



LIST OF MEMBERS

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Mag. Franc Hočevar (M)
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Adviser to the President of the Republic
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*The names of those Members present on the 280th NMEC session of 22th January 2019 & taking decisions on ethical review of research are printed in italics.
Five Members constitute the quorum for ethical review of research. None of the Members had any conflict of interest in the matter on which they voted.*

Signed:

Dr. Božidar Voljč, MD,
Chairman

A handwritten signature in black ink, appearing to read 'Božidar Voljč', written over the printed name of the Chairman.



REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZDRAVJE

Komisija Republike Slovenije za medicinsko etiko

Date: 22th January 2019

Re: *Compliance with Standards of Good Clinical Practice*

TO WHOM IT MAY CONCERN

Herewith we confirm that the National Medical Ethics Committee of the Republic of Slovenia (NMEC) operates in compliance with the ICH/GCP requirements of good clinical practice and all the applicable regulations of the Republic of Slovenia and the EU¹. The NMEC's compliance with laws, regulations, policies, and guidelines is assured also by the *Federalwide Assurance for the Protection of Human Subjects* (FWA)².

Signed:
Dr. Božidar Voljč, MD,
Chairman

¹ The NMEC's remit is based on the Ministerial Decree of 24 April 1995, published in Uradni list RS (Official Gazette of the Republic of Slovenia) No. 30 of 2 June 1995 (pp. 2149-50), and its amendments, dated 20 August 2009 and 14 April 2018, published in Uradni list RS No. 69 of 4 September 2009 (p. 9539) and of 30 March 2018 (p. 3056), respectively.

² The NMEC is registered with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections, as IRB Reg. No. 00002668. The registration is valid until 04/19/2021.