Medicinska istraživanja Vs naučna istraživanja u oblasti zdravstva

Medical Research Vs Health-Related Scientific Research

JPM | PARTNERS

Medicinska istraživanja Vs naučna istraživanja u oblasti zdravstva/ Medical Research Vs Health-Related Scientific Research

Publisher: JPM | Partners
Delta House, 8a Vladimira Popovića street
www.jpm.law
Authors: Ivan Milošević ,Partner, Janez Vončona,Senior Associate
Design and prepress: JPM | Partners

Razumevanje značenja termina u semantičkom i teleološkom kontekstu je preduslov za pravilnu primenu propisa. Izazov u razumevanju termina je još veći ukoliko je reč o specifičnim terminima u različitim industrijama. U ovom članku se razmatraju značenja termina „medicinsko istraživanje“ i „naučno istraživanje u oblasti zdravstva“ iz razloga što je na prvi pogled reč o sinonimima, a zapravo se radi o dve potpuno različite vrste istraživanja.

Postoje razlike u načinu sprovođenja ove dve vrste istraživanja i ciljevima koji se sprovođenjem ovih istraživanja postižu. Odsustvo jasnih pravila i nepostojanje sudske prakse u ovoj materiji dovode do teškoća u radu istraživača i zdravstvenih radnika, ali i u određivanju nadležnosti organa i tela za kontrolu ovih istraživanja

Understanding of the terms in their semantic and teleologic context is a precondition for correct application of regulations. The challenge in understanding of the terms is even more significant in cases of specific terms in various industries. The subject of this article is to address the meaning of the terms „medical research“ and „health-related scientific research“, as those terms are seemingly synonyms, but we are in fact dealing with two completely different types of research.

There are differences in terms of manners of conducting these two types of research and goals to be achieved through conducting of the respective research. Absence of clear rules and non-existence of court practice in this area lead to difficulties in the work of researchers and healthcare workers as well as in determination of competencies of the authorities and bodies, when it comes to performing control over such research.

Dokumenti međunarodnih organizacija i tela

U tački 1 Preambule Helsinške deklaracije Svetske medicinske asocijacije – Etička načela medicinskih istraživanja na ljudima se navodi da se ovim dokumentom uspostavljaju etička načela za medicinska istraživanja na ljudima, uključujući istraživanja koja koriste prepoznatljive ljudske materijale ili podatke. Iz navedene formulacije može jasno da se zaključi da postoje sa jedne strane, medicinska istraživanja na ljudima koja uključuju primenu određenih medicinskih protokola u pružanju zdravstvene zaštite ljudima i sa druge strane druge vrste istraživanja koja uključuju istraživanja na biološkim materijalima i podacima o zdravlju pacijenata.

U uvodu, na strani 3 Smernica Veća za međunarodne organizacije medicinskih nauka sa sedištem u Ženevi iz 2016. godine („Smernice CIOMS“), je navedeno da istraživanja u oblasti zdravstva (health-related research) uključuju biomedicinska, epidemiološka, iskustvena i istraživanja u oblasti društvenih nauka, koja uključuju ljude.

Documents of international organizations and bodies

The item 1 of the Preamble of the Helsinki Declaration of the World Medical Association – Ethical Principles of Medical Research on Humans states that the purpose of this document is to establish ethical principles of medical research on humans, including research that use recognisable human materials and data. From the subject formulation it follows that there are, on the one hand, medical research on humans that encompass application of certain medical protocols in providing healthcare protection to people and, on the other hand, other types of research that encompass research on biological materials and data on the patients' health status.

In the introduction, on the 3rd page of the 2016 Guidelines of the Council for International Organizations of Medical Sciences (CIOMS), headquartered in Geneva ("CIOMS Guidelines"), it is stated that health-related scientific research include biomedical, epidemiological, experiential and social science research involving humans.

Smernica 10 istog dokumenta (Istraživanja koja uključuju biološke materijale i odnosne podatke) obuhvata istraživanja koja koriste ljudske uzorke i podatke, a što ne uključuje pružanje zdravstvene zaštite učesnicima u istraživanju.

Smernice za prikupljanje i izveštavanje o podacima u istraživanju i eksperimentalnom razvoju Organizacije za ekonomsku saradnju u razvoju (OECD Frascati Priručnik) iz 2015. godine, u Poglavlju 2.7.1 – Polja istraživanja i razvoja (FORD) navode da medicinske i zdravstvene nauke obuhvataju kliničku medicinu, zdravstvene nauke, medicinsku biotehnologiju i druga srodna polja.

OECD Frascati Manual (2015) jasno razdvaja:

1. osnovno istraživanje: usmereno na sticanje novog znanja bez neposredne primene;
2. primenjeno istraživanje: usmereno na konkretan cilj ili praktičnu primenu, uključujući razumevanje bolesti, identifikaciju biomarkera, razvoj dijagnostičkih metoda itd.;
3. eksperimentalni razvoj: koristi postojeće znanje za stvaranje novih proizvoda, procesa ili usluga.

Guideline 10 of the respective document (Research involving biological materials and related data) covers research that uses human samples and data, which however does not involve provision of healthcare protection to participants of the research.

Guidelines for collecting of and reporting on data in research and experimental development of the Organisation for Economic Co-operation and Development (OECD Frascati Manual) of 2015 envisage in the Chapter 2.7.1. – Field of research and development (FORD) that medical and health science encompass clinical medicine, health science, medical biotechnology and other related fields.

The OECD Frascati Manual (2015) clearly distinguishes between:

1. basic research: aimed at acquiring new knowledge without direct application;
2. applied research: directed towards a specific objective or practical application, including the understanding of diseases, identification of biomarkers, development of diagnostic methods, etc.;
3. experimental development: involves the use of existing knowledge to create new products, processes or services.

U okviru oblasti zdravstva, u Frascati Manual se navodi da se R&D aktivnosti (istraživanja i razvoj) mogu sprovoditi u visokoškolskim ustanovama, institutima, pa čak i u bolnicama — ali ne moraju uključivati pružanje zdravstvene zaštite.

Within the field of health, the Frascati Manual states that R&D activities (research and development) may be conducted in higher education institutions, research institutes, and even in hospitals — but do not necessarily include the provision of healthcare services.

Nacionalni propisi

Članom 16 Zakona o potvrđivanju Konvencije o ljudskim pravima i biomedicini („Sl. glasnik RS – Međunarodni ugovori“, br. 12/2010) (Zaštita osoba u istraživanju) propisano je da se istraživanje nad osobom smatra intervencijom, što ukazuje da ne mora uključivati pružanje zdravstvenih usluga.

U članu 1 Zakon o pravima pacijenata (“Sl. glasnik RS”, br. 45/2013 i 25/2019 - dr. zakon) se propisuje da se ovim zakonom uređuju se prava pacijenata prilikom korišćenja zdravstvene zaštite, način ostvarivanja i način zaštite tih prava, kao i druga pitanja u vezi sa pravima i dužnostima pacijenata.

National Regulations

Article 16 of the Law on the Ratification of the Convention on Human Rights and Biomedicine (“Official Gazette of the RS – International Treaties”, No. 12/2010) (Protection of persons undergoing research) stipulates that research involving a person is considered an intervention, which indicates that it does not necessarily include the provision of healthcare services.

Article 1 of the Law on Patients’ Rights (“Official Gazette of the RS”, No. 45/2013 and 25/2019 – other law) prescribes that this law governs the rights of patients when using healthcare services, the manner in which such rights are exercised and protected, as well as other matters relating to the rights and obligations of patients.

S obzirom da je predmet regulisanja ovog zakona regulisanje prava pacijenata prilikom korišćenja zdravstvene zaštite, ovaj zakon u članu 25 uređuje medicinska istraživanja. Ovaj zakon ne reguliše naučna istraživanja u oblasti zdravstva.

Naučna istraživanja u oblasti zdravstva su regulisana članom 59 Zakona o visokom obrazovanju ("Sl. glasnik RS", br. 88/2017, 73/2018, 27/2018 - dr. zakon, 67/2019, 6/2020 - dr. zakoni, 11/2021 - autentično tumačenje, 67/2021, 67/2021 - dr. zakon, 76/2023 i 19/2025) i Zakonom o nauci i istraživanjima ("Sl. glasnik RS", br. 49/2019).

Medicinska istraživanja

Međunarodni dokumenti i nacionalni propisi jasno razdvajaju medicinska istraživanja i naučna istraživanja u oblasti zdravstva. Medicinska istraživanja se sprovode u zdravstvenim ustanovama i u okviru ovih istraživanja se učesnicima pružanju usluge zdravstvene zaštite.

Ova istraživanja su neposredno usmerena na poboljšanje zdravlja pojedinaca i uključuju praćenje zdravstvenog stanja, dijagnostiku, prognozu bolesti i primenu novih terapijskih postupaka.

Given that the subject matter of this law is the regulation of patient rights in the context of healthcare service delivery, Article 25 of the law regulates medical research. However, this law does not govern health-related scientific research.

Health-related scientific research is governed by the Article 59 of the Law on Higher Education ("Official Gazette of the RS", No. 88/2017, 73/2018, 27/2018 – other law, 67/2019, 6/2020 – other law, 11/2021 – authentic interpretation, 67/2021, 67/2021 – other law, 76/2023 and 19/2025), as well as the Law on Science and Research ("Official Gazette of the RS", No. 49/2019).

Medical Research

International documents and national regulations clearly distinguish between medical research and health-related scientific research. Medical research is conducted in healthcare institutions and within the scope of such research healthcare services are provided to participants.

These research activities are directly aimed at improving individual health and involve monitoring of health status, diagnostics, disease prognosis, and the application of new therapeutic procedures.

Klasičan primer za medicinsko istraživanje su klinička ispitivanja lekova i medicinskih sredstava u kojima su pacijenti tokom celokupnog istraživanja pod nadzorom lekara, a zdravstvene usluge se pružaju radi utvrđivanja bezbednosti i efikasnosti terapije.

Isto važi za istraživanja eksperimentalnih terapija, kao i za studije koje uključuju kontinuirano praćenje zdravstvenog stanja pacijenata u cilju unapređenja dijagnostike i prognoze bolesti.

Naučna istraživanja u oblasti zdravstva

Naučna istraživanja u oblasti zdravstva se sprovode u akreditovanim naučnoistraživačkim organizacijama (visokoškolske zdravstvene ustanove i naučni instituti i zdravstvene ustanove koje su akreditovane za sprovođenje naučnih istraživanja).

Predmet ovih istraživanja je razumevanje bioloških, genetskih, iskustvenih i socijalnih komponenti zdravlja i bolesti, radi unapređenja medicinskog znanja koje se kasnije, ukoliko su uspešna (što nije zagarantovano za naučno istraživanje) može primeniti u kliničkoj praksi.

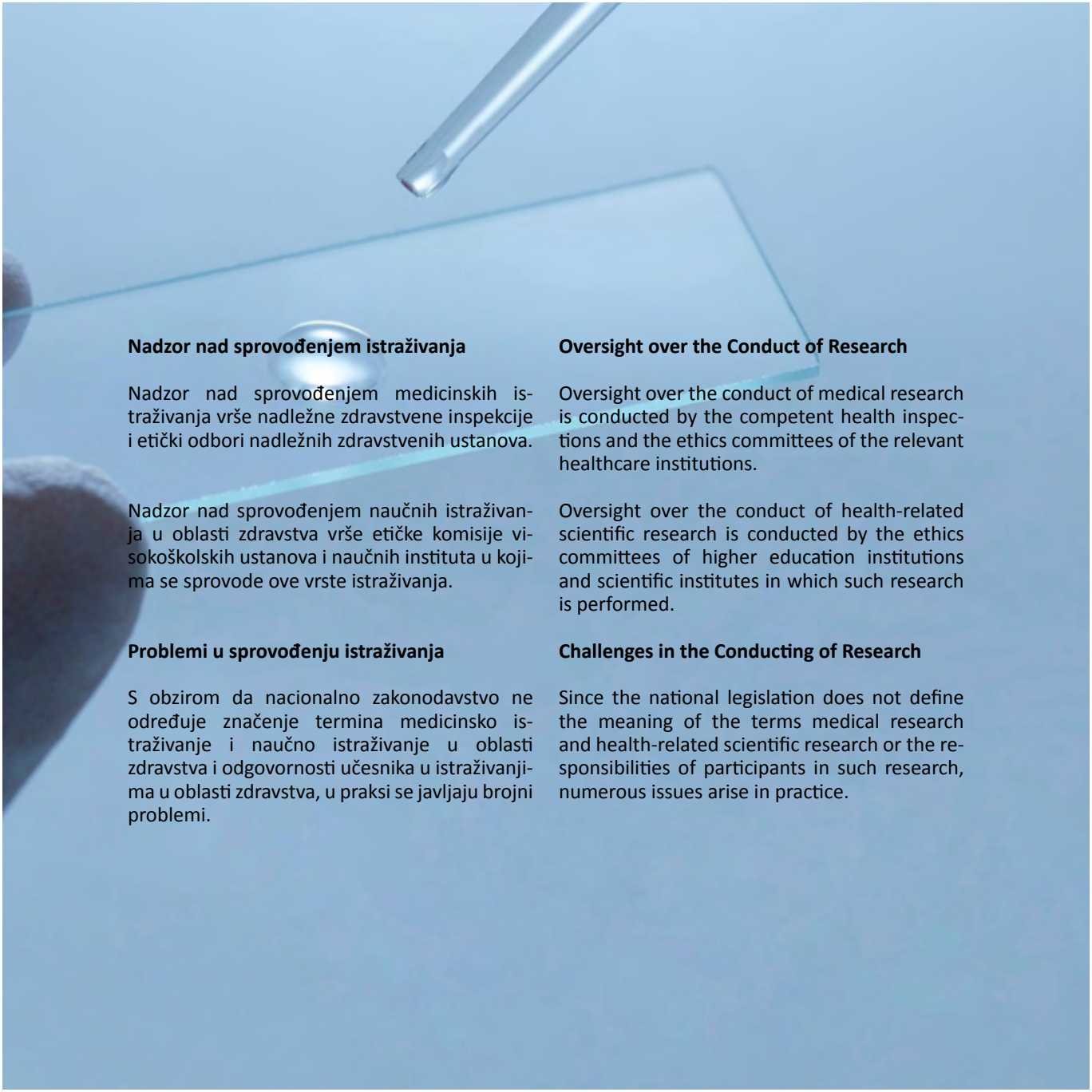
A typical example of medical research includes clinical trials of medicinal products and medical devices, where patients are under continuous medical supervision throughout the entire research process, and healthcare services are provided for the purpose of determining the safety and efficiency of the therapy.

The same applies to research involving experimental therapies, as well as to studies that involve ongoing monitoring of patients' health status for the purpose of improving diagnostics and disease prognosis.

Health-related scientific research

Health-related scientific research is conducted within accredited research organizations (such as higher education health institutions, scientific institutes and healthcare institutions, accredited to conduct scientific research).

The subject of such research encompasses understanding of biological, genetic, experiential and social components of health and disease, with the aim of advancing medical knowledge which, if successful (which is not guaranteed in the case of scientific research), may later be applied inclinical practice.



Nadzor nad sprovođenjem istraživanja

Nadzor nad sprovođenjem medicinskih istraživanja vrše nadležne zdravstvene inspekcije i etički odbori nadležnih zdravstvenih ustanova.

Nadzor nad sprovođenjem naučnih istraživanja u oblasti zdravstva vrše etičke komisije visokoškolskih ustanova i naučnih instituta u kojima se sprovode ove vrste istraživanja.

Problemi u sprovođenju istraživanja

S obzirom da nacionalno zakonodavstvo ne određuje značenje termina medicinsko istraživanje i naučno istraživanje u oblasti zdravstva i odgovornosti učesnika u istraživanjima u oblasti zdravstva, u praksi se javljaju brojni problemi.

Oversight over the Conduct of Research

Oversight over the conduct of medical research is conducted by the competent health inspections and the ethics committees of the relevant healthcare institutions.

Oversight over the conduct of health-related scientific research is conducted by the ethics committees of higher education institutions and scientific institutes in which such research is performed.

Challenges in the Conducting of Research

Since the national legislation does not define the meaning of the terms medical research and health-related scientific research or the responsibilities of participants in such research, numerous issues arise in practice.

Jedan od osnovih problema je kriterijum za određivanje mesta sprovođenja naučnog istraživanja u oblasti zdravstva. Ukoliko se pođe od konstatacije da naučna istraživanja u oblasti zdravstva mogu sprovoditi samo ustanove koje su akreditovane za sprovođenje ovih vrsta istraživanja, te da ugovore o sprovođenju ove vrste istraživanja sa finansijerima mogu da zaključe ove ustanove i da se ova istraživanja sprovode u laboratorijama ovih ustanova, logičan je zaključak da se ova vrsta istraživanja sprovodi u ovim ustanovama i da su istraživači i stručni organi ovih ustanova nadležni za njihovo sprovođenje i nadzor na njihovim sprovođenjem.

Odgovornost stručnih organa ovih ustanova uključuje i izdavanje odobrenja za njihovo sprovođenje. Činjenica da se biološki materijal za sprovođenje ovih istraživanja uzima od pacijenata iz zdravstvenih ustanova ne znači da se ova istraživanja sprovode u zdravstvenim ustanovama.

Naprotiv, ova vrsta istraživanja se i razlikuju od medicinskih upravo po tome što angažovanje zdravstvenih radnika u zdravstvenoj ustanovi ne uključuje pružanje zdravstvenih usluga u okviru njihovog sprovođenja.

One of the fundamental issues is the criterion for determining the venue where health-related scientific research is to be conducted. Starting from the standpoint that such research may only be conducted by institutions accredited for this type of research, that only such institutions may conclude contracts with funding entities and that the research is conducted in the laboratories of those institutions, it logically follows that such research is to be carried out within those institutions, and that the researchers and professional bodies of those institutions are responsible for both its conduct and oversight.

The responsibility of the professional bodies of such institutions also includes issuing approvals for conducting of the research. The fact that biological material used for this type of research is obtained from patients in healthcare institutions, does not mean that the research itself is conducted in healthcare institutions.

On the contrary, this type of research differs from medical research precisely in the fact that the involvement of health professionals within healthcare institutions does not include the provision of healthcare services as part of the research.

Uobičajena je praksa da se biološki materijal koji se koristi u istraživačke svrhe uzima u toku operativnog lečenja pacijenata ili se za istraživanja koristi biološki materijal koji je već nastao u toku operativnog lečenja pacijenata.

Stoga je odgovornost zdravstvenih radnika u sprovođenju ove vrste istraživanja ograničena na pribavljanje informisanog pristanka u skladu sa odredbama pomenute Ovijedo konvencije.

Odgovornosti učesnika u istraživanju se reguliše ugovorom između naučnoistraživačke organizacije i zdravstvene ustanove čiji je sastavni deo i protokol o sprovođenju naučnog istraživanja.

Potpisivanjem ovog ugovora rukovodilac zdravstvene ustanove izjavljuje da je upoznat sa istraživanjem i saglasan sa učešćem zdravstvenih radnika iz te ustanove u istraživanju.

Drugo sporno pitanje se odnosi na rešenja u Zakonu o zdravstvenoj zaštiti.

Zakon o zdravstvenoj zaštiti u delu određivanja obima društvene brige za zdravlje na nivou Republike pominje i „razvoj naučnoistraživačke delatnosti u oblasti zdravstvene zaštite“.

It is common practice for biological material used for research purposes to be collected during surgical treatment of patients, or for research to use biological material that was already generated during such procedures.

Therefore, the responsibility of healthcare professionals in conducting this type of research is limited to obtaining informed consent in accordance with the provisions of the aforementioned Oviedo Convention.

The responsibilities of participants in the research are regulated by a contract between the research organization and the healthcare institution, which also includes the research protocol as an integral part.

By signing this contract, the head of the healthcare institution declares that he is familiar with the research and provides consent to the participation of the institution’s healthcare professionals in the research.

Another problematic issue concerns the provisions of the Law on Healthcare.

In the section defining the scope of public concern for health at the national level, the Law on Healthcare refers to the “development of research activity in the field of healthcare.”

Zdravstvena zaštita obuhvata sprovođenje mera i aktivnosti za očuvanje i unapređenje zdravlja državljana Republike Srbije (u daljem tekstu: građanin), sprečavanje, suzbijanje i rano otkrivanje bolesti, povreda i drugih poremećaja zdravlja i blagovremeno, delotvorno i efikasno lečenje, zdravstvenu negu i rehabilitaciju.

Ovaj zakon definiše zdravstvenu delatnost kao delatnost kojom se obezbeđuje zdravstvena zaštita građana, a koja se sprovodi kroz sistem zdravstvene zaštite.

Sistem zdravstvene zaštite u Republici Srbiji čine zdravstvene ustanove, visokoškolske ustanove koje izvode akreditovane studijske programe za sticanje odgovarajućih znanja i veština za obavljanje poslova u oblasti zdravstvene zaštite (u daljem tekstu: visokoškolske ustanove zdravstvene struke) i druga pravna lica za koja je posebnim zakonom predviđeno da obavljaju i poslove zdravstvene delatnosti, privatna praksa, zdravstveni radnici i zdravstveni saradnici, kao i organizacija i finansiranje zdravstvene zaštite.

Healthcare includes implementation of measures and activities for the preservation and improvement of the health of citizens of the Republic of Serbia (hereinafter: citizen), the prevention, control, and early detection of diseases, injuries and other health disorders, and timely, effective and efficient treatment, healthcare, and rehabilitation.

This law defines healthcare activity as the activity through which healthcare for citizens is provided, and which is implemented through the healthcare system.

The healthcare system in the Republic of Serbia consists of healthcare institutions, higher education institutions that implement accredited study programs for acquiring the necessary knowledge and skills to perform tasks in the field of healthcare (hereinafter: higher education institutions of the health profession) and other legal entities for which it is stipulated by special law that they perform healthcare activities, private practice, healthcare professionals and health associates, as well as the organization and financing of healthcare.

S obzirom da se zdravstvena zaštita građana obezbeđuje kroz sistem zdravstvene zaštite koji čine zdravstvene ustanove, druga pravna lica za koja je posebnim zakonom predviđeno da obavljaju i poslove zdravstvene delatnosti i privatna praksa, a u kojima zdravstveni radnici i zdravstveni saradnici obavljaju zdravstvenu delatnost i visokoškolske ustanove zdravstvene struke koje izvode akreditovane studijske programe za sticanje odgovarajućih znanja i veština za obavljanje poslova u oblasti zdravstvene zaštite, proizilazi da naučnoistraživačka delatnost u oblasti zdravstvene zaštite nužno uključuje i pružanje zdravstvene delatnosti.

Samim tim je i naučnoistraživačka delatnost u oblasti zdravstvene zaštite ograničena na medicinska istraživanja i naučna istraživanja u oblasti zdravstva za koje je odgovorna zdravstvena ustanova koja je akreditovana za njihovo sprovođenje.

Medicinska istraživanja su neposredno usmerena na poboljšanje zdravlja pojedinaca i uključuju praćenje zdravstvenog stanja, dijagnostiku, prognozu bolesti i primenu novih terapijskih postupaka. Sve ove komponente medicinskog istraživanja podrazumevaju pružanje zdravstvenih usluga pacijentima koji učestvuju u istraživanju od strane samim zdravstvenih ustanova.

Given that healthcare for citizens is provided through the healthcare system, which consists of healthcare institutions, other legal entities authorized by special law to perform healthcare activities, and private practice — where healthcare professionals and health associates perform healthcare activities — as well as higher education institutions of the health profession that deliver accredited study programs to acquire the necessary knowledge and skills to perform tasks in the field of healthcare, it follows that research activity in the field of healthcare inevitably includes also the provision of healthcare activities.

Accordingly, research in the field of healthcare is limited to medical research and health-related scientific research, for which the responsibility lies with the healthcare institution accredited to conduct such research.

Medical research is directly aimed at improving individual health and encompasses the monitoring of health status, diagnostics, disease prognosis and the application of new therapeutic procedures. All these components of medical research imply the provision of healthcare services to patients, participating in the research, by the healthcare institutions themselves.

Ukoliko se pođe od konstatacije da su istraživači i stručni organi ustanova u kojima se sprovode naučna istraživanja odgovorni za sprovođenje i nadzor nad ovim istraživanja, nejasno je rešenje u Zakonu o zdravstvenoj zaštiti da etički odbor daje saglasnost za sprovođenje naučnih istraživanja u oblasti zdravstva, medicinskih istraživanja, istraživanja u oblasti javnog zdravlja, kao i da prati njihovo sprovođenje.

Konkretno, postavlja se pitanje da li je etički odbor zdravstvene ustanove nadležan za davanje saglasnosti za sprovođenje naučnih istraživanja u zdravstvenim ustanovama koje su akreditovane za sprovođenje ovih istraživanja ili je nadležan i za davanje saglasnosti za sprovođenje ovih istraživanja u visokoškolskim ustanovama zdravstvene struke i naučnim institutima.

Starting from the standpoint that researchers and professional bodies of institutions in which scientific research is conducted are responsible for the implementation and oversight of such research, the provision in the Law on Healthcare defining that the ethics committee shall give approval for the conduct of health-related scientific research, medical research and public health research, as well as monitor their implementation is unclear.

Specifically, it is unclear whether the ethics committee of a healthcare institution is competent to grant approval for the conduct of health-related research accredited to conduct such research, or whether it is also competent to grant approval for the conduct of such research in higher education institutions of the health profession and scientific institutes.

I da li je, ukoliko je nadležan za davanje saglasnosti u oba slučaja, nadležnost etičkih komisija i odbora visokoškolskih ustanova i naučnih instituta za davanje saglasnosti na sprovođenja ovih istraživanja u skladu sa članom 59 stav 6 Zakona o visokom obrazovanju upitne i nepotrebne ili je samo reč o „preklapanju“ nadležnosti i potrebi da se postigne društveni konsenzus u vezi sa značenjem pomenutih termina i odgovornostima za sprovođenje naučnih istraživanja.

Furthermore, if it is indeed competent in both cases, the question arises whether the competence of ethics committees of higher education institutions and scientific institutes to give approval for the conduct of such research—in accordance with Article 59, paragraph 6 of the Law on Higher Education—is thereby questionable or unnecessary, or whether it is merely about “overlapping” of competences and the need to achieve consensus of the society regarding the interpretation of the aforementioned terms and the responsibilities related to the conduct of scientific research.

Autori/Authors

Ivan Milošević

Partner

E: ivan.milosevic@jpm.law

Janez Vončina

Senior Associate

E: janez.voncina@jpm.law

JPM | PARTNERS
8a Vladimira Popovića,
DELTA HOUSE, V Floor
11070 Belgrade, Serbia
T:+ 381/11/207-6850
E: office@jpm.law

www.jpm.law