





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

Email: ec@uzleuven.be

prof. dr. Ronny Bruffaerts UPC EPSI-UNIT

 Our reference:
 EudraCT-nr:
 Belg. Regnr:

 S64034
 B3222020000085

Evaluatie van de Eerstelijns Psychologie.

## Modification/additional study documents AMEND-Id: 0006

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 25 August 2020.

Documents/answers submitted on 20 September 2022 and 26 September 2022 have been taken into account in the evaluation of the modification.

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

The favourable advice concerns:

Protocol

Protocol v10.0 dd 19Sep2022

The following documents were submitted for notification:

**Annual Progress Report** 

Annual Progress Report dd 19Sep2022 (dd 25Aug2020 - 19Sep2022) Miscellaneous

AM6 - EPCAP Navigator version dd 19Sep2022 NI + Fr

A GDPR questionnaire needs to be completed for each study or research project for which

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UZ/KU Leuven acts either as sponsor or as participating site and in which personal data are processed. We ask the sponsor to verify if the existing information in the GDPR-questionnaire is still up-to-date after this modification. Please submit an adapted GDPR-questionnaire to EC in the next amendment to the study if necessary.

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: <a href="www.fagg-afmps.be">www.fagg-afmps.be</a>.

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

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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,

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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

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

Chair Vice chair prof. dr. Maria-Reinhilde Casteels prof. dr. Dominique Bullens De heer Aernout De Raemaeker De heer Jean-Jacques Derèze De heer Mathijs Swaak Mevr. Angélique Rézer Mevr. Annick Vanclooster

Mevr. Katelijne Van Overwalle Mevr. Lia De Wilde Mevr. Marilien Vandeputte

Mevr. Michèle Dekervel Mevr. Teresia De Fraye Mevr. Veerle Vanparys dr. Kristel Van Landuyt dr. Lut De Groote

dr. Marleen Renard dr. Walter Janssens prof. André Loeckx prof. Ben Van Calster prof. Guy Bosmans

prof. Pascal Borry prof. Rik Gosselink prof. dr. Anne Smits prof. dr. Anne Uyttebroeck prof. dr. Ariel Alonso

prof. dr. Bart Van der Schueren

prof. dr. Benoit Nemery prof. dr. Céline Gillebert prof. dr. Gregor Verhoef prof. dr. Jan Verhaegen prof. dr. Jan de Hoon

prof. dr. Karin Sipido prof. dr. Koen Luyckx prof. dr. Maria Schetz prof. dr. Simon Brumagne prof. dr. Xavier Bossuyt prof. dr. apr. Erwin Dreesen Clinical Pharmacology

**Paediatrics** 

Medical Legislation alternate Medical Legislation alternate Healthy volunteer repres. Medical Legislation alternate

Nurse

Pt representative (alternate) Pt representative (alternate)

Nurse

Medical Legislation alternate

Pt representative Pharmacist (alternate) Reumatology

General Practitioner

Paediatrics

Clinical Pharmacology Pt representative (alternate)

**Statistics** 

Clin. Psychology (alternate)

Ethics Revalidation Paediatrics Paediatrics

Statistics (alternate)

Endocrinology / Pharmacology

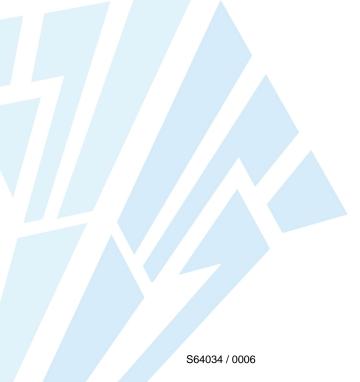
Pneumology

Clin. Psychology (alternate)

Haematology
Laboratory Medicine
Clinical Pharmacology
Experimental Cardiology
Clin. Psychology (alternate)

Intensive care Physiotherapy Immunology

Pharmacist (alternate)



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