

Bioethics Committee  
of the Medical Academy in Wrocław,  
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DECISION OF THE BIOETHICS COMMITTEE  
No. KB-349/2005

The Bioethics Committee of the Medical Academy in Wrocław, appointed by the President of the Medical Academy in Wrocław, directive No. 4XIII R/99 of September 27, 1999, and functioning in the manner foreseen by the directive of the Minister of Public Health and Welfare of May 1, 1999, (Law Gazette No. 47, item 480) on the basis of the act concerning the physician's practice of December 5, 1996 (Law Gazette No. 28 of 1997, item 152 and later amendments), composed of:

Prof. Karol Bal (philosophy)  
Prof. Mieczysław Bernat (surgery)  
Fr. Dr. Janusz Czarny (clergy)  
Prof. Marian St. Gabryś (midwifery, gynecology, anesthesiology)  
Prof. Bogumił Halawa (internal diseases, cardiology)  
Dr. Henryk Kaczkowski (maxillofacial surgery, dental surgery)  
Irena Knabel-Krzyszowska, M. S. (pharmacy), representative of the Lower Silesian Chamber of Pharmacists  
Prof. Jan Kolasa (law)  
Dr. Sławomir Sidorowicz (psychiatry)  
Prof. Zenon Szewczyk (internal diseases, nephrology)  
Danuta Tarkowska (midwifery)  
Prof. Marian Wilimowski (pharmacology)  
Andrzej Wojnar, MD (pathomorphology, dermatology), representative of the Lower Silesian Chamber of Physicians

under the chairmanship of:  
Prof. Franciszek Iwańczak (pediatrics, gastroenterology)

in adherence to the principles of Good Clinical Practice and those of the Declaration of Helsinki, after becoming acquainted with the project:

"Experimental phage therapy in antibiotics-resistant bacterial infection, including  
MRSA infection"

*(Short title: :Experimental phage therapy of bacterial infection")*

proposed by

Prof. Andrzej Górski

employed at

The Institute of Immunology and Experimental Therapy PAN in Wrocław

and with the documents, together with the proposal, consisting of:

- a detailed description of the project and justification of its usefulness and feasibility
- a list of the researchers realizing the project
- information about the conditions of patient insurance together with a copy of the actual insurance policy
- data on the expected therapeutic and cognitive benefits for the persons subjected to the medical experiment
- information for the persons subjected to the medical experiment
- a commitment, signed by the researcher, to obtain informed consent from all research participants (subjects) or their legal representatives
- a sample of the patients' form for informed consent of:
  - participation in the study
  - acceptance of the insurance conditions
  - agreement to the storage of data
- information about the conditions of financing the project

by secret ballot, at the meeting on June 9, 2005, resolved:

to consent to the conducting of the study at the Institute of Immunology and Experimental Therapy (IIET) PAN and at the Non-public Healthcare Center at the IIET PAN in Wrocław under the supervision of Prof. Andrzej Górski.

**The Committee's consent is valid to the expiry date of the insurance policy.**

The issuance of this decision concerns only the examined proposal of the presented project; any change and modification requires obtaining a separate decision. The applicant is obliged to inform of all alterations which may have influence on the Committee's decision, of serious or unexpected undesired events and unforeseen circumstances, of completion of the study, of its results, and of essential decisions of other bioethics committees.

Instruction: The applicant is entitled to the right of appeal to the Appeals Commission through the agency of the Bioethics Committee of the Medical Academy in Wrocław within 14 days of receiving this decision.

CHAIRMAN OF THE COMMITTEE

[signature]

Prof. Franciszek Iwańczak

Wrocław, June 15, 2005