Annex No.1 to the Rules for submitting research topics for the admission to the interdisciplinary education programme in the Doctoral School of Medical and Health Sciences for the academic year 2024/2025

| Research topic submission form   |  |
|--|--|
| to the interdisciplinary education programme                                     |  |
| Discipline   |  |
| Please indicate  | □ medical sciences   |
| Trease mareate   | ☐ pharmacology and pharmacy  X health sciences   |
|  | A fieatth sciences   |
| Submitter - a person willing to act  | as a supervisor  |
| Title/degree<br>Full Name  | Dr hab. Marcin Waligóra, prof. UJ  |
| Category please select the relevant category according to the DSMHS Regulations  | X a person employed at the JU MC holding a post-doctoral habilitation or professor's degree who has submitted a declaration of affiliation of at least 75% to the discipline in which the research topic is being proposed  a person employed in Poland in a university or other entity listed in Article 7(1) of the Act - Law on Higher Education and Science, holding a professor's or post-doctoral habilitation degree, who has submitted a declaration of affiliation of at least 25% to the discipline in which the research topic is being submitted, and has presented the consent of a person meeting the conditions specified in item 1 to undertake the post of a supervisor, after obtaining a positive opinion of the School Board  a person employed at a foreign university or academic institution, if the respective research discipline board   |
| Date of obtaining  | considers that the person has a significant record of achievements in the academic field to which the research topic relates  2007   |
| a) doctoral degree   |  |
| <ul><li>b) post-doctoral habilitation<br/>degree</li></ul>                       | 2017   |
| c) professor's degree  |  |
| Place of employment:   | Jagiellonian University Medical College, Faculty of Health Science, Department of Bioethics  |
| E-mail address:  | m.waligora@uj.edu.pl   |
| Contact phone:   | +48 693 22 01 22   |
| Academic achievements: List of max 5 publications from the last 3 calendar years | <ol> <li>Buedo P, Odziemczyk I, Perek-Białas J, Waligora M. How to embed ethics into laboratory research. Account Res. 2023 Jan 17:1-20, DOI: 10.1080/08989621.2023.2165916.</li> <li>Bicer S, Hutchinson N, Feldhake E, Nelson A, Oliviero E, Waligóra M, Kimmelman J. Timing for First-in-Minor Clinical Trials of New Cancer Drugs. J Pediatr. 2023 Aug 30:113705.</li> <li>Hutchinson N, Klas K, Carlisle BG, Kimmelman J, Waligora M. How informative were early SARS-CoV-2 treatment and prevention trials? a longitudinal cohort analysis of trials registered on ClinicalTrials.gov. PLoS One. 2022;17(1):e0262114.</li> <li>Strzebonska K, Blukacz M, Wasylewski MT, Polak M, Gyawali B, Waligora M. Risk and benefit for umbrella trials in oncology: a systematic review and meta-analysis. BMC Med. 2022; 20:219. doi: 10.1186/s12916-022-02420-2</li> <li>Strzebonska K, Wasylewski MT, Zaborowska L, Polak M, Slugocka E, Stras J, Blukacz M, Gyawali B, Waligora M. Risk and Benefit for Targeted Therapy Agents in Pediatric Phase II Trials in Oncology: A Systematic Review with a Meta-Analysis. Target Oncol. 2021; 16(4):415-424. doi:10.1007/s11523-021-00822-5</li> </ol> |

| Impact Factor summary   | 160  |
|---|--|
| Web of Science Core Collection  | 570  |
| Hirsch index  | 12 (WebOfScience)  |
| Number of promoted doctoral degree holders:   | 3  |
| Number of promoted MA degree holders:   | 1  |
| Current number of PhD students in the Doctoral School of Medical and Health Sciences  | 1  |
| Proposed research topic   | Ethics of High-Risk Clinical Trials in Oncology. Risk, Benefit and Social Value  |
| Please give reasons why the topic and discipline match (max. 100 words)   | It is a (research) ethics topic which match with the health sciences.  |
| A brief description of research methods (max. 250 words)  | The study will consist of series of research performed with a mixed-methods (qualitative and quantitative research) as well as meta-research (cross-sectional analysis, longitudinal analysis, meta-analysis, scoping reviews).  PhD will work within a unique methodological approach connecting meta-research techniques to provide data for evaluation in an extended normative analysis. Methods of meta-research will be used and adopted to answer research questions in the field of health science and bioethics. In particular, systematic evaluation of risk and benefit for participants of high-risk trials in oncology will be performed. A new set of methodological tools to test indicators of the social value of these trials, which will be adopted (e.g. informativeness and transparency of trials, among others) by analysing and comparing details of research protocols with published results. These include tracking changes in the planned versus eventually executed and published clinical trials results. After receiving evidence of the risk/benefit profile and the indicators of the social value of trials, data-driven normative analyses will be performed. |
| Expected place for the project implementation:  | Jagiellonian University Medical College, Faculty of Health Science, Department of Bioethics.   |
| Description of tasks for the PhD<br>student   | Performance of mixed-methodology research in research ethics; data analysis (cross-sectional analysis, longitudinal analysis, meta-analysis) testing research ethics hypothesis, writing of the manuscripts (a part of Phd publication series).  |
| Expectations towards the PhD student: specific skills and experience (the description of expectations cannot indicate a specific candidate) | A candidate with a demonstrated promise or evidence of excellence in research and proven knowledge/experience in drug discovery and development or/and research ethics. Experience in conducting systematic reviews and/or health technology assessments will be a plus. A strong commitment to active involvement in the high-quality work of a dynamic research team. A scientific and research background related to bioethics, drug discovery and development, and clinical trials is highly desirable. Advanced or proficiency-level English is required.   |

| Temporary availability of the PhD student (number of hours/weeks) necessary for the project implementation                | Full time: 40 hours per week. Parts of the research may be performed online. |
|---|--|
| Does the research project require PhD student's independent performance of medical procedures?*  Underline the applicable | No.  |
| Date  | Signed by /Rodpisano.przez: eris signeture Walterra                          |

Date / Data:

\*If the research topic requires the PhD student to perform mappendent medical procedures, then according to the admission procedures (Annex 1 and 2 to Resolution No. 14/II/2024 of the Senate of the Jagiellonian University of 28 February 2024), the candidate must have the professional licence, which must be justified and indicated (licence to practise as a doctor/nurse/physiotherapist, etc.). In the DSMHS admission procedure, the license to practice as a medical doctor or dentist for the duration of postgraduate internship will be treated as equivalent to the license to practice as a medical doctor or dentist in the Republic of Poland.

The research topic submitted must not overlap thematically or conceptually with a project being undertaken by a current PhD student under the supervision of the submitter.

The completed form must be printed, signed in appropriate places, scanned and sent by electronic mail by 30 April 2025 to:

in the discipline of medical sciences: rekrutacja.nmedyczne@cm-uj.krakow.pl

in the discipline of pharmacology and pharmacy: rekrutacja.nfarmaceutyczne@cm-uj.krakow.pl

in the discipline of health sciences: rekrutacja.nozdrowiu@cm-uj.krakow.pl

The email should include the title of the proposed research topic.

## Oświadczenie osoby zgłaszającej temat badawczy

Oświadczam, że realizacja tematu badawczego pt. Ethics of High-Risk Clinical Trials in Oncology.

## Risk, Benefit and Social Value

przez doktoranta Szkoły Doktorskiej Nauk Medycznych i Nauk o Zdrowiu

**nie wiąże się** z działalnością objętą ochroną – należy przez to rozumieć określoną /niepotrzebne skreślić/

w art. 21 ustawy z dnia 13 maja 2016 r. o przeciwdziałaniu zagrożeniom przestępczością na tle seksualnym i ochronie małoletnich (Dz.U. z 2023 r. poz. 1304 ze zm.) działalność związaną z wychowaniem, edukacją, wypoczynkiem, leczeniem, świadczeniem porad psychologicznych, rozwojem duchowym, uprawianiem sportu lub realizacją innych zainteresowań przez małoletnich, lub opieką nad nimi.



## Oświadczenie osoby zgłaszającej temat badawczy

Potwierdzam, że znane mi są zasady rekrutacji do Szkoły Doktorskiej Nauk Medycznych i Nauk o Zdrowiu na Uniwersytecie Jagiellońskim w roku akademickim 2025/2026 określone w uchwale nr 15/II/2025 Senatu Uniwersytetu Jagiellońskiego z dnia 26 lutego 2025 roku.

W szczególności przyjmuję do wiadomości, że:

W sytuacji zakwalifikowania się do szkoły dwóch lub więcej kandydatów wskazujących w rekrutacji ten sam wybrany temat badawczy, temat badawczy zostaje przyznany kandydatowi z największą liczbą punktów. Kolejnym kandydatom oferowane są do wyboru inne pozostałe tematy badawcze, nieobsadzone przez zrekrutowanych kandydatów.

/data/

/pod

Signed by / Podpisano przez: Ithrachadazesław Waligóra

Date / Data: 2025-04-30 11:46