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HUMAN RESEARCH ETHICS COMMITTEES (HREC) AT POLISH TECHNICAL UNIVERSITIES

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Purpose: Human Research Ethics Committees (HRECs) are becoming an increasingly important element in improving research methodology, including at technical universities, despite the fact that their functioning is not currently regulated by Polish law. Research involving human subjects in fields other than biomedicine, such as computer science, management, and engineering, increasingly requires ethical assessment in line with international ethical standards and the requirements of scientific publishers. The aim of this article is to examine the role, functions and organisational practices of HREC committees operating at technical universities in Poland and to analyse their impact on the organisation of research involving human subjects.
Design/methodology/approach: Two studies were conducted to achieve the intended objective. The first study analysed research projects carried out at a selected technical university (Wrocław University of Science and Technology) in terms of their involvement in research involving human subjects subject to review by a committee. The second study analysed the activities of three ethics committees of universities involving human subjects at the Wrocław University of Science and Technology, the Poznań University of Technology, and the Silesian University of Technology. This study consisted of an analysis of documentation and available information on the application evaluation processes and in-depth interviews with members of the ethics committees at all three universities mentioned above.
Findings: Approximately 5% of the research projects analysed at technical universities involve human participation, but the number of applications submitted to the Ethics Committee for Research Involving Human Subjects is significantly lower. HREC committees perform functions that go beyond traditional ethical assessments – they support young researchers, standardise research methods, ensure compliance with regulations (e.g. GDPR), and shape an ethical academic culture. The committees differ in terms of organisation, but their activities have a positive impact on the quality and reliability of the research conducted.
Human Research Ethics Committees (HREC) are an essential part of research procedures at technical universities. Their role goes beyond the formal evaluation of projects, as they improve scientific methods and support the development of social responsibility of the university. Nevertheless, it is necessary to develop common standards of operation and legal regulations

that clearly define their competences and place in the system of ethical research assessment in Poland.
Keywords: Human Research Ethics Committees (HRECs), technical universities in Poland, improving research methodology.
Category of the paper: Research paper**.**

1. Introduction

Research ethics committees play a key role in overseeing research involving human subjects, ensuring compliance with ethical standards, and protecting the rights and well-being of participants. These bodies, often referred to as Human Research Ethics Committees (HRECs), assess the ethical acceptability of research projects based on principles such as autonomy, justice, beneficence and non-maleficence (Mehta et al., 2023; Muralidharan, Schaefer, 2022). They act as independent bodies assessing the relationship between risks and potential benefits, ensuring that the rights and safety of participants take precedence over scientific and social interests (Lecuona, 2011). Their role often goes beyond ethical assessment alone, for example by ensuring public trust in the ethical conduct of research (Riva, Petrini, 2024).

In recent years, the function of ethics committees has also been recognised at technical universities, where it is undergoing significant evolution. Initially, research ethics was mainly associated with clinical research and projects involving biological material or direct experiments on humans. However, with the development of research methodologies, especially in fields such as management and quality sciences, data analysis, and user-centred ergonomic design, increasing importance is being attached to ethical issues that go beyond the traditional biomedical approach. Issues such as safety, psychological wellbeing, data privacy, and informed consent in digital environments are now much more highly valued in terms of ethical requirements. As a result, researchers from non-medical fields, who were previously rarely required to follow formal ethical procedures, must now obtain approval from ethics committees to conduct research involving human subjects. This change brings new challenges, including the need to adapt research projects to previously unknown ethical requirements. This particular situation of HRECs also applies to Polish technical universities, most of which established committees in 2020-2021 (Małek-Orłowska, Jach, 2022, p. 25). The problems faced by newly established committees are primarily related to the lack of uniform standards for issuing opinions and a general lack of regulation in this area.

From the perspective of Polish law, medical experimental research, conducted by medical doctors and positively assessed by relevant bioethics committees, is subject to mandatory prospective ethical review (Czarkowski, 2012). Such a narrow scope of regulation deviates from accepted international standards, which is also an important reason for establishing

HRECs in universities to assess research that requires human participation but does not fall within the category of medical experiments (Małek-Orłowska, Jach, 2022).

The lack of uniform regulation is one of the reasons for the absence of a commonly accepted standard for the establishment, functioning, and organisation of HREC committees at technical universities, which also contributes to the lack of uniform standards for the assessment and management of research risk. This also applies to more specific issues, such as the problem of remuneration for research participants (Różyńska, 2022).

Research on the functioning of HRECs has not yet had a long tradition. This issue has so far been addressed primarily in relation to medical, clinical and bioethical research. In this regard, standards and tools for self-assessment of ethics/bioethics committees have been developed (Sleem et al., 2010). Some researchers argue that the activities of ethics committees should be an integral part of every scientific process, rather than a separate process of external evaluation (Anderson et al., 2023). Others emphasise that ethics committees have not received the attention they deserve (e.g. Bain, 2017). Although this conclusion was made several years ago, it still seems to be valid today.

In technical universities, it is also important to broaden the perspective of research in basic and engineering sciences to include social issues. Obtaining a positive opinion from the HREC provides a kind of guarantee that the proposed research design not only meets the criteria of scientific correctness, but is also exemplary in terms of ethics. From this point of view, ethical excellence, understood as compliance with the principles of scientific integrity, loyalty to research participants and the usefulness of results (Galewicz, 2009), is an element of scientific excellence.

The authors of this paper assume that, in both research risk management and research management in general, consideration of the ethical perspective is an important element of analysis from a management perspective. Only by taking both perspectives into account will it be possible to formulate a model for the organisation and structure of an HREC at a technical university that fully meets the requirements of social responsibility.

2. Research methodology and results

The study consists of two stages: in the first stage, the number of research projects involving human subjects conducted at a selected technical university was estimated using the competent judges method, and in the second stage, the activities of three HRECs were analysed on the basis of a quantitative description and interviews with committee members.

2.1. Estimated number of research involving human subjects

An analysis of 1594 projects carried out at the Wrocław University of Science and Technology between 2007 and 2022, using the competent judges method, identified 87 research projects involving human subjects. Among these, the dominant forms were surveys (50 projects) and prototype testing (28 projects). In addition, 9 projects involved the use of personal data, 8 concerned the participation of protected groups, and 7 were classified as invasive research.

These projects were mainly carried out at the Faculty of Fundamental Problems in Technology (28 projects) and the Faculty of Computer Science and Management (also 28 projects, with a predominance of surveys). The Faculty of Mechanical Engineering was responsible for 10 projects, in which prototype testing predominated.

Therefore, the analysis shows that approximately 5% of all research carried out at Wrocław University of Science and Technology in the period under review involved human subjects. However, it is to be expected that the number of such studies will gradually increase (Małek-Orłowska, Jach, 2022, p. 32). In the case of the HREC at Wrocław University of Science and Technology, this thesis was confirmed already in the initial period of the committee's operation.

2.2. Research evaluated by HREC

Statistics from Wrocław University of Science and Technology (Wrocław Tech), Poznań University of Technology (PUT) and Silesian University of Technology (SUT) for the years 2022-2024 were used to estimate the number of studies reviewed by HRECs.

Table 1.
Number of reviewed studies in 2022-2024

Science Discipline	Management	Biomedical engineering	Computer science	Architecture	Education	Other	Total
Wroclaw Tech	20	116	23	6	6	5	176
PUT	20	0	6	10	0	6	42
SUT	2	3	1	1	0	3	10
Total	42	119	30	17	6	14	228

Source: own study.

According to these data, almost 66% of cases at Wrocław Tech concerned the review of research in the field of biomedical engineering, with optics being the most common area. This is probably due to both the specific nature of the research and the long-standing habit of researchers at to review research in this area. Before the establishment of HREC at Wrocław Tech, researchers from this discipline reviewed research in other committees, e.g. the Bioethics Committee of the Medical University, despite the various difficulties this entailed. Research from other disciplines included Computer Science (13.1%), Management (11.4%), Architecture (3.4%), projects related to academic teaching (3.4%). Other research (2.8%) were conducted in Mechanical Engineering, Environmental Engineering and Health.

In PUT, most of the cases concern Management studies (47.6%), Architecture (23.8%) and Computer Science (14.3%), as well as other disciplines (14.3%) like Environmental Engineering, Automatics and Electronics and the quality assessment of psychological counselling. Biomedical Engineering is not a discipline taught at PUT.

The SUT received the fewest applications. Three applications were submitted in Biomedical Engineering, two in Management, one in Computer Science, one in Architecture and three in Environmental Engineering.

Even with such large differences in the number of applications in individual committees, certain trends emerged, indicating which disciplines practised at technical universities most often undertake research involving human subjects. These can be considered to be: Biomedical engineering, Management, Computer science, Architecture, and Environmental engineering.

The percentage distribution of research in different disciplines is shown in Figure 1.

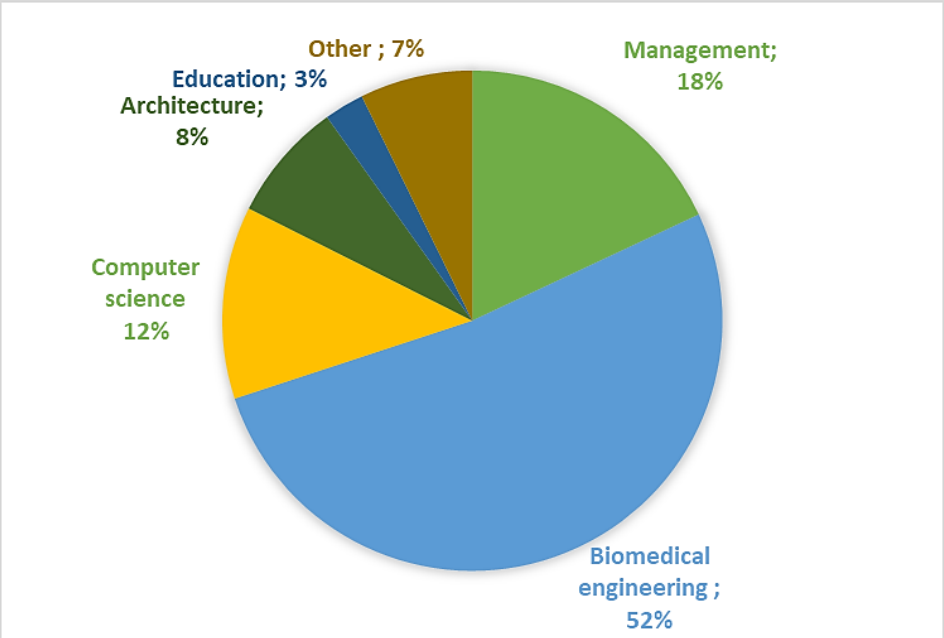

Figure 1. The percentage distribution of research in different disciplines.

Source: own study.

The number of proceedings conducted at both universities is incomparable due to different systems. PUT reviews applications until the desired result is achieved, so individual cases are returned to the committee multiple times. In contrast, at HREC at Wroclaw Tech, different solutions are acceptable. Of the 176 cases reviewed, less than half received approval for research (83; 47.2%), 39 (22.2%) received conditional consent, 34 (19.3%) did not receive consent and 20 (11.4%) were rejected. The reasons for rejection were mainly errors made by researchers, such as submitting to the HREC for review a research that had already been conducted, or research that did not fall within the scope of the committee's activities, such as invasive research involving humans or research involving animals.

In the case of the SUT, the situation appears to be similar to that of the PUT committee. Between 2022 and 2024, 10 applications were processed, of which 1 was ultimately rejected and 9 were approved, including one conditional approval, which means that the authors were required to make corrections.

2.3. Organisation of the HREC work

The Wrocław Tech Committee initially met on an ad hoc basis, depending on demand, according to the applications submitted. According to the first version of the regulations, the committee could make positive or negative decisions. After initial experience, a change was made to the regulations and the possibility of issuing conditional positive decisions was introduced. Due to the increasing number of applications, the Committee planned further work on a weekly basis. The Committee adopted a procedure whereby, in the event of a negative opinion, the applicant is informed of this together with the reasons, and after correction, a new application is submitted.

The PUT Commission also meets as needed, with work beginning immediately after an application is received, after it has been administratively checked for correctness, and then sent to the designated commission for the preparation of a preliminary opinion. A different system of issuing opinions has been adopted than in Wrocław Tech: applications that have been given a preliminary opinion are sent to the applicants for correction and, after they have been resubmitted, are considered by a designated working group of the committee. This iterative process continues until a positive opinion can be issued on the proposed research methodology. For this reason, the committee approved almost all applications, as in two cases it decided not to issue an opinion. This was in accordance with the committee's rules of procedure (there are no negative opinions, only positive ones, or no opinion). This procedure meant that some cases required several iterations, with most being concluded after three exchanges of correspondence.

The SUT Commission met as needed. However, there were relatively few applications. Upon receipt of an application, the chair of the commission asked the members of the commission to review the documentation, and then, during the meeting, the commission made a positive, negative, or conditionally positive decision, depending on the findings. The applicant could amend the application according to the recommendations of the committee. In the event of a negative decision, the applicant receives a full justification of the decision with the possibility of amending the application, which is then returned to the committee for reconsideration. If the application is not brought into line with the committee's recommendations, it is again rejected. The resolution of the committee is a binding document. In the case of a conditional positive decision, compliance with the committee's recommendations is required, but it is not necessary for the application to be resubmitted to the committee for reconsideration. The chairperson checks that the amendments made are in line with the committee's recommendations. If they are, the procedure is successfully completed.

2.4. Typical problems identified by the HREC

According to committee members, the problems identified by the HREC in the application review process are primarily due to errors made by applicants. The most common ones include:

- Problems related to the wording of consent to the processing of personal data – lack of a GDPR clause in the research, lack of consent to the processing of personal data in the research, lack of a clear description of how personal data will be processed.
- Problems related to the method of data processing, e.g. insufficient description or inappropriate method of data anonymization.
- Incorrect submission of requests.
- Formal and logical errors in the substantive content of the research, e.g. questionnaires with inseparable questions – although these are errors that theoretically fall outside the scope of the committee's opinion, they are often noticed by the committee.
- Requests for opinions on research that has already begun or completed.

Other identified problems related to issues specifically related to the planned research. These included, for example, the lack of a psychologist on a research team studying the use of smart wear technology while simultaneously conducting psychological tests on participants, or the absence of information regarding who would supervise underage participants.

In conclusion, the main source of problems was errors related to participant safety, particularly with regard to personal data protection. However, in many cases, the opinion of the HREC allowed researchers to identify shortcomings and improve their study design.

3. Discussion on the role of the HREC

The above material paints a picture of the HREC as a body with both an advisory and a regulatory function. As part of its advisory function, the committee reviews research applications, cheques the formal correctness of consents to participate in research, verifies the correctness of data anonymisation and, where justified, points out methodological and logical errors in the proposed research design. As part of its regulatory function, it refuses to issue an opinion on an application or refers it to the competent authority. An example of the first situation is the submission of an application for research during or after its completion. The second situation may concern the submission of an application for which another body is competent, e.g. a bioethics committee.

The literature emphasises that the typical roles of a research ethics committee involving human subjects include (Mehta et al., 2023):

- protecting the rights, safety and well-being of research participants,
- ensuring that research projects comply with ethical principles such as autonomy, justice, beneficence and non-maleficence,
- assessing the relationship between risks and potential benefits for participants and society,
- exercising independent oversight of the research process,
- building public trust in research,
- preventing conflicts of interest and promoting transparency and accountability in scientific research.

Research conducted in three committees confirms this intuition and adds even more to it. In addition to the typical functions performed by HRECs at technical universities, a whole range of other functions can be identified, less frequent but equally important. The authors identified these on the basis of interviews with committee members and an analysis of advisory proceedings and the structure of applications:

- supporting researchers as authors, i.e., ensuring that they meet the requirements set by journals that apply ethical publishing standards (preventive function),
- standardisation of research methods, especially surveys (normalising function),
- resolving semantic differences and measurement scales between fields at a technical university (normalising function),
- formal and legal protection of the research entity by ensuring compliance with legal regulations (GDPR) (preventive function),
- improvement of research methodology, in particular among younger researchers who are encountering the rigour of the research process for the first time (educational function),
- monitoring projects involving people in various fields of engineering, with particular emphasis on computer science, artificial intelligence and system design (predictive function),
- raising ethical awareness among technical researchers, as well as supporting the development of an ethical culture among researchers and students of technical disciplines (educational function),
- adapting ethical assessment procedures and methods to the specific nature of interdisciplinary research, e.g. by simplifying assessment processes in low-risk or multi-centre research (normalising function).

Of the functions listed above, the normalising function in particular seems to be a complex problem. For example, resolving semantic differences and measurement scales between fields operating at a technical university. This requires scientific reflection on the compatibility of

measurement levels and the adequacy of the measures adopted to the nature of the phenomena studied in different disciplines. Engineering disciplines often operate with numerical data, using ratio and interval scales that allow precise measurements and statistical analysis. In management sciences and ergonomics, on the other hand, ordinal and nominal scales are commonly used, often in the form of subjective assessments or declarations, making direct comparisons between research results difficult. Therefore, it is necessary to develop a common methodological framework that allows both data transformation between scales and the conscious design of measurement tools, taking into account their properties (such as reliability, validity, and level of measurement).). Only in this way is it possible to reliably integrate the results of interdisciplinary research and create reliable models describing complex phenomena operating at the intersection of different fields of science.

The above list outlines a fairly wide range of functions that the HREC committee would have to perform at a technical university. Given that the status, scope of competence, and range of tasks of the HREC committee are not regulated in any way, this creates a situation full of substantive and organisational challenges. This is undoubtedly a difficult situation for committees operating in a non-standardised manner and without administrative support. This problem was already noticed by other authors (Guillemin et al., 2012).

However, the lack of statutory regulation can also be seen as an opportunity for technical universities. By comparison, bioethics committees operating under legal regulations have their responsibilities and methods of operation clearly defined by the legislator. They have no freedom of action as to what research they review and to what extent. They cannot also take action outside of the statutory regulations.

From this point of view, the situation of HRECs is much better. Due to the lack of statutory regulation, it can be assumed that they operate on the basis of organisationally designated prerogatives (i.e. at the university level) within the scope of what is not expressly prohibited by law. This gives the university the opportunity to make the HREC an important tool for shaping research policy, managing research and implementing selected social responsibility objectives of the university.

The university may decide that the HREC also performs managerial and social-community functions. Through appropriately assigned managerial functions, the HREC may become an important body of the university in the field of research governance. It is also worth considering the extent to which the HREC could participate in the process of informing the public about research involving human subjects conducted at the university, as well as the extent to which it could support the fulfilment of equality and accessibility requirements in the area of research.

However, equipping the committee with functions that go beyond advisory and regulatory ones requires not only careful consideration, but above all further research in this area and the formulation of forecasts and guidelines based on this research. Our proposal is based on the belief that HRECs established to review applications for research involving human subjects should assess not only the formal correctness of these applications, but also their reliability,

particularly with regard to the identification of risks by researchers and the proposed means of minimising them. Both the literature on the subject and normative acts (e.g. the Helsinki Declaration) emphasise that research conducted in a manner inconsistent with accepted principles cannot be considered reliable (Małek-Orłowska, Jach, 2022; Emanuel et al., 2000). In addition, one of the most important reasons why researchers conducting research involving human subjects are required to submit their research projects to prospective ethical review is to ensure the safety of research participants. Therefore, it can be assumed that HRECs play an important role in the process of managing scientific research at universities.

From this broad range of functions, three modes of operation can be identified: 1. strictly formal, limited to issuing opinions on applications, 2. extended to include substantive advice, and 3. implementing elements of research governance. Mode 1 seems insufficient in light of existing HREC committees. The committees whose work was observed by the authors of this article already perform functions corresponding to mode 2, often advising researchers on how to improve their research designs or educating them in the field of research ethics. The implementation of mode 3, on the other hand, seems to be a much greater challenge at present, due to the fact that the committees operate in an unstandardised manner, effectively without administrative support and without the backing of an appropriate organisational model. However, it is worth considering the possibility of such a solution, as its implementation could bring significant benefits to researchers, universities and external stakeholders, including the wider public.

4. Summary

One of the most important reasons for reviewing research projects involving human subjects is to assess the adequacy of ethical risk identification and the effectiveness of measures to minimise each risk. When reviewing projects, HRECs decide which of the submitted projects meets the ethical standards for conducting research involving human subjects, thus helping to manage research risk. Obtaining a positive opinion from an HREC provides a kind of guarantee that the proposed research design not only meets scientific standards but is also ethically sound. From this point of view, ethical excellence, understood as compliance with the principles of scientific integrity, loyalty to research participants and the usefulness of results, is an element of scientific excellence.

The participation of HREC in the research process can contribute to improving the quality of research, more effective research management and fuller implementation of the principles of social responsibility of universities. For this reason, it is worthwhile for technical universities to consider not only the need to standardise the work of HREC committees but also to optimally define the scope of their functions and competences. The role of HREC at a technical university

may go far beyond the narrow framework of confirming the formal correctness of applications submitted by researchers conducting research involving human subjects.

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