INFORMED CONSENT IN BIOBANK-DONOR RELATIONS: PROPER REGULATION FOR UKRAINE NEEDED

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More and more biomaterials such as blood or tissue samples and health data are stored in long-term, interconnected biobanks in which they are available for current and future research questions. The aim of this work is to analyze different forms of informed consent regarding its suitability for ensuring the protection of the probands personal rights; to analyze the legel nature of informed consent to define which requirements, it must respond in order to be valid. As a result the author formulates the norm to regulate the informed consent in biobank relationships, which can ensure the balance between the probants autonomy and the freedom of scientific activity.

Key words: informed consent, probant, biobank, legal regulation.

Усе більше біологічних матеріалів, таких як клітини, проби крові чи тканин та дані про здоров'я чи навіть генетичні дані, зберігаються у довгострокових взаємопов'язаних між собою біобанках, у яких вони доступні для поточних та майбутніх досліджень. З такими масштабними проєктами виникає питання регулювання меж та порядку отримання згоди про бантів на використання їх біологічних матеріалів та даних.

Метою даної роботи є аналіз різних форм поінформованої згоди в контексті її ефективності для забезпечення захисту особистих немайнових прав пробантів; проаналізувати характер правової природи поінформованої згоди, щоб визначити, яким вимогам вона повинна відповідати, щоб бути дійсною.

У статті досліджено різні форми поінформованої згоди та проаналізовано їх переваги та недоліки для забезпечення автономії пробантів, охорони їх особистих немайнових прав та реалізації біобанками свободи дослідницької діяльності.

У результаті проведеного дослідження автор пропонує власне бачення правової природи поінформованої згоди у відносинах між біобанком та пробантом. Також автор формулює власне бачення найбільш ефективного правового регулювання отримання поінформованої згоди у відносинах біобанку та пробанта, яка зможе забезпечити баланс між автономією пробантів та свободою наукової діяльності дослідницьких біобанків. Зокрема, автор пропонує надати право вибору форми поінформованої згоди самому пробанту, яке він має реалізувати після належного його інформування управителем біобанку про правові наслідки надання генеральної чи динамічної згоди для можливості реалізації ним його особистих немайнових прав у цій сфері. При цьому автор пропонує додаткову гарантію для дослідників, у разі обрання пробантом динамічної згоди, а саме: встановлення для пробанта обов'язку повідомляти дослідника чи управителя біобанку про зміни його контактних даних, а також наслідки порушення ним такого обов'язку.

Ключові слова: інформована згода, пробант, біобанк, регулювання.

Все больше и больше биоматериалов, таких как образцы крови или тканей и данные о состоянии здоровья, хранятся в долгосрочных взаимосвязанных между собой биобанках, в которых они доступны для текущих и будущих исследований. Целью данной работы является анализ различных форм информированного согласия относительно его пригодности для обеспечения защиты личных неимущественных прав пробантов; исследование юридической природы информированного согласия, чтобы определить, каким требованиям оно должно отвечать, чтобы быть действительным. В результате автор формулирует норму, регулирующую информированное согласие в отношениях между биобанком и пробантом, которая может обеспечить баланс между автономией пробантов и свободой научной деятельности исследовательских биобанков.

Ключевые слова: информированное согласие, пробант, биобанк, правовое регулирование

Formulation of the problem. Research biobanks are created and used to develop medical science and to develop new medicaments or treatment methods. The lack of complex legal regulation of research involving human beings in general in Ukraine, as well as studies of human biological materials and personal data related to a person's health in particular, which are part of research biobanks, create favorable conditions for violation of donors personal non-property rights. The creation and usage of research biobanks may and should be limited by the rules of both national and international law, but requires a very deliberate approach by the lawmaker to this issue.

The current state of regulation in Ukraine is as follows, in addition to the Licensing conditions that govern only the order of biobanks creation, activity on their use is still unregulated and is limited only by the general rules of constitutional law and the research rules, contained in the Fundamentals of Health Law. However, many European countries already regulate these important issues at the level of special laws, and Ukraine should not be an exception. In particular, it is necessary to ensure, through the rules of law, on the one hand, the protection of the rights and interests of probationers, and, on the other, to establish reasonable frameworks for the use of research biobanks, which will not restrict the freedom of scientific activity and have no negatively disruptive impact on the development of science.

Research and publications analyze. The issues of informed consent as a legal tool to ensure the medical interventions validity have been investigated in the works of A.A. Hertz, R.A. Maydanik, O.Yu. Kashintseva, O.O. Kohanovska, I.Ya. Senyuta, V.Yu. Stetsenko, S.G. Stetsenko. Instead, the issue of informed consent as a condition for the proper use of the biobank has been the subject of research mainly by foreign scientists only.

The aim of this research is to analyze the foreign experience and requirements of the European standards for the rights protection of the subjects that transmit biological material and data to biobanks, to offer an optimal model of informed consent and a functional way of its legal regulation. The purpose of the study is also to outline the specifics of the informed consent legal nature in these relationships, in order to determine the specific requirements that it must meet in order to be valid.

Results. First of all, it should be emphasized that different form types of such consent are used in the world practice, which should be analyzed. In particular, one of these types is the so-called complete or as it is called blanket consent, which is provided for all types of research and allows unrestricted use of data and samples without any further authorization [16, p.53]. Therefore, by giving informed consent in this form, the person refuses to further communicate with the biobank manager. Broad consent is also a form of consent whereby a donor allows a biobank to use its sample and/or data in future research, with the biobank independently deciding how to use that sample or data [14, p.227]. This form of consent is still referred to in the doctrine as "open consent" or "general agreement"[8]. In international legal doctrine, broad consent is also interpreted as being provided for the use of bio-samples and data for certain types of scientific research, where consent is given only for a specific type of intended use, limited to the purpose agreed by the donor, and therefore when changing the purpose of the research, it terminates its action [15, p.236]. Sectoral consent is granted for research in a particular field, this form of consent is limited to the scope of research in a particular field of medi-

cine (for example, consent to research in the field of central nervous system diseases, oncology, etc.) [8].

Another form of consent, which is relatively new to both international and national science, and the emergence of which has been necessitated by the creation of legislative guarantees for the protection of the personal non-property rights of the donor, is in particular the so-called dynamic consent. Its peculiarity is that the donor and the manager of the biobank are in constant contact. The dynamic nature of this consent form is manifested in the fact that the primary informed consent provided by the donor may change or even be withdrawn in the course of conducting a particular type of study because of new circumstances, that could not have been foreseen at the time of the initial consent or in case, when biological material and donor data are to be used for further, new types of research. The occurrence of such circumstances will require donor informing by the biobank manager about it, providing him with detailed information about the research, its nature, purpose, on the basis of which the donor will decide to consent or deny the continued use of his biological material and/or data.

It is also important to understand that biomedical research can be conducted not only within one country but can also have an international nature. What means, that donors, biobank manager and researchers could underlie different jurisdictions, which will further complicate the ongoing dynamic personal contact between them and in the same time can provide to the conflict of law. In this case, remote means of communication, such as the Internet, the exchange of information via e-mail or messengers, the use of electronic signatures of the parties, etc., may be used for the use of dynamic consent. But even the possibility of remote communication may not always solve the problem of obtaining a dynamic informed consent in practice, the high level of mobility of the modern society and frequent changes of residence, which can lead to the loss of contact of the biobank manager, the researcher with the donor. In such a case, an imperative requirement to obtain a dynamic form of donor consent in the legislation may significantly limit the freedom of scientific activity and adversely affect the development of science in general. Therefore, on the one hand, one cannot disagree with the view that dynamic consent is characterized by "flexibility" and the use of such a consent model makes the donor an active participant in research and is most focused on protecting his rights and interests. But, on the other hand, the most appropriate to ensure the balance of donors-researchers interests is to provide into the legislation the obligation of the biobank manager, upon obtaining the informed consent of the donor, to propose to him/her the choice of consent form to be given, for which he/she should be available to make a conscious decision about the form after getting an explanation of all the risks and consequences of each of these informed consent forms. And, in addition, it seems appropriate to provide in the special legislation a rule, that in case of choosing a dynamic consent, the donor is obliged to inform the manager about changes of his contact information within a reasonable time. It is also necessary to regulate the consequences of breach of such donors obligation, in particular to give to the biobank manager, after the expiration of the legal term, the right for unilateral samples disposal, on the same time the biobank manager will be obliged to impersonate (anonymize) the donors personal data.

Informed consent as a condition for biological material and personal data legal obtaining is an important legal fact without which in most cases relationships regarding the creation and use of biobanks could not have arisen. However, it should be understood that such an obtaining may occur in different ways, which also determines the specific legal regulation of consent procedure. In particular, biological material and data may be obtained as a result of diagnostic or therapeutic measures for a person having the patient status. In this case a person consents to intervention according to Art. 42-45 of the Fundamentals of the legislation of Ukraine on health care, and the consent for the further use of biological material and data, obtained for purpose of medical care and its transfer to the biobank may be provided by the person at the same time with the consent to diagnostic and/or therapeutic intervention, or after obtaining, if at that moment the possibility of such transfer could not have been prognosticated. The rule, which can be applied for such consent is in particular Art. 14 Abs. 10 of the new Transplantation Law, but its effect is limited because it only extends to obtaining consent for the use of such biological material for the manufacture of bioimplants, but not for the scientific use etc.

Instead, a person's consent to the removal of biological material and gaining data for the primary and sole purpose of transferring it to a biobank is of a completely different nature and is governed by other rules. In particular, if it concerns the removal of biological material for the purpose of realizing a person's non-property right to donate, and therefore for the transplantation or production of bioimplants, the procedure for such removal, including the procedure for obtaining informed consent of the donor, is governed by the Transplantation Law, in particular section 3. If a person decides to transfer biological material and/or data to the research biobank - then it can be stated that there is no legal regulation of these relations in Ukraine today. In this case, we can only apply the general aforementioned rules of the Basics of the Ukrainian legislation on health care regarding the conditions of admissibility of medical intervention. The same applies to the removal of biological material for transfer to personal storage and use. However, in our opinion, the issue of informed consent in these cases, namely in relation to the transfer of biological material to the biobank, requires special legal regulation, which should be contained in a special law.

Therefore, informed consent in the researched relationships is not only a condition for the proper obtaining of the biological material/data, but also a condition for its legal use. Therefore, in our opinion, it is important to consider the legal nature of informed consent from a civil law perspective. This is a debatable issue in the science of civil law, but the need to research it is driven by the need to determine the conditions that must be met for such consent to be valid.

In German civilistic doctrine, there are three approaches to determining the legal nature of informed consent, namely, referring it to unilateral acts, to legal or factual actions. Consider the argumentation of these three approaches. In the first place, the assignment of informed consent to unilateral transactions is justified by the fact that it can be considered valid only when all the requirements for the validity of the legal transaction are fulfilled [17, p.62, 66, 148]. However, such an approach, which fully identifies informed consent with the legal transaction, has over time been criticized, and representatives of such a «softened» position have expressed the view that the assignment of informed consent to the legal transaction does not mean that the application of the rules to the validity of the legal transaction is always mandatory [11, p.133; 10, p.204,212,214; 6, p.958]. In particular, rules on the representation of the interests of underages by their legal representatives in the case of informed consent for medical intervention, ie in the field affecting personal non-property rights (dignity, physical integrity, etc.), these rules, unlike property rights, can not be subject unconditional application, since in this field the underage person is already in some cases able to understand the meaning of his actions and able to make his own decisions [11, p.134-135]. Some researchers also point out that when informed consent is provided in an area that is closely related to the person granting it, the right to self-determination is of particular importance, and it is therefore necessary to verificate the compliance of this consent with the provisions on the validity of the legal transaction [3, p.54]. Other scientists, who support referring informed consent to the legal transaction indicate that when applying the rules relating to legal transactions in this case, the so-called «theological amendment» should also be made in isolated cases [10, p.205].

There is also no unity in how to interpret the interference within the individual's non-property rights. In particular, since informed consent is a binding refusal of a person to make claims for damages in the future (after intervention), they are treated as forgiveness or pectum de non petendo. However, such an approach is limited only by the possibility of a person refusing to apply the substantive effects of the intervention, in particular in the form of compensation for harm, without extending to the non-material sphere [5, p.10; 7, p.142]. Other scholars who deny this understanding of the legal nature of the intervention say that it is a fiction to believe that the parties of such a legal transaction have the intention of renouncing such legal consequences. Instead, the content of the consent is to grant permission, and the consequences in the form of damages are usually not even considered by the parties of the legal transaction [17, p.54]. However, such consent excludes only the legal consequences of intentional misconduct and not the illegality of the intervention itself [5, p.12]. Other proponents of this theory view informed consent as a one-sided legal transaction

that excludes the illegality of the intervention itself [3, p.50; 10, p.197; 9, p.200-201]. In the context of the Ukrainian legislation, if the informed consent is interpreted as a unilateral legal transaction, in accordance with Art. 222 Abs.5 of the Civil Code of Ukraine, the general provisions on obligations and contracts will be applied to the legal relations arising from such legal transaction, if this is not contrary to the civil acts or the legal nature of the legal transaction itself. Such wording makes it perfectly possible, in cases which have been identified, not to apply these provisions if this is contrary to the nature of the legal transaction, as an argument to deny the extension of informed consent to the transaction rules.

Proponents of referring informed consent to legal actions rather than to deeds, justify their position that it is aimed to grant a permission to intervene in the personal sphere of the individual (consent to the risks to life, health, the possibility of encroaching bodily integrity, personal integrity of the person), and therefore the norms of a person's civil capacity as a condition of the validity of his or her will can be applied only in certain cases by analogy. The objection to the legal nature of informed consent as a legal transaction can also be found in German case law. In particular, BGHZ 29.33 stated that informed consent to intervene in a person's body was not a willful expression of a legal transaction, since it was not a matter of consent in the context of a binding right, but was a matter of permission or authorization to commit factual actions, that will interfere with the legal field of the authorizing person (affecting his or her rights and interests). Non-property benefits such as life, bodily integrity and dignity will be protected against the encroachment of third parties. However, these non-property benefits will not be the subject of the right of their bearer, and the bearer of these rights will not be empowered to dispose of them freely, like he can dispose of the thing or property right belonging to him [1]. This position has received widespread support in german science, and therefore informed consent is now generally regarded as a legal act, which is defined as a statement (declaration) of a person aimed at factual rather than legal consequences, and legal consequences do not arise. from the will of the authorizing person, but from the norms of the law that establishes them [5, p.15].

The minority of informed consent legal nature scholars are supporting its interpretation as factual action. Proponents of this position deny that informed consent is attributable to the legal transaction, because it does not create, modify or terminate civil rights and obligations [12, p.24]. In particular, its granting is not a ground for the right of another person to interfere with the rights of the grantor, as consent may be revoked by that person at any time [2; 4 ; 12, p.30-31]. The justification for the occurrence of rights to violate a person's non-pecuniary rights based on the provision of informed consent in their opinion is void. The objection to the legal nature of informed consent as a legal act is justified by the fact that it would be admissible only if such consent resulted in the appearance, termination or alteration of the right of the person granting it, which in their opinion does not occur in the case of informed consent. In particular, according to one of the supporters of the factual nature of the informed consent, Schenke W., it is a legal act sui generis, whicht eliminates the fact of illegallty of the act (intervention). Deutsch E., on the other hand, sees the informed consent as a rejection of the rights protection, which is a reason for liability exclusion for such an action.

If we analyze the approaches to the legal nature of informed consent in Ukrainian civil science, it should be noted that recent studies, for example, about consent to participate in clinical trials, express a position on its contractual nature, since a number of mutual rights and obligations of the researched person and researcher arise from the subject, at the same time, researchers emphasize its bilateral, consensual, term and in some cases remunerative nature [18, p.45]. Other researchers for informed consent for medical or diagnostic intervention indicate that such consent is a legal fact that creates a civil relationships between a patient and a health care institution, distinguishing two of its functions - informative and protective [19, p.79].

In our opinion, providing informed consent for the removal of biological material for the purpose of transferring it to a biobank for foreign use, as a result of which the person loses personal connection with this biological material is a unilateral transaction, as a result of which the person transfers the right to dispose of his own biological material to the biobank manager. If the transfer to the

biobank does not involve loss of personal connection and the person retains the right to dispose of his biological material, this is a legal act by which the person authorizes the biobank manager to take certain actual actions against it (its processing, storage, transfer for use, etc.) to the extent authorized by the right holder.. With regard to the possibility of treating informed consent as a contract in the case of transfer of biological material for research purposes, in our opinion, in this case it is impossible to say that such consent implies mutual rights and obligations, as is the case with the direct participation of a person in clinical trials. Therefore, in this case, we consider it appropriate to apply the same approach as stated above, depending on whether or not a personal connection with the biological material is lost.

Therefore, one of the most important components of the right to self-determination of a probant (person, who disposes his or her biological material and/or personal data to the research biobank) to ensure his autonomy is the right to express his will, that is, to provide informed consent for the transfer of his biological material and personal data to the biobank. Informed consent is one of the key principles in bioethics, and it applies not only in scientific and medical experiments, but also applies to all human health interventions, that also logically extends to the relationships between the probant and the researcher, since the researcher has direct signs of interference with the probant's health.

Therefore, we propose to consolidate and regulate this right in a separate article of a special law, outlining it as follows:

"The informed consent of the probant / authorized person is obtained prior to the transfer of his biological material and personal data to the biobank. The probant has the right to give the general informed consent to the use of all his biological materials and personal data in future studies, which relieves the biobank manager to obtain informed consent from the probant for any upcoming individual research that could not be foreseen at the time of obtaining consent.

If the probant does not have sufficient capacity (incapacitated, minors) informed consent to the transfer and use of his biological material and personal data is provided by the authorized person, except when there is a written order of the incapacitated probate, which confirms for future his/her consent or refusals to participate in such research (the so-called medical will).

Samples of biological material for scientific research may only be taken from a person who cannot give informed consent, provided that such a probant has been informed in advance, in an accessible form in the presence of his or her legal representative, about all the important circumstances and risks, after which he clearly did not refuse to be a probant, which must be certified in writing by a legal representative.

The collection of biological material, which requires the surgical intervention, may be carried out by a minor or incapacitated probate only in his own interest.

The informed consent of the probant or, in cases established by law, the person authorized to do so is valid only on condition that the biobank manager fulfills the obligation of clarification, and must be done in written form.»

Such wording of this norm fully meets the requirements for consent to medical intervention, which are set out in Art.43 Abs.1 of the Fundamentals of the legislation of Ukraine on health care, including the peculiarities of providing informed consent by legal representatives of minor children and incapacitated persons. The peculiarity of the proposed norm is that probant is not always a patient, since it is also possible to study biological materials of healthy individuals, and the transfer of biological materials for research is not always accompanied by medical intervention.

Although it should be emphasized that research on juveniles and incapacitated persons can be conducted only in the interests of such persons (for the purpose of diagnosis or treatment of certain diseases, they have), which excludes the possibility of researching biological materials of healthy minors or incapacitated persons, and therefore the feature of this category of probants will be that by their legal status they will simultaneously be patients.

Also a feature of the proposed wording in comparison with the aforementioned provision of Art. 43 of the Fundamentals of the legislation of Ukraine on health care is that, in the light of German experience, we consider it necessary to clarify not only the legal representative, but also the represented person in an accessible form for

his/her understanding, with the aim of avoiding the possibility of such research and the gaining of biological material contrary to the will of such persons and ensuring respect for their dignity.

It should also be emphasized that the proposed wording outlines the dual legal nature of the biobank as a combination of biological material and probant's personal data. This means that a mandatory part of the informed consent of the probant is his consent to the processing of his personal data by the biobank manager, which provides the need to indicate in the text of this consent about the method of such processing and its consequences, namely when it comes to pseudonymization of the probant's data, then personal relation with biological material is retained and feedback from the researcher is possible, for example in the case of reporting the results of the study or the identification of important additional findings.

It is also possible for a probant to exercise his/her right to cancel previously given informed consent in totaly or partialy, at a time when the impersonation (anonymization) of the probant's personal data means the loss of his personal connection with his biological material, and therefore the impossibility of exercising the abovementioned right. Therefore, it is important to include this information into the informed consent, which will ensure that the probant is fully informed and that the biobank manager can refer to the text of his informed consent as a written proof.

In the context of the peculiarities of the personal data processing, based on the content of the purposed rule, namely that biological materials of minors and incapacitated persons can be reserched only in their interests, it can be concluded that the personal data of such persons cannot be anonymized, since in such a case the interests of such individuals will not be secured as feedback and communication about the results of such studies becomes impossible. Therefore, it is understandable that for this category of probants, only pseudonymization is a possible way of processing personal data.

It should also be emphasized that, in terms of the scientific and research activity freedom, it is very important, as it was written in part one of this article, to provide the probant with the so-called general consent to the use of his biological materials in future research. This, firstly, enables the probant to exercise his/her autonomy right of self-determination by granting such broad consent, and secondly, absolves researchers from the sufficiently burdensome duty to obtain the informed consent of the probant each time they need to examine samples for the purpose, which couldn't have been foreseen at the time of obtaining consent. It is understandable that science is developing and there will be always a need for new researches, and if the general consent was not provided as an option in the legislation, this would automatically mean that a biobank created for some specific purpose would be subject to abolishment after its achievement, or it would also require consent from all the probants for further research, which would significantly limit scientific activity or make it even impossible. However, when granting such general consent to future investigations by the probant, he shall not lose the right to withdraw such consent at any time without explanation, except for exceptions provided by law. Therefore, this provision is one of the elements that aim to balance the autonomy right of the probant with the freedom of scientific and research activities.

Conclusions.

1. It is suggested, that the most appropriate to ensure the balance of donors-researchers interests is to provide into the legislation the obligation of the biobank manager, upon obtaining the informed consent of the donor, to propose to him/her the choice of consent form to be given, for which he/she should be available to make a conscious decision about the form after getting an explanation of all the risks and consequences of each of these informed consent forms.

2. It was purposed to provide in the special legislation a rule, that in case of choosing a dynamic consent, the donor is obliged to inform the manager about changes of his contact information within a reasonable time. It is also necessary to regulate the consequences of breach of such donors obligation, in particular to give to the biobank manager, after the expiration of the legal term, the right for unilateral samples disposal, on the same time the biobank manager will be obliged to impersonate (anonymize) the donors personal data.

3. Providing informed consent for the removal of biological material for the purpose of transferring it to a biobank for foreign use, as a result of

which the person loses personal connection with this biological material is a unilateral transaction, as a result of which the person transfers the right to dispose of his own biological material to the biobank manager. If the transfer to the biobank does not involve loss of personal connection and the person retains the right to dispose of his biological material, this is a legal act by which the person authorizes the biobank manager to take certain actual actions against it (its processing, storage, transfer for use, etc.) to the extent authorized by the right holder. The same concept, depending on whether or not a personal connection with the biological material is lost, is appropriate to apply also for informed consent to biological material/data transfer for research purposes.

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