

**From:** Eticka komisija <[etickakomisija@med.bg.ac.rs](mailto:etickakomisija@med.bg.ac.rs)>  
**Date:** 18 June 2025 at 13:37:11 GMT+3  
**To:** [aleksandra.z.jotic@gmail.com](mailto:aleksandra.z.jotic@gmail.com), Вера Здравковић <[vera.zdravkovic@med.bg.ac.rs](mailto:vera.zdravkovic@med.bg.ac.rs)>, [gatanasijevic@sbb.rs](mailto:gatanasijevic@sbb.rs), [drhrncic@yahoo.com](mailto:drhrncic@yahoo.com), Викторија Поповић <[viktorija.popovic@med.bg.ac.rs](mailto:viktorija.popovic@med.bg.ac.rs)>, [dejanr09@yahoo.com](mailto:dejanr09@yahoo.com), [dejana1309@gmail.com](mailto:dejana1309@gmail.com), [sasha.kadija@gmail.com](mailto:sasha.kadija@gmail.com), [p.otasevic@yahoo.com](mailto:p.otasevic@yahoo.com), Жељка Станојевић др <[zeljka.stanojevic@med.bg.ac.rs](mailto:zeljka.stanojevic@med.bg.ac.rs)>, [natamax07@yahoo.com](mailto:natamax07@yahoo.com), [dr.koncar@gmail.com](mailto:dr.koncar@gmail.com), [drulovicjelena@gmail.com](mailto:drulovicjelena@gmail.com)  
**Cc:** Sofija Savić <[sofija.savic@med.bg.ac.rs](mailto:sofija.savic@med.bg.ac.rs)>  
**Subject:** Fw: Inquiry Regarding Research Integrity Contact

Поштовани чланови Етичке комисије,  
С обзиром на то да, и поред планираног договора да се седница ЕК одржи у понедељак, 16.6.2025. у 13 часова, није било кворума, а узимајући у обзир период годишњих одмора и професионалне обавезе свих чланова, заказујем електронску седницу Етичке комисије за понедељак, 23.6.2025. године са почетком у 9 ч. Рок за изјашњавање је исти дан до 17 ч.

Дневни ред седнице је:

1. Одговор издавачу MDPI

Молим вас да се изјасните гласањем ЗА, ПРОТИВ или УЗДРЖАН.

Уколико имате примедбе или захтеве за допуну приложеног материјала, молим да их доставите до петка, 20.6.2025. године, при чему користите опцију **REPLY TO ALL**, како бисмо сви имали увид у међусобну комуникацију.

У прилогу се налазе неопходна документа.

Срдачан поздрав,

Софија Савић  
Етичка комисија  
Медицински факултет

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**From:** [djukic@mdpi.com](mailto:djukic@mdpi.com) <[djukic@mdpi.com](mailto:djukic@mdpi.com)>  
**Sent:** Friday, May 23, 2025 11:54 AM  
**To:** Eticka komisija <[etickakomisija@med.bg.ac.rs](mailto:etickakomisija@med.bg.ac.rs)>  
**Subject:** RE: Inquiry Regarding Research Integrity Contact

Dear Ethics Committee Representative,

Thank you for your prompt response.

We have received a formal communication from the Ministry of Health of the Republic of Serbia raising concerns about the ethical oversight and legal compliance of the studies, as stated, associated with the UROMOL project. In their letter, the Ministry asserts that the published studies were not conducted in accordance with applicable national regulations and has requested that MDPI retract all related publications.

Publications in question are listed below:

- [“GSTM1 and GSTP1 Polymorphisms Affect Outcome in Colorectal Adenocarcinoma](#)

- ["The Association of Polymorphisms in Genes Encoding Antioxidant Enzymes GPX1 \(rs1050450\), SOD2 \(rs4880\) and Transcriptional Factor Nrf2 \(rs6721961\) with the Risk and Development of Prostate Cancer"](#)
- ["Polymorphisms of Antioxidant Enzymes SOD2 \(rs4880\) and GPX1 \(rs1050450\) Are Associated with Bladder Cancer Risk or Its Aggressiveness"](#)
- ["GPX3 rs8177412 Polymorphism Modifies Risk of Upper Urothelial Tumors in Patients with Balkan Endemic Nephropathy"](#)
- ["The Polymorphisms in GSTO Genes \(GSTO1 rs4925, GSTO2 rs156697, and GSTO2 rs2297235\) Affect the Risk for Testicular Germ Cell Tumor Development: A Pilot Study"](#)
- ["The Role of Glutathione Transferase Omega-Class Variant Alleles in Individual Susceptibility to Ovarian Cancer"](#)
- ["Oxidative Homeostasis in Follicular Fluid and Embryo Quality—A Pilot Study"](#)

In order to proceed responsibly and fairly, and to ensure that we have fully understood the jurisdictional and ethical considerations involved, we are seeking an official statement from the Ethics Committee of the Faculty of Medicine at the University of Belgrade.

Specifically, we would greatly appreciate your independent assessment and clarification on the following points:

1. The scope of the Faculty of Medicine's ethical oversight, particularly as it relates to research conducted by Prof. Dr. Simić and any projects potentially linked to the UROMOL study.
2. Your position on the Ministry of Health's claim of jurisdiction and whether, in your view, the Faculty's ethics processes were duly followed and sufficient for the studies in question.
3. Whether the Ministry of Health's statements regarding the ethical oversight and legal compliance of the research conducted by Prof. Dr. Simić and her team, as presented in the above-mentioned papers, are accurate.
4. Could you please clarify whether the studies mentioned above are part of the UROMOL project or otherwise related to it?
5. Any additional context that would help clarify the Faculty's role and procedures in ensuring compliance with national ethical and legal standards for biomedical research.

We sincerely appreciate your time and assistance in helping us ensure due process and uphold the highest standards of research ethics and transparency.

Best regards,  
Mr. Aleksandar Djukic  
Research Integrity Specialist

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**From:** Eticka komisija <[etickakomisija@med.bg.ac.rs](mailto:etickakomisija@med.bg.ac.rs)>  
**Sent:** Wednesday, May 21, 2025 19:50  
**To:** [djukic@mdpi.com](mailto:djukic@mdpi.com)  
**Subject:** Re: Inquiry Regarding Research Integrity Contact

**CAUTION - EXTERNAL:** This email originated from outside of MDPI organisation. BE CAUTIOUS especially to click links or open attachments.

Dear Mr. Djukic,  
Thank you for your message.  
We would like to inform you that the Ethics Committee of the Faculty of Medicine, University of Belgrade, is the competent body for reviewing matters related to the ethical aspects of research conducted by faculty members of our institution.  
Please feel free to provide the relevant information and documentation so that we can review the case in accordance with our procedures and regulations.  
We remain at your disposal for any further information.  
Sincerely,  
Ethics Committee  
Faculty of Medicine  
University of Belgrade

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**From:** [djukic@mdpi.com](mailto:djukic@mdpi.com) <[djukic@mdpi.com](mailto:djukic@mdpi.com)>  
**Sent:** Wednesday, May 21, 2025 8:26 AM  
**To:** Eticka komisija <[etickakomisija@med.bg.ac.rs](mailto:etickakomisija@med.bg.ac.rs)>  
**Subject:** Inquiry Regarding Research Integrity Contact

Dear Ethics Committee Representative,

I am reaching out as a representative of MDPI regarding concerns raised about certain articles published by authors affiliated with the Faculty of Medicine, University of Belgrade, Serbia. We have been contacted by a representative of the **Ministry of Health, Republic of Serbia** and have received an email along with official documents issued by the Ministry.

Before sharing further details and any potentially sensitive information, I would appreciate your guidance on the appropriate contact within the institution who handles such matters. Could you kindly confirm if this is the appropriate address to which such issue should be directed, or direct me to the appropriate individual or department?

Thank you for your time and assistance. I look forward to your response.

Kind regards,  
Mr. Aleksandar Djukic  
Research Integrity Specialist

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Dear Mr. Djukic,

We would like to inform you that the Ethics Committee of the Faculty of Medicine, University of Belgrade, at the meeting held on Monday 9, 2025, discussed your inquiry regarding the ethical and legal aspects of the following studies:

- “GSTM1 and GSTP1 Polymorphisms Affect Outcome in Colorectal Adenocarcinoma
- “The Association of Polymorphisms in Genes Encoding Antioxidant Enzymes GPX1 (rs1050450), SOD2 (rs4880) and Transcriptional Factor Nrf2 (rs6721961) with the Risk and Development of Prostate Cancer”
- “Polymorphisms of Antioxidant Enzymes SOD2 (rs4880) and GPX1 (rs1050450) Are Associated with Bladder Cancer Risk or Its Aggressiveness”
- “GPX3 rs8177412 Polymorphism Modifies Risk of Upper Urothelial Tumors in Patients with Balkan Endemic Nephropathy”
- “The Polymorphisms in GSTO Genes (GSTO1 rs4925, GSTO2 rs156697, and GSTO2 rs2297235) Affect the Risk for Testicular Germ Cell Tumor Development: A Pilot Study”
- “The Role of Glutathione Transferase Omega-Class Variant Alleles in Individual Susceptibility to Ovarian Cancer”
- “Oxidative Homeostasis in Follicular Fluid and Embryo Quality—A Pilot Study”

Following a detailed review of our records and available documentation, we would like to provide the following official statement:

**1. The scope of the Faculty of Medicine’s ethical oversight, particularly as it relates to research conducted by Prof. Dr. Simić and any projects potentially linked to the UROMOL study**

The request for ethical approval for the UROMOL project was submitted on April 30, 2010, to the Ethics Committee of the MFUB. Along with the request, a project justification and all necessary documentation containing information for patients were provided. Ethical approval was granted on June 14, 2010 (Attachment No 1). The activities of the UROMOL project were performed at the Institute of Clinical Biochemistry of the Faculty of Medicine and the Clinic of Urology, upon the approval of its former director, Prof. Cane Tulic.

Additional secondary ethical approvals for further research on the material obtained within the scope of the Project were issued also by the Ethics Committee of the Faculty of Medicine (Attachments No 2, 3).

Regarding the above mentioned studies, after careful analysis of submitted documents and ethical approvals, we concluded that published papers are not linked to UROMOL studies and are conducted in accordance with the research protocols submitted to the Ethics Committee.

**2. Your position on the Ministry of Health’s claim of jurisdiction and whether, in your view, the Faculty’s ethics processes were duly followed and sufficient for the studies in question**

Based on Article 146. of the Statute of the Faculty of Medicine, University of Belgrade, and Article 3. of the Rulebook of the Ethics Committee of the Faculty of Medicine, University of

Belgrade, the Ethics Committee of the Faculty is the relevant authority for approving conducting scientific research at the Faculty of Medicine, University of Belgrade. Moreover, the Ethics Committee of the Faculty of Medicine, University of Belgrade is the ONLY relevant authority for issuing ethical approvals for PhD theses at the Faculty of Medicine. Please find attached the institutional review board (IRB) organization (IORG) registration document IORG0010813, which represents the overall registration, and each IRB receives a distinct identification number under the IORG (Attachment No 4). The following IRB is registered with the Office for Human Research Protections (OHRP): IRB00012823 School of Medicine, University of Belgrade IRB #1 (RENEWED).

In order to apply for Ethics Committee approval, the candidate needs to submit the application, protocol of the research, informed consent, statement on the protection of personal data, signed by the researcher, CV of the researcher, and the approval issued by the relevant authorities (Director of the Clinic) OR Ethics Committee of the institution/-s where the research is to be conducted. Therefore, the studies you have listed were conducted in full compliance with national legislation and international ethical standards, except the study no. 5 “The Polymorphisms in GSTO Genes (GSTO1 rs4925, GSTO2 rs156697, and GSTO2 rs2297235) Affect the Risk for Testicular Germ Cell Tumor Development: A Pilot Study”. This article was not part of PhD thesis, but it was the topic of the written assessment issued by the Ethics Committee in January 27, 2025 (Attachment No 5). All other studies that you listed were granted by the Ethics Committee of the Faculty of Medicine by official ethical approval, following our previously explained standard evaluation procedures (Attachments No 6-11). Since the approvals are issued in the official Serbian language, we can provide an official translation upon your request, if necessary.

Thus, the ethics procedures were duly followed.

**3. Whether the Ministry of Health’s statements regarding the ethical oversight and legal compliance of the research conducted by Prof. Dr. Simić and her team, as presented in the above-mentioned papers, are accurate**

The Ethics Committee of MFUB is an independent entity that addresses all ethical concerns related to the scientific research and educational endeavors of Faculty members, associates, and students at the MFUB. It also grants the necessary approvals for the conduct of doctoral theses and other scientific research endeavors. Consequently, for research conducted at our Faculty (accredited by the National Accreditation and Quality Assurance Body in Higher Education, decision number 612-00-00315/6/2020-03, dated May 11, 2021) (Attachment No 12), as previously mentioned, the Ethics Committee of the Faculty of Medicine, University of Belgrade is the ONLY relevant authority for issuing ethical approvals for PhD theses and the research conducted by the academic staff with the Faculty of Medicine participating the research.

The process for issuing ethical approval at the Faculty of Medicine, University of Belgrade, includes a thorough review of the research plan, informed consent procedures, data protection measures, and risk assessment for participants. Additionally, as previously emphasized, each institution needs to approve the research, either by written approval of the Director/Head of

Institution, or by the Ethics Committee of the Institution. In each of the aforementioned cases, as previously mentioned, all criteria were duly met in accordance with applicable regulations.

Therefore, after reassessment of the official documents, the Ethics Committee did not find any violations of ethical and legal procedures.

**4. Could you please clarify whether the studies mentioned above are part of the UROMOL project or otherwise related to it**

As previously mentioned, the above mentioned studies are not part of the UROMOL project, nor are they formally associated with it in any way. Upon reviewing the relevant research protocols, project applications, and supporting materials, we have found no connection between the mentioned publications and the UROMOL study.

**5. Any additional context that would help clarify the Faculty's role and procedures in ensuring compliance with national ethical and legal standards for biomedical research**

The Faculty and its Ethics Committee remain fully committed to upholding the integrity of scientific research and to operating in accordance with the Law on Health Care, the Law on Personal Data Protection, and other relevant legal frameworks of the Republic of Serbia.

In case you need any additional information or clarification regarding the matter, we are at your disposal.

We kindly ask you not to forward this response to third parties, not involved in this case.

Sincerely,

Ethics Committee

Faculty of Medicine, University of Belgrade