Stichting Beoordeling Ethiek Biomedisch Onderzoek

Bijlage C METC - SOP

LETTER OF APPROVAL

INDEPENDENT ETHICS COMMITTEE

Study (title)	:	*
Study code	:	*
Study Centre	:	*
Sponsor	:	*
Sponsor code	:	*
CCMO code	:	NL*

The Independent Ethics Committee (Medisch Ethische ToetsingsCommissie) of the Foundation 'Evaluation of Ethics in Biomedical Research' (Stichting Beoordeling Ethiek Biomedisch Onderzoek), Assen, The Netherlands, is constituted according to the Dutch national act on medical-scientific research in human beings [Wet Medisch- wetenschappelijk Onderzoek met mensen (WMO)], the Regulations of the U.S. Food and Drug Administration as laid down in the Code of Federal Regulations, 21 CFR, Part 56 (Institutional Review Board), and the ICH Harmonised Tripartite Guideline E6 on Good Clinical Practice (ICH-GCP).
In accordance with the WMO the Committee has been accredited by the Central Committee on Research Involving Human Subjects [Centrale Commissie Mensgebonden Onderzoek (CCMO)] and by the Dutch Association of Ethics Committees [Nederlandse Vereniging van Medisch-Ethische Toetsingscommissies (NVMETC)].

The members of the Committee have taken into consideration the contents of the above-mentioned Regulations and the Declaration of Helsinki (1964), as lately amended by the 64th General Assembly, of the World Medical Association (Fortaleza,Brasil,2013) and the EU Clinical Trial Directive 2001/20/EC.

The Committee has reviewed the information as indicated in Appendix I from ethical, legal and medical points of view and considers the protocol adequate for the aims to be investigated. All activities of the Committee were performed in accordance with the METC-SOP, version - 6, dated 26 October 2015.

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In the opinion of the Committee all human subjects have been adequately informed and sufficient safeguards for the protection of rights and welfare of the human subjects, participating in this investigation, have been assured by the Protocol and the participating investigators. The Committee points out that the investigators should comply with the stipulations of the Declaration of Helsinki (1964), as lately amended by the 64th General Assembly, of the World Medical Association (Fortaleza, Brazil, 2013).

Revised Protocols or Amendments that are implemented after the date of the approval must be subjected to the additional approval of the Committee.

The Committee must be kept informed about the progress of the study and must be immediately informed (within 24 hours) about serious adverse events (including those indicated in Article 10, sub 1, of the medical Research in Human Subjects Act [also known by its Dutch abbreviation WMO] and about suspected unexpected serious adverse events. The Committee should also be informed about the beginning and the (premature) termination of the study.
The Committee must be provided with a detailed report on the study, within one year after completion of the study.

The Committee is of the opinion that all conditions mentioned in article 3 of the WMO have been met.

The approval has a limited period of validity of one year after the date of signing as far as the start of the study is concerned.
In case of a multi centre trial, approval is only granted for the parts to be carried out at centres that have provided a Research Declaration (see Appendix I).

With the above considerations, and considering that the questions raised during the meeting were answered adequately and revisions to the dossier were made where necessary, the undersigned declare that the Committee gives her approval to perform the investigations in accordance with the above-mentioned Protocol.

Finally we would like to point out that based on article 23 of the WMO the party concerned can lodge an administrative appeal against this decision with the Central Committee on Research Involving Human Subjects (CCMO), within six weeks after the day upon which the decision was made public. Such a notice of appeal should be addressed to the CCMO, P.O. Box 16302, 2500 BH The Hague.

Assen, *

Chairman,

B. Wilffert, Ph.D., Pharm.D.
J.R.B.J. Brouwers, Ph.D., Pharm. D.

Secretary,

J.P. van Dijk, Ph.D., M.D., LL.M.
Mrs. Y.E. van Dijk, LL.M.

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APPENDIX I

The Independent Ethics Committee (Medisch Ethische ToetsingsCommissie) of the 'Stichting Beoordeling Ethiek Biomedisch Onderzoek', Assen, The Netherlands, reviewed in the meeting of * the information on the study with * code *, entitled:

'*

The following documents, provided by the applicant, have been submitted to the Independent Ethics Committee on *, and/or revised versions, as a result of the meeting, on *.

A1 Cover Letter to IEC, dated *, and resubmission letter, dated *
A2 Authorisation letter sponsor, dated *
A3 Confirmation of EudraCT number, dated *

B1 CCMO-registration number: NL*, ABR-Form version *
B3 EudraCT number: *, EudraCT Application Form, dated *

C1 Clinical Study Protocol and Appendices, dated *

D1 Investigator's Brochure on *, dated *
D2 Investigational Medicinal Product Dossier on *, dated *
D3 Examples of labels (in Dutch), dated *
D4 Statement on a manufacturer's license, dated *

E1/2 Informed Consent including Statement of Willingness (English and Dutch version), dated *
E3 Advertisements and recruitment text, dated *

F1 Questionnaires
F2 Patient diary
F3 Patient card

G1 WMO subject insurance for ** with **,
Policy number: **
G2 Liability insurance for ** with **,
Policy number: **

H1 CV of the Independent Physician: **
I2 Research Declaration of *, dated *
I3 CV of the Medical Investigator: *

K3 Clinical Research Agreement between * and **

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APPENDIX II

Study code: *

'xx (study title)'

Members of the INDEPENDENT ETHICS COMMITTEE

J.G. Aarnoudse, M.D., Ph.D.	Emeritus Professor of Obstetrics and Gynaecology University of Groningen
G.L. Bartels, M.D., Ph.D.	Cardiologist Martini Hospital, Groningen
M.J. de Bree, M.A.	Assistant Professor of Medical Ethics, Ethicist University Medical Center Groningen
Mrs. D.S. Bosscher, M.A., R.N.	Nurse Practitioner Specialist in Lung Transplantation University Medical Center Groningen
Mrs. A.A. Broekema, M.D., Ph.D.	Specialist in Anaesthesiology University Medical Center Groningen
J.R.B.J. Brouwers, Ph.D., Pharm.D., chairman *(chairman chamber B)*	Emeritus Professor of Pharmacotherapy Hospital Pharmacist / Clinical Pharmacologist Department of Pharmacy University of Groningen
S.M.G.J. Daenen, M.D., Ph.D.	Specialist in Internal Medicine, Haematologist University Medical Center Groningen
J.P. van Dijk, M.D., Ph.D., LL.M. *(secretary chamber A)*	Associate Professor of Social Medicine University Medical Center Groningen University of Groningen
Mrs. Y.E. van Dijk, LL.M. *(secretary chamber B)*	Legal Policy Advisor Zorgpartners Friesland Leeuwarden - Heerenveen
K.H. Groenier, Ph.D.	Epidemiologist / Biostatistician Assistant Professor of General Practice University Medical Center Groningen
A.C. van Grootheest, M.D., Ph.D.	Emeritus Professor of Pharmacovigilance University of Groningen
E. Hak, Ph.D.	Professor of Clinical Pharmacoepidemiology Department of Pharmacy, University Groningen Department of Epidemiology, University Medical Center Groningen

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Members of the INDEPENDENT ETHICS COMMITTEE *(continued – 2/3)*

H.J. Hoekstra, M.D., Ph.D.	Professor of Surgical Oncology University Medical Centre Groningen
Mrs. A.C.M. ter Horst-Haitink	Lay member, with special responsibilities to protect the interests of the volunteers, Borger
F.G.A. Jansman, Ph.D., Pharm.D.	Hospital Pharmacist / Clinical Pharmacologist Deventer Hospital, Deventer
J.P. de Jong, Ph.D.	Healthcare Consultant, Ethicist, 'de Argumentenfabriek', Amsterdam
Mrs. M. Kesting-Koopmans, M.Sc., R.N.	Research Coordinator Department of Intensive Care Medical Center Leeuwarden
A.S. Keverling Buisman, Ph.D.	Retired Radiation Protection Expert Nuclear Research and consultancy Group (NRG), Petten Schoorl
Mrs. L.M. Kraan, LL.M. *(substitute secretary)*	Lawyer, Specialist in Health Law and Civil Law Zwolle
L.M.F.H. de Leij, Ph.D.	Professor in Medical Biology Faculty of Medical Sciences University of Groningen
Mrs. E.L.M. Maeckelberghe, Ph.D.	Assistant Professor of Ethics, Ethicist University Medical Center Groningen
J.G. Maring, Ph.D., Pharm.D.	Hospital Pharmacist / Clinical PharmacologistDepartment of Pharmacy Meppel/Hoogeveen Head of Medical Staff Diaconessenhuis, Meppel
Mrs. A.E. van Melle, M.A.	Lay member, with special responsibilities to protect the interests of the volunteers, Groningen
Mrs. Y.T. Nawijn, M.A., R.N.	Rehabilitation Nurse Centre 'De Vogellanden', Zwolle
P. Nieboer, M.D., Ph.D.	Specialist in Internal Medicine, Oncologist Wilhelmina Hospital, Assen
Mrs. A.N. Raat, Ph.D.	Medical Ethicist Coordinator Medical Education and Researcher Medical Education Faculty of Medical Sciences University of Groningen

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Members of the INDEPENDENT ETHICS COMMITTEE *(continued – 3/3)*

D.R.A. Uges, Ph.D., Pharm.D.	Emeritus Professor of Clinical and Forensic Toxicology Hospital Pharmacist / Clinical Pharmacologist Former Head of Laboratory of Drug Analysis Department of Pharmacy University Medical Center Groningen
N.J.G.M. Veeger, Ph.D.	Clinical Epidemiologist / Methodologist Thorax Center University Medical Center Groningen
L.J.G. Veehof, M.D., Ph.D.	Assistant Professor in General Practice Faculty of Medical Sciences University of Groningen
R. Venekamp, M.D.	Director Seneca – abt Consultant, Coach and Trainer for Professionals in Health Care concerning Education Issues Haren
Mrs. E.M. ten Vergert, Ph.D.	Sociologist, Methodologist Deventer
B. Wilffert, Ph.D., Pharm.D., vice-chairman *(chairman chamber A)*	Professor of Pharmacotherapy Clinical Pharmacologist Department of Pharmacy University of Groningen
Mrs. H.J. Zand	Lay member, with special responsibilities to protect the interests of the volunteers, Assen