STATEMENT

by Prof. Dr. Juliana Krumova Marinova, MD, PhD.

for the dissertation

"Ownership of patient information in the context of big data"

by Assistant Professor Martin Ognyanov Mirchev

doctoral student in doctoral program

Public Health Management (enlisted by Order No. 109-458 / 17.07.2018), Professional Field 7.4 Public Health, Higher Education Area 7. Health and Sports

I submit this statement as a member of the Scientific Jury, appointed by Order No. R 109-342 / 26.09.2019 of the Rector of the Medical University "Prof. Dr. Paraskev Stoyanov "- Varna based on a decision of the Academic Council of the Medical University -" Prof. Dr. Paraskev Stoyanov "(Protocol №143 / 27.09.2019) for evaluation of the dissertation work of Martin Ognyanov Mirchev - doctoral at the Department of Social Medicine and Health Organization, Faculty of Public Health, University of Medicine - Sofia. Varna with scientific mentor Prof. Dr. Albena Kerekovska, MD. The dissertation work was discussed and proposed for defense by the extended departmental council of the Department of Social Medicine and Health Organization, Faculty of Public Health at the Medical University "Prof. Dr. Paraskev Stoyanov "- Varna.

Biographical data: Martin Mirchev has graduated as Bachelor in philosophy at Sofia University Kliment Ohridski (2006-2010), Master of Laws (2007-2015) and History of Philosophy (2010-2011). In addition he holds a Master's degree in Public Health from the Medical University "Prof. Dr. Paraskev Stoyanov "-Varna (2017-2018).

Martin Mirchev started his professional development in 2014 in the Department of Social Medicine and Healthcare Organization as a part-time assistant professor in medical ethics. From 2015 until now he has been an assistant at the same department, providing teaching in medical ethics to Bulgarian and English speaking students.

The applicant is a member of the Bulgarian Association for Bioethics and Clinical Ethics (BABKE), the European Public Health Association (EUPHA) and the Bulgarian Scientific Society for Public Health.

He participated in a one-week training course in public health and law at the Open Medical Institute in Salzburg, Austria, 06-12.10.2019. At BABKE, he participated

in one-day training in moral reasoning on case and conflict management. He is fluent in English.

General Description of the Thesis: The dissertation contains 257 pages, structured in five main chapters, illustrated with 4 figures, 11 tables and 2 annexes. The bibliographic list contains 359 references (used literature: 332; publications used in Scoping Review: 27), of which 4 are in Cyrillic and 355 in Latin.

Relevance and importance of the thesis topic: The topic of the thesis "Ownership of patient information in the context of" big data" is in line with the doctoral candidate's profile as a philosopher, lawyer, teacher and researcher in the field of biomedical ethics. I congratulate the doctoral student and the scientific mentor on this choice and the challenge taken to develop a dissertation in an almost unexplored field, not only in Bulgaria, but globally.

Aim, tasks, research hypotheses: they are precisely defined on two pages of the dissertation. **The aim** is set in three directions: - to identify major moral, ethical and regulatory issues related to ownership of patient information in the context of Big Data; - to present and analyze trends in the perception of patient information as property; - to propose a fair approach to ownership. The research **tasks** are presented in 8 points, directly related to the achievement of the goal. **Four research hypotheses** have been formulated.

Material and methods are presented on 16 pages of the dissertation. They are clearly substantiated and adequate, respectively, to the interdisciplinary nature of the topic and described in detail are about 5 methodological approaches that the doctoral student has mastered and successfully applied in the development of the dissertation. The methodology applied for the first time in Bulgaria for performing the so-called preliminary review of the scope of the scientific literature on the studied problem (scoping review) is presented in detail, which is of exceptional merit to this work with high applied practical value. The following are also accurately described: historical method for analyzing the development of the Information Revolution and Big Data; documentary method for analysis of regulatory documents; philosophical analysis of the concept of ownership of patient information; ethical analysis based on fundamental principles in contemporary biomedical ethics.

The literature review is structured in three main areas: 1.) a brief historical overview of the emergence and development of the Information Revolution and Big Data; 2.) definition, volume and importance of big data in healthcare; 3.) the concept of "ownership" in the specific context of patient information. Martin Mirchev conscientiously and thoroughly addresses these issues, focusing on the historical aspects, the current state of the problems with their multidimensionality and discussion, with different interpretations and evaluations. It presents the modern concept of Big Data and their potential, containing the benefits, risks and ambiguities arising from the "paradoxes" (paradox of transparency, identity, power paradox) that outline a wide range of problems for the individual and society as a whole, the benefits, but also unexpected threats that would exacerbate inequality and exploitation. In this context, the importance of the "ownership" of patient information is presented, thoroughly presented and discussed by the doctoral student in relation to a variety of solutions, including public and private property opportunities in the contemporary picture of healthcare and the possibilities for actually applicable patient information rights in its three varieties:

electronic medical record; electronic health record; personalized health record. The review is commendable in its entirety. The author's ability to handle and discuss scientific literature in a complex interdisciplinary field, almost unexplored in our country, should be emphasized. It is written in clear language and reflects a thorough knowledge of the issues discussed.

Analysis (results and discussion): this is the most extensive part of the dissertation, covers 60% of its content and has been developed in 4 sections, corresponding to the applied methods in the dissertation. **The first** section of 30 pages presents, discusses and analyzes the results of the preliminary scoping review of the scientific literature. The study included 27 sources, the selection process of which was described in detail in the section "Material and Methods" included in Appendix 2 to the thesis. This section is structured in three sub-sections: results, analysis and discussion, and conclusions. This preliminary review is the first for the Bulgarian academic community, conducted according to the methodology presented by Martin Mirchev on scoping review. The second section: "Big Data in Healthcare and the Place of Patient Information - Challenges, Risks and Benefits, Potential Opportunities" is structured in 7 sub-sections, presented on 70 pages of the dissertation. The third section is structured in 5 sub-sections of 40 pages and presents a critical philosophical analysis of the concept of patient information personification with the application of basic philosophical techniques and teachings - ontology, epistemology, axiology and anthropology. The fourth section, structured in 4 sub-sections of 35 pages, contains an ethical analysis of the above concept based on fundamental principles in biomedical ethics - autonomy, non-maleficence, beneficence and justice. As a Social Medicine Specialist and Medical Ethics Lecturer without special qualifications in Philosophy, I can evaluate this part of the dissertation without allowing myself to comment on the third section containing philosophical analysis. For the other sections, I could summarize: adequate structuring, logical coherence, sequence of presentation, analysis and synthesis. The doctoral student demonstrates skills in applying the various methodologies used in this dissertation. In presenting the results and the discussion, the author's in-depth knowledge of the problems is evident, the author's ability to interpret the results in a complex, poorly studied, multilayered field.

Logically bound, based on the reasoned rejection of the fourth research hypothesis, follows the **Proposal for a Fair Approach** to Ownership of Patient Information in the Context of Big Data. In the end, based on his own analysis, the doctoral student proposes as a fair approach to the ownership of patient information in the context of Big Data, "leaving aside possible options for propertization": both public and private. Martin Mirchev also presents an alternative involving a property regime with limited rights: "if it is a valuable artifact for medical science and practice, patients right to prevent this use in one way or another should be restricted"; and further expresses as the most reasonable "to consider the Okams Razor as a guiding principle: to seek an approach on the path of the lowest resistance."

Following are the **conclusions and contributions** from the dissertation. The conclusions are formulated in 16 points, corresponding to the research tasks and hypotheses. The contributions are presented in two groups: **scientific and theoretical** and **applied and practical** and are an expression of the importance and relevance of the dissertation.

In connection with his dissertation, Martin Mirchev presents: three full-text publications in refereed periodicals in Bulgaria: Scripta Scientifica Salutis Publicae; Social medicine; Ethical research; one summary of participation in an international scientific forum (11th European Public Health Conference), published in the European Journal of Public Health, Supplement; two participation in scientific forums, one of them international.

Abstract: The abstract is written in 70 pages, is structured according to the requirements and reflects the main results achieved in the dissertation.

CONCLUSION

The dissertation contains scientific, theoretical, methodological and applied results, which represent an original contribution to science and **meet all the requirements** of the Law for the Development of the Academic Staff in the Republic of Bulgaria (ZRASRB), the Regulations for the implementation of the ZRASRB and the Rules of the MU - Varna. The submitted materials and dissertation results fully comply with the specific requirements, adopted in connection with the Regulation of the Medical University - Varna for the application of ZRARB. The dissertation shows that the doctoral student Martin Mirchev **possesses deep theoretical knowledge and professional skills** and **demonstrates qualities for conducting independent research**.

This gives me reason to confidently give a **positive assessment** of the research presented by the dissertation reviewed above, the abstract, results achievements and contributions.

I propose to the Honorable Scientific Jury to award the educational and scientific degree "**Doctor**" to **Assistant Professor Martin Ognyanov Mirchev** in the doctoral program and specialty "**Public Health Management**", professional field 7.4 "Public Health", Higher Education Area 7.Healthcare and Sports.

14.11.2019 г.

Stara Zagora

Prof. Juliana Marinova, MD, PhD