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Nomor : 852 /UN2.F1/ETIK/2017

KETERANGAN LOLOS KAJI ETIK

ETHICAL APPROVAL

Komite Etik Penelitian Kesehatan Fakultas Kedokteran Universitas Indonesia dalam upaya melindungi hak asasi dan kesejahteraan subyek penelitian kedokteran, telah mengkaji dengan teliti protokol berjudul:

The Ethics Committee of the Faculty of Medicine, University of Indonesia, with regards of the Protection of human rights and welfare in medical research, has carefully reviewed the research protocol entitled:

"Oral Prednisolone for Acute otitis media in chiLdren: A pilot pragmatic randomised open-label single-blind study (OPAL Study)".
No. protokol: 17-08-0858

Peneliti Utama
Principal Investigator : **dr. Respati Wulansari Ranakusuma, Sp.THT-KL**

Nama Institusi
Name of the Institution : **Unit Clinical Epidemiology and Evidence-Based Medicine (CEEBM) RSCM – FKUI**

dan telah menyetujui protokol tersebut di atas.
and approves the above mentioned protocol.

Jakarta, 11 SEP 2017
Ketua
Chairman

Prof. Dr. dr. Rianto Setiabudy, SpFK

* *Ethical approval* berlaku satu tahun dari tanggal persetujuan.
** Peneliti berkewajiban
1. Menjaga kerahasiaan identitas subyek penelitian.
2. Memberitahukan status penelitian apabila
   a. Setelah masa berlakunya keterangan lolos kaji etik, penelitian masih belum selesai, dalam hal ini *ethical approval* harus diperpanjang.
   b. Penelitian berhenti di tengah jalan.
3. Melaporkan kejadian serius yang tidak diinginkan (*serious adverse events*).
4. Peneliti tidak boleh melakukan tindakan apapun pada subyek sebelum protokol penelitian mendapat lolos kaji etik dan sebelum memperoleh *informed consent* dari subjek penelitian.
5. Menyampaikan laporan akhir, bila penelitian sudah selesai.
6. Cantumkan nomor protokol ID pada setiap komunikasi dengan KEPK FKUI-RSCM.

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Nomor : 1088 /UN2.F1/ETIK/X/2017 23 Oktober 2017
Hal : Amandemen Protokol Penelitian

Yth. dr. Respati W. Ranakusuma, Sp. THT-KL
Peneliti Utama
Unit CEEBM RSCM-FKUI
Jakarta

Sehubungan dengan protokol penelitian berikut :
Judul : ***"Oral Prednisolone for Acute Otitis Media in Children: A Pilot Pragmatic Randomised Open-Label Single-Blind Study (OPAL Study)"***.
Peneliti Utama : dr. Respati W. Ranakusuma, Sp. THT-KL
No. Protokol Etik : 17-08-0858
Surat Keterangan Lolos Kaji Etik No. 852/UN2.F1/ETIK/2017.

Komite Etik Penelitian Kesehatan FKUI-RSCM telah menerima dan meninjau surat sejawat:

Tanggal	Nomor surat	Perihal	Dokumen
18 Oktober 2017	241/CEEBM.K/ RKS.05/10/2017	Perubahan Protokol Penelitian (Amandemen).	1. Protokol Penelitian, 1 kopi

Isi Amandemen :
1. Perubahan pada bentuk sediaan obat uji klinis (prednisolon) : penggunaan prednisolon dalam **sediaan sirup** menjadi **tablet**.
2. Perubahan durasi pemberian obat uji klinis, dari **7 hari** menjadi **5 hari**.
3. Penambahan kriteria inklusi penelitian **yaitu** administrasi obat melalui rute injeksi.

Komite Etik Penelitian Kesehatan FKUI-RSCM menyetujui amandemen penelitian tersebut.

Atas laporan dan kerjasamanya, kami ucapkan terima kasih.

UNIVERSITAS INDONESIA FAKULTAS KEDOKTERAN

Prof. Dr. dr. Rianto Setiabudy, SpFK
Ketua

Number : 1088/UN2.F1/ETIK/X/2017 23 October 2017
Subjects : Amendment of research protocol

To:

Dr. Respati W. Ranakusuma, ORL
Clinical Epidemiology and Evidence-Based Medicine (CEEBM) Unit
Dr Cipto Mangunkusumo Hospital – Faculty of Medicine University of Indonesia
Jakarta

Regarding the following research protocol:

Title	:	"Oral prednisolone for acute otitis media in children: a pilot pragmatic, randomised, open-label, single-blind study (OPAL study)"
Principal Investigator	:	dr. Respati W. Ranakusuma, ORL
Ethics protocol number	:	17-08-0858
Ethics approval form number	:	852/UN2.F1/ETIK/2017

The Research Ethics Committee Faculty of Medicine University of Indonesia has received and reviewed your letter as follows:

Date	Letter number	Subject	Document
18 October 2017	241/CEEBM.K/RKS.05/10/2017	Amendment of approved research protocol	One (1) copy of research protocol

The amendments are:

1. The change of the study medication (prednisolone): the prednisolone use from liquid (syrup) to tablet
2. The change of the duration of study medication: from seven days to five days
3. The additional of exclusion criteria: the administration of study medication via injection route

The Research Ethics Committee Faculty of Medicine University of Indonesia approves the above mentioned amendment protocol.

Thank you for the amendment report and cooperation.

Prof. Dr. dr. Rianto Setiabudy, SpF

Chairman

HUMAN RESEARCH
ETHICS COMMITTEE
Bond University
Gold Coast Queensland 4229
Australia

Phone: +61 7 5595 4194
(from overseas)

Email: ethics@bond.edu.au

ABN 88 010 694 121
CRICOS Provider Code 00017B

28 November 2017

Chris Del Mar
Health Sciences and Medicine
Bond University

Dear Chris

Application ID:	**16151**
Project Title:	**Oral prednisolone for acute otitis media in children: a pilot pragmatic randomised open-label single-blind study (OPAL study)**
Researchers:	**Chris Del Mar, Elaine Beller, Amanda McCullough, Sugigdo Sastroasmoro, Yupitri Pitoyo, Widyaningsih, Arie Sulistyowati, Respati Wulansari, Eka D Safitri,**

I am pleased to confirm that your project was reviewed by Bond University Human Research Ethics Committee and you have been granted approval to proceed.

The Committee requires, as a condition of approval, that all investigations be carried out in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007). Approval is subject to conduct of the research in accordance with the requirements set out in the National Statement.

Approval is given subject to the protocol of the study being undertaken as described in your application, and approved amendments. As you may be aware the Ethics Committee is required to annually report on the progress of research it has approved. We would greatly appreciate if you could respond promptly and fully to the request for information on this project which will be distributed in March/April each year.

Under the terms of the National statement BUHREC has a role to monitor approved research projects and if necessary may withdraw approval. Conduct of unapproved research or deviation from the approved protocol may constitute academic misconduct and will be investigated in accordance with Part B of the *Australian Code for the Responsible Conduct of Research* (2007). Please refer to the Research Ethics website for more detail on Research Integrity and Bond University processes for dealing with instances of research misconduct.

You are reminded that the Principal Investigator must immediately report anything that might warrant review of ethical approval of the project. Should you have any queries or experience any problems, please contact us promptly.

We wish you well with your research project.

Yours sincerely

Dr Mark Bahr
Chair Bond University Human Research Ethics Committee