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INFORMED CONSENT AS A MECHANISM FOR PROTECTING NEW HUMAN RIGHTS IN THE FIELD OF HEALTHCARE: CONCEPT, TYPES AND LEGAL REGULATION

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INTRODUCTION

The relevance of this work is due to the fundamental transformation of the very concept of informed consent in the context of the expansion of the doctrine of human rights, the digitalization of medicine, the development of biobanking, personalized medicine and the globalization of biomedical research. It should be noted that the theoretical and applied problems of protecting patients' rights, including in the context of protecting new rights in the field of health care, have already been the subject of our scientific research[1]. In modern conditions, informed consent ceases to be an exclusively formal legal prerequisite for carrying out medical intervention and acquires the importance of one of the key institutions in the field of health care, combining ethical, medical and legal components and ensuring the realization of individual autonomy, the right to self-determination, respect for dignity and privacy.

The strengthening of the patient's role as an active subject of medical legal relations, the expansion of clinical trials, transplantation, the use of assisted reproductive technologies, as well as the growth of the volume of processing of medical (in particular, genetic) and other personal data necessitate a rethinking of the legal nature of informed consent, as well as the classic "static" model of consent and the introduction of new approaches, such as dynamic, multi-level and meta-consent. This necessitates a comprehensive theoretical and legal analysis of

[1] Zaborovskyy V., Buletsa S., Bysaga Yu., Manzyuk V., Lenher Ya. Professional activity of medical lawyer. *Georgian Medical News*. 2020. № 3 (300). P. 146-152. URL: https://dspace.uzhnu.edu.ua/items/71194cc0-ad88-4987-8b61-ea9d65da1a76; Булеца С.Б., Заборовський В.В. Самозахист пацієнта та лікаря. *Наше право*. 2017. № 1. С. 159-163. URL: http://nbuv.gov.ua/UJRN/nvuzhpr_2016_ 41%281%29__24; Заборовський В. В. Виклики та перспективи застосуванні інноваційних технологій в сфері охорони здоров'я (трансплантологія і ДРТ) та проблеми забезпечення конфіденційності медичної інформації у воєнний час. *Аналітично-порівняльне правознавство*. 2025. № 2. С. 545-552. https://doi.org/10.24144/2788-6018.2025.02.81; Заборовський В. В. Проблемні аспекти формування та застосування медичних баз даних в умовах цифрової трансформації сфери охорони здоров'я. *Innovative Research in Science and Economy:* Collection of Scientific Papers with Proceedings of the 1st International Scientific and Practical Conference (Brussels (Belgium), July 30 – August 1, 2025). Brussels: International Science Unity. 2025. P. 108-110. DOI: https://doi.org/10.70286/isu-30.07.2025

the concept, types and legal regulation of informed consent through the prism of new rights in the field of healthcare.

The issue of informed consent as a mechanism for protecting modern human rights in the field of health care is in the focus of attention of a wide range of domestic and foreign researchers. Among the scientists who have studied individual aspects of this issue, it is appropriate to single out the works of: N.T. Boutin, I. Budin-Ljøsne, C. Camtepe, F.K. Dankar, L. Gasparini, E. Gefenas, E. Harbinja K. Kaur, M.I. Khalid, N.V. Kvit, R.B. Mikkelsen, M. Mourbya, A. Oliva, O.P. Omelchenko, O.P. Rumyantsev, I.Ya. Senyuta, Yu.Yu. Sizintsova, S.G. Stetsenko, V.Yu. Stetsenko, C. Thapa E. Vayena and others.

The purpose of this scientific work is a comprehensive theoretical and legal analysis of the concept, legal nature, features of legal regulation and types of informed consent as a multifunctional mechanism for protecting modern human rights in the field of healthcare.

The author sets himself the following main tasks: to investigate the pluralism of scientific approaches to defining the concept of informed consent and to reveal its ethical and legal nature in the human rights system; to carry out a comparative legal analysis of the legal regulation of informed consent in Ukrainian legislation and international acts in the field of healthcare; to analyze the classification of types of informed consent and characterize their features in the field of medical intervention, clinical research, transplantation and biobanking; to substantiate the feasibility of using dynamic, multi-level and meta-consent as modern forms of ensuring a balance between the interests of the individual, medical institutions and the state.

1. The concept and essence of informed consent: theoretical and legal approaches

In one of our previous scientific works, we drew attention to the fact that the universality of informed consent allows scientists to consider it in different contexts, and in the field of transplantation and ART it is appropriate to characterize it as having a dual legal nature: both as a process of interaction between a doctor and a patient and a legal document that enshrines a person's decision, and as a unilateral transaction, for example, regarding the use of a donor's biological material, where his expression of will is a sufficient and necessary condition for the removal of a cell, tissue or organ and the emergence of the corresponding legal relationship[2].

[2] Заборовський В.В., Манзюк В.В. Інформована згода як гарантія прав пацієнта: правова природа, етичні засади і особливості реалізації у сфері трансплантації та в умовах екстраординарних правових режимів. *Аналітично-порівняльне правознавство*. 2026. № 2. Ч. 1. С. 131-137. https://doi.org/10.24144/2788-6018.2026.02.2.21

The presence of different approaches to understanding the nature of informed consent also results in the lack of a single position among scientists regarding the definition of the concept of "informed consent". Thus, Yu.Yu. Sizintsova, based primarily on the provisions of the Fundamentals of Ukrainian Legislation on Health Care[3] (in particular, Article 43), concludes that informed consent is the consent of the patient or his legal representative to medical intervention, which is provided by him based on complete and comprehensive information received from the attending physician in a form accessible to the patient, namely about the purpose, nature, methods of this intervention and the probable risk associated with it, as well as possible medical, social, economic, psychological and other consequences, as well as alternative types of medical care and the consequences and risks associated with them[4]. A similar position is held by the compilers of the textbook "Medical Law of Ukraine", who understand informed consent to medical intervention as the voluntary, competent acceptance by the patient of the treatment option offered to him, which is based on the latter receiving complete, comprehensive and objective information about the future treatment, as well as possible complications and alternative treatment methods[5].

In our opinion, the basis for these definitions was principle 11 (consent to treatment) of Resolution 46/119 “Protection of persons with mental illness and improvement of mental health care”, according to which informed consent is considered to be obtained freely, without threats and inappropriate motivation, after providing the patient with adequate and understandable information in a form and language accessible to the patient, which includes: diagnostic assessment; purpose, method, probable duration and expected benefit of the proposed treatment; alternative methods of treatment; dangers and side effects of the proposed treatment[6].

A somewhat different understanding of informed consent in the aspect of transplantology is given by O.P. Rumyantsev, in his thesis research, who understands the concept of "informed consent of the patient to the provision of medical care with the use of transplantation" as a standardized procedure for providing the patient (both the donor and the recipient) with adequate and

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[3] Основи законодавства України про охорону здоров'я: Закон України 19 листопада від 1992 року № 2801-XII. URL: https://zakon.rada.gov.ua/laws/show/2801-12#Text

[4] Сізінцова Ю. Ю. Інформована згода на медичне втручання: юридичний захист пацієнтів і медичних працівників. *Науковий вісник Ужгородського національного університету : Серія: Право*. 2013. Вип. 23. Ч. 1. Т. 1. С. 267. URL: https://dspace.uzhnu.edu.ua/items/59ad79ce-0d12-4d8c-90c9-c7763ee54f1e

[5] Стеценко С. Г., Стеценко В. Ю., Сенюта І. Я. Медичне право України: Підручник. Правова єдність, 2008. 507 с. URL: https://library.nlu.edu.ua/POLN_TEXT/KNIGI-2012/ medpravo2008.pdf

[6] United Nations General Assembly Resolution 46/119 on the protection of persons with mental illness and the improvement of mental health care, 17th December 1991 (UN Doc A/RES/46/119). URL: https://digitallibrary.un.org/record/ 135851?v=pdf

understandable medical information about the intervention in each specific case in a form and in a language that is accessible to each patient, as well as obtaining from their informed voluntary written consent to carry out such an intervention according to the established form[7]. Informed consent as a procedure by which the subject voluntarily confirms his/her consent to participate in a certain clinical trial after familiarization with all the features of the study that may affect one's decision is also considered by the order of the Ministry of Health of Ukraine «On approval of documents on quality assurance of medicinal products»[8], while other orders of the Ministry of Health of Ukraine consider informed consent as a decision to participate in a clinical trial[9].

2. Legal regulation of informed consent in Ukraine and international legal standards

The legal basis for the regulation of informed consent in Ukrainian legislation is the provisions of Article 28 of the Constitution of Ukraine (everyone has the right to respect for his dignity), according to which no person may be subjected to scientific, medical or other experiments without his free consent. In turn, the Fundamentals of the Legislation of Ukraine on Health Care[10], which actually initiated the concept of informed consent in Ukraine, proceed from the necessity of such consent when applying any methods of diagnosis, prevention and treatment (Article 43), while the current form of informed consent of the patient for diagnosis, treatment, surgery and anesthesia, as well as for the presence or participation of participants in the educational process, was approved by the Order of the Ministry of Education and Science of Ukraine No. 2837[11].

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[7] Румянцев О.П. Адміністративно-правове регулювання трансплантації в Україні: дис. канд. юрид. наук: спец. 12.00.07. Київ, 2021. с. 63-64 URL: https://uacademic.info/ua/document/0421U103768#google_vignette

[8] Про затвердження документів з питань забезпечення якості лікарських засобів: Наказ Міністерства охорони здоров'я України від 16.02.2009 р. № 95. URL: https://zakon.rada.gov.ua/rada/show/v0095282-09#Text

[9] Про затвердження Порядку проведення клінічних випробувань лікарських засобів та експертизи матеріалів клінічних випробувань і Типового положення про комісії з питань етики: Наказ Міністерства охорони здоров'я України від 23.09.2009 р. № 690. URL: https://zakon.rada.gov.ua/laws/show/z1010-09#Text**;** Про затвердження Порядку проведення клінічних випробувань тканинних і клітинних трансплантатів та експертизи матеріалів клінічних випробувань й унесення змін до Порядку проведення клінічних випробувань лікарських засобів та експертизи матеріалів клінічних випробувань: наказ Міністерства охорони здоров'я України від 13.02.2006 № 66. URL: https://zakon.rada.gov.ua/laws/show/z1206-07/sp:dark:max25#Text

[10] Основи законодавства України про охорону здоров'я: Закон України 19 листопада від 1992 року № 2801-XII. URL: https://zakon.rada.gov.ua/laws/show/2801-12#Text

[11] Інструкція щодо заповнення форми первинної облікової документації № 003-6/о «Інформована добровільна згода пацієнта на проведення діагностики, лікування та на проведення операції та знеболення і на присутність або участь учасників освітнього процесу:

In the context of transplantation and the use of reproductive technologies, the main acts that regulate, among other things, the need and procedure for obtaining informed consent are, first of all, the Law of Ukraine "On the use of transplantation of anatomical materials in humans"[12], the resolution of the Cabinet of Ministers of Ukraine on some issues of implementing the said Law[13], and the order of the Ministry of Health of Ukraine "On approval of the Procedure for the use of assisted reproductive technologies in Ukraine"[14].

The general analysis of the above-mentioned regulatory acts allows us to conclude that in fact any medical intervention requires prior informed consent. In this aspect, the provisions of Ukrainian legislation generally comply with fundamental international acts in the field of health care. Thus, the Declaration on the Protection of Patients' Rights in Europe enshrines the norm that the patient's informed consent is a mandatory condition for any medical intervention, from which he has the right to refuse or suspend it, with a corresponding thorough explanation of the consequences of this (paragraph 3)[15]. A similar position is reflected in the Convention on Human Rights and Biomedicine[16], according to which, intervention in the sphere of a person's health may be carried out only after his or her voluntary and informed consent to it on the basis of previously received information about the purpose and nature of the intervention, as well as about its consequences and related risks (Article 5) and the Additional Protocol to this Convention on Transplantation of Organs and Tissues of Human Origin, which enshrines the right of the donor to provide free, informed and specific consent to the removal of an organ or tissue in writing or in an official body, after receiving appropriate information (Article 12)[17].

наказ Міністерства охорони здоров'я України від 14.02.2012 р. № 110 (у редакції наказу від 09 грудня 2020 року № 2837). URL: https://zakon.rada.gov.ua/laws/show/z0697-12#n2

[12] Про застосування трансплантації анатомічних матеріалів людині: Закон України від 17 травня 2018 року № 2427-VIII. *Відомості Верховної Ради України*. 2018. № 28. Ст.232. URL: https://zakon.rada.gov.ua/laws/show/2427-19#Text

[13] Деякі питання реалізації Закону України «Про застосування трансплантації анатомічних матеріалів людині»: постанова Кабінету Міністрів України від 27 грудня 2018 р. № 1211. URL: https://zakon.rada.gov.ua/laws/show/1211-2018-п#Text

[14] Про затвердження Порядку застосування допоміжних репродуктивних технологій в Україні: Наказ Міністерства охорони здоров'я України від 09.09.2013 р. № 787. URL: https://zakon.rada.gov.ua/laws/show/z1697-13

[15] The Declaration on the Promotion of Patients' Rights in Europe consultation on the rights of patients. 28-30 March 1994. URL: https://www.activecitizenship.net/multimedia/files/charter-of-rights/the-forerunners-of-the-charter/The-Declaration-on-The-Promotion-of-Patients-Rights-in-Europe.pdf

[16] Конвенція про захист прав і гідності людини щодо застосування біології та медицини: Конвенція про права людини та біомедицину від 4 квітня 1997 року. URL: https://zakon.rada.gov.ua/laws/show/994_334#Text

[17] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin. Strasbourg, 24.1.2002. URL: https://rm.coe.int/1680081562

In the context of our study, it is also necessary to analyses the provisions of the General Data Protection Regulation (GDPR)[18], which is a legally binding regulatory act and establishes strict rules for the collection, processing, storage and protection of personal data in the EU. The concept of "consent" according to the provisions of this Regulation means any freely given, informed, specific and unambiguous indication of the wishes of the data subject by which he confirms his consent to the processing of his personal data, by making a statement or by showing clear affirmative actions (in particular, in the form of a written statement, including by electronic means, or in the form of an oral statement). These provisions of the Regulation are considered by scientists as establishing very high requirements for informed consent to the processing of personal data, as well as clear alternative grounds for the processing of data about the health of an individual (consent is considered only as one of the legal mechanisms for the processing of special category data, which does not have a predetermined priority over other mechanisms)[19]. Thus, Article 6 of the General Data Protection Regulation provides that the consent of the data subject to the processing of his or her personal data is only one of the lawful grounds for their processing, while Article 9 establishes ten exceptions to the prohibition on the processing of special categories of personal data (in particular, genetic data, data concerning health).

3. Types of informed consent and prospects for their application in biomedical research and transplantology

Regarding the correlation between the concepts of "informed consent to clinical trials (medical intervention)" ("interventional consent") and "consent to the processing of personal data", we share the position of those scientists that although there is a certain connection between them (for example, refusal to consent to the processing of personal data may lead to the doctor's refusal to perform a medical intervention[20]), there is a significant difference between them. This is also noted by the European Commission's Directorate-General for Health

[18] Регламент Європейського Парламенту і Ради (ЄС) 2016/679 від 27 квітня 2016 року про захист фізичних осіб у зв'язку з опрацюванням персональних даних і про вільний рух таких даних, та про скасування Директиви 95/46/ЄС (Загальний регламент про захист даних). URL: https://zakon.rada.gov.ua/laws/show/984_008-16#Text

[19] Gefenas E., Lekstutiene J., Lukaseviciene V., Hartlev M., Mourby M., Cathaoir K. Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road. *Med Health Care Philos*. 2022. № 25(1). PP. 23-30. DOI: 10.1007/s11019-021-10060-1.

[20] Mourbya M., Cathaoirb K.Ó., Collinc C. B.. Transparency of machine-learning in healthcare: The GDPR and European health law. *Comp. Law Security Rev*. 2021. DOI: 10.1016/j.clsr.2021.105611

and Food Safety[21], emphasizing that the requirement for informed consent under the Clinical Trials Regulation (EU) 536/20141 should not be confused with consent as a legal basis for processing personal data under the GDPR, as the former is the main condition under which a person can be included in a clinical trial and is not perceived as a tool to ensure the compliance of data processing and is a guarantee rather than a legal basis for data processing (for example, in cases where consent to the processing of personal data is not appropriate as a basis for their processing under the provisions of the General Data Protection Regulation[22]).

In our opinion, the position of those scientists who distinguish between informed consent in research involving physical or other forms of intervention and "interventional consent" (emphasizing its fundamental role and considering this consent as the fundamental normative core of the World Medical Association (WMA) Declaration of Helsinki on Medical Research Involving Humans[23], which is a global act on research ethics) and "informed consent", which plays a central role in the case of conducting research that only involves the processing of a person's health data, when any changes or withdrawal of consent are permitted only in exceptional cases[24]. A similar position is held by scientists[25], who distinguish between "consent to research ethics" ("interventional consent"), as consent to the researcher's intervention and the participant's free expression of will to participate in a research project, and "informed consent", which is the basis for processing personal data in accordance with national and EU legislation, drawing attention to the fallacy of the statements of those scientists who do not distinguish between different forms of consent or consider one form of informed consent as subsuming another.

In the scientific literature, other types of informed consent are also distinguished. Thus, C. Tapa and S. Camtepe based on the fact that such consent is an important tool for protecting personal privacy, confidentiality and autonomy

[21] Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation. European Commission Directorate-General for Health and Food Safety. URL: https://health.ec.europa.eu/ document/download/c3042973-b36d-4094-a1fb-a6fc980f065e_en

[22] A Preliminary Opinion on data protection and scientific research. The European Data Protection Supervisor. 2020. URL: https://www.edps.europa.eu/sites/ default/files/publication/20-01-06_opinion_research_en.pdf

[23] Declaration of Helsinki Medical Research Involving Human Participants. URL: https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/

[24] Gefenas E., Lekstutiene J., Lukaseviciene V., Hartlev M., Mourby M., Cathaoir K. Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road. *Med Health Care Philos*. 2022. № 25(1). PP. 23-30. DOI: 10.1007/s11019-021-10060-1.

25 Kaur K, Grama B., Chaudhuri R., Recalde-Vela M.J. Ethics and Epistemic Injustice in the Global South: A Response to Hopman's Human Rights Exceptionalism as Justification for Covert Research. *Journal of Human Rights Practice*. 2023 Volume 15, Issue 2. P. 347-373. https://doi.org/10.1093/jhuman/huad008

of the individual, and is mandatory for the processing of health data, including collection, analysis and storage, distinguish three types of consent, namely: explicit consent (consent to participate, which is mandatory for all aspects of clinical trials, in which the purpose of collecting personal information, its use, processing and disclosure of information are presented with the possibility of choosing it); implicit consent, which in most cases is obvious at the time of its receipt (for example, in the case when a doctor takes blood samples from his patient for laboratory tests); consent with the possibility of refusal, when participants are informed about the purpose of the consent with the possibility of rejecting it (if such consent is not rejected, it is considered given)[26].

Also noteworthy is the study by O.P. Omelchenko, who points to the use of the following types of informed consent in biomedicine:

– blanket consent – for unlimited use of data for all types of research and without the need to obtain any further permissions;

– broad consent – the person allows the biobank to use their data in future research, and the biobank independently decides how to use them;

– sectoral consent is given for research in a specific field and is limited to a specific area of medicine; and

– dynamic consent, which is characterized by its flexibility, and under which the donor and the biobank are in constant contact with each other, and the initial informed consent provided by the donor can be edited, changed or withdrawn in the process of carrying out a specific study due to the emergence of new circumstances (the donor will decide whether to consent to the further use of his biological material and/or data in the study or not)[27]. It should be noted that the right of a person to freely withdraw his consent to any intervention in the field of health is provided for in both Art. 5 of the Convention on Human Rights and Biomedicine[28] and Art. 13 of the Additional Protocol to this Convention on Transplantation of Organs and Tissues of Human Origin[29]. The Guide on the Quality and Safety of Tissues and Cells for Human Use, published by the European Directorate for the Quality of Medicines and Healthcare Products of the Council of Europe (EDQM), states that donors should be informed that they can withdraw their consent at any time. In the case of donors of hematopoietic stem

[26] Thapa C, Camtepe S. Precision health data: Requirements, challenges and existing techniques for data security and privacy. *Comput Biol Med*. 2021. DOI: 10.1016/j.compbiomed.2020.104130

[27] Омельченко О.П. Інформована згода донора як правовий інструмент регулювання діяльності дослідницьких біобанків. *Актуальні проблеми вітчизняної юриспруденції: науковий збірник*. 2018. Випуск 1. С. 90. URL: http://apnl.dnu.in.ua/arkhiv?id=64

[28] Конвенція про захист прав і гідності людини щодо застосування біології та медицини: Конвенція про права людини та біомедицину від 4 квітня 1997 року. URL: https://zakon.rada.gov.ua/laws/show/994_334#Text

[29] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin. Strasbourg, 24.1.2002. URL: https://rm.coe.int/1680081562

cells, they should be informed of the possible consequences for the recipient if they withdraw their consent after the recipient's preparation regimen has already begun, however, this situation should not be used to coerce the donor and their final decision should be respected[30].

Although the use of dynamic informed consent, in particular in transplantology, has certain disadvantages, among which we can highlight that its use: is expensive to implement and maintain, and registration of participants in studies through online portals may not take into account their educational level and low medical literacy[31]; requires excessive time from participants to understand the entire set of data about them and obtain consent for each study, which can lead to information overload[32]. The possibilities of using dynamic consent in many cases depend on the funding of the study[33]. At the same time, the positive side of dynamic consent, according to scientists, is that the person providing their data has the opportunity to control their use, since the dynamic consent mechanism provides a method of digital communication between the data subject, the data controller and the persons who need this data in a way that allows the data subject to provide consent to specific personal information and to track and manage who can collect, access and use their data and for what purposes[34]. Other researchers hold a similar position, noting that dynamic consent allows participants to review and change their consent choices over time through a personalized digital interface, which can improve communication between researcher and participant, as well as participant autonomy and engagement in general[35].

Along with dynamic consent (personalized consent with two-way communication, under which the data subject can update and provide different types of consent and control the use of their health data, as well as withdraw it),

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[30] The Guide to the quality and safety of tissues and cells for human application is published by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM). 4th Edition 2019. URL: https://www.aebt.org/wp-content/uploads/2020/03/Guide-to-the-quality-and-safety-of-tissues-and-cells-CoE-4th-ed.pdf

[31] Boutin N.T., Mathieu K., Hoffnagle A.G., Allen N.L., Castro V.M. etc Implementation of Electronic Consent at a Biobank: An Opportunity for Precision Medicine Research. *J Pers Med*. 2016/ № 6(2). DOI: 10.3390/jpm6020017

[32] Vayena E., Blasimme A. Health Research with Big Data: Time for Systemic Oversight. *J Law Med Ethics.* 2018. № 1. PP. 119-129. DOI: 10.1177/1073110518766026.

[33] Dankar F.K., Gergely M., Malin B., Badji R., Dankar S.K., Shuaib K. Dynamic-informed consent: A potential solution for ethical dilemmas in population sequencing initiatives. *Comput Struct Biotechnol J.* 2020. № 18. PP. 913-921. DOI: 10.1016/j.csbj.2020.03.027

[34] Khalid M.I., Ahmed M., Kim, J. Enhancing Data Protection in Dynamic Consent Management Systems: Formalizing Privacy and Security Definitions with Differential Privacy, Decentralization, and Zero-Knowledge Proofs. Sensors 2023, 23, 7604. https://doi.org/10.3390/s23177604

[35] Lay W., Gasparini L., Siero W., Hughes E.K. A rapid review of the benefits and challenges of dynamic consent. *Research Ethics*. 2024. № 21(1). PP. 180-202. https://doi.org/ 10.1177/17470161241278064

there is also static consent (provided for any future use of the data at the time of collection), the disadvantage of which is primarily that it does not address problems related to changing circumstances and requirements over time (for example, regarding the reuse of data for another health project different from the one originally authorized)[36]. In general, examples of data reuse are what some scholars call an "alternative to consent," for example, when the Privacy Advisory Group in England and the Public Benefit and Privacy Commission in Scotland are empowered to waive the confidentiality obligation of such data in certain circumstances, in particular, the provision of certain identifiable information for purposes, including those related to medical research (the relevant activity must be carried out solely in the public interest or in the interests of improving patient care)[37].

In addition to dynamic and static, researchers also distinguish multi-level and meta-consent. Multi-level consent allows potential participants to at least partially adapt their consent preferences for future research in general, rather than for specific research projects (consent can be given for research on specific diseases or their categories (e.g., kidney transplantation or ART research), public/private research, identified/anonymous use, specific research institutions, or specific researchers). As for meta-consent, it is characterized by even greater flexibility, as it allows participants to associate different types of consent with different levels (e.g., a research subject may decide that he wants to give specific consent for all future research related to transplantation for military needs and is willing to give a single broad consent for all future publicly funded health research)[38]. This approach gives participants precise control over how their data is used, but eliminates the need to manage requests for each individual study[39].

Analyzing different types of informed consent, N.V. Kvit in his dissertation study, in order to ensure a balance of interests of donors and researchers, points out the need to establish in the legislation the possibility of choosing the form (dynamic or general) specifically by the donor (provided that one is provided with information about all the risks and consequences of each of them in an appropriate and accessible form), while in order to ensure a balance of rights and interests of donors and biobank managers, it is necessary to provide in special legislation that

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in the event of dynamic consent by the donor, he is obliged to inform about changes in his contact details within a reasonable time, with the establishment in the legislation of the consequences of violating such an obligation (granting the right to unilaterally dispose of samples to the biobank manager)[40].

CONCLUSIONS

Informed consent has evolved from a formal legal requirement to a multifunctional legal mechanism for the implementation of individual autonomy. Informed consent can no longer be considered solely as an act of consent to medical intervention, and in modern conditions it acquires the meaning of a complex legal construct, which simultaneously functions as: a mechanism for protecting the constitutional rights of a person to life and respect for his dignity; a tool for legitimizing medical intervention; an ethical standard of good medical practice; a certain procedural guarantee of the quality of medical care; a tool for building trust between the patient, donor, researcher and the state, etc.

It is important to understand informed consent not as a one-time act, but as a long-term process of communication that has its own internal structure (providing information, its awareness, free expression of will, the possibility of withdrawal), temporal dynamics and requires constant dialogue between a medical professional and a patient, especially in the context of long-term interventions or multi-stage procedures. Pluralism regarding definitions of informed consent is due to the different purposes of its application, which further confirms the appropriateness of using a sectoral approach to the legal regulation of consent instead of attempting to establish a single universal model.

It is necessary to distinguish between "interventional consent" (consent to medical intervention and participation in a research project) and "informed consent" to the processing of personal data. Informed consent in the field of biomedicine ("interventional consent") has an ethical and legal nature and is a determining condition for the admissibility of medical intervention, and can serve as a guarantee of the lawfulness of the processing of a patient's medical and other personal data, while consent under the GDPR is only one of the possible legal grounds for such processing. This difference is not only theoretical, but also practical, since mixing these concepts leads to incorrect application of the GDPR rules in medical research and unjustified restrictions on scientific research and should be clearly reflected in national legislation.

The crucial recognition of the right of an individual to withdraw their consent at any stage of a medical intervention or research is a manifestation of the absolute nature of patient autonomy. However, this right raises complex ethical and

[40] Квіт Н.М. Цивільно-правові форми створення та використання біобанків в Україні : дис. … докт. юрид. наук : спец. 12.00.03. Львів,. 2020, 494 с. URL: https://law.lnu.edu.ua/wp-content/uploads/2020/11/Diss.pdf

practical dilemmas, especially in the context of transplantology (when the preparation of the recipient has already begun) and long-term research (when the results are already partially obtained). Legislation should provide not only for the right of withdrawal itself, but also for clear procedures and consequences of such withdrawal for all participants involved.

In the field of transplantation and biobanking, dynamic, multi-level, and meta-consent are of particular importance, allowing a person to maintain control over biological materials and data for a long time. This reflects a paradigm shift: from a one-time act of consent to long-term legal relations between the donor, medical institutions and the state. The concept of dynamic consent, which most fully meets the challenges of the digital age and personalized medicine, deserves special attention. Although its implementation in some cases may be objectively limited (for example, organ removal is irreversible; after organ transplantation, withdrawal of consent cannot have retrospective effect), and its implementation requires significant organizational and financial resources, it is this approach that provides a person with real control over the use of their biological materials and medical data over time, which is especially important for long-term research and biobank activities.

SUMMARY

The institute of informed consent is studied as a complex legal mechanism for implementing new generation human rights in the field of healthcare in the context of the development of biomedicine, biobanking, and digitalization of medical processes. Modern scientific approaches to defining the concept, legal nature, and functional purpose of informed consent are analyzed, as well as its significance for ensuring the principle of personal autonomy, respect for human dignity and the right to self-determination in medical legal relations.

Special attention is paid to the classification of types of informed consent and the features of their application in the field of medical intervention, clinical research, transplantation of organs, tissues and human cells, as well as in the context of collecting, processing and reusing medical and genetic data. Attention is focused on the distinction between informed consent to medical intervention ("interventional consent") and consent to the processing of personal data in accordance with the requirements of the General Data Protection Regulation (GDPR), which is of important theoretical and practical importance for proper law enforcement.

The modern typology of informed consent is analyzed: static, dynamic, multilevel, and metaconsent. The position is substantiated according to which dynamic consent most fully meets the challenges of the digital age and personalized medicine, as it provides a person with real control over the use of their biological materials and medical data over time. Special attention is paid to the peculiarities of the application of various types of consent in the field of

transplantology, biobanking and assisted reproductive technologies. The growing role of informed consent as a tool for ensuring a balance between the interests of the development of science, the effectiveness of medical care and the appropriate level of protection of human rights and freedoms in the field of healthcare is emphasized.

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