Leuven, 30 May 2022

Ethics Committee
Research UZ/KU Leuven
Herestraat 49
B 3000 Leuven (Belgium)

Email : ec@uzleuven.be

prof. dr. Djalila Mekahli
KINDERGENEESKUNDE

Our reference:	EudraCT-nr:	Belg. Regnr:
S59638		B322201732941

An international web-based database for longitudinal data registry of children with Autosomal Dominant Polycystic Kidney Disease (ADPKD).

Modification/additional study documents

AMEND-Id: 0002

Dear colleague

The Ethics Committee Research (EC Research) of University Hospitals Leuven (UZ Leuven) has initially given a positive advice for the above mentioned protocol on 6 July 2017.

Documents/answers submitted on 19 April 2022, 26 April 2022, 16 May 2022 and 25 May 2022 have been taken into account in the evaluation of the modification.

A favourable advice for this modification was given on 30 May 2022.

The favourable advice concerns:

Protocol
Version 4 dd 01Jan2022 (amendment 1)
Informed Consent Form
ICF ADPedKD adult v6 dd 6may2022 Nl
ICF ADPedKD parent v6 dd 6may2022 Nl
ICF ADpedKD -18j v7 dd may2022 Nl
GDPR questionnaire
Submitted on 26Apr2022

The changes in the ICF should be clearly communicated to the patient.
We would like to point out that in case of amendments to the ICF, it is strongly

advised to use an ICF addendum for ongoing participants. The ICF addendum lists only the changes or new information which is more clear to the participant than an amended ICF where changes are highlighted. When enrolment is still ongoing, an amended ICF is required for new participants.

The following documents were submitted for notification:

Not applicable

EC Research confirms working in accordance with the ICH-GCP principles (International Conference on Harmonization Guidelines on Good Clinical Practice), the latest version of the Declaration of Helsinki, the Oviedo Convention on Human Rights and Biomedicine and applicable laws and regulations.

EC Research confirms that - in case of conflict of interest - involved members do not take part in the vote concerning the study.

List of members: see appendix.

Points of concern: (if applicable)

The conformity of translated documents compared to the Dutch documents, is the responsibility of the sponsor.

In case of modifications to protocol and/or clinical trial agreement for UZ Leuven, they must also be submitted to the Clinical Trial Center (CTC) of UZ Leuven.

We would like to draw your attention to the fact that EC Research expects her initial comments to be taken into account ab initio at the next submission by the same sponsor.

Studies with investigational medicinal products and certain studies with "medical devices" should be submitted by the client (PI or sponsor) to the FAMHP (Federal Agency for Medicines and Health Products).
Studies with investigational medicinal products are only allowed to be conducted, provided that the minister (FAMHP) does not state objections within legal deadlines as described in art. 13 of the Belgian law of 7/5/2004 concerning experiments on the human person.
Certain studies using medical devices are also covered by legal deadlines (KB of 17/3/2009). Please consult the FAMHP website for more information: www.fagg-afmps.be.

Research on embryos in vitro is covered by the law of May 11, 2003. Before the research project can start, such research also requires a positive advice of the Federal Committee for medical and scientific research on embryos in vitro.

Please take into account the regulations of the hospital concerning tissue management

and the regulations of the law of December 19, 2008.

This favourable advice of EC Research does not imply that she will assume responsibility for the planned study. You will remain responsible for the study. In addition, you, as involved principal investigator, should ensure that your opinion as an involved researcher is reproduced in publications, reports for the government, etc. which are the result of this study. You are reminded that concerning clinical studies, any observed serious event needs to be reported immediately to the sponsor and the ethics committee, even if the causal relationship with the study is unclear.

We request you to inform us if the study will not be initiated.

Finally, we request you to report the termination (early or planned) of the study within the legal deadlines and provide the ***Clinical Study Report*** *(CSR) to EC Research.*

In case of a clinical trial (EudraCT), please be informed that the results must be published in the European Clinical Trial Register. The report of these results can be sent to the EC Research as the CSR.

Yours sincerely,

Prof. dr. Minne Casteels
Chair
Ethics Committee Research UZ Leuven

Cc:
FAMHP (Federal Agency for Medicines and Health Products)

CTC (Clinical Trial Center UZ Leuven)

Participating centres

Local Committee	*Principal investigator*	*Date advice*
UCL St-Luc	dr. Nathalie Godefroid	12 October 2018
CHU Sart-Tilman	dr. Marie-Sophie Ghuysen	14 May 2018
ZNA Antwerpen	dr. Martine Docx	14 May 2018
CHR de la Citadelle	dr. Jacques Lombet	2 May 2018
UZ Gent	dr. Ann Raes	22 August 2018
CHU Tivoli	dr. Pernille Hansen	3 May 2018
CHC MontLégia	dr. Anne Guffens	30 March 2018
Hôpital Universitaire des enfants Reine Fabiola (HUDERF)	dr. Benedetta Chiodini	4 June 2018
Europa Ziekenhuizen	dr. Bogdan Dima	4 May 2018

List of members EC Research UZ/KU Leuven on 30 May 2022:

Chair	prof. dr. Maria-Reinhilde Casteels	Clinical Pharmacology
Vice chair	prof. dr. Dominique Bullens	Paediatrics
	De heer Aernout De Raemaeker	Medical Legislation alternate
	De heer Jean-Jacques Derèze	Medical Legislation alternate
	De heer Mathijs Swaak	Healthy volunteer repres.
	Mevr. Angélique Rézer	Medical Legislation alternate
	Mevr. Annick Vanclooster	Nurse
	Mevr. Katelijne Van Overwalle	Pt representative (alternate)
	Mevr. Lia De Wilde	Pt representative (alternate)
	Mevr. Marilien Vandeputte	Nurse
	Mevr. Michèle Dekervel	Medical Legislation alternate
	Mevr. Teresia De Fraye	Pt representative
	Mevr. Veerle Vanparys	Pharmacist (alternate)
	dr. Kristel Van Landuyt	Reumatology
	dr. Lut De Groote	General Practitioner
	dr. Marleen Renard	Paediatrics
	dr. Walter Janssens	Clinical Pharmacology
	prof. André Loeckx	Pt representative (alternate)
	prof. Ben Van Calster	Statistics
	prof. Guy Bosmans	Clin. Psychology (alternate)
	prof. Pascal Borry	Ethics
	prof. Rik Gosselink	Revalidation
	prof. dr. Anne Smits	Paediatrics
	prof. dr. Anne Uyttebroeck	Paediatrics
	prof. dr. Ariel Alonso	Statistics (alternate)
	prof. dr. Bart Van der Schueren	Endocrinology / Pharmacology
	prof. dr. Benoit Nemery	Pneumology
	prof. dr. Céline Gillebert	Clin. Psychology (alternat
	prof. dr. Gregor Verhoef	Haematology
	prof. dr. Jan Verhaegen	Laboratory Medicine
	prof. dr. Jan de Hoon	Clinical Pharmacology
	prof. dr. Karin Sipido	Experimental Cardiology
	prof. dr. Koen Luyckx	Clin. Psychology (alternate)
	prof. dr. Maria Schetz	Intensive care
	prof. dr. Simon Brumagne	Physiotherapy
	prof. dr. Xavier Bossuyt	Immunology
	prof. dr. apr. Erwin Dreesen	Pharmacist (alternate)