

It is Problematic to Subject Scientific Research on COVID-19 to Permission from the Ministry of Health

The COVID-19 pandemic is a disaster that caught the whole world unprepared. We were not familiar with its biological and clinical characteristics and could not foresee its social and economic consequences. The first step to be taken in dealing with this disaster is to explore the characteristics of the virus and the pandemic as quickly as possible by means of scientific research. When the Ministry of Health established a Scientific Advisory Board in the early stages of the pandemic and introduced certain precautionary measures upon the recommendations of the Scientific Advisory Board, this was appreciated and trusted both by the public and the scientific community. This trust is essentially rooted in trust in science. Therefore, supporting scientific publications about COVID-19 is highly important.

On 28 April 2020, the Ministry of Health sent an official letter¹ drafted by the Directorate General of Health Services on behalf of the Minister, to all Governorships - Provincial Health Directorates and to all universities through the Council of Higher Education (YÖK), reaching all faculty members, not only in health sciences, and to all bodies regulating research, including Clinical Research Ethics Committees. The letter announced that a "COVID-19 Scientific Research Evaluation Commission" was established within the Directorate General of Health Services under the Ministry, "to facilitate access to data needed for scientific work, to support the creation of a network to work on large data series when necessary, to establish a conceptual framework that will enable comparative work and to include the resulting research publication in the TÜSEB² publication support program".

According to the letter; "[...] this Commission is to be notified of all scientific research and retrospective studies on humans, including clinical trials, before the (mandatory) application process to ethics committees. For research on COVID-19, which has previously obtained the permission of an ethics committee, an application must be made to the Commission within at most 10 (ten) days."

Although it is stated that the Ministry of Health aims to encourage and support scientific publications, it should be emphasized that the method chosen for this purpose is highly problematic. When the letter, the

¹ Sayı: 60867207/605.99/Konu: COVİD-19 Konusunda Bilimsel Araştırma Çalışmaları

² Türkiye Sağlık Enstitüleri Başkanlığı (https://www.tuseb.gov.tr/AnaSayfa/)

website³ where the applications are to be submitted and the forms required for applying are looked at in detail, the following observations can be made:

- 1. It is compulsory to apply to the COVID-19 Scientific Research Evaluation Commission for *any* scientific research about COVID-19, except for case reports;
- 2. No information is available on the membership of this Commission and their competencies;
- 3. The criteria for the assessment of the research applications and the scope of the assessment are not disclosed;
- 4. It is not clear whether it is possible to reject a research proposal based on such an assessment. However, according to the information on the early outcomes, the Commission has found some applications "not appropriate";
- 5. An application to an ethics committee cannot be made without having applied to the Commission and received a feedback first;
- 6. Ethics committees will decline any application that has not obtained a permission from the Commission;
- 7. The Application Form requires sensitive data such as the subject of the research, data collection tools and methods, whether the data obtained is intended to be used in another research and whether the researcher is willing to be included in a multicentre study.
- 8. The applicant makes a further commitment to the fact that he/she will sign "all commitments <u>after</u> the application is accepted" in addition to the commitment regarding the accuracy of information provided. However, it is not clear what additional commitment will have to be made after the application is accepted.

This approach is problematic as well as in contradiction with the essence, purpose and basic principles of scientific research. The purpose of scientific research is to learn and test the unknown through experimentation and observation. Research on any topic, including the current and vital issues of COVID-19, should be independent from preapproval and prejudice, so that the unknown and the unpredictable can be freely investigated to lead to reliable and useful information. The very ultimate judge of scientific research should be verifiable facts about nature, about society and human beings.

Surely, prior to launching, a research project is evaluated; 1) ethically, based on the principle of not harming people, animals and the environment, and 2) ethically and scientifically, in terms of the methods to be used to reach accurate information as well as principles of scientific integrity and feasibility. The evaluation for the first part is already done for clinical research by the Ministry of Health and the ethics committees of hospitals.⁴ And the latter evaluation is done by the institutions to which scientists apply for support before starting their research, i.e. public scientific agencies such as TÜBİTAK, universities'

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³ https://bilimselarastirma.saglik.gov.tr/

⁴ In a <u>text</u> published by UNESCO IBC & COMEST at the beginning of April, the basic principles were outlined for conducting scientific research for the benefit of humanity and everyone in the time of the pandemic. Here, too, the importance of conducting research under the supervision of ethics committees is emphasized. However, considering the urgency of the situation, it is underlined that the measures to be taken by the ethics committees should be compatible on the global scale. While the effort to conduct more research, an opportunity created by the pandemic, leads to an explosion of publications all over the world, the increase in publications that are not based on sound scientific evidence and referee evaluations also causes information pollution. For other important texts and their translations on this topic, see. https://vprd.ku.edu.tr/etik-kurullar/.

research funds, other public and private national and international institutions supporting scientific research.

After the research is completed referees of scientific journals, check these results before allowing publication. Other scientists can repeat the experiments and observations to test the accuracy of the results. It is of fundamental importance that the boards, panels and referees involved in these evaluation processes are selected according to scientific merit and operate only on the basis of scientific merit. Should these processes be managed by bureaucratic and political decisions, the result would be inefficiency, misinformation. Reliable information would be inhibited or ignored. Policies not based on reliable science, or only pretending to have a scientific basis will cause harm to society.

This preliminary permission mechanism for studies on COVID-19 leads to delays in national and international projects, in a time of emergency, by putting a restriction on research. In addition, it overrides the existing scientific evaluation mechanisms of research support institutions such as TÜBİTAK. Instead of coordinating with TÜBİTAK, the Ministry of Health introduces an unspecified additional process. It is not disclosed by whom and how this process will be carried out. Moreover, this preliminary permission process has been put in place for "all scientific studies and retrospective research on human regarding COVID-19, including planned clinical trials." It is understood that the Ministry of Health also subjects mathematical modelling and social science field research pertinent to the COVID-19 outbreak to its own permission.

It should not be forgotten that, according to Article 27 of the Constitution, "Everyone has the right to freely learn and teach science and art, to explain, disseminate and to do all kinds of research in these areas." Also, according to Paragraph 4 of Article 130, "Universities, faculty and assistants can freely participate in all kinds of scientific research and publications." It is clear that any limitation to the freedom of science, which is under constitutional protection, can only be through law (Art.13 of the Constitution) and it cannot be imposed with a letter from the Ministry of Health. It is also worth noting that Article 57, 64 and 279 of the Public Health Law No. 1593 submitted by the Ministry of Health as a justification for the letter in question, are not even related to scientific studies. These laws rather regulate the Ministry's mandate in the case of an epidemic, the obligation of health workers to report all data to the Ministry and to collect data from private and public hospitals. The rationale for any restrictions on the freedom of science can, according to the Constitution only be "an activity against the existence and independence of the state and the integrity and indivisibility of the nation and the country".

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⁵ Constitutional Court, E. 2018/105, K. 2019/71, 19.09.2019: "20. Paragraph 1 of Article 27 of the Constitution, (Everyone has the right to freely learn and teach science and art, to explain, disseminate and to do all kinds of research in these areas), guarantees the freedom of science and the arts. In this regard, there is no doubt that academic staff has the right to learn, teach, explain and disseminate its research freely and do all kinds of research by scientific studies." *Constitutional Court, Kemal Gözler (2) Decision*, B. No. 2015/5612, 10.12.2019: "38. There is no doubt that an academic's research and publishing his/her findings is part of his/her academic freedom. Furthermore, the Constitutional Court agrees with the European Court of Human Rights' view that academic freedoms include the freedom of academics to express their views and opinions in the fields of research, professional expertise and competence, even if the ideas are controversial or unpopular. 39. Surely, it cannot be claimed that everything that academics say is absolutely correct. However, it is an agreed upon fact that alternative and different views enable more space for thinking for everyone. Therefore, it is vital for a society and a country that academics can challenge even the most prevalent views on the most critical and sensitive issues."

In all scientifically developed countries and regions of the world (USA, Canada, UK, European Union), states have been launching new programs to support medical, epidemiological, social, economic and humanitarian research projects to fight against the Covid-19 pandemic, publishing guidelines for the execution of projects, speeding up reviews and encouraging publications. The only exception to this has been China where the state attempted to strictly supervise research.⁶ In Turkey, TÜBİTAK provided support for research on the medical, social, human and economic aspects of the pandemic early on and this was seen as a positive step by the academic community. However, the fact that another state institution (the Ministry of Health) has decided to pre-evaluate projects, no matter what the results of this pre-evaluation may be, is contrary to universal traditions of free scientific research. It will unsettle the scientific community and damage the medium of independent scientific research. Furthermore, this will lead Turkey, which seemed to be on a successful path in terms of medical practice, to be seen as less significant in the field of research and to be largely excluded from international collaborations.

A well-functioning democratic society should primarily rely on accurate information and science. This has been proven right by the recent pandemic, and the importance and urgency of trusting science and reason has once again been demonstrated in our country and around the world.

We respectfully present our statement to the public and to the authorities.

Executive Board of Science Academy

12 May 2020

⁶ https://www.nature.com/articles/d41586-020-01108-y