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Towards a Framework for Research Ethics Education for Physicians in Serbia

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Abstract

With growing opportunities for medical doctors to work either in academia and industry, research ethics education for health sciences research, meaning research which includes humans and animals and/or their tissues and cells with the goal to understand underlying mechanisms of disease occurrence and disease treatment, is of paramount importance, especially in regions, such as Serbia, where comprehensive research ethics curricula for physician researchers are lacking. This article addresses the spectrum of research ethics topics that were identified through analysis of the existing research ethics curricula in medical schools, international organizations, Serbian legislative codes and the PubMed database applying the key search terms: *ethics, research, biomedical, education, curriculum, program, course* and their combinations. Selected topics were classified in eight syllabi based on their similarity: #1 Responsible conduct of research, #2 Justice in human subjects research, #3 Research on human subjects, #4 Vulnerable population groups, #5 Conflict of interest, #6 Research on animals, #7 Research on genes, cells and embryos, and #8 Organization of research ethics. Justifications for each syllabus are discussed based on empirical evidence and local context. Higher education authorities could use this framework to strengthen, adjust or refine research ethics education for physician researchers in Serbia.

Keywords Curriculum · Education · Ethics · Medicine · Research

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Introduction

Medical research represents a contemporary imperative not only to increase generalizable knowledge, but also to offer possibilities for novel, more effective treatments and prevention strategies. Physicians are often involved in animal research (Ferdowsian and Beck 2011) and are at the forefront of research on human participants (Rahman et al. 2011). In fact, medical research on human participants is being conducted in almost all countries worldwide (U.S. National Library of Medicine. Clinical Trials 2019). Still, there is but a small number of countries and universities where research ethics specific to research with human/animal subjects is being taught. It is, therefore, essential to offer and stimulate in-depth knowledge of human/animal subjects research ethics among physician researchers.

A previous report indicated that schools of medicine in Southeast Europe have two times less classes in medical ethics compared with countries of the European Union (27 vs. 44 h) (Claudot et al. 2007). In the Western Balkan countries (Macedonia, Montenegro, Serbia, Croatia and Bosnia and Herzegovina), some elements of research ethics have been incorporated in undergraduate medical ethics curricula (Mijaljica 2014). This finding suggests that there is a need for modernization of education systems, structures and processes, towards the acceptance and development of the pedagogical trend that emerged from the multilateral Bologna Agreement agenda (O'Brien 2007).

The Republic of Serbia has a population of approximately 7 million. Evidence suggests that research potential in Serbia has increased over the past decades. In 2017, 0.3% of all publications worldwide originated from Serbia, ranking it 46th out of 140 countries (Open Access Infrastructure for Research in Europe 2019). Of 279 institutions conducting research in Serbia (2018), medical and health-related research facilities accounted for 6.1% (a total of 17 units comprising 6 non-financial, 3 governmental and 8 higher education institutions) (Statistical Office of the Republic of Serbia 2019). However, the largest number of research projects funded by the Ministry of Education, Science and Technological Development, and the largest proportion of publications, are related to medicine (National Council for Scientific and Technological Development 2017). Currently, around 300 clinical trials are being conducted nationwide (Medicines and Medical Devices Agency of Serbia 2019; Ranković and Mijatović 2016). Each clinical trial requires approval of the Medicines and Medical Devices Agency of Serbia and Ethics Committees of the institutions where the approved trial would be conducted. While each Ethics Committee uses the Declaration of Helsinki issued by the World Medical Association for managing its activities, Ethics Committee members are not required to receive formal training in research ethics (Petrović 2015).

To address that lack of training, and offer training in research ethics not only to physicians at the beginning of a career in science, but to all physicians who consider research ethics relevant for their work, it is essential to develop a research ethics education framework. Fundamental challenges in the process of development of a new program are:

- (1) Which core knowledge, skills and values should be included in the proposal for research ethics education?
- (2) Would acquisition and development of such knowledge, skills and values, and associated competencies, enable physician researchers to deal with challenges in research with human and animal participants?
- (3) How can the process of learning be relevant and interesting to enrollees in post-graduate education?

With growing opportunities for physicians to work either in academia and industry, education on research ethics is and will remain vital for physician researchers. Physicians are often expected to conduct or oversee research on humans and animals. Having knowledge in research ethics is prerequisite, on the one hand, for writing research proposals that receive approval from the Ethics Committees and reviewing research protocols as members of the Ethics Committees, on the other. Relevance of research ethics education and lack of comprehensive curricula in research ethics in this part of Europe (Mijaljica 2014) has motivated several universities and institutions from the Danube region to collaborate on a project aimed at developing research ethics modalities applicable in translational research; the project is entitled “Bioethical Standards in Translational research: an integrated approach of the Bioethics education in biomedical sciences and its role in development of the Knowledge Society in the Danube Region countries” (BEST-Network) and is supported by the European Union through START Danube Region Project Fund (Grant No. 16_PA07-C1) (<http://best-network.usamvcluj.ro/>).

Activities within the BEST-Network project served as a baseline point to develop the present research. During BEST-Network project seminars, round tables, webinars and workshops, partner members discussed how to develop and implement new research ethics curricula or improve the existing research ethics curricula in the respective university facilities. The key conclusion of project meetings and activities was that medical faculties in Serbia lack a comprehensive research ethics curriculum. Therefore, the goal of this research was to find a spectrum of research ethics topics that could serve as a base for tailoring future research ethics curricula for physician researchers in Serbia.

Materials and Methods

Data Collection

To obtain relevant topics, a review of the following resources was performed over the course of five months (January to May 2016): (1) current research ethics curricula in Serbian medical schools as well as those curricula from medical schools worldwide with permanently accessible data online; (2) research ethics curricula proposed by the international organizations that include research on humans and

animals within their scope of activities; (3) legal regulations in medical research and bioethics in Serbia and (4) peer-reviewed articles on research ethics education programs available in the PubMed database.

1. Research ethics curricula in medical schools

First, courses on research ethics held in all five Schools of Medicine in Serbia were identified, because these are the target institutions for implementation of research ethics courses. Although in all five Schools of Medicine medical ethics is being taught, none of the five has a comprehensive research ethics curriculum. Medical ethics courses at the undergraduate level differ in their form and extent between Schools of Medicine in Serbia. In four of them, medical ethics is part of a larger mandatory course for the first year of studies (*Medicine and society* at three Schools of Medicine, and *Medical ethics and sociology* at one), while at one School of Medicine, medical ethics is being taught only as an elective course in the last study year. Curricula of these courses are mainly focused on historical foundations of medical ethics, ethical theories, basic ethical principles in clinical practice and main ethical codes. In addition, four out of the five Schools of Medicine have up to ten lectures (7.5 h in average) of research ethics incorporated in the current postgraduate studies for physician researchers. However, these lectures cover only a few aspects of research ethics and are not standardized. Because of this, we have focused on the available curricula worldwide.

Second, the research curricula from other Schools of Medicine were reviewed. Taking into account that legislations in both medicine and research ethics differ between countries and regions, study authors set the following search criteria for research ethics curricula: (1) similarity of conditions in health care and education to those in Serbia (this means that programs conducted in high and middle income countries were selected), (2) curricula written in English and Serbian languages and (3) fully available online programs. We especially aimed at identifying all medical schools that offer research ethics courses in the English language as well as those medical schools in the Danube region that offer research ethics courses (given that the BEST-Network project was relevant for the Danube region) in the Avicenna Directory for Medicine (University of Copenhagen <http://avicenna.ku.dk>) (Mijaljica 2014).

2. Research ethics curricula of international organizations

Because a rather small number of medical schools with fully available online presentations of research ethics curricula was identified, as a next step, a review of all international organizations offering fully available research ethics programs and curricula was performed. Research ethics curricula proposed by the following international organizations were examined: United Nations Educational, Scientific and Cultural Organization (UNESCO) (Bioethics Core Curriculum. Section 1: Syllabus Ethics Education Program 2008), National Institute of Health (NIH)/United States Agency of International Development (USAID) (Research Ethics Training Curriculum 2009), World Health Organization (WHO) (Operational Guidelines for Ethics Committees That Review Biomedical Research 2000; Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011), European Commission (EC) (Ethics for

Researchers 2013; European Textbook on Ethics in Research 2010, 2013), Department of Health and Human Services USA (Steneck 2007), Medical Research Council (MRC) (MRC Ethics Guide 2004), and the Global Health Training Center (2016).

3. Serbian legal regulations in medical research and bioethics

Furthermore, to account for the rules and regulations in effect in the Republic of Serbia, legislative codes of research and professional biomedical ethics and activities were thoroughly analyzed (Official Gazette of Republic of Serbia Nos. 18/2010 and 112/2015; Vuckovic-Dekic et al. 2007; University of Belgrade 2016). Key topics specified by given laws were identified and reviewed. Moreover, topics identified from other mentioned sources were compared with legal regulations in order to confirm their appropriateness for the Serbian regulatory system.

4. Peer-reviewed articles

The PubMed database (www.pubmed.gov) was screened for peer-reviewed literature applying the key search terms: *ethics*, *research*, *biomedical*, *education*, *curriculum*, *program*, *course* and their combinations. Articles in English and Serbian languages relevant for this study were retrieved, regardless of date of publication. This database was searched because it is the largest and most widely used medical journal database that includes most health-related and medical education journals (where relevant articles for physician researchers would likely be published). Topics/issues/ethical discussions covered in social science/ethics/humanities journals were considered far beyond the level of knowledge required for a physician enrolled in a postgraduate program (i.e. physicians are likely not familiar with the theoretical background of articles published in those journals because, in fact, it is a realm of a different profession). Therefore, as the course is intended for physicians, only those articles on research ethics that were published in medical journals available on PubMed were analyzed. First, all publications corresponding to the applied key search terms were extracted (3134 in total). Subsequently, after applying filters, manuscripts that were available freely online in their entirety were identified (460 in total). Of those, after reviewing, articles that did not mention exact curricula or topics that could be used in our study were excluded (83 articles included).

The Process of Topics Selection

All aforementioned sources of data on research ethics in medical sciences served as the base for retrieving relevant topics on the subject. The process of topic selection for this research is presented in Fig. 1.

Each curriculum and selected articles were examined to make a compilation of all the identified research ethics topics. To compile the final list, agreement between all study authors was a prerequisite for the inclusion of each topic (considering arguments for and against the inclusion of a specific topic). Differences in opinion were resolved by consensus. The main inclusion criteria were significance and frequency of appearance of a research ethics topic in the reviewed literature (selected topics had to be identified in the evaluated curricula and/or other reviewed literature at

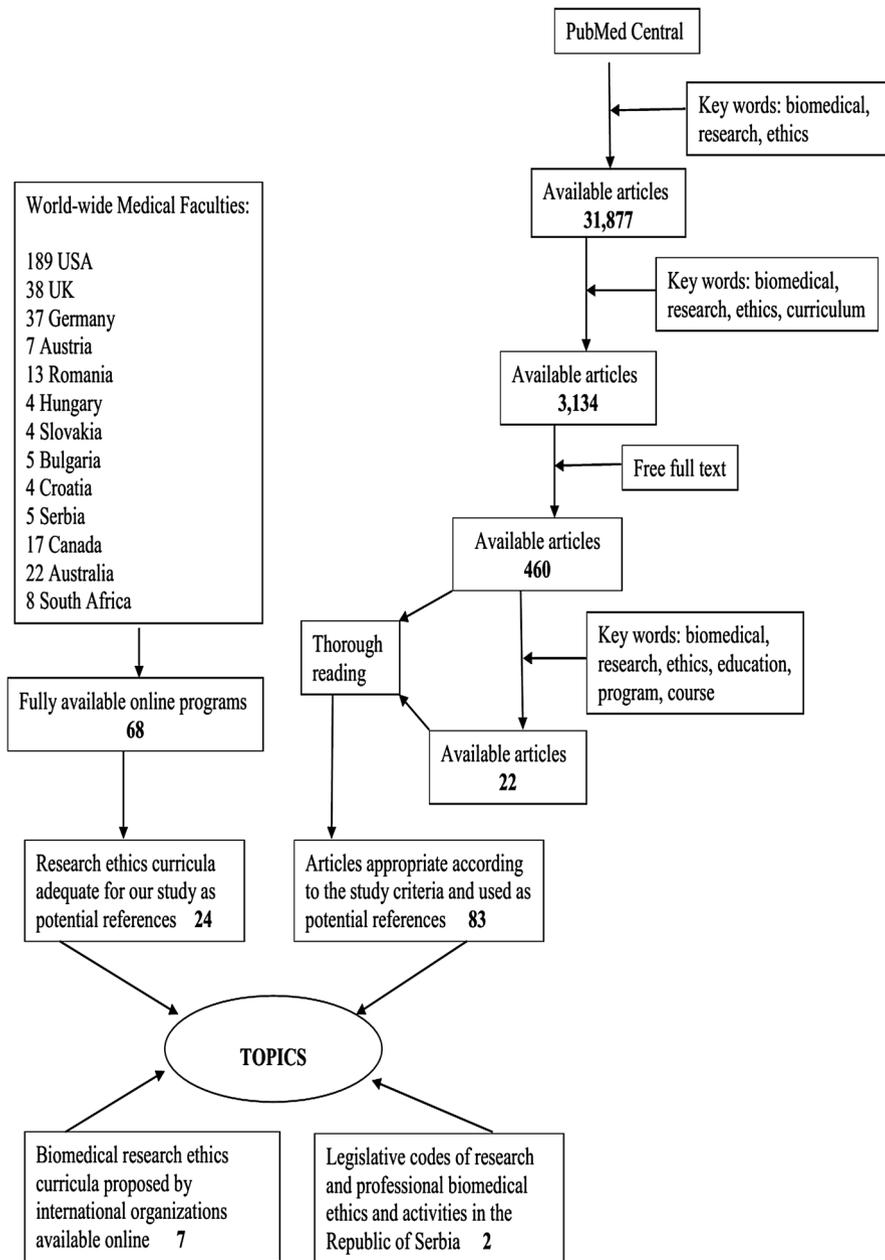


Fig. 1 Flowchart of the selection of research ethics topics

least three times). Retrieved topics were compiled into group topics (entitled syllabi) based on their similarity.

Finally, all the retrieved topics were discussed during BEST-Network project activities. In this manner, not only the study authors, but all project members debated the relevance of the topics in the project context. Because of this, it was considered that other partners in the BEST-Network project had provided external review and validation of the included topics through round tables, webinars and on-site discussions.

Topics Consistency

To assess consistency of topics selected in this research with topics in reviewed literature, the percentage of occurrence in the reviewed curricula, articles and research ethics legislative documents for every selected topic was calculated. Each aforementioned data source was reviewed and topics within each source were marked. After reviewing all data sources, the frequency of appearance of each topic within all reviewed data sources was calculated. The percentage of appearance of each topic was labeled as 'topic consistency' between topics included in the present research and data sources.

Results

A total of 67 different topics were identified in line with the inclusion criteria. Of these, 36 were finally selected, considering their relevance and applicability for physician researchers in Serbia, as well as taking into account the legal regulations in Serbia. The final list of topics is presented in Table 1.

Percentage of occurrence in the reviewed curricula, articles and research ethics legislative documents was calculated for every topic. The mean \pm standard deviation (SD) for topic consistency i.e. agreement between the selected topics and literature data was 74.69 ± 21.38 percent. The most commonly found topics in all the evaluated literature were those topics that were finally selected in this research. Of all the topics, those listed as no. #1, #3 and #5 had 100% agreement with the reviewed literature. Topics #17 and #28 appeared least frequently in the reviewed literature (37.52%).

Selected topics were classified in eight syllabi based on their similarity: #1 Responsible conduct of research, #2 Justice in human subjects research, #3 Research on human subjects, #4 Vulnerable population groups, #5 Conflict of interest, #6 Research on animals, #7 Research on genes, cells and embryos, and #8 Establishing Ethics Committees (Table 1).

#1 Responsible conduct of research provides the notion of responsibilities and duties of a young physician researcher. Education on scientific misconduct is often a starting point for understanding, recognizing and avoidance of research errors.

Table 1 Research ethics topics and syllabi

No.	Topics	Syllabus
1	Definition of research, professional ethics and principles of research ethics; moral reasoning and conduct	Responsible conduct of research
2	History and development of current research ethics; historical examples of research misconduct	
3	Codes and laws in research ethics (Nuremberg Code, Helsinki Declaration, etc.)	Justice in human subject research
4	Mentoring and supervision of research	
5	How to evaluate ethical issues in research: fraud, falsification, fabrication	
6	Publication ethics—responsibility to publish and disseminate research results	
7	Potential research benefit and harm; risk–benefit assessment	
8	Therapeutic misconception	
9	Privacy and confidentiality, data protection	
10	Human dignity, human rights, equality, justice, equity	
11	Informed consent and assent; impaired capacity to consent	
12	Autonomy, individual responsibility and responsibility for others	
13	Respect for cultural diversity and pluralism; solidarity and cooperation	Research on human subjects
14	Discrimination, stigma and respect for person's integrity	
15	Observational studies on human subjects	
16	Behavioral and social science research	
17	Surgical and clinical research	
18	Recruiting research participants—healthy volunteers in human subject research	
19	Ethics of phase I–IV of randomized and placebo controlled trials	
20	Research on women and children	Vulnerable population groups
21	Research on the disadvantaged and impaired-decision making	
22	Research on institutionalized persons (prisoners, nursing homes)	
23	Research on minority groups, immigrants and homeless persons	

Table 1 (continued)

No.	Topics	Syllabus
24	Conflict of interest	Conflict of interest
25	Inducement and undue inducement	
26	Liability and compensation for injury	
27	Media, marketing, advertisements and responsibility of sponsors	
28	Animal rights	Research on animals
29	Treatment of laboratory animals	
30	Legislation and research embryos	Research on genes, cells and embryos
31	Research with biological samples, human tissues, stem cells and biobanking	
32	Ethical principles of research with genetic material and genetic counseling	
33	Forming of ethics committees and its duties. Evaluation of effectiveness of Ethics Committees	Establishing Ethics Committees
34	New technologies, protection of environment and safety monitoring	
35	Institutional and international collaboration	
36	Research in countries with limited resources	

#2 The issue of justice in research concerns both exploitation of and discrimination against populations and individual volunteer participants. Physician scientists at the beginning of their research careers need to be aware of fair selection of participants in research and respect individual autonomy when recruiting volunteer participants for their research, as well as to get themselves acquainted with modalities of the informed consent process for participation in research.

#3 Physician scientists should have understanding of various methods in human subject research, such as interventional (clinical, field and community trials where procedure of randomization is used) and observational studies including quantitative (retrospective and prospective cohort studies, case-control and cross-sectional studies) and qualitative approaches (interviews, focus groups). All studies involving human participants may raise ethical dilemmas and potentially cause both physical and psychological harm.

#4 Physician scientists at the beginning of their research career should understand specificities of research with vulnerable population groups, such as children, mentally disabled, economically or educationally disadvantaged persons, or captive populations, because they either do not have the capacity to consent for research participation and thus independently assess risks and benefits of research participation or because they lack power .

#5 Conflict of interest is particularly relevant for young physician scientists because of close ties between the health-care sector and commercial industries that might conduct human participant research (e.g. the pharmaceutical industry, medical devices industry, biotechnology companies etc.) as well as non-commercial research funded by charities or academic organizations. Physician researchers should be able to define and discuss conflict of interest challenges as they intersect with human/animal subjects research in the local context.

#6 Research on animal models is often a crucial step before conducting research on human participants in certain kinds of research. Physician researchers are required to appreciate validity, usefulness and relevance of their research to minimize harm and suffering of the animal subjects. Moreover, they need to ensure humane treatment of the animals and provide optimum living conditions.

#7 Worldwide, there is no uniform legal and moral treatment of the embryo and human biological material. In Serbia, it is illegal to create embryos only for research purposes. Physician researchers should discuss these issues, and how they intersect with human/animal subjects research and potentially put forward a proposal for establishing local policy or practice.

#8 Establishing Ethics Committees is essential part of a research process. Ethics Committee assessment is mandatory for both the scientific and ethical aspects of human subjects research protocols. Members of the Ethics Committees should include, among others, physician researchers who are expected to be knowledgeable on research ethics, as this would enable them to make decisions based on ethical principles.

Discussion

In this paper eight syllabi are suggested as the base for future research ethics curricula taught in postgraduate studies, such as Master or PhD, for all physician researchers in Serbia. Local higher education authorities could use this framework to build-up and further elaborate additional topics and syllabi to strengthen, adjust or refine research ethics education for physician researchers. It is also important to emphasize that to implement the results of this research as actual curriculum in medical schools in Serbia, two additional conditions need to be met. First, written assignments, final examination and grading for the course should be tailored by each medical school according to their standard practices. Second, a procedure of accreditation is required for a curriculum to be valid. Accreditation involves evaluation of a curriculum draft by an external review committee to ensure that curriculum agenda meets quality standards.

Responsible Conduct of Research

Apart from creativity and curiosity, the responsible conduct of research demands honesty, transparency and trust. Competence in research implies that physician researchers understand and recognize what constitutes responsible research conduct. Previous research carried out among early career researchers across Europe suggested that young scientists showed great interest in research integrity issues (Krstic 2015). Nevertheless, they acknowledged insufficient training on the topic, as well as being unaware of how to obtain the relevant knowledge (Krstic 2015). In Serbia, in a sample of predominantly medical doctors in PhD or post-doc training, all participants were aware of various forms of research misconduct; however, few participants expressed willingness to whistle blow and were in favor of punishment for misconduct in research (Vuckovic-Dekic et al. 2011). However, the observed negative attitude towards punishment for violation of ethical research conduct before the education intervention changed to a more positive outlook after a 10-lecture course on research integrity in the same study sample (Vuckovic-Dekic et al. 2012). Moreover, it was shown that even a short lecture of 45-minutes duration on plagiarism can deliver positive results in terms of increased awareness (Brkic et al. 2012). While prior results do not offer evidence as to whether education on research misconduct actually prevents or reduces research errors, these findings suggest that education on research misconduct is important for physician researchers and could potentially be vital in a multifaceted effort to foster good research practice in the scientific community.

It has been debated, however, whether education on research misconduct can foster long-term scientific integrity (Masic et al. 2014; Wiwanitkit 2016). While a number of factors, aside from education, contribute to the strengthening of scientific integrity in research institutions, such as incentive management, quality assurance, improvement of work environment and work satisfaction or increased transparency of science misconduct (Forsberg et al. 2018), 'leading by example' has been

suggested as the key component to promote excellence in research (Yarborough and Hunter 2013), not only among Serbian physician researchers, but among scientists worldwide.

Justice in Human Subject Research and Vulnerable Population Groups

The topic of justice in the proposed list of syllabi is closely related to the issue of vulnerability and will be discussed in light of vulnerable population groups. For instance, Roma people (estimated 150,000 in Serbia) can potentially be exposed to institutional and interpersonal discrimination (Janevic et al. 2017). Similarly, the Roma population is more likely to be in worse health (Janevic et al. 2012), and face permanent barriers in access to health care (Idzerda et al. 2011). Physician researchers need to be aware of vulnerabilities in Roma populations, as they present a significant minority in the Serbian population.

Special considerations need to be in place when conducting research among persons who experience intimate partner violence. This is especially relevant, because research data showed that a number of men and women in Serbia hold the opinion that violence is justified (Djikanovic et al. 2018). Because there is stigma around this issue, research on intimate partner violence should indeed be conducted. The limitations and specificities of such research concern vulnerability of volunteer participants who were subjected to violence, often for extended time periods. Furthermore, issues in research among men who have sex with men (Stojisavljevic et al. 2017), transsexual persons (Bizic et al. 2018) and other marginalized groups such as sex workers (Simic and Rhodes 2009) or recently, foreign migrants crossing through Serbia (Arsenijevic et al. 2018) should be tackled due to likelihood of stigmatization and exclusion. Therefore, in addition to the issues among well-established vulnerable groups, aforementioned issues in the Serbian context require further discussion and awareness among physician researchers at the beginning of a career in science.

Conflict of Interest

A previous report documented evidence on informal payments to physicians in Serbia (Buch Mejsner and Eklund Karlsson 2017), due to low net income in the health sector and limited resources of the health care system. Therefore, physician researchers might be exposed to more instances when financial conflict of interest may arise. When Eastern European and U.S. medical students who have physician family members were compared in terms of cooperation with the pharmaceutical industry, the author observed a large discrepancy in attitudes, whereby students from Eastern Europe held a more favorable opinion as to industry collaboration and benefits (Makowska 2017), which could be, again, linked to the annual net income differences between the two regions. These findings are applicable for the Serbian setting as well, where some physician researchers and health care institutions are involved in both domestic and international investigations with commercial potential. Because of a fairly underdeveloped economy and limited market possibilities in Serbia (Dickov 2015), financial incentives from industry (pharmaceutical, medical

devices, biotechnology companies etc.) or other sources might pose considerable conflicts of interest. The content of the conflict of interest syllabus is especially relevant for physician scientists in Serbia due to previously observed shortcomings of the Serbian health care system (Dickov 2012).

Research on Animals

The law on animal welfare (Official Gazette of RS No. 41/2009) and regulation on welfare of animals intended for experimental purposes (Official Gazette of RS No. 39/2010) were passed in Serbia in 2009 and 2010, respectively. These legal acts regulate experiments on animals in terms of their registration, accommodation conditions and breeding, training and caring, handling and methods of sacrificing animals for research purposes. It is important to mention that a national animal welfare council and animal ethics committees were established in research institutions in Serbia and reporting of animal usage statistics has also been mandatory. Aside from Ethics Committees assessing research on human participants, a separate organization body i.e. Animal Ethics Committee (AEC) assesses project proposals within the realm of animal research. For example, at the School of Medicine, University of Belgrade, the AEC is composed of three physician researchers experienced in animal research, one statistician, one veterinary surgeon and one expert in animal care—both affiliated with the School of Veterinary Medicine, University of Belgrade. The seventh member of the AEC is a lay person, usually a member of an animal welfare non-governmental organization (School of Medicine, University of Belgrade). While important steps have been made in prioritization of animal welfare in Serbia (especially through training on care and use of animals of those physician researchers who opt for experimental research branches), the authors suggest that all physician researchers should receive basic research ethics education on animal research.

Research on Genes, Cells and Embryos

In 2009, the government of the Republic of Serbia passed a law on transplantation of tissues and cells, which has recently been entitled as the Law on human cells and tissues (Official Gazette of RS No. 57/2018). In the same year, the Law on biomedical assisted fertilization came into force with an update in 2017 (Official Gazette of RS No. 40/2017). According to the law, commercial use of reproductive cells and embryos is not allowed, while reproductive cells of donors can only be used for the purpose of assisted fertilization. Similarly, creating embryos solely for the purpose of undertaking research or obtaining genetic material, cells, tissues and organs for therapeutic purposes as well as cloning is not legal (Official Gazette of RS No. 40/2017). Spare embryos created in the process of assisted fertilization may be used in research purposes only if both partners grant this by signing permission of use (Official Gazette of RS No. 40/2017). Because prospects of collaboration between Schools of Medicine and Universities in Serbia and beyond have been initiated to promote research on regenerative medicine (Curricula Development in the Fields of Reproductive Biology/Assisted Reproductive Technologies and Regenerative

Medicine in Serbia), education on research ethics in work with embryos will certainly be relevant and necessary.

Establishing Ethics Committees

Review of scientific and ethical aspects of research performed by Ethics Committees is an important aspect of medical research (Shamoo and Resnik 2009). The main role of an Ethics Committee is to perform an ethical assessment of protocols for biomedical research and trials performed on human participants, as well as to assess the risks and benefits for participation. Members of Ethics Committees should consider the following issues when reviewing research protocols: scientific rigor of the proposed study, level of risks to participants, risk–benefit ratio, process and equity of recruiting participants, protection of confidentiality, process and documentation of informed consent, protection of vulnerable subjects, international collaborations and research in developing countries, safety monitoring, and disclosure of conflicts of interests (Shamoo and Resnik 2009). Because most Ethics Committee members are scientists themselves, it is crucial that physicians at the beginning of a career in science know principles of research ethics specific to research with human subjects and receive education through research ethics courses.

Since 2005, all health care institutions in the Republic of Serbia are legally required to have an Ethics Committee (Official Gazette of RS 113/2017). Following this act, many Ethics Committees have been formed over the past decade. Because of this, there is an increasing need for physicians who are at least familiar with, if not well-educated on research ethics issues. It has been underscored that Ethics Committees in Serbia are composed of physicians and other professionals working in health-related field, such as dentists, pharmacists, nurses as well as lawyers, while philosophers were, by and large, omitted (Rakic and Bojanic 2011). The presence of philosophers in Ethics Committees is needed to strengthen the board competence and efficacy, but also to provide a point of view that physician researchers might not be aware of. Despite some improvements (Rakic 2013), more education on roles and activities of Ethics Committees in the research process is needed to fully appreciate duties and responsibilities of a well-established Ethics Committee.

Limitations

This research has certain limitations. While the information pool examined for the purpose of this research was rather large, it does not represent a systematic review of all the available research ethics curricula ever proposed or conducted. Although we searched the largest database of medical articles, we included only one database in our search. Still, our literature search was comprehensive and based upon established clear inclusion criteria. In addition, the result that the topics chosen had 75% agreement with those found in the literature suggests that many ethical concerns are also relevant for the Serbian research milieu. Although there were clear and formal inclusion criteria for inclusion of the topics, some topics were excluded based on authors' agreement which is open to bias. Many of the study limitations

are a consequence of pragmatic decisions made because the primary purpose of this work was to provide relevance of these research topics in the Serbian setting. However, differences in the evaluated curricula and the proposed topics are expected and should exist, to adjust programs according to needs of a particular region and/or institution. Finally, other similar studies available in literature were also designed in a similar manner, i.e. they represent a combination of literature review and recommendations and comments of the authors (Silverman et al. 2010; Taylor et al. 2012; Nikravanfard et al. 2017).

Conclusion

In conclusion, the eight syllabi identified in this study are recommended as the core content of research ethics education for physician researchers at the beginning of their scientific career. The proposed core content of research ethics education could have a critical role in tailoring future research ethics curricula and/or programs for physician researchers. Comprehensive education of physician researchers in research ethics is necessary in the process of capacity building and improvement of skills among physician researchers in Serbia to match their counterparts at a global level.

Author Contribution All authors contributed to study conception and design. Formal data analysis was performed by TG, JD, VJS and DKT. Draft preparation: TG, JD, DD and VJS. Review and editing: DKT. All authors approved the final version of the manuscript ahead of submission and agree to be held accountable for all aspects of this work.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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