



**DOCTORAL SCHOOL OF THE INSTITUTE
OF IMMUNOLOGY AND EXPERIMENTAL THERAPY
POLISH ACADEMY OF SCIENCES**

Rudolfa Weigla 12, 53-114 Wrocław, Poland szkoladoktorska.hirszfeld.pl

Doctoral School Syllabus

Course Title	Fundamentals of Clinical Trials
Form of classes	Lecture/Workshop
Lecturer	Dr Dominika Jakubczyk
Number of hours	10
Subject status	Optional
Languages of classes	English
Entry requirements	None
Course description	The course provides an introduction to the principles, structure, and implementation of clinical trials. It covers key definitions, planning and documentation, regulatory and ethical requirements, and the fundamentals of clinical trial management. The final session includes a group-based practical assignment in which students design a mock clinical study and prepare essential study documents.
Learning outcomes	After completing the course, students will be able to: 1) Define core terminology and concepts used in clinical trials; 2) Describe the main phases, processes, and documentation required in clinical research; 3) Explain ethical principles and the role of ethics committees; 4) Identify responsibilities of investigators and patient rights in clinical trials; 5) Outline key components of clinical trial planning and management (time, cost, scope, quality, risk); 6) Develop a simplified clinical trial design and prepare basic study documents. P8S_WG, P8S_WK, P8S_UW
Method of verification of learning outcomes	1) Group project: preparation of a mock clinical trial design and key documents (study outline + patient information leaflet). 2) Oral group presentation of the project during the final session 3) Active participation in discussions and practical exercises.



Supplementary literature	1) ICH E6 Good clinical practice - Scientific guideline; https://www.ema.europa.eu/ 2) Badania kliniczne. Praktyka, prawo, etyka. Praca zbiorowa. Warszawa: CeDeWu, 2024.
Additional information	Up to 12 participants per group