ClinicalTrials.gov Study Document

Informed Consent Form for Legally Authorized Representative / Parent or Guardian

English Version

Official Title	Accelerated Correction of Vitamin D Deficiency in Cholestatic Children: A Comparative Trial of Vitamin D2 Monotherapy Versus Combination Therapy With Calcitriol
Brief Title	Vitamin D2 Versus Vitamin D2 Plus Calcitriol in Cholestatic Children With Vitamin D Deficiency
Acronym	VITD-CHOL
NCT Number	NCT number to be assigned
Document Date	February 5, 2026

Note: This document is an English translation of the approved Thai informed consent form template for the legally authorized representative, parent, or guardian. No participant names are included in this blank form.

Institution: Department of Pediatrics, Faculty of Medicine, Chulalongkorn University / King Chulalongkorn Memorial Hospital, Bangkok, Thailand

Informed Consent Form

For Legally Authorized Representative / Parent or Guardian

Research Study Title: Accelerated Correction of Vitamin D Deficiency in Cholestatic Children: A Comparative Trial of Vitamin D2 Monotherapy Versus Combination Therapy With Calcitriol

Date of Consent: Day _____ Month _____ Year _____

I, as the legally authorized representative, parent, or guardian, have a relationship as _____ of the participant named below:

Master / Miss / Mr. / Mrs. / Ms. _____ (participant full name).

I have read the details in the attached Participant Information Sheet for the legally authorized representative, parent, or guardian, dated _____. I voluntarily give permission for the participant named above to take part in this research study.

I have received a copy of this signed and dated informed consent form, together with the Participant Information Sheet for the legally authorized representative, parent, or guardian.

Before signing this informed consent form, the researcher explained to me in detail the purpose of the research, duration of the study, study procedures, possible risks or adverse effects that may occur from the research or from the study medicines, expected benefits of the research, and alternative treatment options. I had sufficient time and opportunity to ask questions until I understood the information well. The researcher answered all of my questions willingly and without concealing information, to my satisfaction.

I have been informed by the researcher that if any harm occurs as a result of participation in this research, the participant will receive medical care without charge.

I understand that I have the right to withdraw my consent at any time without giving a reason. Withdrawal of consent will not affect the participant's medical treatment or any other rights or benefits to which the participant is entitled.

The researcher assures me that the participant's personal information will be kept confidential and will be disclosed only with my permission, except as permitted by applicable regulations for research oversight. Representatives of the research sponsor, the Research Ethics Committee, and the Food and Drug Administration may be allowed to review and process the participant's information solely for the purpose of verifying the accuracy of the study data. By agreeing to participate in this study, I give permission for the participant's medical records to be reviewed for this purpose.

Any remaining biological samples from the research, such as leftover blood samples, and data obtained from the participant will be destroyed according to standard procedures after completion of the research, unless otherwise permitted by the approved study documents and applicable regulations.

The researcher assures me that no additional information will be collected after I withdraw consent and request destruction of study documents and/or identifiable samples that can be traced back to the participant.

I understand that I have the right to review or correct the participant's personal information and to withdraw permission for the use of the participant's personal information by notifying the researcher.

I understand that research data, including de-identified medical information, may undergo processes such as data collection, recording in case record forms and computers, verification, analysis, and reporting for academic purposes. De-identified medical information may also be used in the future for academic or pharmaceutical research purposes only, as permitted by applicable regulations and ethics approval.

I have read and understood all of the above statements. I voluntarily give my consent and therefore sign this informed consent form.

Signatures

_____

Signature of legally authorized representative / parent or guardian

(_____)

Printed name of legally authorized representative / parent or guardian

Relationship to participant: _____

Date: Day _____ Month _____ Year _____

_____

Signature of researcher

(_____)

Printed name of researcher

Date: Day _____ Month _____ Year _____

_____

Signature of witness

(_____)

Printed name of witness

Date: Day _____ Month _____ Year _____

Researcher Statement

I have explained in detail the purpose of the research, study procedures, possible harms, adverse effects, or risks that may occur from the research or from the study medicines, and the expected benefits of the research to the legally authorized representative, parent, or guardian of the participant named above. The representative, parent, or guardian understood the information and signed this informed consent form voluntarily.

Additional Witness Signatures Required if a Fingerprint Is Used Instead of a Written Signature

(If the participant or representative uses a fingerprint instead of a written signature, two witnesses are required.)

_____

Signature of witness

(_____)

Printed name of witness

Date: Day _____ Month _____ Year _____

_____

Signature of witness

(_____)

Printed name of witness

Date: Day _____ Month _____ Year _____