



COA No. 694/2015

IRB No. 276/58

## INSTITUTIONAL REVIEW BOARD

Faculty of Medicine, Chulalongkorn University

1873 Rama 4 Road, Patumwan, Bangkok 10330, Thailand, Tel 662-256-4493

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### Certificate of Approval

The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, has approved the following study in compliance with the International guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS Guideline and International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

**Study Title** : Association of vitamin d, bone mineral density and liver fibrosis in biliary atresia

**Study Code** : -

**Principal Investigator** : Miss Krittapak Homchan

**Affiliation of PI** : Center of Excellence in Clinical Virology, Department of Pediatrics, Faculty of Medicine, Chulalongkorn University.

**Review Method** : Full board

**Continuing Report** : At least once annually or submit the final report if finished.

**Document Reviewed** :

1. Protocol Version 2.2 Dated 16 Sep 2015
2. Protocol Synopsis Version 1.2 Dated 16 Sep 2015
3. Information sheet for representative (For children) Version 1.0 Dated 15 May 2015
4. Informed consent to participate in research projects for the representative. (For children) Version 1.0 Dated 15 May 2015
5. Information sheet for representative (For regular) Version 1.0 Dated 15 May 2015
6. Informed consent to participate in research projects for the representative (For regular) Version 1.0 Dated 15 May 2015





7. Information sheet for children aged 7-12 years (for children) Version 1.0 Dated 15 May 2015
8. Informed consent to participate in research projects for children aged 7-12 years (for children)  
Version 1.0 Dated 15 May 2015
9. Information sheet for children aged 7-12 years (for regular) Version 1.0 Dated 15 May 2015
10. Informed consent to participate in research projects for children aged 7-12 years (for regular)  
Version 1.0 Dated 15 May 2015
11. Information sheet for children aged 12-18 years (for children) Version 1.0 Dated 15 May 2015
12. informed consent to participate in research projects for children aged 12-18 years (for children)  
Version 1.0 Dated 15 May 2015
13. Information sheet for children aged 12-18 years (for regular) Version 1.0 Dated 15 May 2015
14. Informed consent to participate in research projects for children aged 12-18 years (for regular)  
Version 1.0 Dated 15 May 2015
15. Curriculum Vitae
16. GCP Training

Signature:..... (Emeritus Professor Tada Sueblinvong MD) Chairperson The Institutional Review Board	Signature:..... (Assistant Professor Prapapan Rajatapiti MD, PhD) Member and Secretary Secretary The Institutional Review Board
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Date of Approval : October 6, 2015

Approval Expire Date : October 5, 2016

Approval granted is subject to the following conditions: (see back of this Certificate)