

TOPICAL ASPECTS OF MODERN SCIENTIFIC RESEARCH



**PROCEEDINGS OF III INTERNATIONAL
SCIENTIFIC AND PRACTICAL CONFERENCE
NOVEMBER 23-25, 2023**

**TOKYO
2023**

TOPICAL ASPECTS OF MODERN SCIENTIFIC RESEARCH

Proceedings of III International Scientific and Practical Conference

Tokyo, Japan

23-25 November 2023

Tokyo, Japan

2023

UDC УДК 347.12(477)

**THE ESTABLISHMENT AND USE OF BIOBANKS IN UKRAINE: IN
TERMS OF MEDICINE AND THE DEVELOPMENT
OF THE INNOVATION ECOSYSTEM**

Rohovets Olha Volodymyrovna

The obstetrician-gynaecologist of the highest qualification category,
medical center "Dobrobut"

Urazovska Olha Serhiivna

The Deputy Head of the Innovation Ecosystem Development Department of
the Division for Development of Innovations of the IP Office

Annotation: the main principles of development, creation and use of biobanks in Ukraine in terms of medicine and development of the innovation ecosystem are considered. It is discovered that the relations concerning the creation and use of biobanks, due to their novelty and combination of legal, medical and ethical aspects of their implementation, and the sphere of economic and moral rights of physical persons require a detailed and comprehensive legal regulation. The mission is outlined: one of the tools for building a strong state is the development of an innovation ecosystem to preserve and enhance the country's gene pool, especially during wartime and post-war.

Key words: biobank, biological material, donor, biomedical research, contract on personal storage of biological material, personal data protection, reproductive rights.

At the beginning of the twentieth century, bolshevism and fascism engulfed the countries of Europe. The fate of millions of people depended on dictators. Socio-political pressure encouraged the elimination of a huge proportion of the Ukrainian population, which led to a change in the gene pool, due to the fact that this proportion was excluded from the process of population reproduction and did not take part in reproduction. Every Ukrainian generation underwent socio-political

"cleansing" (i.e., the elimination of a large part of the Ukrainian population): World War I, the Civil War of 1918-1920, the Famine of 1922-1923, 1932-1933, World War II, the Famine of 1946-1947, losses in Afghanistan, the Chernobyl disaster of 1986, the depopulation of 1993-1999, losses related to the war in Ukraine from 2014 to the present (especially after 24 February 2022). All these events comprise genocide against the future generation of Ukraine, since adolescents, children, women and men of reproductive age were killed [1].

In December 2022, the Verkhovna Rada adopted Law No. 2834-IX "On the Basic Principles of the State Policy in the Field of Ukrainian Nation and Civil Identity Building". This Law specifies the peculiarities of the formation and implementation of the state policy in the field of establishing the Ukrainian national and civic identity as a component of ensuring the national security of Ukraine. The Explanatory Note to the law indicated: "The existence and prosperity of the Ukrainian state is impossible without a general awareness of citizens of their civic identity... The entirety of all individuals who underwent such self-determination is the indispensable foundation for the formation of a powerful civil society, a strong nation and a robust state" [2].

To preserve the Ukrainian national and civic identity, especially during the war, it is essential that biobanks are being created and developed in Ukraine as part of the healthcare system infrastructure. Meanwhile, the healthcare system influences the development of the innovation ecosystem via its research and developments, the emergence of new knowledge, the advancement of high-tech production and the creation of mass innovative products. For the dynamic development and success of the state, preserving the gene pool, ensuring the security and sovereignty of the state, and its competitiveness in the modern world, it is crucial to promote the development of activities with high knowledge intensity (such as medicine), namely, it is necessary to move from a low-tech resource-based to a high-tech innovation economy.

It is significant to emphasize that the concept of a biobank should be interpreted in a broad sense, as biobank managers can be either business entities (commercial biobanks) or non-profit organizations (public biobanks), and the latter

are mainly established in the form of charitable foundations or at scientific (research) institutions and/or by individual scientists or groups of scientists in the field of healthcare, essentially for the purpose of conducting research, diagnostic and/or therapeutic purposes; their activities will not only be subject to licensing but also to bioethical examination and intensified control by the state through the authorized bodies.

Biobanks are repositories designed for storing human biological material. At both the international and national levels, there is a problem with legal regulation of biobank activity due to the imperfection of legislation and a lack of legal acts that would comprehensively regulate the activities of biobanks, taking into consideration the specifics of such activities. Biobanks, as a set of biological materials and personal data, including genetic data, can be used both in research and personalized medicine, for transplantation or the manufacture of bioimplants. Services for the storage of biomaterials under civil law contracts with individuals to meet their personal needs. In fact, such biobanks, managed by private (commercial) entities, are currently the most common in Ukraine.

It is worth noting that biobanks should be accessible to all interested individuals and servicemen should have a mandatory procedure for the sampling and storage of biological material prescribed by law. Thus, the Verkhovna Rada of Ukraine adopted in the first reading the Draft Law No. 8011 "On Amendments to Certain Laws of Ukraine to Ensure the Rights of War Participants to Biological Post-Traumatic Fatherhood/Motherhood" dated 08.09.2022, which allows for the possibility at the state level to establish the right to sampling and using germ cells by the Ukrainian military if they have lost their reproductive function due to injury, trauma or concussion. A new concept - post-traumatic motherhood/paternity – is being introduced; the possibility of sampling not only reproductive cells but also tissues is covered; funding for the above measures, as well as the choice of healthcare institutions for sampling biological material, are prescribed. If the law is adopted, it will apply not only to servicemen but also to the National Guard, the Security Service of Ukraine and police officers performing official tasks in the areas of military

operations. Namely, they will be granted the right to free sampling, conservation and storage of reproductive cells [3]. However, the draft law does not specify the organizational component: how will the state organize the mass donation of reproductive cells by servicemen? When and in which order will the biological material be sampled/donated? Should this procedure take place when joining the ranks of the defenders at once for all without any exception as a mandatory one, or is it optional, or before being dispatched to the war zone before or after special training? And, whether the method of sampling biological material in a military unit is legitimate and expedient, which in turn limits, and even more so, makes it impossible to access all biological material that can be used in assisted reproductive technology (hereinafter - ART) in the future... and who should go to the military unit, give permission for this procedure, where the biological material should be stored, etc. What guarantees will the state provide if it initiates this process? Numerous issues arise and in order to address them, it is necessary to establish a coordination center between the Ministry of Defence of Ukraine and the Ministry of Health of Ukraine.

According to part 1 of Article 290 of the Civil Code of Ukraine, a capable natural person of age shall have the right to be the donor of blood, its components, as well as organs, other anatomic materials and reproductive cells. Since the law grants a person the right to donate his or her biological material, the legal status of a donor in the context of biobanks needs to be improved. It is necessary to implement provisions in the legislation that will enable donors to exercise their rights to respect for human dignity, information, autonomy and protection of personal data [4].

The procedure for the sampling and storage of biological samples and related information for research requires special legal regulation. Informed consent is one of the basic principles of human biological sampling. At present, the current legislation does not provide for the state measures introduction to ensure maternity/paternity in case of the death of Ukrainian defenders. The legislative non-regulation of this issue has posed an acute problem for the Ukrainian legal system. There is a need to develop a procedure for the postmortem (posthumous) use of biological materials from perished soldiers. This can be accomplished at the level of bylaws. It is

important to regulate the circle of persons and establish the period during which gametes and embryos of dead patients are allowed to be managed; develop standard forms of applications from the patient/patients that will be subject to mandatory notarization before the procedure of conservation of biological material. It will also stipulate the terms of its use in case of death.

It is worth noting that in accordance with the Law of Ukraine "On State Registration of Human Genomic Information", "The Procedure for Sampling Biological Material from Military Servicemen, Police Officers, Private and Senior Civilian Personnel of the Civil Protection Service and its Storage" was adopted to regulate the mechanism and terms of sampling biological material from military servicemen, police officers, private and senior civilian personnel of the civil protection service and its storage for conducting state registration of human genomic information. The sampling of biological material from military servicemen, police officers, private and senior civilian personnel of the civil protection service is carried out: on the basis of an application for sampling biological material and written consent to the processing of personal data, which are attached to a paper envelope together with the package containing the biological material; mandatory in case of the declaration of martial law in Ukraine or in certain areas of Ukraine. The sampling of biological material during martial law is conducted within the timeframe established by the Law of Ukraine "On State Registration of Human Genomic Information". Biological material is sampled using means (systems) for sampling biological specimens intended for long-term storage. The storage period of the collected biological material shall not exceed the storage period established by the manufacturer of the means (systems) for sampling biological samples. In case of termination of the contract (dismissal from service) of servicemen, police officers, private and senior civilian personnel of the civil protection service, the biological material is returned to these persons, as indicated in the register [5].

A crucial matter is the preservation of fertility - the reproductive potential for women defenders, which should be accomplished with the help of [6].

- oocyte cryopreservation (with improved use of cryoprotectants and the

introduction of the ICSI infertility treatment method (this method involves the introduction (intracytoplasmic injection) of a sperm into an oocyte in an in vitro fertilization (IVF) program and the transfer of embryos into a woman's uterine cavity);

- cryopreservation of ovarian tissue and maturation of follicles and oocytes in vitro (an alternative approach is the cryopreservation of ovarian tissue pieces or biopsies containing a lot of immature, dormant oocytes. The maturation of which, under in vitro conditions, is possible if the issue of their cultivation and subsequent use for fertilization and induction of pregnancy is addressed. Nevertheless, this method also needs to be improved);

- original ovarian tissue (thawed original pieces may be transplanted either into the patient's preserved ovarian portion or into an ectopic spot. In medical practice, successful attempts at autotransplantation of human ovarian strips after cryopreservation have been published, but folliculogenesis is restored only for a short time due to the fact that a limited number of oocytes can survive).

The main challenges of oocyte cryopreservation [7, 8]:

- To maintain the ability of oocytes to fertilize;
- Support the preservation of genetic material for the creation of a genetically healthy embryo.

For male defenders, it is necessary to provide for the preservation of fertility and reproductive potential with the aid of:

- preservation of testicular tissue (cryopreservation of testicular tissue);
- Cryopreservation of large amounts of sperm (ejaculate): a highly successful, painless, atraumatic, widespread and realistic practice.

The issue of preserving embryos of couples in which one or both spouses are servicemen and women, with the subsequent use of embryos by the wife in case of disability or death of the husband and by the husband for surrogacy in case of injury/disability or death of the wife, remains open.

Considering the realities of today - wartime and all the ramifications connected with military operations - stem cell preservation and therapeutic cloning for the

treatment of degenerative diseases and repair of damaged tissues are issues of utmost importance. However, it is much more complicated to obtain a stem cell line in humans, so many problems and challenges will need to be addressed before stem cell therapy can be implemented into practice.

Each person's body contains so-called stem cells, which are capable of differentiating ("transforming") into cells of any organ or tissue of our body at the appropriate moment to repair its damaged cells. An organism of an adult contains such cells but in very small quantities. At the same time, hundreds of scientific studies and dozens of clinical trials have already been conducted, proving that the introduction of stem cell medicine allows for the treatment of many severe diseases.

Umbilical cord blood contains the largest number of stem cells. If the umbilical cord blood is sampled at the time of birth, stem cells can be extracted from it and stored in the Cryobank for an unlimited period of time. Cord blood sampling is a simple and quick procedure performed by an obstetrician after cutting the umbilical cord. Thus, it is safe for both a baby and a mother. The blood is gathered in a special collection kit. After cord blood preparations, stem cells remain, which are placed in a special container. Containers, in turn, are placed in collections where the cells can be stored until they are needed. The entire process should be performed in accordance with the relevant quality standards. Stem cells derived from the umbilical cord blood, as well as bone marrow and peripheral blood cells, can be stored in liquid nitrogen vapor (-196°C) for more than 50 years after the addition of cryoprotectants (substances that prevent damage to biological objects during their freezing and subsequent thawing). In recent scientific publications by Professor H. Broxmeyer, the President of the American Society of Hematology and one of the pioneers in the use of umbilical cord blood, it refers to the use of stem cells from umbilical cord blood that have been stored for 24 years. More than one million cord blood units have already been sampled worldwide in family and public banks [9].

Summary. In light of the aforementioned, it is the innovation potential that must drive economic growth and contribute to the development of all sectors of the economy, including healthcare. Ukraine has a number of competitive advantages

(market capacity, innovation ability, availability of educated personnel, etc.) that allow it to produce intellectual products and scientific and technological innovations successfully.

The basis of Ukraine's innovation competitiveness should be the knowledge and results of scientific research. Their effective implementation in Ukraine with the possibility of entering the world markets will contribute to the development of the state, and the main objective is to rebuild Ukraine in the post-war period with minimal loss of the Ukrainian gene pool.

Having a goal, by organizing the legal framework, studying the shortcomings and improving the methods, we have a prospect to prolong the gene pool of the nation!

LITERATURE:

1. Sluzhynska Z., Kalyniuk P. The impact of environmental and socio-political factors on the gene pool of a population. URL: <http://dspace.nbuv.gov.ua/bitstream/handle/123456789/73451/12-Sluzhynska.pdf?sequence=1>.
2. The Law of Ukraine "On the Basic Principles of the State Policy in the Field of Ukrainian Nation and Civil Identity Building" URL: <https://zakon.rada.gov.ua/laws/show/2834-20#Text>.
3. The draft law "On Amendments to Certain Laws of Ukraine to Ensure the Rights of War Participants to Biological Post-Traumatic Fatherhood/Motherhood" URL: <https://itd.rada.gov.ua/billInfo/Bills/Card/40292>.
4. The Civil Code of Ukraine. URL: <https://zakon.rada.gov.ua/laws/show/435-15#Text>.
5. The Law of Ukraine "On State Registration of Human Genomic Information", URL: <https://zakon.rada.gov.ua/laws/show/2391-20#Text>.
6. A woman's health from A to Z. Preservation of fertility at different ages. A series of training seminars. URL: <https://gynecology091023.ticketforevent.com/>.
7. Dakhno F. V., Yuzko A. M., Kaminskyi V. V. Auxiliary reproductive