Dr Joanna Różyńska
Uniwersytet Warszawski
ORCID: 0000-0002-5235-3700

Dr Emilia Kaczmarek
Uniwersytet Warszawski
ORCID: 0000-0002-2684-7723

Protecting research participants against undue influence and exploitation. An ethico-legal analysis of Article 23b(2) of the Polish Act on the Professions of Physician and Dentist[1]

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Summary

This article provides a thorough ethical and legal analysis of Article 23b(2) of the Polish Act on the Professions of Physician and Dentist (APPD). The analyzed provision prohibits taking advantage of a forced situation of persons participating in medical experiments. However, despite its brevity, its normative content remains unclear. First, we reject the interpretation proposed in the literature of reading the provision as excluding all individuals in forced situations from scientific experiments. We argue that Article 23b(2) should be interpreted as prohibiting the exercise of undue influence and exploitation of all potential and enrolled research participants who are in dire situations or weaker positions, not only those belonging to groups traditionally considered particularly vulnerable to manipulation, harm, and abuse. By comparing the protective measures against

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undue influence and exploitation adopted by the prominent international ethical standards for human biomedical research and those endorsed by the APPD, we demonstrate that such an interpretation of Article 23b(2) of the APPD is not only legally justified, but also ethically necessary to shield all participants of medical experiments against these unethical practices. Our interpretation of Article 23b(2) of the APPD provides researchers and research ethics committees with valuable, practical guidance. We maintain that the provision analyzed should be recognized as one of the key pillars of Polish regulation on medical experimentation.

Key words: medical experiments, vulnerability, undue influence, undue inducement, exploitation

Introduction

This paper focuses on Article 23b(2) of the Act on the Professions of Physician and Dentist[2] (hereafter referred to as the "APPD"), which prohibits taking advantage of medical research participants in a "forced situation"[3]. This provision was added to the APPD by the Act of July 16, 2020, and went into force on January 1, 2021[4]. However, despite having

[2] Act of 5 December 1996 on the Professions of Physician and Dentist, *Journal of Laws* 2024, item 1287, as amended [in PL].

[3] The APPD uses the Polish term „przymusowe położenie," which is difficult to translate. Here, we have opted to remain as faithful to the original as possible by translating it as „a forced situation". While this translation is not without flaws, it is better than alternative proposals by some Polish legal translators, such as "state of necessity", "involuntary position", "compulsory position", or even Faden and Beauchamp's "coercive situation," because it does not involve ethically loaded and ambiguous concepts, such as necessity, involuntariness, compulsion, or coercion. See: Legalis C.H. Beck, The Polish Law Collection. The Civil Code Translation 2025, accessed via the University of Warsaw Library; Ch. von Bar, E. Clive, H. Schulte-Nölke et al. (eds). Study Group on a European Civil Code & the Research Group on EC Private Law (Acquis Group), *Principles, definitions and model rules of European private law. Draft Common Frame of Reference* (DCFR), 2009, p. 436; https://www.law.kuleuven.be/personal/mstorme/european-private-law_en.pdf; M. Gąsior, *Medical experiments in the light of the amendment of the Act on the Profession of a Physician and a Dentist*, „Wiadomości Lekarskie" 2021, vol. 74, no. 8, p. 1991; R. R. Faden, T. L. Beauchamp, *A history and theory of informed consent*, New York 1986, pp. 344-346.

[4] Act of July 16, 2020 Amending the Act on the Professions of Physician and Dentist and Certain Other Acts, *Journal of Laws* 2020, item 1291 [in PL].

been in effect for four years, there have been very few legal commentaries on it thus far[5]. Our aim is to address this by providing a thorough analysis of Article 23b(2) of the APPD. This analysis will draw on legal and ethical scholarship, as well as international guidelines and regulations relating to human medical research. Contrary to the view of some commentators, we will argue that this provision should not be read as excluding certain groups of individuals from all or some kinds of medical experiments, but rather as providing protection to all participants in medical experiments against undue influence (undue inducement) and unfair exploitation. This interpretation is not only justified by the rules of legal interpretation, but also by the fact that it aligns the APPD's regulations on medical experiments more closely with widely accepted standards for human medical research.

This paper builds upon our previous article concerning Article 23b(1) of the APPD, which regulates payments made to individuals taking part in medical experiments. This includes reimbursement of incurred expenses, as well as "incentives and financial rewards" for participation[6]. We recommend that readers, particularly those unfamiliar with Polish law on medical experiments, read the latter article as well. This will help them to fully understand the Polish regulatory framework for medical research and the problems it faces.

[5] A vast majority of the literature on the changes introduced to the APPD by the 2020 amendment, at best, mentions Article 23b(2), but offers no detailed commentary on its content or normative role. See, for example, A. Gałęska-Śliwka, *Eksperymenty medyczne po nowelizacji ustawy o zawodach lekarza i lekarza dentysty – wybrane zagadnienia*, „Prawo i Prokuratura" 2022, no. 10, pp. 55–77; A. Gałęska-Śliwka, Eksperyment medyczny w nowej rzeczywistości prawnej, „Medycyna Ogólna i Nauki o Zdrowiu" 2023, vol. 29, no. 3, pp. 176–186; M. Gąsior, *Medical experiments in the light of the amendment*…, p. 1991; R. Kubiak, *Nowe uwarunkowania prawne przeprowadzania eksperymentów medycznych*, „Przegląd Sądowy" 2021, no. 1, p. 13; Serwach M., *Nowe zasady przeprowadzania eksperymentów medycznych na ludziach*, „Medycyna Praktyczna" 2021, no. 708, pp.132–139; Wrzesińska-Wal I., Hajdukiewicz D., Augustynowicz A., Janiszewska L., Sarnacka E., Waszkiewicz M., *New regulations on current medical problems*, „Wiedza Medyczna" 2022, vol. 4, no. 1, pp. 16–20. Some short commentaries are provided by P. Konieczniak, *Eksperyment medyczny – sytuacja prawa po nowelizacji ustawy lekarskiej*, „Przegląd Prawa Medycznego" 2021, vol. 3, no. 1-2: 110-111; K. Sakowski, *Art. 23b* [in:] *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, 3rd Ed., ed. E. Zielińska, Warszawa 2022, pp. 736–737 (focusing on criminal liability for violating the norms expressed in Article 23b).

[6] J. Różyńska, E. Kaczmarek, *Paying participants in medical research. An ethico-legal analysis of Article 23b(1) of the Polish Act on the Professions of Physician and Dentist*, „Przegląd Prawa Medycznego" 2025, no 3, pp. 5–40.

1. Protection by exclusion?

Article 23b(2) of the APPD reads: "It is forbidden to conduct a medical experiment by taking advantage of a forced situation of a person participating in such an experiment". Despite its brevity, the provision is open to various interpretations regarding its normative role and content. The key question is whether it implies the general exclusion of persons in forced situations from participating in medical experiments, or at least so-called "scientific experiments", i.e., experiments "primarily intended to increase medical knowledge" (Article 21(3) of the APPD, sentence 1), as opposed to "therapeutic experiments", which are intended to "obtain a direct benefit for the health of a sick person" (Article 21(2) of the APPD, sentence 1).

Rafał Kubiak has proposed such an interpretation, arguing that the analyzed provision should be seen as complementary to Article 23a(1) of the APPD. The latter strictly prohibits the conduct of scientific experiments on "the conceived child", incapacitated persons, soldiers, and other individuals in hierarchical relationships that limits their freedom to give voluntary consent, as well as on individuals deprived of liberty or subjected to detention[7]. In other words, Kubiak asserts that individuals in forced situations should not be permitted to participate in scientific experiments. However, this interpretation contradicts the literal, systemic and functional readings of Article 23b(2) of the APPD for the following four reasons[8].

Firstly, this provision applies to more than just scientific experiments. It uses the term "medical experiment", which, according to Article 21(1) of the APPD, includes both scientific and therapeutic experiments (including experimental therapies). The term also applies to experiments involving human biological material (Article 21(4) of the APPD). Therefore,

[7] R. Kubiak, *Odpowiedzialność karna za przestępstwa związane z nielegalnym przeprowadzeniem eksperymentu medycznego*, „Diametros" 2023, vol. 20, no. 78, pp. 50–53.

[8] Cf. W. Ciszewski, *Dwie uwagi do artykułu Rafała Kubiaka*, „Diametros" 2023, vol. 20, no. 78, pp. 113–115.

the analyzed provision should be interpreted as applying to all individuals in a forced situation, regardless of their health status, age, legal capacity or other factors, who participate (or are invited to participate) in any type of medical experiment. However, given that Article 23b(2) of the APPD covers all individuals in dire situations and all types of medical experimentation, interpreting it as endorsing a "protection by exclusion" approach would have a detrimental effect on many research participants and areas of research practice. Such an interpretation would prevent patients in desperate clinical conditions from participating in potentially beneficial therapeutic experiments, including experimental therapies[9]. Furthermore, many scientific experiments on healthy volunteers would also be prohibited, as these volunteers are often people in dire financial situations who participate in medical research for "quick and easy" money[10].

Secondly, if the drafters of the APPD had intended to prevent individuals in forced situations from participating in scientific experiments, as Kubiak suggests, this group would have been included in the list of excluded persons in Article 23a(1) of the APPD. Alternatively, they would have clearly stated this in the commented provision and limited its scope to scientific experiments. Furthermore, they would not have used the term "participants" in Article 23b(2), since this refers to individuals who are or will be enrolled in an experiment.

Thirdly, as Ciszewski rightly points out[11], Article 23b(2) of the APPD does not categorically prohibit researchers from conducting medical experiments on persons in forced situations. Rather, it prohibits such

[9] Ibidem, p. 115.

[10] R. Abadie, The *professional guinea pig: big pharma and the risky world of human subjects*, Durham and London 2010, p. 6 et al. For more information on the motivations of healthy volunteers in research, see: L. Almeida, B. Azevedo, T. Nunes, M. Vaz-da-Silva, P. Soares-da-Silva, *Why healthy subjects volunteer for phase I studies and how they perceive their participation?*, „European Journal of Clinical Pharmacology" 2007, vol. 63, no. 11, pp. 1085–1094; L. Stunkel, C. Grady, *More than the money: a review of the literature examining healthy volunteer motivations*, „Contemporary Clinical Trials" 2011, vol. 32, no. 3, pp. 342–352; J.A. Fisher, L. McManus, M.M. Wood, M. D. Cottingham, J.M. Kalbaugh, T. Monahan, R.L. Walker, *Healthy volunteers' perceptions of the benefits of their participation in phase I clinical trials* „Journal of Empirical Research on Human Research Ethics" 2018, vol.13, no. 5, pp. 494–510.

[11] W. Ciszewski, *Dwie uwagi do artykułu*… pp. 114–115.

experiments being conducted in a manner that exploits the participants' difficult position. The drafters placed the analyzed provision in paragraph 2 of Article 23b, which prohibits investigators from engaging in certain practices that raise concerns about undue influence and unfair exploitation, particularly when vulnerable individuals or populations are involved – namely, rewarding participants for their contribution (para. 1) or charging individuals for participation in research (para. 3). This fact should be taken into account when interpreting this provision.

Finally, Kubiak's interpretation is based on the assumption that being in a forced situation "significantly interferes with freedom of decision"[12], thereby undermining the ability to give legally valid consent to participate in a medical experiment. However, this is not how people in forced situations are treated in the context of market transactions or healthcare, either in law or everyday practice[13].

If someone is in desperate need of money and decides to sell their most valuable possession for a fair price after weighing up all the pros and cons, no one questions the validity of his or her decision[14]. Why, then,

[12] R. Kubiak, *Odpowiedzialność karna*…p. 52

[13] See, for example, M. Agrawal, *Voluntariness in clinical research at the end of life*, „Journal of Pain and Symptom Management" 2003, vol. 25, no. 4, pp. S25–S32; C.C. Denny, C. Grady, *Clinical research with economically disadvantaged populations*, „Journal of Medical Ethics" 2007, vol. 33, no. 7, pp. 382–385; T. Swift, *Desperation may affect autonomy but not informed consent*, „AJOB Neuroscience" 2011, vol. 2, no. 1, pp. 45–46; A. Wertheimer, *Poverty, voluntariness, and consent to participate in research* [in:] *Poverty, Agency, and Human Rights*, ed. D. Tietjens Meyers, New York 2014, pp. 273–298.

[14] There is no room in this article for an in-depth philosophical analysis of the notion of voluntary choice or action. For the purposes of the present discussion, it should be noted that, when understood descriptively (psychologically), the concept of voluntariness should be considered a matter of degree rather than a binary category. A fully voluntary decision could, for instance, be characterized as one that an individual would choose to make irrespective of external circumstances, or as one with which they fully identify. In this sense, a decision made under economic necessity may appear less voluntary than the unrestricted realization of one's own wishes. However, recognizing as normatively valid only those decisions that are fully voluntary in this descriptive sense (e.g. those with purely internal motivation) would call into question the validity of the vast majority of agreements entered into by individuals – for example, situations in which a person accepts employment that does not fully correspond to their preferences. For more on the various ways of conceptualizing voluntariness, especially in the context of consent for research, see: P. S. Appelbaum, C. W. Lidz, R. Klitzman, *Voluntariness of consent to research: a conceptual mode*l, „Hastings Center Report" 2009, vol. 39, no. 1, pp. 30–39; R. M. Nelson, T. Beauchamp, V.A. Miller, W. Reynolds, R.F. Ittenbach, M.F. Luce, *The concept of voluntary consent*, „The American Journal of Bioethics" 2011, vol. 11, no. 8, pp. 6–16; A. Wertheimer, *Voluntary consent:*

should we think differently about a well-informed decision to participate in scientifically and ethically sound research made by a healthy volunteer in a difficult economic situation whose only motivation for enrolling is the fair financial reward? By posing these types of questions, we do not intend to suggest that participation in a medical experiment should be viewed like any other market transaction, nor do we intend to suggest that informed consent to participate in an experiment is equivalent to accepting an offer to sell goods or services or accepting a labor contract. However, we do point out that simply being in a forced situation does not necessarily exclude the possibility of providing valid consent.

Similarly, when a competent person with a fatal disease is presented with the option of a new, approved therapy by their physician and gives informed consent, no one considers his or her consent to this treatment to be invalid. Likewise, why should we question the voluntariness of a decision to participate in scientifically and ethically sound therapeutic research (or experimental treatment) made by a patient who has exhausted all therapeutic options, and who has a reasonable and well-informed belief that participation in that research (or experimental treatment) may, on balance, be beneficial? Patients in desperate health situations do not necessarily lose the ability to understand the goals, methods and risk–benefit profile of a proposed intervention, whether approved or experimental, and can make a deliberate, rational decision to try it, even if they feel somewhat compelled by their illness.

It is worth noting that, under Polish law, persons in a forced situation are not considered incapable of entering into valid legal contracts. Instead, they are seen as being vulnerable to unfair exploitation and are legally protected from it by the right to demand modification or annulment of an exploitative contract (Article 388 of the Polish Civil Code[15]). Those who exploit the vulnerability of others to gain a grossly unfair advantage are punished (Article 304 of the Polish Penal Code[16]).

why a value-neutral concept won't work, „Journal of Medicine and Philosophy" 2012, vol. 37, no. 3, pp. 226–254; M. Kiener, *Voluntary consent. Theory and practice*, New York & Abingdon, Oxon 2023, chap. 8.

[15] Act of 23 April 1964 – The Civil Code, *Journal of Laws* 2025, item 1071, as amended [in PL].

[16] Act of 6 June 1997 – The Penal Code, *Journal of Laws* 2025, item 383, as amended [in PL].

2. Taking advantage of the participant's forced situation

How should we understand the prohibition on taking advantage of participants who are in a forced situation in medical experiments? Article 23b(2) of the APPD applies when both of the following conditions are met: (1) the (potential) participant (or targeted population) of an experiment is in a forced situation; and (2) investigators (including medical professionals involved in the enrolment process) take advantage of the (potential) participant's forced situation to further their own goals, particularly to obtain their consent to participate.

The term "forced situation" is interpreted quite broadly by Polish legal scholars and courts when dealing with cases of unfair exploitation in transactions[17]. According to the Polish Supreme Court, "a forced situation occurs when a party finds themselves in such material, personal, or family circumstances that compel them to enter into an agreement, even without equivalence of benefits (at any cost), and prevent them from engaging in free negotiations"[18]. Admittedly, Article 388 of the Polish Civil Code on unfair exploitation treats forced situations as distinct from "infirmity, inexperience or lack of sufficient understanding of the subject matter of the contract", but it is debatable whether such a distinction should also be made in the context of Article 23b(2) of the APPD. However, it is undisputed that this provision can apply to a variety of situations. These include, but are not limited to, being in economic hardship; facing danger to one's life or health (or that of a loved one); facing unmet medical needs, including a lack of therapeutic alternatives; and being in

[17] See more on the subject of unfair exploitation under the Polish Civil Code: P. Zakrzewski, *Art. 388* [in:] *Kodeks cywilny. Komentarz. Vol. III. Zobowiązania. Część ogólna (art. 353–534)*, eds. M. Habdas, M. Fras, Warszawa 2018, pp. 236–250, esp. pp. 243-244; P. Machnikowski, *Wyzysk* [in:] *System prawa prywatnego. Vol. 5. Prawo zobowiązań – część ogólna,* 3rd Ed., ed. K. Osajda, Warszawa 2020, pp. 629–641, esp. p. 637; W. Popiołek, *Art. 388* [in:] *Kodeks cywilny. Vol I. Komentarz. Art. 1–449[10]*, 10th Ed., ed. K. Pietrzykowski, Warszawa 2020, esp. sec. 6-7; M. Gutowski, *Art. 388* [in:] *Kodeks cywilny. Vol. II. Komentarz. Art. 353–626*, 3rd Ed., ed. M. Gutowski Warszawa 2022, esp. sec. 15; P. Tereszkiewicz, *Art. 388* [in:] *Zobowiązania. Część ogólna. Vol. II. Komentarz*, ed. P. Machnikowski, Warszawa 2024, esp. sec. 16-21.

[18] Judgment of the Supreme Court of 27 September 2005, V CK 191/05, I CK191/05, OSP 2007 nr 7-8, poz. 87 [in PL].

a relationship of trust, dependence, or subordination with the offeror or his collaborator[19]. It is irrelevant who or what makes the person feel "forced" to accept the unfair deal. What matters is that the person believes she has no reasonable alternative but to accept an objectively bad offer, because the alternatives would be worse. In other words, she feels trapped between two or more bad options and has to choose the least bad one[20].

Determining what conditions must be met to say that someone is taking advantage of another person's forced situation is a very difficult task. We cannot fully address it here. For the purposes of this analysis, however, we will assume that taking advantage of a (potential) participant's forced situation requires that[21]: (a) researchers have knowledge of the forced situation of the participant, or could reasonably be expected to have such knowledge; and (b) in order to obtain compliance, particularly consent, (c) they make an offer to participate in research that they know, or ought to know, is, broadly speaking, unethical, yet it will be difficult, if not impossible, for the participant to reject the offer because of his or her vulnerable position and lack of better alternatives.

There are many reasons why an offer to participate in a research project may be considered unethical. The most obvious example is an invitation to take part in a project that is poorly designed from ethical and/or methodological perspectives. This includes a project that violates established standards of scientific and social value, methodological validity, a favorable risk/benefit ratio, or adequate risk minimization[22]. An offer to participate in such a study should never be made because projects like this should never be approved by a research ethics committee for implementation. Poorly designed projects expose participants to unnecessary and excessive risks, i.e., risks that are not "compensated" by any potential benefit to science and society or direct therapeutic benefits to partici-

[19] P. Tereszkiewicz, *Art. 388* [in:] *Zobowiązania*…, sec. 16–17.

[20] P. Machnikowski, *Wyzysk* [in:] *Prawo zobowiązań – część ogólna* …, p. 637.

[21] Compare, W. Popiołek, *Art. 388* [in:] *Kodeks cywilny*…, sec. 5; M. Gutowski, *Art. 388* [in:] *Kodeks cywilny, Vol. II, Komentarz*…, sec. 9-10.

[22] See, E. J. Emanuel, D. Wendler, C. Grady, *What makes clinical research ethical*?, „JAMA" 2020, vol. 283, no. 20, pp. 2701–2711.

pants, if expected. Such projects violate the principles of beneficence and nonmaleficence in research and are not permitted.

However, invitations to participate in scientifically sound projects may also raise ethical questions. This may be due to the manner in which they are communicated, which could be coercive, overly controlling, disrespectful, manipulative, or misleading. Consequently, it could undermine the potential participant's ability to give fully voluntary and informed consent. It is also unethical to invite people to participate in projects that do not meet the requirements of justice. This is particularly the case when projects involve the unfair selection criteria and/or unfair distribution of research risks and potential benefits. In the two following sections, we will take a closer look at the two aforementioned forms of taking advantage of persons in forced situations, namely undue influence (undue inducement) and exploitation.

3. Protection against undue influence in research ethics and international standards for human research

The concept of undue influence is one of the most important concerns regarding the validity of participants' consent for research. Broadly speaking, it refers to controlling influences that unjustifiably pressure a person, thus undermining their ability to give voluntary and informed consent. As the Nuremberg Code of 1947 famously stated, the voluntariness of consent requires, apart from competence and comprehension of the provided information, that the potential participant be "so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion"[23]. Following the Nuremberg Code, all modern international, regional and national standards for human medical research and clinical trials require researchers and research ethics committees to prevent or at least minimize the risk of influences that would pre-

[23] The Nuremberg Code [in:] *Trials of war criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*. Vol. 2., Washington D.C. USA., 1949, pp. 181–182. Also published at https://encyclopedia.ushmm.org/content/en/article/the-nuremberg-code [Accessed 12.08.2025].

vent potential participants from "exercising free power of choice" when deciding whether to participate in the study. Let's briefly review some of the most important ones. This will allow us to identify critical points of divergence and consensus regarding the nature of undue influence.

The famous Belmont Report, issued in 1979 by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, stresses that valid consent for participation must be voluntarily given, which requires "conditions free of coercion and undue influence"[24].The report further explains that: "Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable"[25].

Three features of the Belmont Report's understanding of undue influence must be highlighted. First, it treats undue influence and coercion as two separate concepts, although it acknowledges that both constitute forms of unjustifiable pressure, albeit of different levels of force and irresistibility. The majority of scholars and regulators accept this view[26],

[24] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. U.S. Department of Health and Human Services, Washington D.C. 1979, part C(1), https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html [Accessed 12.08.2025].

[25] Ibidem.

[26] See, for example, R. Nozick, *Coercion* [in:] *Philosophy, science, and method*, ed. S. Morgenbesser, P. Suppes, M. White, New York 1969, pp. 440–742; R.R. Faden, T. L. Beauchamp, *A history and theory of informed consent* …, pp. 340-346; A. Wertheimer, *Coercion,* Princeton, N.J. 1987, chapters 9, 11-13; J.S. Hawkins, E. J. Emanuel*, Clarifying confusions about coercion*, „Hastings Center Report" 2005, vol. 35, no. 5., pp. 16–19; N. Dickert, C. Grady, *Incentives for research participants* [in:] *The Oxford textbook on the ethics of clinical research*, eds. J.E. Emanuel, C. Grady, R.A. Crouch, R.K. Lie, F. G. Miller, D. Wendler, New York 2008, pp. 388-390; A. Wertheimer, F.G Miller, *Payment for research participation: a coercive offer?*, „Journal of Medical Ethics" 2008, vol. 34, no. 5, pp. 389–392; E .A. Largent, H. Fernandez Lynch, *Paying research participants: regulatory uncertainty, conceptual confusion, and a path forward*, „Yale Journal of Health Policy, Law, and Ethics" 2017, vol. 17, no. 1, pp. 100–112.

but as will be shown below, not all of them do[27]. Second, the Report emphasizes that it is impossible to draw a precise line a priori between due and undue influence, i.e. between acceptable and unacceptable methods and modes of inciting others[28]. This is because the nature and effect of influence depends on the relationship and power dynamic between those involved, their individual circumstances, and other objective and subjective features of a given situation. This contextual nature of undue influence is widely accepted in the literature. Third, the Report explicitly points out that the vulnerability of one of the parties is what enables the stronger one to exert undue influence. It states: "Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition"[29]. It is important to note that the Belmont Report introduced the concept of vulnerability to research ethics. It influentially drew attention to research participants who might not be fully capable of protecting their own interests and who are particularly susceptible to being taken advantage of. This marked a significant shift in research ethics and sparked ongoing and heated debates about the proper understanding of vulnerability and adequate protection of those who are vulnerable in research[30]. Despite

[27] There is a lively debate in research ethics about whether a genuine offer of an attractive/irresistible reward to research participants may constitute coercion (a coercive offer). See, e.g., J. McGregor, *Undue influence as coercive offers in clinical trials*, [in:] *Coercion and the state*, eds. D.A. Reidy, W.J. Riker, Dordrecht, Netherlands 2008, pp. 45-59; J. Millum, M. Garnett, *How payment for research participation can be coercive*, „The American Journal of Bioethics" 2019, vol. 19, no. 9, pp. 21–31 (and open peer commentaries in this issue of the AJOB).

[28] E.g., R.R. Faden, T. L. Beauchamp, *A history and theory of informed consent* …, pp. 337–381.

[29] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*…, part C(3).

[30] For more on the discussion regarding the concept of vulnerability and its role in research ethics, see: K. Kipnis, *Vulnerability in research subjects: a bioethical taxonomy* [in:] *Ethical and policy issues in research involving human participants*, National Bioethics Advisory Commission, Bethesda, MD, 2001, pp. 1–10;

these debates, the conceptual connection between vulnerability and susceptibility to undue inducement and exploitation remains a cornerstone of all ethical guidelines and regulations for human research.

The World Medical Association's Declaration of Helsinki[31], the best-known and constantly evolving ethical standard for biomedical research involving humans, does not use the term "undue influence" (or "undue inducement") as such. However, it clearly recognizes that "some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm" (para. 19). It further emphasizes that the vulnerability of individual participants, as well as involved and affected groups, should not result in their a priori exclusion from research. Instead, they should be included "fairly and responsibly", meaning they should receive "specifically considered support and protections" (para. 19), including protection against exploitation and undue influence. To minimize the risk of undue influence on vulnerable participants, the Declaration explicitly recommends that physicians and other researchers be particularly cautious when seeking informed consent from individuals who are in a dependent relationship with them or who may consent under duress (para. 27). "In such situations, the informed consent must be sought by an appropriately qualified individual who is independent of this relationship" (para. 27, sentence 2).

The problem of undue influence is addressed in greater detail in the 2016 International Ethical Guidelines for Health-Related Research Invo-

C. Levine C., R. Faden, C. Grady, D. Hammerschmidt, L. Eckenwiler, J. Sugarman, *The limitations of "vulnerability" as a protection for human research participants*, „The American Journal of Bioethics" 2004, vol. 4, no. 3, pp. 44–49; D. Schroeder, E. Gefenas, *Vulnerability: too vague and too broad?*, „Cambridge Quarterly of Healthcare Ethics" 2009, vol. 18, no. 2: 113–121; P. Łuków, Persons and groups: protection of research participants with vulnerabilities as a proces [in] *Medical research ethics: challenges in the 21st century*, eds. T. Zima. D.N. Weisstub, Cham, Switzerland 2023, pp. 49-63; D. Schroeder,K. Chatfield, R. Chennells, H. Partington, J. Kimani, G. Thomson, J. Adhiambo Odhiambo, L. Snyders, C. Louw, *Vulnerability revisited. Leaving no one behind in research*, Cham, Switzerland 2024.

[31] World Medical Association, *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants,* Helsinki, Finland, October 2024, https://www.wma.net/policies-post/wma-declaration-of-helsinki/ [Accessed 12.08.2025].

lving Humans[32], issued by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation. These guidelines build upon the Declaration of Helsinki, paying particular attention to conducting research in low-resource settings, community engagement in research and the need to adequately and responsibly include potentially vulnerable groups in health-related research. Guideline 9 regarding informed consent explicitly obliges researchers to provide participants with the opportunity to decide whether or not to participate without being subjected to coercion or undue influence (or deception). Guideline 15 further stresses that researchers and research ethics committees must ensure that specific protections are in place to safeguard the rights and welfare of vulnerable individuals and groups participating in research. The commentaries on these guidelines highlight that various factors may affect the voluntariness of consent for research and/or render individuals vulnerable to undue influence and exploitation. These factors include, but are not limited to, absolute, relative or circumstantial "impairments in decisional capacity, education, resources, strength, or other attributes needed to protect [one's own] interests"[33]. Thus, individuals with general decision-making capacity may still need special protection from unduly controlling influences in a given research context. This includes individuals in dependent or subordinate relationships, as well as those facing political or social powerlessness, such as people in hierarchical relationships (e.g. lower medical personnel, members of the armed forces or police); institutionalised individuals (e.g. prisoners, residents of nursing homes); persons affected by poverty, unemployment, and/or homelessness (including refugees or displaced persons); members of some ethnic and racial minorities; members of other disadvantaged, stigmatised, or marginalised groups (including women in highly patriarchal societies or LGBT+ individuals); patients with severe illness, especially those with a pre-existing therapeutic relationship with a physician-researcher;

[32] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Health-Related Research Involving Humans*, Geneva, Switzerland 2016, https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf [Accessed 12.08.2025].

[33] Ibidem, p. 57.

and people who perceive participation in research as the only means of accessing medical care[34]. The presence of these circumstances does not necessarily mean that the individuals involved are unable to give informed consent for a given research study. However, they do suggest that these potential participants may be more susceptible to influences that could negatively impact the quality and validity of their consent. Therefore, "research ethics committees must determine for each individual protocol if influences on voluntary consent cross the threshold of being undue, and if so, which safeguards are appropriate"[35]. In the case of a dependent or hierarchical relationship, for example, the research ethics committee should consider whether informed consent should be obtained or witnessed by a neutral third party, such as a research nurse or qualified collaborator[36]. Another solution could be to consult the research project and the process of obtaining consent with relevant stakeholders, community representatives or individuals appointed to research ethics committees to advocate for members of a given vulnerable group[37].

The CIOMS Guidelines pay special attention to undue influence in the form of undue inducement when addressing the practice of paying research participants for their contributions. Guideline 13 states: "Research participants should be reasonably reimbursed for costs directly incurred during the research, such as travel costs, and compensated reasonably for their inconvenience and time spent. Compensation can be monetary or non-monetary. The latter might include free health services unrelated to the research, medical insurance, educational materials, or other benefits. Compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment ("undue inducement"). A local research ethics committee must approve reimbursement and compensation for research participants"[38]. Commen-

[34] Ibidem, p. 58–59.

[35] Ibidem, p. 35.

[36] Ibidem, p. 35–36.

[37] Ibidem, p. 57–59.

[38] Ibidem, p. 53.

tary to Guideline 13 further notes that determining whether undue inducement is present can be challenging, partly because the compensation required to persuade some individuals to volunteer against their better judgment varies according to personal and socio-economic circumstances. Therefore, research ethics committees must consider the nature and level of compensation offered within the context of the relevant culture and population. Their assessment should focus on whether the average participant in that setting might be unduly induced to join the study by the compensation offered[39].

It is worth stressing that "undue inducement" is commonly used in research ethics to highlight the concern that some payment offers may seem irresistible to individuals and undermine their ability to make an autonomous decision about participating in research. However, there is no agreement on what exactly an attractive reward must do to the potential participant's decision-making processes in order to qualify as undue. The literature offers various answers, ranging from compromising the voluntariness of prospective participants to distorting their ability to understand and evaluate the risks and benefits of the research, thereby exposing them to serious harm or causing them to make choices contrary to their better judgment or deeply held beliefs[40]. Some scholars are concerned that overly attractive payments may prompt participants to engage in deceptive behaviors, such as withholding or misrepresenting health information critical for their eligibility for recruitment or continued par-

[39] Ibidem, p. 54.

[40] See, for example, R. Macklin, *'Due' and 'undue' inducements: on paying money to research subjects*, „IRB: Ethics & Human Research" 1981, vol. 3, no. 5, pp. 1–6; N. Dickert, C. Grady, *Incentives for research participants*…, pp. 389-390; M. Wilkinson, A. Moore, *Inducement in research*, „Bioethics" 1997, vol. 11, no. 5, pp. 373–389; M. Wilkinson, A. Moore, *Inducements revisited*, „Bioethics" 1999, vol. 13, no. 1, pp. 114-130; C. Grady, *Money for research participation: does it jeopardize informed consent?*, „American Journal of Bioethics" 2001, vol. 1, no. 2, pp. 40–44; E.J. Emanuel, *Ending concerns about undue inducement,* „Journal of Law, Medicine & Ethics" 2004, vol. 32, no. 1, pp. 100–105; R.W. Grant, J. Sugarman, *Ethics in human subjects research: do incentives matter?*. „The Journal of Medicine and Philosophy" 2004, vol. 29, no. 6, pp. 717–738; E. J. Emanuel, *Undue inducement: nonsense on stilts?*, „American Journal of Bioethics" 2005, vol. 5, no. 5, pp. 9–13; E.A. Largent, H. Fernandez Lynch, *Paying research participants:regulatory uncertainty, conceptual confusion* …, pp. 100-112; E.A. Largent, H. Fernandez Lynch, *Paying research participants: the outsized influence of "undue influence"*, „IRB: Ethics & Human Research" 2017, vol. 39, no. 4, pp. 1–9.

ticipation[41]. This may expose them to additional risk and/or negatively impact the scientific value and integrity of the research data.

Last but not least, let's take a quick look at the provisions of the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research[42]. Due to Poland's failure to sign and ratify the protocol, it remains non-binding. Nevertheless, it is still a politically and normatively important point of reference for the adequate regulation of research practice. Article 12 of the Protocol stipulates that: "The ethics committee must be satisfied that no undue influence, including that of a financial nature, will be exerted on persons to participate in research. In this respect, particular attention must be given to vulnerable or dependent persons". Like all the above-cited standards, the Protocol explicitly links undue influence and vulnerability. However, unlike the Belmont Report and the CIOMS Guidelines, it defines the concept of undue influence in much broader manner, encompassing all forms of controlling influences, including coercion. This is clearly stated in the Explanatory Report to the Protocol: "The usual legal concept of undue influence involves coercion. The coercion need not involve confinement or violence. It may be exerted in particular on a person in a weak or feeble condition, so that very little pressure will overbear the person's will, and make the individual feel that he or she must agree, although it is not the individual's wish to do so"[43]. The Explanatory Report informs

[41] See, for example, N.W. Dickert, *Concealment and fabrication: the hidden price of payment for research participation*?, „Clinical Trials", 2013, vol. 10, no. 6, pp. 840-841; R. Dresser, *Subversive subjects: Rule-breaking and deception in clinical trials*, „The Journal of Law, Medicine & Ethics" 2013, vol. 41, no. 4, pp. 829-840; E.G. Devine, M.E. Waters, M. Putnam, C. Surprise, K. O'Malley, C. Richambault, R.L. Fishman, C.M. Knapp, E.H. Patterson, O. Sarid-Segal, C. Streeter, L. Colanari, D.A. Ciraulo, *Concealment and fabrication by experienced research subjects*, „Clinical trials" 2013, vol.10, no. 6, pp. 935–948; C.P. Lee, T. Holmes, E. Neri, C.A. Kushida, *Deception in clinical trials and its impact on recruitment and adherence of study participants*, „Contemporary Clinical Trials" 2018, vol. 72, pp.146–157.

[42] Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, CETS 195, Strasbourg, France 2005, https://rm.coe.int/168008371a [Accessed 12.08.2025].

[43] Council of Europe, *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, CETS 195, Strasbourg, France 2005, sec. 62, https://rm.coe.int/16800d3810 [Accessed 12.08.2025].

that such broadly defined undue influence may take many different forms, including the use of a position of trust, informal authority, or formal superiority; direct and veiled threats or promises of favors (including those relating to access to healthcare); and offers of excessive financial and non-financial rewards[44]. All these practices require special attention when a project involves individuals or groups, who are dependent or vulnerable due to cognitive, situational, institutional, deferential, medical, economic, and social factors[45]. As with all the above-mentioned documents, the role of research ethics committees in protecting (potential) research participants against undue influence is emphasized.

4. Protection against exploitation in research ethics and international standards for human research

Exploitation is a very ambiguous and complex concept that cannot be thoroughly analyzed here[46]. In the context of human research, it usually refers to two concerns[47]: (i) the broader concern that the burdens and benefits of research are distributed unfairly across different social strata, populations, or groups, with those who are worse off bearing the burdens while those who are better off receive the benefits; and (ii) the narrower concern about the unfair distribution of goods and services in a specific interaction between researchers and participants, arising because "one

[44] Ibidem, sec. 69-70.

[45] Ibidem, sec. 68-69

[46] See, for example, A. Wertheimer, *Exploitation*, Revised Ed., Princeton, N.J. 1999; M. Zwolinski, B. Ferguson, A. Wertheimer, *Exploitation* [in:] *The Stanford Encyclopedia of Philosophy*, eds. E. N. Zalta, U. Nodelman 2022, https://plato.stanford.edu/archives/win2022/entries/exploitation/ [Accessed 12.08.2025].

[47] J. Różyńska, *The ethical anatomy of payment for research participants*, „Medicine, Health Care and Philosophy" 2022, vol. 25 no. 3, pp. 455-456; See also L.D. De Castro, *Exploitation in the use of human subjects for medical experimentation: a re-examination of basic issues*, „Bioethics" 1995, vol. 9, no. 3-4, pp. 259–268; A. Wertheimer, *Exploitation in clinical research* [in:] *The Oxford textbook on the ethics of clinical research,* eds. J. E. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, D. Wendler, New York NY 2008, pp. 201–210; D.B. Resnik, *Exploitation in biomedical research*, „Theoretical Medicine and Bioethics" 2008, vol. 24, no. 3, pp. 233–259; E. Malmqvist, *Exploitation in biomedical research* [in:] *Handbook of bioethical decisions. Vol. II: Scientific integrity and institutional ethics*, eds. E. Valdés, J .A. Lecaros, Cham, Switzerland 2023, pp. 111–127.

party to the interaction is in a weak position, due to poverty, ignorance, or extreme urgency, which the other party can take advantage of, offering few benefits"[48].

Numerous international ethical guidelines on human biomedical research address these problems by establishing standards for fair subject selection[49], fair benefit sharing[50], and ensuring other fairness-based requirements in research conducted in low-resource settings[51]. According to the Belmont Report, the principle of justice is one of the pillars of ethical human research[52]. "Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only 'undesirable' persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be

[48] E.J. Emanuel, *Ending concerns about undue inducement*…p. 101.

[49] See also L.A. Meltzer, J. F. Childress, *What is fair participant selection*? [in:] *The Oxford textbook on the ethics of clinical research*, eds. J.E. Emanuel, C. Grady, R.A. Crouch, R.K. Lie, F. G. Miller, D. Wendler, New York 2008, pp. 377–385.

[50] See also E. J. Emanuel, *Benefits to host countries*, [in:] *The Oxford textbook on the ethics of clinical research*, eds. E. J. Emanuel, C. Grady, R.A. Crouch, R.K. Lie, F. G. Miller, D. Wendler, New York 2008, pp. 719–728; J. Millum, *Sharing the benefits of research fairly: two approaches*, „Journal of Medical Ethics" 2012, vol. 38, no. 4, pp. 219–223.

[51] See also E. J. Emanuel, D. Wendler, J. Killen, C. Grady, *What makes clinical research in developing countries ethical? The benchmarks of ethical research*. „Journal of Infectious Diseases", 2004, vol. 189, no. 5, pp. 930–937; J. S. Hawkins, E. J. Emanuel, eds., *Exploitation and developing countries: the ethics of clinical research*, Princeton 2008.

[52] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*…part B(3).

involved as research subjects, if at all, only on certain conditions"[53]. The report was published in 1979, when the practice of "exporting" clinical research to low- and middle-income countries was virtually nonexistent. For this reason, it primarily addresses preventing injustices against vulnerable "local" groups, including minors, racial minorities, the economically disadvantaged, the very sick, and those in institutions. However, the Report acknowledges that research exploitation often stems from "social, racial, sexual, and cultural biases institutionalized in society"[54], whether local or global. Moreover, this exploitation is often fueled by mere administrative convenience and economic considerations. As shown earlier, the Belmont Report firmly stresses that the increased availability, compromised position, and/or manipulability of some individuals or groups due to their institutionalization, dependency, or socioeconomic or clinical circumstances should never be used as recruitment criteria. Research participants should be selected based on "reasons directly related to the problem being studied"[55], and they should always be offered a fair access to benefits from subsequent applications of the research.

Promoting justice and preventing exploitation in research are also key considerations in the WMA Declaration of Helsinki and the CIOMS Guidelines. Both documents emphasize the importance of these principles, particularly in research involving vulnerable individuals and communities, including those in low-resource settings. The Declaration of Helsinki[56] acknowledges that medical research occurs within a context of structural inequities and socioeconomic disparities (paras. 6, 19-20). Therefore, to avoid perpetuating or exacerbating these inequities, researchers and research ethics committees should pay particular attention to how the benefits, risks, and burdens of research are distributed (para. 6). They should also ensure that vulnerable individuals, groups, and communities are included in research fairly and responsibly (paras. 19). This includes

[53] Ibidem, part C(3).

[54] Ibidem.

[55] Ibidem.

[56] World Medical Association, *WMA Declaration of Helsinki*….

providing opportunities for "meaningful engagement" of potential and enrolled participants and their communities in research design and implementation, as well as in the understanding and dissemination of its results (para. 6). Additionally, the Declaration stipulates that: "Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions" (para. 20). Research involving participants in this category should be conducted exclusively when studying less vulnerable groups is not feasible, or when excluding them from research would result in the perpetuation or exacerbation of their disparities (para. 20). The Declaration firmly states that "appropriate compensation and treatment for participants harmed as a result of participating in research must be ensured" (para. 15). Without these arrangements, participants are vulnerable to exploitation because they are used for the benefit of science and society without receiving adequate support or remedies if the risks they face in research materialize.

The 2016 CIOMS International Ethical Guidelines for Health-Related Research Involving Humans[57] contains numerous detailed recommendations regarding justice, fairness, and non-exploitation in research. These recommendations further specify and develop the general directives of the Belmont Report and the Declaration of Helsinki. Of particular importance in this regard are: Guideline 2: *Research conducted in low-resource settings*; Guideline 3: *Equitable distribution of benefits and burdens in the selection of individuals and groups of participants in research*; Guideline 7: *Community engagement*; Guideline 14: *Treatment and compensation for research-related harms*; Guideline 13: *Reimbursement and compensation for research participants*; and Guideline 15: *Research involving vulnerable persons and groups* (with subsequent guidelines for conducting research on members of groups traditionally considered vulnerable). Due to space limitations, these guidelines cannot be discussed in detail here. However, it is important to note that the

[57] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Health-Related Research Involving Humans*…

CIOMS Guidelines are among the few international ethical standards that address concerns about exploitation in the context of paying research participants.

Commentary on Guideline 13 states that: "participants should not have to pay for making a contribution to the social good of research, whether in the form of direct expenses (for example, transportation costs), and must therefore be reasonably reimbursed for such expenses. In addition, participants must be appropriately compensated for the time spent and other inconveniences resulting from study participation. The amount of compensation should be proportional to the time spent for research purposes and for travel to the research site. This amount should be calculated using the minimum hourly wage in the region or country as a reference value"[58]. Although the proposed method of calculating compensation for research participants does not have universal support, the majority of research ethicists agree that justice requires reimbursing and rewarding research participants for their contributions[59]. No payment or underpayment constitutes unfair exploitation and should be avoided. This is particularly important in research involving economically disadvantaged populations[60]. Researchers should not take advantage of the difficult so-

[58] Ibidem, p. 53.

[59] See the recently published powerful statement authored by the most prominent scholars in the field – R. Abadie, E. Anderson, J. Eberts, H. Fernandez Lynch, J. Fisher, L. Gelinas, E. Largent, L. McNair, *Pursuing fair and just compensation for research participants: an open letter to the research ethics community,* „The American Journal of Bioethics" 2025, vol. 25, no. 7, pp. 3–7. Also J. Różyńska, *The ethical anatomy of payment for research participants*…

[60] For more discussion on fair payment for research participants, especially those from economically disadvantaged populations, including healthy volunteers, see, for example: T. Lemmens, C. Elliott, *Guinea pigs on the payroll: the ethics of paying research subjects*, „Accountability in Research" 1999, vol. 7 no. 1: 3–20; C.C. Denny, C. Grady, *Clinical research with economically disadvantaged populations* ….; C. Elliott, R. Abadie, *Exploiting a research underclass in phase 1 clinical trials*, „New England Journal of Medicine" 2008, vol. 358, no. 22, pp. 2316–2317; D.B. Resnik, *Increasing the amount of payment to research subjects*, „Journal of Medical Ethics" 2008, vol. 34, no. 9, p. e14; M. Stones, J. McMillan, *Payment for participation in research: a pursuit for the poor?*, „Journal of Medical Ethics" 2010, vol. 36, no. 1, pp. 34-36; T. Phillips, *Exploitation in payments to research subjects*, „Bioethics" 2011, vol. 25, no. 4: 209–219; D.B. Resnik, *Bioethical issues in providing financial incentives to research participants*, „Medicolegal and Bioethics" 2015, vol. 5, pp. 35–41; S. Belfrage, *Exploitative, irresistible, and coercive offers: why research participants should be paid well or not at all*, „Journal of Global Ethics" 2016, vol. 12, no. 1, pp. 69-86; M. Lamkin, C. Elliott, *Avoiding exploitation in phase I clinical trials: more than (un)just compensation*, „The Journal of Law, Medicine & Ethics" 2018,

cioeconomic situation of potential participants by offering disproportionately low monetary or non-monetary compensation in relation to the participants' contribution simply because they presume that, due to the lack of alternatives, participants will accept the unfair payment anyway, and/or because they want to cut down the costs of the study. This type of unfairness is evident when researchers offer participants from different socioeconomic backgrounds payment of different values for the same "work", knowing that a small amount of money has greater utility value for the poor than for the rich. Thus, they expect poorer people to participate in research even if they receive much less money than their wealthier counterparts. Such exploitative offers violate requirements of due respect for persons and justice/fairness, including equal treatment and non-discrimination. Moreover, they exacerbate and perpetuate existing social inequalities and disparities. However, as we have already argued, they do not necessarily invalidate the participant's consent. Accepting too little money may suggest that the person had "no choice" but to accept an unfair offer. Nevertheless, accepting such an offer may still be a voluntary and fully reasonable decision given the consenter's personal and socio-economic situation. After all, a small payment is better than no payment, even if it goes against what is just or fair.

5. Protection against undue influence and exploitation in the APPD

Despite its highly protectionist and even paternalistic approach to research participation, the APPD does not use the concepts of undue influence, undue inducement, or unfair exploitation. Nevertheless, it contains numerous mechanisms that serve to minimize or prevent these problems, albeit not in the most ethically balanced manner. We argue that, following the introduction of Article 23b(2), these protective solutions can be divided into three main categories that partially overlap.

The first category targets potential participants in scientific medical

vol. 46, no. 1, pp. 52–63; L. Gelinas, S.A. White, B.E. Bierer, *Economic vulnerability and payment for research participation,* „Clinical Trials" 2020, vol. 17, no. 3, pp. 264–272.

experiments, especially those from populations traditionally considered vulnerable. The crucial protective tool here is excluding certain individuals with an absolute, relative, or circumstantial inability to give fully voluntary and informed consent from non-therapeutic experiments altogether. As we have demonstrated, international research ethics standards no longer endorse this approach due to its potentially harmful and unjust consequences for vulnerable populations and medical progress. Nevertheless, the APPD continues to apply the "protection by exclusion" approach to fetuses, incapacitated persons, soldiers, and others in hierarchical relationships that limit freedom to consent; persons deprived of liberty or subject to detention (Article 23a(1) of the APPD); and adults who are not incapacitated but incapable of making decisions (Article 25(7), *a contrario*). The idea behind prohibiting scientific experiments on these vulnerable individuals and populations is that not allowing them to participate is the best way to shield them from manipulation, undue influence, exploitation, and other wrongs or harm in medical experiments.

Other legal mechanisms adopted by the APPD against taking advantage of participants of purely scientific experiments who do not belong to the above-enlisted categories include: (i) limiting the permissible risk in all scientific experiments — including those with competent volunteers — to "no or minimal risk" (Article 21(3)), and (ii) introducing additional safeguards for minors participating in scientific experiments, including the requirement of peer benefit and the requirement that there is no alternative to conducting the study of persons of legal age (Article 23a(2)). Furthermore, as in all legal contexts involving minors or incapacitated adults, the APPD requires the consent of their legal representatives or a court order to enroll them in therapeutic experiments or scientific experiments, if permissible (Article 25).

The second group of protective mechanisms consists of the rules for paying research participants and charging them for participating in experiments. According to Article 23b(1) of the APPD, payments to participants, except for reimbursement, are prohibited for anyone other than "participants of legal age who can give legally valid consent, and healthy participants". We extensively discussed this provision in our previous pa-

per, so there is no need to repeat our critical comments here[61]. It is worth noting, though, that when interpreted as allowing "incentives or financial rewards" for adult, healthy, and consenting individuals only, the provision itself does not prohibit payments that, due to their overly attractive nature, may constitute undue inducement, nor does it prohibit payments that, due to their inadequately low value, constitute unfair exploitation. It also does not prevent unhealthy participants in therapeutic or scientific experiments from being exposed to the risks and burdens of research without adequate compensation. However, by excluding any payments to participants who are incapable of giving consent, except reimbursement, it does protect these populations from the risk of being unduly incentivized to participate in medical experiments or from being exploited for financial gain by their guardians[62].

According to Article 23b(3) of the APPD, the entity (or person) conducting a medical experiment may not charge the participant, the participant's legal representative, or any person who may be directly affected by the results of the experiment any fees for participation in the experiment. This provision was added to the APPD in 2023[63] in response to expert debates[64] and media reports[65] that highlighted abuses in commercial the-

[61] J. Różyńska, E. Kaczmarek, *Paying participants in medical research*…

[62] See, also Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Health-Related Research Involving Humans*…, p. 54.

[63] Article 81(2) of the Act of March 9, 2023 on Clinical Trials of Medicinal Products for Human Use, *Journal of Laws* 2023, item 605, as amended [in PL].

[64] See, for example, the 2019 critical statement of the Committee on Biotechnology of the Polish Academy of Sciences (no longer available at the committee's official website); Supreme Medical Council of Poland, Position of the Expert Group for cell therapy and stem cells of the Supreme Medical Council Regarding the commercial offering of treatments using stem cells, including those carried out as part of medical therapeutic experiments, 2022, https://nil.org.pl/uploaded_files/art_1649071800_stanowisko-zespolu-nrl-komorki-macierzyste-3032022.pdf [Accessed 12.08.2025]; J. Dulak, M. Pecyna, *Unproven cell interventions in Poland and the exploitation of European Union law on advanced therapy medicinal products*, „Stem Cell Reports" 2023, vol. 18, no. 8, pp.1610-1620.

[65] E.g., M. Rotkiewicz, P. Walewski, Śledztwo 'Polityki': Złudne terapie komórkami macierzystymi, „Polityka" 2019, December 12, https://www.polityka.pl/tygodnikpolityka/nauka/1935142,1,sledztwo-polityki-zludne-terapie-komorkami-macierzystymi.read [Accessed 12.08.2025]; M. Rotkiewicz, *Terapie komórkami macierzystymi – niesprawdzone i ryzykowne, przypominają naukowcy*, „Polityka" 2020, June 4, https://www.polityka.pl/tygodnikpolityka/nauka/1959230,1,terapie-komorkami-macierzystymi--niesprawdzone-i-ryzykowne-przypominaja-naukowcy.read [Accessed 12.08.2025]; M. Janczura, *Expe-*

rapeutic experiments involving stem cells – or products that were inaccurately and misleadingly referred to as "stem cells" – in Poland[66]. Providers of these experimental "stem cell therapies" took advantage of patients' (or their families') desperate medical conditions by charging high prices for unproven and risky interventions that offered little to no chance of therapeutic success due to a lack of scientific evidence regarding their safety and efficacy. They exploited the vulnerable by selling false hope at a high price. To prevent such unethical practices, the Polish legislator introduced the aforementioned general prohibition on accepting payment from research participants and other specified individuals. However, not all patients-sponsored clinical research looks like this. Thus, the question of whether a general ban on participants covering the costs of medical experiments is justified remains up for debate[67]. Perhaps a more nuanced and balanced solution would be more appropriate. But we must save that discussion for another time.

The third – and, in our opinion, most critically important – mechanism for providing protection against undue influence and exploitation in medical experiments in Poland is prescribed by Article 23b(2) of the APPD. This provision applies to all research participants, in all contexts and designs, that are not covered by the aforementioned instruments.

riment. Radio documentary series, Tokfm.pl 2022, https://audycje.tokfm.pl/audycja/518,Eksperyment-Radiowy-serial-dokumentalny [Accessed 12.08.2025].

[66] The practice of offering paid, unproven, stem cell-based treatments or experimental therapies is a well-known international problem that has been addressed by many professional organizations, e.g., M. Dominici et al. [2013–2015 ISCT Presidential Task Force on Unproven Cellular Therapy], *Positioning a Scientific Community on Unproven Cellular Therapies: The 2015 International Society for Cellular Therapy Perspective*, „Cytotherapy" 2015 vol. 7, no. 12, pp. 1663-1666; European Academies Science Advisory Council & Federation of European Academies of Medicine, EASAC-FEAM, *Challenges and potential in regenerative medicine: a joint report from EASAC and FEAM*, 2020, https://easac. eu/publications/details/challenges-and-potential-in-regenerativemedicine/ [Accessed 12.08.2025]; European Medicine Agency, Committee for Advanced Therapies, *EMA warns against using unproven cell-based therapies* (EMA/CAT/94295/2020), 2020, https://www.ema.europa.eu/en/documents/public-statement/ema-warns-against-using-unproven-cell-based-therapies_en.pdf [Accessed 12.08.2025]

[67] Compare, U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Charging for investigational drugs under an IND: Questions and answers. Guidance for industry*, 2024, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/charging-investigational-drugs-under-ind-questions-and-answers [Accessed 12.08.2025]

This includes unhealthy adults invited to therapeutic experiments and healthy adults volunteering for scientific experiments. As explicitly noted in the above-quoted international standards, these individuals may be at risk of undue influence and abuse in research, especially when they are in a forced situation. Therefore, they should not be left without adequate protection.

Consider, for example, a group of competent patients with an advanced disease whose physician is recruiting for a new research study with therapeutic potential. These patients trust their physician and depend on him for specialized ongoing care. Due to their dependency, they are vulnerable to being unduly influenced to participate in the study, especially if they presume or are led to believe that their continued care depends on their enrollment. Or consider competent patients who have exhausted all therapeutic options. It is easy to take advantage of their dire medical condition by deliberately inducing a "therapeutic misconception" and offering false hope in order to secure their consent to participate in research[68]. Or think of a sick professional soldier who is "encouraged" by a senior officer to participate in a therapeutic experiment "for the benefit of his military career". It would be extremely difficult for the soldier to refuse, knowing that refusal could block or reduce the likelihood of promotion. Last, but least, take a healthy adult who is struggling with mounting debt and/or unemployment, for example, due to a criminal record, illegal immigrant status, lack of education or work experience, or a personal commitments that are incompatible with even a part-time job[69]. Alternatively, consider potential participants from low-resource settings who struggle every day to put food on the table and can only dream of having access to basic healthcare. Such economically disadvantaged in-

[68] See, P. S. Appelbaum, L. H. Roth, C. Lidz, *The therapeutic misconception: informed consent in psychiatric research*, „International Journal of Law Psychiatry" 1982, vol. 5, no. 3-4, pp. 319–329; P. S. Appelbaum, L. H. Roth, C. W. Lidz, P. Benson, W. Winslade, *False hopes and best data: Consent to research and the therapeutic misconception*, „The Hastings Center Report" 1987, vol. 17, no. 2, pp. 20–24.

[69] A number of studies have shown that this is a characteristic of many healthy volunteers who participate in research for financial reasons. See, R. Abadie, The *professional guinea pig*…; J. A., Fisher, *Adverse events: race, inequality, and the testing of new pharmaceuticals*, New York 2020.

dividuals can easily be unduly induced to join a project to which "they would normally object based on risk or other fundamental values"[70] by an offer of financial rewards or free access to basic healthcare in exchange for their participation. However, as we have already shown, they are also vulnerable to unfair exploitation when asked to take significant research risks and burdens while being deprived of access to research benefits or being offered less than fair remuneration for their time and contribution.

These scenarios clearly demonstrate the necessity of protecting individuals in forced situations from being taken advantage of in research, regardless of their health status or the nature of the medical experiment for which they are recruited. Article 23b(2) of the APPD should be interpreted as a fundamental principle prohibiting unethical research practices of this kind. Specifically, it obligates researchers and research ethics committees to prevent excessive influence on individuals' decisions to participate or continue participating in research. The article also obligates researchers and research ethics committees to ensure that research designs are non-exploitative. This means that they must involve fair selection criteria, fair risk and benefit distribution, and fair payment schemes.

Conclusions

Apart from protecting against unnecessary and excessive risk, an ethically adequate regulation of human medical research must protect all potential and enrolled participants from undue influence (including undue inducement) and exploitation. This is essential for respecting participants' dignity and autonomy and ensuring they are not treated as mere means for the benefit of science and society (or for researchers' personal or economic gain). Furthermore, socially valuable and trustworthy research practices should not exacerbate or perpetuate existing social inequities, disparities, or biases. Researchers and research ethics committees should promote fairness in access to research and in the distribution of risks and benefits,

[70] National Research Ethics Advisors' Panel, Health Research Authority UK, *Payments and incentive in research*. 2024, para. 2.1 (defining undue inducement), https://www.hra.nhs.uk/about-us/committees-and-services/nreap/payments-and-incentives-research/ [Accessed 12.08.2025]

including collateral benefits such as payment offered to participants for their contributions.

We have argued that Article 23b(2), which was recently added to the APPD, should play a pivotal role in ensuring that Polish medical experimentation practices align more closely with these ethical requirements. The provision generally prohibits taking advantage of participants' forced situations. This imposes new obligations on researchers and research ethics committees, which they must implement. This will not be easy because undue influence and exploitation are context-sensitive phenomena that must be identified, minimized, or mitigated on a case-by-case basis. It is even more difficult in the absence of specific, detailed guidelines. Nevertheless, we hope that our ethical-legal analysis of Article 23b(2) of the APPD will help investigators and research ethics committees recognize and adequately react to risks of undue influence and exploitation in research projects they design or review.

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S t r e s z c z e n i e

Ochrona uczestników badań przed nadmiernym/niewłaściwym wpływem i wykorzystywaniem. Analiza etyczno-prawna art. 23b ust. 2 ustawy o zawodzie lekarza i dentysty

Artykuł zawiera kompleksową analizę etyczno-prawną art. 23b ust. 2 ustawy o zawodach lekarza i lekarza dentysty, który zabrania prowadzenia eksperymentów medycznych z wykorzystywaniem przymusowego położenia uczestnika. Pomimo swojej zwięzłości, treść normatywna tego przepisu pozostaje niejasna. W pierwszym kroku odrzucamy proponowaną w literaturze interpretację, zgodnie z którą analizowany przepis wyklucza wszystkie osoby znajdujące się w przymusowym położeniu z udziału w badawczych eksperymentach medycznych. Argumentujemy, że art. 23b ust. 2 należy interpretować jako zakaz wywierania nadmiernego/niewłaściwego wpływu oraz wykorzystywania (wyzyskiwania) wszystkich potencjalnych i aktualnych uczestników badań, którzy są w trudnej sytuacji lub mają słabszą pozycję, nie tylko tych należących do grup tradycyjnie uważanych za szczególnie narażone na manipulację, pokrzywdzenie i wykorzystanie. Porównujemy mechanizmy ochrony uczestników badań przed nadmiernym/niewłaściwym wpływem i wykorzystywaniem, przyjęte w czołowych międzynarodowych standardach etycznych dotyczących badań biomedycznych z udziałem ludzi, z właściwymi przepisami ustawy o zawodach lekarza i lekarza dentysty. I wykazujemy, że zaproponowana przez nas interpretacja art. 23b ust. 2 jest nie tylko prawnie uzasadniona, ale także etycznie konieczna, aby chronić wszystkich uczestników eksperymentów medycznych przed tymi nieetycznymi praktykami. Nasza interpretacja art. 23b ust. 2 dostarcza badaczom i komisjom bioetycznym cennych i praktycznych wskazówek. Postulujemy uznanie komentowanego przepisu za jedną z czołowych zasad polskiej regulacji eksperymentów medycznych.

Słowa kluczowe: eksperymenty medyczne, podatność na skrzywdzenie, nadmierny/niewłaściwy wpływ, nadmierna/niewłaściwa zachęta, wyzysk