Protokol Etik Penelitian Kesehatan

Yang Mengikutsertakan Manusia Sebagai Subyek

Isilah form dibawah dengan uraian singkat dan berikan tanda contreng (X/V) pada kotak atau lingkari pada salah satu pilihan jawaban yang menggambarkan penelitian.

P: Nomor Urutan Protokol CIOMS 2016 – Lampiran 1;

S: Standar Kelaikan Etik (WHO-2011 dan Pedoman KEPPKN 2017);

C: Check List/Daftar Tilik

G: Guideline CIOMS 2016

IC: CIOMS 2016 – Lampiran 2

Daftar Isi:

## Judul Penelitian (p-protokol no 1)\*

## Ringkasan usulan penelitian (p-protokol no 2)

## Isyu Etik yang mungkin dihadapi

## Ringkasan Daftar Pustaka

## Kondisi Lapangan

## Disain Penelitian

## Sampling

## Intervensi

## Monitor Hasil

## Penghentian Penelitian dan Alasannya

## Adverse Event dan Komplikasi (Kejadian Yang Tidak Diharapkan)

## Penanganan Komplikasi

## Manfaat

## Jaminan Keberlanjutan Manfaat

## Informed Consent

## Wali

## Bujukan

## Penjagaan Kerahasiaan

## Rencana Analisis

## Monitor Keamanan

## Konflik Kepentingan

## Manfaat Sosial

## Hak atas Data

## Publikasi

## Pendanaan

## Komitmen Etik

## Daftar Pustaka

## AB. Lampiran

1. CV Peneliti Utama
2. Sampel Formulir Laporan kasus

**Protokol Etik Penelitian Kesehatan**

**Yang Mengikutsertakan Manusia Sebagai Subyek**

Nomor : .... / ... /KEPK/........ (Diisi Komite Etik Penelitian Kesehatan)

Isilah form dibawah dengan uraian singkat dan berikan tanda contreng (X/V) pada kotak atau lingkari pada salah satu pilihan jawaban yang menggambarkan penelitian.

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## Judul Penelitian (p-protokol no 1)\*

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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
 |  |   |
| 1. 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

1. Anggota Peneliti :

Institusi

Sponsor (p9)

Nama :

Alamat :

## Ringkasan usulan penelitian (p-protokol no 2)

1. ringkasan dalam 200-400 kata, (ditulis dalam bahasa yang mudah difahami oleh “awam” bukan dokter/profesi)

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1. Justifikasi penelitian (p3). Tuliskan mengapa penelitian ini harus dilakukan, manfaat nya untuk penduduk diwilayah penelitian ini dilakukan (Negara, wilayah, lokal)- Standar 2/A (Adil)

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## Isyu Etik yang mungkin dihadapi

1. Pendapat peneliti tentang isyu etik yang mungkin dihadapi dalam penelitian ini, dan bagaimana cara menanganinya (p4) – sesuaikan dengan 7 butir standar kelaikan etik (S) dan G berapa

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## Ringkasan Daftar Pustaka

1. Ringkasan hasil 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 hewan. Maksimum 1 hal (p5)- G 4

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## Kondisi Lapangan

1. Gambaran singkat tentang lokasi penelitian lihat P-2

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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 (P-1; S-1,2)

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1. Deskripsi detil tentang desain penelitian.

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1. Bila uji coba klinis, deskripsi harus meliputi apakah kelompok treatmen ditentukan secara random, (termasuk bagaimana metodenya) P-5, 21 dan apakah blinded atau terbuka. (*Bila bukan ujicoba klinis cukup tulis: tidak relevan) (p12)*

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## Sampling

1. Jumlah subyek yang dibutuhkan sesuai tujuan penelitian dan bagaimana penentuannya secara statistik (P-1, 3, 5)

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1. Kriteria partisipan atau subyek *dan justifikasi exclude/include*. (P-3)

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1. **Sampling kelompok rentan**: alasan melibatkan anak anak atau orang dewasa yang tidak mampu memberikan persetujuan setelah penjelasan, atau kelompok rentan, serta langkah langkah bagaimana meminimalisir bila terjadi resiko (P-15 sd 19)  *(p15)*

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## Intervensi

(pengguna data sekunder, kualitatif, cukup tulis tidak relevan, lanjut ke manfaat)

1. Desripsi dan penjelasan semua intervensi (metode administrasi treatmen, termasuk rute administrasi, dosis, interval dosis, dan masa treatmen produk yang digunakan (investigasi dan komparator

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1. Rencana dan jastifikasi untuk meneruskan atau menghentikan standar terapi selama penelitian

(p 4 dan 5)

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1. Treatmen/Pengobatan lain yang mungkin diberikan atau diperbolehkan, atau menjadi kontraindikasi, selama penelitian

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1. Test klinis atau lab atau test lain yang harus dilakukan

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## Monitor Hasil

1. Sampel dari form laporan kasus yang sudah distandarisir, metode pencatatan respon terapeutik (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)

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## Penghentian Penelitian dan Alasannya

1. Aturan atau kriteria 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)

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## Adverse Event dan Komplikasi (Kejadian Yang Tidak Diharapkan)

1. Metode pencatatan dan pelaporan adverse events atau reaksi, dan syarat penanganan komplikasi (P-4, 6)

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1. Risiko-2 yang diketahui dari adverse events, termasuk risiko yang terkait dengan masing masing rencana intervensi, dan terkait dengan obat, vaksin, atau terhadap prosudur yang akan diuji cobakan (P-4, 5)

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## Penanganan Komplikasi (p-14)

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

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## Manfaat

1. Manfaat penelitian secara pribadi bagi subyek dan bagi yang lainnya (P-4)

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1. Manfaat penelitian bagi penduduk, termasuk pengetahuan baru yang kemungkinan dihasilkan oleh penelitian (P-1, 4)

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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 (P-6, 14)

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## Informed Consent

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

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1. Khusus Ibu Hamil: adanya perencanaan untuk memantau kesehatan ibu dan kesehatan anak jangka pendek maupun jangka panjang (P-14, 19)

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## Wali (p-10, 16, 17)

1. Adanya wali yang berhak bila calon subyek tidak bisa memberikan informed consent (P-10, 16, 17)

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1. Adanya orang tua atau wali yang berhak bila anak paham tentang informed consent tapi belum cukup umur.

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## Bujukan

1. Deskripsi bujukan atau insentif pada calon subyek untuk ikut berpartisipasi, seperti uang, hadiah, layanan gratis, atau yang lainnya (P-13)

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

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1. Perencanaan untuk menginformasikan hasil penelitian pada subyek atau partisipan (P-24)

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## Penjagaan Kerahasiaan

1. Proses rekrutmen (misalnya lewat iklan), serta langkah langkah untuk menjaga privasi dan kerahasiaan selama rekrutmen (P-3)

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1. Langkah 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 (P- 4, 11, 12 dan 24

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1. Informasi tentang bagaimana kode; bila ada, untuk identitas subyek dibuat, di mana di simpan dan kapan, bagaimana dan oleh siapa bisa dibuka bila terjadi emergensi (P-11, 12)

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1. Kemungkinan penggunaan lebih jauh dari data personal atau material biologis

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## Rencana Analisis

1. Deskripsi tentang rencana tencana analisa statistik, termasuk rencana analisa interim bila diperlukan, dan kriteria bila atau dalam kondisi bagaimana akan terjadi penghentian prematur keseluruhan penelitian (P-4);

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## Monitor Keamanan

1. Rencana-2 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 (P-4);

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## 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 (P-25)

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## Manfaat Sosial

1. Untuk riset yang dilakukan pada seting sumberdaya lemah/rendah, kontribusi yang dilakukan sponsor untuk *“capacity building”* untuk telaah ilmiah dan etik dan untuk riset riset kesehatan; dan jaminan bahwa tujuan capacity building adalah agar sesuai nilai dan harapan para partisipan dan komunitas tempat penelitian (P-8)

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1. Protokol riset atau dokumen yang dikirim ke komite etik harus meliputi deskripsi rencana pelibatan komunitas, dan menunjukkan sumber sumber yang dialokasikan untuk aktivitas aktivitas pelibatan tersebut. Dokumen ini menjelaskan apa yang sudah dan yang akan dilakukan, kapan dan oleh siapa, untuk memastikan bahwa masyarakat dengan jelas terpetakan untuk memudahkan pelibatan 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 (P-7)

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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 (P-24) (B dan H, S1,S7);

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## Publikasi

Rencana publikasi hasil pada bidang tertentu (seoerti epidemiology, generik, sosiologi) yang bisa berisiko berlawanan dengan kemaslahatan komunitas, masyarakat, keluarga, etnik tertentu, dan meminimalisir risiko kemudharatan kelompok ini dengan selalu mempertahankan kerahasiaan data selama dan setelah penelitian, dan mempublikasi hasil hasil penelitian sedemikian rupa dengan selalu mempertimbangkan martabat dan kemulyaan mereka (P-1, 4)

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Bila hasil riset negatip, memastikan bahwa hasilnya tersedia melalui publikasi atau dengan melaporkan ke otoritas pencatatan obat obatan (P-24)

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## Pendanaan

Sumber dan jumlah dana riset; lembaga penyandang dana, dan deskripsi komitmen finansial sponsor pada kelembagaan penelitian, pada para peneliti, para subyek riset, dan, bila ada, pada komunitas (P-25)

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## Komitmen Etik

1. Pernyataan peneliti utama bahwa prinsip prinsip yang tertuang dalam pedoman ini akan dipatuhi

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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

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1. Pernyataan bahwa bila terdapat bukti adanya pemalsuan data akan ditangani sesuai policy sponsor untuk mengambil langkah yang diperlukan

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Tanda tangan Peneliti Utama

\_\_\_\_\_\_\_\_\_\_\_\_\_\_, tanggal\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

## Daftar Pustaka

Daftar referensi yang dirujuk dalam protokol  (p40)

## AB. Lampiran

1. CV Peneliti Utama
2. Sampel Formulir Laporan kasus

*\* Urutan nomor pada Protokol Asli CIOMS 2016*