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The role and competences of the Supreme Bioethics Committee and local bioethics committees in the context of protecting the rights of clinical trial participants in Poland

Michał Molenda[1,2], Adam Busławski[3], Dorota Krówczyńska[4,5,6], Dorota Zierkiewicz[7,8], Stanisław Manulik[9], Piotr Pobrotyn[10], Mariola Głowacka[11]

[1] Department of Legal Advisors, 4th Military Clinical Hospital, Wroclaw, Poland
[2] Lower Silesian Cell Transplantation Centre Ltd., Wrocław, Poland
[3] Department of Management and Logistics, WSB Merito University in Opole, Opole, Poland
[4] Cardinal Stefan Wyszynski Institute of Cardiology in Warsaw, Warsaw, Poland
[5] Department of Nursing and Obstetrics, Collegium Mazovia, Siedlce, Poland
[6] Department of Nursing, Faculty of Rehabilitation, Józef Piłsudski University of Physical Education in Warsaw, Warsaw, Poland
[7] Division of Anesthetic and Surgical Nursing, Department of Nursing Faculty of Nursing and Midwifery, Wroclaw Medical University, Wroclaw, Poland
[8] Department of Gastrointestinal Cancer, Lower Silesian Oncology, Hematology and Pulmonology Center, Wroclaw, Poland
[9] Division of Healthcare Organization, Department of Nursing, Faculty of Nursing and Midwifery, Wroclaw Medical University, Wroclaw, Poland
[10] Citodent Dental Center Furtak-Pobrotyn & Company Limited Partnership, Olawa, Poland
[11] Department of Nursing, Faculty of Health Sciences, The Mazovian University in Płock, Płock, Poland

Authors	**E-mail**	**ORCID**
M. Molenda	mmolenda@4wsk.pl	https://orcid.org/0009-0002-2282-736X
A. Busławski	adambuslawski@gmail.com	https://orcid.org/0000-0002-6329-278X
D. Krówczyńska	dkrowczynska@o2.pl	https://orcid.org/0000-0002-3928-3162
D. Zierkiewicz	dorota.zierkiewicz@umw.edu.pl	https://orcid.org/0009-0002-4102-7261
S. Manulik	stanislaw.manulik@umw.edu.pl	https://orcid.org/0000-0003-4292-161X
P. Pobrotyn	pobrotynp@gmail.com	https://orcid.org/0000-0001-9216-451X
M. Głowacka	m.glowacka@mazowiecka.edu.pl	https://orcid.org/0000-0002-5734-116X

Correspondence:
Piotr Pobrotyn, Citodent Dental Center Furtak-Pobrotyn & Company Limited Partnership, plac Zamkowy 5, 55-200 Oława, Poland; E-mail: pobrotynp@gmail.com

Abstract
The introduction in Poland of a centralized system for the ethical evaluation of clinical trials of medicinal products, under which the Supreme Bioethics Committee (NKB) was established, is a response to the need to harmonize procedures, increase transparency, and strengthen the protection of trial participants. The purpose of this article is to discuss the tasks and competences of the NKB and local bioethics committees (LKB) in the light of the applicable legal provisions, in particular the Act of March 9, 2023, on clinical trials of medicinal products and implementing regulations. The authors analyze the structure, composition, and mode of operation of both types of committees, as well as the principles of cooperation and supervision between them. Particular attention is paid to the ethical review procedure, the role of patient representatives, the prevention of conflicts of interest, and mechanisms for protecting the rights of participants. The article also points out how the new regulations strengthen the transparency, quality, and uniformity of bioethical standards in clinical trials conducted in the Republic of Poland. The article is of a review and analytical nature and refers to current legal sources, institutional documents, and practices implemented by the NKB and superior entities such as the Medical Research Agency (ABM). The tabular summaries and descriptions of institutional relationships presented are intended to facilitate understanding of the complex system of ethical supervision in clinical trials, in particular from the perspective of participant protection as a core value.

Keywords: Central Bioethics Committee (CBC), local bioethics committee (LBC), protection of clinical trial participants, ethical review, clinical trial law

Introduction

Clinical trials involving human participants require special attention to the protection of their rights and safety. To ensure the ethical conduct of such research, independent ethics committees are established, whose primary role is to safeguard the well-being, rights, and dignity of individuals participating in medical experiments. A bioethics committee is an independent body authorized to issue ethical opinions on research projects, including with the involvement of non-expert members, particularly patient representatives or organizations. The participation of patient advocates allows ethics committees to incorporate the perspective of the participant, thus providing an additional guarantee for the protection of their rights in clinical trials [1].

Traditionally, Poland has operated local bioethics committees (LBCs) affiliated with medical universities, research institutes, or regional chambers of physicians. Their existence and activities are legally grounded. According to the Act on the Professions of Physician and Dentist, every medical experiment project must receive an ethical opinion before commencement. However, this system has undergone significant reform in the context of clinical trials involving medicinal products. With the implementation of European regulations, Poland has introduced a new centralized model for issuing ethical opinions. This model aims to harmonize standards of ethical review and strengthen oversight mechanisms for the protection of research participants [2].

This article discusses the roles and competencies of the Supreme Bioethics Committee (SBC) - a new nationwide body established in 2023 – as well as the continuing functions of local bioethics committees, within the framework of current legal provisions. Particular emphasis is placed on how these institutions contribute to the protection of the rights of clinical trial participants in Poland [3].

Legal framework and the new structure of bioethics committees

The principal legal act regulating clinical trials of medicinal products in the European Union is Regulation (EU) No 536/2014 of the European Parliament and of the Council, which establishes a harmonized procedure for authorizing clinical trials across EU member states [4]. Among its key provisions is the requirement for a single, unified ethical assessment of a trial at the national level. In Poland, this regulation was implemented through the Act of 9 March 2023 on Clinical Trials of Medicinal Products Used in Humans (Journal of Laws 2023, item 605). This act introduced a new organizational structure for bioethics committees reviewing clinical trials, centered on the SBC. The primary aim of this reform was to centralize the previously fragmented system of bioethics committees and to streamline legal provisions to ensure consistent and high ethical standards nationwide [5].

According to the act, the Supreme Bioethics Committee for Clinical Trials was established at the Medical Research Agency (MRA) as an independent authority responsible for the ethical evaluation of clinical trials involving medicinal products. Simultaneously, a mechanism for accrediting local bioethics committees (LBCs) was introduced, stipulating that only committees listed in a special register maintained by the SBC are authorized to issue ethical opinions under the new system. In this way, the legislator established a two-tier structure: the central SBC oversees and coordinates the ethical review process, while selected LBCs from the official list conduct the detailed assessments of individual research applications [5].

The Supreme Bioethics Committee – tasks, competences, and composition

The Supreme Bioethics Committee (SBC) is an independent entity established under Article 91(1) of the Act of 9 March 2023 on Clinical Trials. Its mission is to issue ethical opinions on clinical trials of medicinal products and to uphold the protection of the rights, safety, and well-being of clinical trial participants. The SBC operates under the aegis of the Medical Research Agency (ABM), which provides its administrative and organizational infrastructure. According to statutory provisions, the main responsibilities of the SBC include [5,6]:

- issuing ethical evaluations of clinical trials of medicinal products, in cooperation with designated local bioethics committees (LBCs);
- cooperating with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) in the ethical evaluation process, ensuring coordination with the procedure for clinical trial authorization by URPL;
- reviewing applications for inclusion on the official list of bioethics committees authorized to issue ethical opinions that is, accrediting LBCs for participation in the clinical trial evaluation system;

- organizing training programs for committee members on bioethics and research methodology involving human participants, as well as for administrative personnel supporting the committees.

In addition to its evaluative functions, the Supreme Bioethics Committee (SBC) acts as a coordinating and supervisory body for the entire network of bioethics committees assessing clinical trials. It oversees the ethical review process and organizes the functioning of the committees, including by evaluating applications from local bioethics committees (LBCs) for inclusion on the official list, verifying their subsequent performance, and providing training. The SBC also develops internal regulations that facilitate the system's operation, for example, the Chair of the SBC issues guidelines and directives on maintaining the official list of authorized committees, qualification criteria for patient representatives, and the operational rules for reviewing teams. Through these instruments, the SBC ensures nationwide standardization of ethical assessment procedures [5].

The SBC may comprise a maximum of 30 members, appointed for a four-year term by the Minister of Health. Candidates are nominated by the President of the Medical Research Agency (ABM). The Committee includes not only experts in various fields of medicine but also representatives from non-medical disciplines (e.g., law, ethics), as well as patient representatives from organizations listed in the register maintained by the Ombudsman for Patients (RPP. This broad and interdisciplinary composition is intended to ensure a multi-dimensional review process covering scientific and medical aspects as well as patient rights and participant perspectives. The Committee is chaired by a member elected to serve as Chair, with a Deputy Chair assuming responsibilities in their absence. Although decisions are made collectively, the SBC may establish specialized review panels (working groups of selected members) to evaluate individual applications, thereby ensuring efficiency while maintaining procedural safeguards (e.g., meeting minutes, conflict of interest policies, as set out in the Minister of Health's ordinance - the SBC's Rules of Procedure) [6].

Importantly, the Chair of the SBC is responsible for communication with the European Clinical Trials Information System (CTIS) [7]. The Chair ensures that complete data and documents concerning Poland's ethical evaluations are uploaded to the EU portal. As such, the SBC serves as Poland's representative within the European system for the ethical assessment of multicenter clinical trials.

Local bioethics committees - roles and responsibilities in the clinical trial system

Local bioethics committees (LBCs), also known as institutional ethics committees, have long operated within medical universities, clinical hospitals, research institutes, and professional chambers, issuing opinions on research projects involving human participants. Their traditional role is to assess whether a proposed medical experiment meets ethical and legal standards before it is conducted. LBCs serve as the first line of protection for research participants by evaluating study protocols, informed consent forms, investigator qualifications, insurance safeguards, and related documentation to ensure that patients' rights will be respected [8–10].

In the context of clinical trials involving medicinal products, the role of LBCs was revised with the entry into force of the 2023 Act. Under the new provisions, the ethical evaluation of a clinical trial is conducted either by the SBC or by a local bioethics committee designated by the SBC Chair from the official list of accredited committees. This means that an LBC may issue an ethical opinion on a clinical trial application only if it is listed in the SBC-maintained register and has been formally assigned to the specific application. The previous model, where each research center was required to obtain a separate opinion from its affiliated LBC, has been replaced by a single national opinion system, typically prepared by a selected LBC operating under delegation from the SBC.

Procedure for accreditation and listing of authorized bioethics committees

The Chair of the SBC maintains an official register of LBCs authorized to conduct ethical evaluations of clinical trials. An LBC seeking inclusion on this list must submit an application to the SBC, including its internal regulations, documentation confirming the qualifications and education of its members, and evidence of appropriate IT infrastructure (capable of handling documentation in accordance with the requirements of the EU Clinical Trials portal).

The SBC assesses whether the applicant committee meets the legally prescribed criteria, including the ability to provide adequate scientific and organizational support for the ethical evaluation process. These requirements include: a multidisciplinary composition of the committee (experts from various fields), internal regulations that allow for collaboration with patient representatives and external experts where needed, procedures for member training, clear rules for document management and communication during evaluations, and protocols for cooperation with the SBC. Consequently, eligibility for listing requires that the committee has internal mechanisms to ensure a high standard of ethical review and demonstrates openness to involving patients and external experts in the evaluation process.

If the committee fulfills the criteria, the SBC Chair enters it into the register; otherwise, the committee is informed of deficiencies and the conditions necessary to remedy them. The act of listing (or refusal to list) does not constitute an administrative decision but is considered a technical act within the SBC's supervisory remit. Currently, the list includes several bioethics committees from various centers in Poland, including those affiliated with medical universities, research institutes, and selected hospitals. These committees have been positively assessed in terms of their expertise and infrastructure, ensuring their capacity to evaluate even complex clinical trial protocols [5,6].

The process of ethical evaluation of a clinical trial by a local bioethics committee

Once a sponsor submits an application for clinical trial authorization via the EU Clinical Trials Portal, the Chair of the SBC designates one of the authorized LBCs to perform the ethical review of the proposed study. The assigned LBC receives the complete trial documentation (including the protocol, informed consent form, investigator's brochure, etc.) and begins its assessment.

According to the Act, the Chair of the designated committee appoints an ethical review panel composed of 5 to 7 members from within the LBC. This panel typically includes several committee members with relevant scientific or medical expertise, at least one patient representative (a person unaffiliated professionally with medicine who represents the perspective of trial participants), and (if needed) an external expert in a specialized field. The inclusion of lay and independent members is an ethical requirement, ensuring that the evaluation reflects not only the researcher's perspective but also that of participants and the broader public.

The panel assesses, in detail, such elements as: the study's objective and scientific rationale, methodological justification, risk–benefit balance for participants, inclusion and exclusion criteria, the process for obtaining informed consent, data protection measures, safety monitoring plans, and insurance and compensation mechanisms for potential harms. In other words, the review determines whether the proposed trial meets all ethical, scientific, and legal requirements as outlined in applicable regulations and Good Clinical Practice (GCP) guidelines. Throughout the review, the LBC may communicate with the sponsor via the portal, e.g., to request clarifications or supplementary information. This is an important tool that enables the committee to resolve uncertainties or request amendments before issuing its final opinion [11,12].

Ethical evaluation and authorization of a clinical trial

The final outcome of the committee's work is the ethical opinion on the clinical trial, issued in the form of a resolution by the designated bioethics committee. This opinion may be positive (either unconditional or conditional) or negative. According to the applicable law, sponsors and investigators cannot appeal against the ethical assessment underscoring the independence and finality of the ethical judgment. However, the legislation provides a safeguard mechanism in cases where a negative ethical opinion results in the refusal of trial authorization by the Office for Registration of Medicinal Products (URPL). In such cases, the regulatory authority may request a re-evaluation of the application by the bioethics committee, which must be conducted by a different review panel. This "appeal-like" procedure enables a fresh assessment of the trial proposal and ensures that the negative opinion was justified. It provides a balance between the protection of participants (by not allowing unethical studies to proceed) and scientific opportunity (by allowing a second chance for reassessment in the case of a strict initial judgment) [4,13].

It is important to note that LBCs continue to evaluate other types of human research not governed by the Clinical Trials Act, such as clinical investigations of medical devices, non-drug medical experiments, or observational studies. These are regulated under separate legal frameworks, and opinions are issued by LBCs in accordance with the Regulation of the Minister of Health of 26 January 2023 on bioethics committees and the Appeals Bioethics Committee (Journal of Laws 2023, item 218) [2]. Nonetheless, even in such cases, the SBC exerts a positive, indirect influence on ethical standards, for example, by organizing training programs for all committees and promoting best practices. Still, within the scope of clinical drug trials, the designated LBCs and the SBC jointly carry out the ethical evaluation process under the new centralized model.

Cooperation between the SBC and LBCs and oversight of the system

The relationship between the SBC and LBCs is both hierarchical and cooperative in nature. The SBC serves a supervisory and coordinating function over the LBCs, while simultaneously relying on their expert knowledge and experience in assessing specific research projects. Key aspects of this cooperation and oversight include the Following [5,6,9,12]:

- Maintaining the register of authorized committees: the SBC determines which LBCs are eligible to participate in the ethical evaluation of clinical trials. Through the formal application procedure (described earlier), the SBC verifies each committee's competencies and organizational readiness. This acts as an initial quality filter, as only those LBCs that meet the required standards (appropriate membership composition, internal regulations, infrastructure) are admitted to the system. Furthermore, the SBC reserves the right to remove a committee from the register if it no longer meets the criteria or violates its obligations (e.g., failing to adhere to assessment standards). This authority encourages LBCs to maintain a consistently high standard of performance in line with ethical guidelines.
- Appointing LBCs to evaluate specific studies: the Chair of the SBC, who has access to information on the current workload and expertise profiles of each registered LBC, designates the committee responsible for the ethical assessment of a given application. These decisions may take into account potential conflicts of interest (e.g., an LBC affiliated with a site conducting the study may not be impartial), availability of relevant subject-matter experts, and the equitable distribution of workload. In practice, this ensures that each project is reviewed by the most appropriate committee, thereby enhancing the quality and objectivity of the evaluation and ultimately strengthening the protection of research participants.
- Standards and guidelines: the SBC develops detailed guidance to regulate the functioning of bioethics committees, for example, criteria for patient representatives (what qualities or experience they should have), rules for collaboration with external experts, and schedules or procedures for review teams. Guidelines issued by the Chair of the SBC help standardize the approach of LBCs to ethical assessment and ensure alignment with national legislation and EU regulations. This guarantees that certain minimum procedural standards are upheld regardless of which LBC is assigned to evaluate a given project (e.g., mandatory inclusion of a patient representative in the review team, recording of meetings for transparency, etc. requirements outlined in the SBC's internal regulations and their subsequent updates).
- Training and substantive support: one of the statutory duties of the SBC is to organize training for members of bioethics committees and their administrative staff. To fulfill this task, the SBC established a dedicated Training Team responsible for preparing educational programs for LBCs (e.g., on current trends in bioethics, clinical trial methodology, or relevant legislation). Regular training sessions enhance the competencies of LBCs, which directly contributes to the quality of ethical assessments. Committee members stay up to date with evolving standards and issues (e.g., ethics of genetic research, studies involving new technologies, GDPR compliance in clinical trials), enabling them to better protect participants' rights in rapidly developing scientific areas.

- Monitoring and reporting: as part of its supervisory function, the SBC may request periodic reports or specific information from LBCs regarding their activities. This may involve reviewing selected ethical opinions issued by a committee to assess compliance with standards or auditing its internal procedures. Additionally, the SBC collects data on committee workload, frequency of meetings, and timelines for issuing opinions. This allows the SBC to identify potential problems (e.g., prolonged assessment periods, staffing shortages) and respond appropriately, whether through educational or organizational support, or in extreme cases, suspension of a committee's ability to review new submissions until deficiencies are resolved. This form of real-time oversight is crucial for maintaining the efficiency and credibility of the entire system.
- Cooperation during the review process: while in principle, individual applications are reviewed independently by LBCs, the SBC is not entirely excluded from this process. In practice, consultations between the designated committee and the SBC may occur, particularly in atypical or ethically controversial cases. The SBC may issue interpretative recommendations, share the expertise of its members, or, in exceptional situations, take over the ethical review itself (e.g., if no LBC can be designated due to a conflict of interest or a lack of relevant expertise). The legislation also grants the SBC certain powers during the conduct of the trial, for example, in the event of significant protocol amendments or serious ethical violations, the SBC may intervene in collaboration with the Office for Registration of Medicinal Products (URPL). This ensures that participant protection does not end with

This model can be described as a system of interlinked vessels, where the SBC and LBCs jointly safeguard the ethical conduct of clinical trials. The SBC establishes the framework and monitors compliance, while LBCs carry out the detailed evaluation of individual research projects. Both entities must work in close cooperation to ensure that participant protection is effective - from the planning stage through to the conclusion of the study **(Table 1)** [5,6,9,12].

Table 1. Comparative overview of competencies: Supreme Bioethics Committee (SBC) vs. Local Bioethics Committees (LBCs)

Criterion	Supreme Bioethics Committee (SBC)	Local Bioethics Committees (LBCs)
Statutory Tasks	Ethical assessment of clinical trials involving medicinal products – the SBC is responsible for issuing ethical opinions for clinical trials in humans (in cooperation with LBCs). It also collaborates with the President of the URPL, organizes training for committee members, processes applications for LBC registration, and ensures the protection of participants' rights, safety, and welfare.	Ethical assessment of medical experiments and other research projects – LBCs issue opinions on medical experiments involving humans (e.g., academic research, PhD projects) and clinical trials of medical devices. They assess the ethical acceptability, justification, and feasibility of proposed research. For clinical trials of medicinal products, LBCs may only issue ethical assessments if officially designated by the SBC.

Composition	Up to 30 members, including representatives from various medical and non-medical professions and patient organizations. Members serve a 4-year term; the Chair is appointed from among them. The committee ensures multidisciplinary representation (e.g., physicians, pharmacists, nurses, lawyers, bioethicists, patient advocates) to comprehensively assess study protocols.	Usually 11–15 members, appointed by medical universities, research institutes, or medical chambers. Members must have high qualifications and impeccable ethics, representing various disciplines (e.g., physicians, ethicists, lawyers), with at least one member from the regional medical chamber. The multidisciplinary composition ensures well-rounded ethical assessments.
Appointment Process	Appointed centrally by the Minister of Health – members are nominated based on recommendations from the President of the Medical Research Agency (ABM). The Chair and Deputy Chair are also appointed by the Minister. The SBC was established by the Clinical Trials Act (March 9, 2023) and operates under the ABM (with administrative support from ABM).	Appointed locally by institutional authorities – e.g., medical university rectors or research institute directors decide the composition and appoint members. LBCs operate under national regulations (e.g., the Physicians Act, the 2023 Regulation on Bioethics Committees) and their internal statutes.
Scope of Activities	Nationwide jurisdiction for clinical trials involving medicinal products – the SBC is the central authority for issuing ethical opinions on such trials conducted in Poland. It assesses each trial in which Poland participates or acts as the lead country, coordinating ethical review at the national level.	Geographically and institutionally limited – LBCs operate within specific institutions (universities, hospitals, research institutes) and review research conducted locally. For medicinal product trials, their role is auxiliary – they may be designated by the SBC to review specific studies, especially if specialized expertise is needed. Without such designation, they cannot independently issue opinions on CTR-governed drug trials.
Independence	The SBC is an independent statutory body – it operates impartially and free from sponsor or administrative influence. Measures to ensure independence include a separate administrative office (distinct from ABM) and mandatory conflict of interest and financial disclosure statements. All decisions are based strictly on ethical and legal considerations.	LBCs must also ensure independent, reliable, and timely ethical assessments. Although affiliated with institutions, members must act impartially (e.g., not assessing projects they are involved in). The diverse composition (including external members) and internal regulations support independence from sponsors and investigators.
Relations with URPL	Close cooperation – the SBC prepares ethical evaluations as part of the URPL authorization process for clinical trials. It receives documentation via the CTIS system and issues opinions, which are required before the URPL can approve a trial. The SBC and URPL coordinate timelines and sponsor queries to streamline the assessment process.	No direct communication with URPL under the new legal framework – LBCs do not correspond directly with URPL on drug trials. If designated, they send their ethical opinions to the SBC, which then integrates them into the URPL decision. Prior to 2022, sponsors submitted LBC opinions directly, but this has been replaced with centralized review via the SBC.
Relations with Patients	Integrates the patient perspective – the SBC includes patient representatives (from advocacy organizations), ensuring their voice is reflected in overall assessments. Each review team must consult a patient representative to consider participant viewpoints. The SBC also provides public information (e.g., on the Compensation Fund) and recruits patient representatives, enhancing social involvement in ethical review.	LBCs also prioritize participant protection – they assess whether studies safeguard patients' rights and interests (e.g., through informed consent forms, compensation mechanisms, privacy measures). Most LBCs include non-medical or external members to reflect broader societal interests. By law, review teams (including at LBCs) must consult with patient representatives. LBCs also serve as local contact points for ethical concerns or monitoring site conditions.

Protection of clinical trial participants' rights by the bioethics committee's system

The primary goal of both the SBC and LBCs is to ensure the protection of clinical trial participants' rights at every stage of the study. These committees act as guardians of ethical standards developed over decades of biomedical research such as the principles of the Declaration of Helsinki, the ICH-GCP guidelines, and national regulations concerning patient rights. In practice, the protection of participants' rights by bioethics committees is reflected in several key areas [14–16].

Bioethics committees rigorously review the informed consent forms provided to study participants. They verify whether the documents are written in plain, understandable language, whether they comprehensively describe the study's purpose, procedures, potential benefits and risks, and clearly outline the participant's right to withdraw at any time [12]. If needed, the committee may request revisions from the sponsor to ensure that participants fully understand what they are consenting to. Informed and voluntary consent is a cornerstone of research ethics, no clinical trial may proceed without it. The committees ensure that consent is not illusory (e.g., coerced or based on incomplete information).

A fundamental right of the participant is the right to safety. Each committee assesses whether the potential benefits of the study (for the individual or for broader patient populations) outweigh the possible risks and burdens. If the risks to participants' health or life appear disproportionate to the expected scientific benefits, the committee will not issue a favorable opinion. Committees also require the protocol to include all possible risk-minimization measures and safety monitoring procedures (e.g., regular review of adverse events, the possibility of early study termination in case of danger). This principle of maximizing safety and avoiding harm is one of the most essential in clinical research [1,12].

Scientific integrity is essential not only to the meaningfulness of a clinical trial but also to the safety and welfare of its participants. Bioethics committees therefore assess whether a study has a scientifically justified objective and a properly designed protocol ensuring that participants are not exposed to risk in unnecessary or poorly planned research. This includes evaluating whether the number of participants is no greater than needed (to avoid unnecessary exposure), whether inclusion/exclusion criteria are appropriate and protect vulnerable populations, and whether medical procedures are aligned with current scientific knowledge. Committees also assess the qualifications of the principal investigator and study staff, participants have the right to receive care and monitoring from competent professionals. If the principal investigator lacks clinical trial experience or specialization in the relevant medical field, the committee may question their eligibility to lead the study. In fact, this issue is sometimes subject to additional review by the SBC, which publishes guidelines on how to assess investigator qualifications. As a result, participants are ensured care from adequately trained personnel.

Participants also have the right to privacy and confidentiality. Committees review whether the documentation includes adequate data protection measures – such as anonymization and compliance with GDPR for personal data processing [17]. They also verify whether the information being collected is limited to what is necessary for the research purpose. If needed, the committee may request modifications, such as reducing the scope of data collected or implementing additional safeguards (e.g., data encryption, restricted access). Furthermore, committees uphold the principle of respect for human dignity.

As a rule, a study protocol must not include procedures that violate the dignity or physical/psychological integrity of participants beyond what is absolutely necessary.

An important right of clinical trial participants is the right to compensation in the event of harm to their health caused by trial participation. Polish law provides two complementary mechanisms: the mandatory civil liability (OC) insurance policy held by the sponsor and the Clinical Trials Compensation Fund, administered by the Patient Ombudsman and funded by sponsor contributions. Bioethics committees ensure that each trial is adequately insured they require proof of insurance coverage and confirmation that participants are properly informed about the available compensation mechanisms. Additionally, the committee assesses whether participants will receive the necessary medical care in case of complications, for example, whether the protocol provides for continuation of treatment after the trial ends or covers treatment of adverse effects. These safeguards help ensure that participants are not left without care or financial support should any harm occur due to study participation [18–20].

Participant protection is not a one-time action, but a continuous process. After issuing a positive ethical opinion, the LBC continues to exercise oversight responsibilities. Investigators are required to report serious adverse events (SAEs) [21], or suspected unexpected serious adverse reactions (SUSARs) [22] and provide updates on study progress. The committees may periodically review safety reports submitted by the sponsor as well as other data on the study's conduct to assess whether any intervention is warranted. If participant safety is deemed to be at risk, the committee has the authority to recommend suspension or early termination of the study. This ongoing monitoring of clinical trials is another layer of protection. Even with a thorough initial review, circumstances may change during the trial, and the committee ensures continuous vigilance and timely response [18–20].

LBCs also ensure that participants are clearly informed of their right to withdraw from the study at any time without consequences. They also verify that the documentation does not contain clauses limiting other patient rights such as the right to be informed about their health status or the right to lodge a complaint. Any restriction of participants' rights must have clear ethical and legal justification. For instance, any attempt to introduce penalties for withdrawal or to obligate participants to undergo unlicensed procedures would be strongly criticized by the committee. Upholding voluntary participation as a cardinal principle, the committee safeguards the participant's dignity and autonomy ensuring they are treated as subjects, not objects, of research [12].

Summary

The reform of the bioethics committee system in Poland - which established the SBC and a network of authorized LBCs - was driven by the need to strengthen the protection of clinical trial participants and to streamline the ethical evaluation process. The SBC assumed centralized responsibility for coordinating ethical assessments, setting national standards, and ensuring consistent quality of opinions across the country. LBCs, operating under the authority of the SBC, contribute their expert knowledge and awareness of local contexts to thoroughly review specific study protocols.

Both levels of the system have clearly defined roles and responsibilities, unified by a shared goal: to ensure that the rights, dignity, and well-being of participants remain paramount in all clinical trials. The legal framework, from EU regulations, through the national Clinical Trials Act, to detailed ordinances from the Minister of Health and guidelines issued by the SBC Chair who provides the structure within which the committees operate. These frameworks emphasize independent review, inclusion of patient perspectives, procedural transparency, and strict adherence to ethical principles.

The Polish system for ethical evaluation of clinical trials meets European standards, and (in some respects) even strengthens them through additional mechanisms (e.g., the Clinical Trials Compensation Fund for participants). The tasks and responsibilities of the SBC and LBCs complement one another, forming a comprehensive system for participant protection from the initial planning phase of a trial, throughout its implementation, and even after its conclusion, including access to compensation mechanisms. Therefore, it can be concluded that Poland currently offers robust guarantees for the rights of clinical trial participants, with bioethics committees (led by the SBC) playing a central role in upholding those protections.

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Not applicable

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The datasets generated and/or analyzed during the present study are available from the corresponding author (PP) upon reasonable request.

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