Committee for Bioethics in Medicine at the Medical University of Lodz PI. Hallera 1B, 90-647 Lodz, ph. 0 785 911 596, 42 272-52-43, bioetyka@umed.lodz.pl

RESOLUTION OF THE BIOETHICS COMMITTEE ON THE MEDICAL EXPERIMENT PROJECT

Number RNN/394/19/KE of November 12, 2019.

(in all correspondence concerning this decision, please provide the above number and date of the Resolution)

Principal researcher

Wojciech Kuczyński MD, PhD, Department of Sleep Medicine and Metabolic Disorders, Chair and Department of Experimental and Clinical Physiology of the Medical University of Lodz, Mazowiecka 6/8, 92-215 Lodz

Title: Evaluation of selected anthropometric and hormonal factors, levels of circadian rhythm regulator proteins, quality of life and sleep among students.

Pursuant to the Act of December 5, 1996 on the professions of physician and dentist (Journal of Laws of 2017 item 125, as amended), the Act of September 6, 2001 - Pharmaceutical Law (i.e. Journal of Laws of 2016 item 2142, as amended), the Regulation of the Minister of Health of May 2, 2012 on sample documents submitted in connection with a clinical trial of a medicinal product and on the amount and manner of payment of fees for submission of an application for a clinical trial (Journal of Laws of 2012, item 491), the Act of May 20, 2010 on medical devices (Journal of Laws of 2017 item 211, as amended),the Regulation of the Minister of Health of February 17, 2016 on sample applications submitted in connection with a clinical trial, the amount of fees for submission of applications and the final report on the execution of a clinical trial (Journal of Laws, item 208), the Regulation of the Minister of Health and Social Welfare of May 11, 1999 on the detailed principles of appointment and financing and the mode of operation of committees for bioethics in medicine (Journal of Laws No. 47 item. 480), directive No. 8/2015 of February 16, 2015 of the Rector of the Medical University of Lodz on the introduction of the Regulations of the Committee for Bioethics in Medicine at the Medical University of Lodz and Directive No. 57/2017 of September 5, 2017 of the Rector of the Medical University of Lodz,

the Committee for Bioethics in Medicine at the Medical University of Lodz, having analyzed the application, having read the draft opinion on the submitted study, in a secret ballot, (fulfilling the obligations of the ICH GCP) resolves as follows:

§ 1

1. to give a favorable opinion on the application, without objections, on the basis of the documents submitted, the list of which is set out in Annex 1. The resolution shall enter into force on the date of its adoption.

§ 2

The opinion relates only to the pending project application. Each change and modification requires a separate opinion. The applicant is obliged to inform of any corrections, adverse events and unforeseen circumstances.

An appeal against this resolution shall be submitted via the Committee for Bioethics in Medicine at the Medical University of Lodz to the Appeals Committee for Bioethics in Medicine, within 14 days as of the date of receiving the resolution expressing the opinion.

Chair of the Committee for Bioethics in Medicine at the Medical University of Lodz

> Professor Józef Drzewoski MD, PhD. /-/ handwritten signature illegible

Dorota Salus

Attendance list for the meeting of Committee for Bioethics in Medicine at the Medical University of Lodz on November 12, 2019

No.	Name, surname	Profession, specialty	Place of work	Signature
1.	Professor Józef Drzewoski, MD, PhD. Chair of the Committee	MD, internist, diabetologist, clinical pharmacologist	Professor Emeritus of the Medical University of Lodz	/-/ handwritten signatur illegible
2.	Rev. PhD. Jan Wolski Vice-Chair of the Committee	Priest, bioethicist	Higher Theological Seminary in Lodz	/-/ handwritten signature illegible
3.	Professor Andrzej Głąbiński MD, PhD.	MD, neurologist	Department of Neurology and Stroke of the Medical University of Lodz	/-/ handwritten signature illegible
4.	Professor Iwona Kłoszewska MD, PhD.	MD, psychiatrist	Department of Geriatric Psychiatry and Psychotic Disorders of the Medical University of Lodz	
5.	Maja Kufelnicka- Babout MD, PhD.	MD, obstetrician, gynecologist	Perinatology Clinic, 1st Department of Gynecology and Obstetrics of the Medical University of Lodz	/-/ handwritten signature illegible
6.	Professor Janusz Piekarski MD, PhD.	MD, surgical oncologist	Surgical Oncology Clinic of the Medical University of Lodz	Authorized absence
7.	Professor Henryk Stępień MD, PhD.	MD, endocrinology,	Laboratory of Immunoendocrinology of the Medical University of Lodz	/-/ handwritten signature illegible
8.	Associate Professor Marta Woldańska- Okońska MD, PhD.	Medical rehabilitation	Rehabilitation and Physical Medicine Clinic of the Medical University of Lodz	/-/ handwritten signature illegible
9.	Professor Krzysztof Zeman MD, PhD.	MD, pediatrician, clinical immunology	Pediatrics, Preventive Cardiology and Developmental Immunology of the Medical University of Lodz	Authorized absence
10.	Rafał Budzisz, LL.D.	Attorney-at-law	Medical University of Lodz	/-/ handwritten signature illegible
11.	Elżbieta Kubańska, MSc.	Nurse	Retired	Authorized absence
12.	Elżbieta Piotrowska- Rutkowska, MSc.	Pharmacist	Supreme Pharmaceutical Chamber , Długa 16 in Warsaw	/-/ handwritten signature illegible
13.	Elżbieta Jaszczuk, MD, PhD.	MD, anesthesiology and intensive care	Representative of the District Medical Council in Lodz	/-/ handwritten signature illegible

I, Dorota Salus, a sworn English-Polish translator, entered into the Register of Sworn Translators of the Ministry of Justice under No. TP/5280/05, hereby certify the above translation and its conformity to the original document made in Polish.

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