIAN KESEHATAN

**(institusi…..)**

Isilah form dibawah dengan uraian singkat dan berikan tanda centang pada kotak atau lingkari pada salah satu pilihan jawaban yang menggambarkan penelitian.

## Judul Penelitian (p1)

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* 1. Lokasi Penelitian :

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* 1. Waktu Penelitian direncanakan (mulai – selesai):

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Ya Tidak

* 1. Apakah penelitian ini multi -senter
	2. Jika Multi senter apakah sudah mendapatkan persetujuan etik dari senter/institusi yang lain (lampirkan jika sudah)

## Identifikasi (p10)

* 1. **Peneliti**

(Mohon CV Peneliti Utama dilampirkan) Peneliti Utama (PI) :

Institusi :

Anggota Peneliti :

Institusi :

## Sponsor (p9)

Nama :

Alamat :

## Komitmen Etik

* 1. Pernyataan peneliti utama bahwa prinsip prinsip yang tertuang dalam pedoman ini akan dipatuhi (p6)

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* 1. (*Track Record*) Riwayat usulan review protokol etik sebelumnya dan hasilnya (isi dengan judul dan tanggal penelitian, dan hasil review Komite Etik(p7)

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* 1. Pernyataan bahwa bila terdapat bukti adanya pemalsuan data akan ditangani sesuai kebijakan sponsor untuk mengambil langkah yang diperlukan (p48)

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Tanda tangan Peneliti Utama

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( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

## Ringkasan usulan penelitian (p2)

* 1. Ringkasan dalam 200 kata, (ditulis dalam bahasa yang mudah difahami oleh awam bukan dokter)

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* 1. Justifikasi Penelitian (p3). Tuliskan mengapa penelitian ini harus dilakukan, manfaat nya untuk penduduk di wilayah penelitian ini dilakukan (Negara, wilayah, lokal)

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## Isu Etik yang mungkin dihadapi

* 1. Pendapat peneliti tentang isu etik yang mungkin dihadapi dalam penelitian ini, dan bagaimana cara menanganinya (p4)

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## Ringkasan Daftar Pustaka

* 1. Ringkasan berbagai hasil studi sebelumnya sesuai topik penelitian, termasuk yang belum dipublikasi yang diketahui para peneliti dan sponsor, dan informasi penelitian yang sudah dipublikasi, termasuk jika ada kajian-kajian pada binatang. Maksimum 1 hal (p5)

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## Kondisi Lapangan

* 1. Gambaran singkat tentang lokasi penelitian(p8)

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* 1. informasi ketersediaan fasilitas yang layak untuk keamanan dan ketepatan penelitian

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* 1. Informasi demografis / epidemiologis yang relevan tentang daerah penelitian

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## Disain Penelitian

* 1. Tujuan penelitian, hipotesa, pertanyaan penelitian, asumsi dan variabel penelitian (p11)

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* 1. Deskipsi detil tentang desain penelitian. (p12)

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* 1. Bila ujicoba klinis, deskripsi harus meliputi apakah kelompok perlakuan ditentukan secara random, (termasuk bagaimana metodenya), dan apakah acak atau terbuka. **(*Bila bukan ujicoba klinis cukup tulis: tidak relevan) (p12)***

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## Sampling

* 1. Jumlah subjek yang dibutuhkan sesuai tujuan penelitian dan bagaimana penentuannya secara statistik (p13)

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* 1. Kriteria partisipan atau subyek *dan justifikasi exclude/include*. (Guideline 3) (p12)

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* 1. Sampling kelompok rentan: alasan mengikutsertakan anak anak atau orang dewasa yang tidak mampu memberikan persetujuan setelah penjelasan, atau kelompok rentan, serta langkah langkah bagaimana meminimalisir bila terjadi resiko (Guidelines 15, 16 and 17) *(p15) (bila tidak ada, cukup tulis tidak relevan)*

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## Intervensi

**(pengguna data sekunder/observasi, cukup tulis tidak relevan)**

* 1. Desripsi dan penjelasan semua intervensi (metode pemberian treatmen, termasuk cara pemberian, dosis, interval dosis, dan masa treatmen produk yang digunakan (investigasi dan komparator (p17)

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* 1. Rencana dan jastifikasi untuk meneruskan atau menghentikan standar terapi selama penelitian (Guidelines 4 and 5) (p18)

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* 1. Treatmen/Pengobatan lain yang mungkin diberikan atau diperbolehkan, atau menjadi kontraindikasi, selama penelitian (Guideline 6) (p19)

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* 1. *Test* klinis atau lab atau *test* lain yang harus dilakukan (p20)

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## Monitor Hasil

* 1. Sampel dari form laporan kasus yang sudah distandarisir, metode pencataran respon teraputik (deskripsi dan evaluasi metode dan frekuensi pengukuran), prosedur *follow-up*, dan, bila mungkin, ukuran yang diusulkan untuk menentukan tingkat kepatuhan subyek yang menerima treatmen (lihat lampiran) (p17)

### (pengguna data sekunder, cukup tulis tidak relevan)

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## Penghentian Penelitian dan Alasannya

* 1. Aturan atau kreteria kapan subyek bisa diberhentikan dari penelitian atau uji klinis, atau, dalam hal studi multi senter, kapan sebuah pusat/lembaga di non aktipkan, dan kapan penelitian bisa dihentikan (tidak lagi dilanjutkan) (p22)

### (pengguna data sekunder, cukup tulis tidak relevan)

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1. ***Adverse Event* dan Komplikasi**
	1. Metode pencatatan dan pelaporan *adverse events* atau reaksi samping, dan syarat penanganan komplikasi (Guideline 4 dan 23) (p23)

### (pengguna data sekunder, cukup tulis tidak relevan)

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* 1. Berbagai resiko yang diketahui dari *adverse events*, termasuk resiko yang terkait dengan setiap rencana intervensi, dan terkait dengan obat, vaksin, atau terhadap prosedur yang akan diuji cobakan (Guideline 4) (p24)

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## Penanganan Komplikasi (p27)

* 1. Rencana detil bila ada resiko lebih dari minimal/ luka fisik, membuat rencana detil,
	2. Adanya asuransi,
	3. Adanya fasilitas pengobatan / biaya pengobatan
	4. Kompensasi jika terjadi disabilitas atau kematian (Guideline 14)

### (pengguna data sekunder, cukup tulis tidak relevan)

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## Manfaat

* 1. Manfaat penelitian secara pribadi bagi subyek dan bagi yang lainnya (Guideline 4) (p25)

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* 1. Manfaat penelitian bagi penduduk, termasuk pengetahuan baru yang kemungkinan dihasilkan oleh penelitian (Guidelines 1 and 4) (p26)

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## Jaminan Keberlanjutan Manfaat (p28)

* 1. Kemungkinan keberlanjutan akses bila hasil intervensi menghasilkan manfaat yang signifikan,
	2. Modalitas yang tersedia,
	3. pihak pihak yang akan mendapatkan keberlansungan pengobatan, organisasi yang akan membayar,
	4. berapa lama (Guideline 6)

### (pengguna data sekunder, cukup tulis tidak relevan)

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## Informed Consent

* 1. Cara yang diusulkan untuk mendapatkan informed consent dan prosudur yang direncanakan untuk mengkomunikasikan informasi penelitian kepada calon subyek, termasuk nama dan posisi wali bagi yang tidak bisa memberikannya. (Guideline 9) (p30)

### (pengguna data sekunder, cukup tulis tidak relevan)

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* 1. Khusus Ibu Hamil: adanya perencanaan untuk memonitor kesehatan ibu dan kesehatan anak jangka pendek maupun jangka panjang (Guideline 19) (p29)

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## Wali (p31)

* 1. Adanya wali yang berhak, bila calon subyek tidak bisa memberikan *informed consent*

(Guidelines 16 and 17)

### (pengguna data sekunder, cukup tulis tidak relevan)

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* 1. Adanya orang tua atau wali yang berhak bila anak paham tentang *informed consent* tapi belum cukup umur (Guidelines 16 and 17)

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## Bujukan

* 1. Deskripsi bujukan atau insentif pada calon subyek untuk ikut berpartisipasi, seperti uang, hadiah, layanan gratis, atau yang lainnya (p32)

### (pengguna data sekunder, cukup tulis tidak relevan)

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* 1. Rencana dan prosedur, dan orang yang bertanggung jawab untuk menginformasikan bahaya atau keuntungan peserta, atau tentang riset lain tentang topik yang sama, yang bisa mempengaruhi keberlangsungan keterlibatan subyek dalam penelitian (Guideline 9) (p33)

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* 1. Perencanaan untuk menginformasikan hasil penelitian pada subyek atau partisipan (p34)

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## Penjagaan Kerahasiaan

* 1. Proses rekrutmen (misalnya lewat iklan), serta langkah langkah untuk menjaga privasi dan kerahasiaan selama rekrutmen (Guideline 3) (p16)

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* 1. Langkah proteksi kerahasiaan data pribadi, dan penghormatan privasi orang, termasuk kehatihatian untuk mencegah bocornya rahasia hasil test genetik pada keluarga kecuali atas izin dari yang bersangkutan (Guidelines 4, 11, 12 and 24) (p 35)

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* 1. Informasi tentang bagaimana kode; bila ada, untuk identitas subjek dibuat, di mana di simpan dan kapan, bagaimana dan oleh siapa bisa dibuka bila terjadi kedaruratan (Guidelines 11 and 12) ( p36)

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* 1. Kemungkinan penggunaan lebih jauh dari data personal atau material biologis (p37)

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| **U.** |  | **Rencana Analisis** |
|  | 1. | Deskripsi tentang rencana rencana analisa statistik, termasuk rencana analisa interim |
|  |  | bila diperlukan, dan kriteria bila atau dalam kondisi bagaimana akan terjadi penghentian |
|  |  | prematur keseluruhan penelitian (Guideline 4) (B,S2); |
|  |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **V.** |  | **Monitor Keamanan** |
|  | 1. | Rencana untuk memonitor keberlangsungan keamanan obat atau intervensi lain yang |
|  |  | dilakukan dalam penelitian atau trial, dan, bila diperlukan, pembentukan komite |
|  |  | independen untuk data dan *safety monitoring* (Guideline 4) (B,S3,S7); |
|  |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **W.** |  | **Konflik Kepentingan** |
|  | 1. | Pengaturan untuk mengatasi konflik finansial atau yang lainnya yang bisa |
|  |  | mempengaruhi keputusan para peneliti atau personil lainya; menginformasikan pada |
|  |  | komite lembaga tentang adanya conflict of interest; komite mengkomunikasikannya ke |
|  |  | komite etik dan kemudian mengkomunikasikan pada para peneliti tentang langkah |
|  |  | langkah berikutnya yang harus dilakukan (Guideline 25) (p42)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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## Manfaat Sosial

* 1. Untuk riset yang dilakukan pada seting sumber daya lemah, kontribusi yang dilakukan sponsor untuk *capacity building,* untuk telaah ilmiah dan etik dan untuk riset riset kesehatan di negara tersebut; dan jaminan bahwa tujuan capacity building adalah agar sesuai nilai dan harapan para partisipan dan komunitas tempat penelitian (Guideline 8) (p43)

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* 1. Protokol riset atau dokumen yang dikirim ke komite etik harus meliputi deskripsi rencana keterlibatan komunitas, dan menunjukkan seluruh sumber yang dialokasikan untuk aktivitas keterlibatan tersebut. Dokumen ini menjelaskan apa yang sudah dan yang akan dilakukan, kapan dan oleh siapa, untuk memastikan bahwa masyarakat dengan jelas terpetaka,n untuk memudahkan keterlibatan mereka selama riset, untuk memastikan bahwa tujuan riset sesuai kebutuhan masyarakat dan diterima oleh mereka. Bila perlu masyarakat harus dilibatkan dalam penyusunan protokol atau dokumen ini (Guideline 7) (p44)

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## Hak atas Data

* 1. Terutama bila sponsor adalah industri, kontrak yang menyatakan siapa pemilik hak publiksi hasil riset, dan kewajiban untuk menyiapkan bersama dan diberikan pada para PI draft laporan hasil riset (Guideline 24) (B dan H, S1, S7);

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## Publikasi

Rencana publikasi hasil pada bidang tertentu (seperti epidemiologi, genetik, sosiologi) yang bisa beresiko berlawanan dengan kemaslahatan komunitas, masyarakat, keluarga, etnik tertentu, dengan meminimalkan resiko kemudharatan kelompok ini dan selalu mempertahankan kerahasiaan data selama dan setelah penelitian, dan mempublikasi hasil penelitian sedemikian rupa dengan selalu mempertimbangkan harkat dan martabat mereka (Guideline 4) (p47)

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Bila hasil riset negatif, memastikan bahwa hasilnya tersedia melalui publikasi atau dengan melaporkan ke Badan POM (Guideline 24) (p46)

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## AA. Pendanaan

Sumber dan jumlah dana riset; lembaga funding, dan deskripsi komitmen finansial sponsor pada kelembagaan penelitian, pada para peneliti, para subjek riset, dan, bila ada, pada komunitas (Guideline 25) (B, S2); (p41)

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## BB. Daftar Pustaka

Daftar referensi yang dirujuk dalam protokol (p40)

## CC. Lampiran

* 1. CV Peneliti Utama
	2. Sampel Formulir Laporan kasus