Ethical considerations and interdisciplinary approach to research on COVID-19 pandemic: The response of Iran University of Medical Sciences

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Abstract

Background: Research ethics committees are comprised of policymakers, supervisors, and decision-makers and aim at increasing adherence to professional ethics standards in conducting health-related research. The existential philosophy of these committees is to preserve the patients’ health, maintain and promote public trust in health care providers, protect the rights of both patients and health care providers, and promote organizational ethics. However, this task can be complex and challenging during a public health emergency. Research ethics committees set the standard of research in the emergency situations through defining which research has the potential to promote the quality of response to a public health emergency.

Methods: This study aims at collecting and classifying the valuable experiences of the research ethics committee members and reviewers during the early days of the COVID-19 epidemic in Iran University of Medical Sciences, one of the major universities in Tehran. It provides a basic understanding of the key concepts and challenges in reviewing and approving research by research ethics committees and the recommendations to overcome these challenging issues.

Results: To accelerate the review process of COVID-19 research proposals, the scientific, methodological and ethical review panel was integrated as a large committee called ‘IUMS Corona Research Team’. The first meeting was held on March 7, two weeks after the official announcement of the first case of the disease and is continued once a week. A total of 130 projects have been discussed and evaluated in this committee, among which 83 proposals were approved after modification.

Conclusion: An interdisciplinary approach supports a flexible and effective scientific and ethical review of research leading to more protection of research subjects as well as promotion in the treatment and management of the pandemic ahead.

Keywords: Research ethics committee, Pandemic, COVID-19

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Introduction

Following the Coronavirus epidemic crisis worldwide, the Director of Public Relations and Information Depart-

What is “already known” in this topic:
Research conducted during global health emergencies raises particularly complex ethical challenges and there are a few research ethics guidelines, providing general recommendations on how research ethics committees should address these challenges.

—What this article adds:
This report presents the experience of Iran University of Medical Sciences in ethically managing research during early COVID-19 outbreak in Iran and provides a context-based guide to improve emergency response and preparedness regarding future outbreaks.
The response of ethics committees in COVID-19 pandemic

The COVID-19 research topics can be divided into 2 categories:

Group 1: Projects that are performed to answer the clinical and managerial questions raised by professionals and policymakers, and the answer needs to be presented to them as soon as possible for their decision-making.

Group 2: Projects that are expected to document the epidemic experience in Iran and share them with the world.

Below are the operations performed by the committee:

1. The first meeting of the IUMS COVID-19 research committee was held on Saturday, March 17, 2020; to date, 5 meetings have been convened in-person and some others virtually.

2. The committee usually exchanges information through emails and social networks and holds its meetings once a week.

3. Despite expediting the process of evaluating the projects on Coronavirus, the process of reviewing and approving the projects is done with strict compliance with the quality criteria.

4. Three main working groups have been set up to manage research in Coronavirus, including (1) research on epidemiology and public health, (2) clinical research, and (3) basic science and virology research. In meetings and social networks, all 3 groups discuss each and every research proposal.

5. After the scientific review of the proposals at these meetings, all research proposals are forwarded to research ethics professionals for review within 48 hours.

6. Proposals can obtain code of ethics only if the researchers have properly followed the recommendations of the reviewers, in accordance with national and international guidelines for ethics in research.

7. All research projects are recorded at the website of Iran National Committee for Ethics in Biomedical Research and subsequently will be accessible to the public.

8. If the National Committee for Ethics determines ethical considerations have not been fully met in the approval of a research project, it shall suspend the implementation of the project and revoke the issued ethics code after coordinating with the committee for research ethics of the approving university.

9. Challenges and strategies of ethics reviewers presented in the Coronavirus Epidemic Plans 2019 are summarized in Table 1.

Methods

The committee started its duties and activities from the same date. Working with the members of the university’s Ethics Committee in Research and the members medical ethics department of the university, the committee was determined to provide maximal protection for patients and individuals involved in these projects. The committee consists of three groups: (1) relevant university managers, including university chancellor and vice chancellors, CEOs of 4 university hospitals involved with COVID-19 patients; (2) three members of the university ethical review board; and (3) university faculty members from various disciplines/departments, including medical virology, immunology, infectious disease and tropical medicine, internal medicine/pulmonology, emergency medicine, psychiatry, community medicine, anesthesiology, epidemiology, biostatistics, occupational and environmental health, medical informatics, disaster management, health economy, health system management, and health policy.

Results

Considering importance of the issue, the research committee meetings were held on March 7th, 14th, 8th, 25th, 30th and on April 11th and 21st of 2020, and they still continues at least once a week. To date (April 21, 2020), 130 projects have been discussed in this committee, of which 7 were related to mental health, 32 to epidemiological and public health, 28 to clinical research, and 11 to basic science and virology. Workgroup and study typerecorded in Table 2.

Also, according to the views and recommendations of the scientific referees, cost referees and ethics referees, the proposals were modified by the authors and finally approved. Three proposal of clinical trials group are still being reviewed ethically. Reviewer/committee concerns regarding

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Discussion and Conclusion

Research ethics committees are comprised of policymakers, supervisors, and decision-makers and aimed at increasing adherence to professional ethics standards in conducting all health-related research. The existential philosophy of research ethics committees is to preserve the patients’ health, to maintain and promote researcher-to-patient confidence in health services, to protect patients’ rights and service providers, and to promote organizational ethics.

These committees strive to accomplish their mission comprehensively in a wide variety of ways. The main goals of these committees are as follows: considering human principles and values in health research; informing people about their rights as patients and their social responsibilities; protecting human dignity and rights of patients as stated in the Declaration of Helsinki and in Ethics Guidelines for Research on Human Subjects; and monitoring, supervising, and evaluating of the researches.

In addition, the committees provide a valuable help in addressing ethical challenges in research environments and

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<tr>
<th>Table 1. Challenges and solutions of ethics reviewers</th>
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<tr>
<td>Research ethics criteria</td>
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<tr>
<td>Scientific design</td>
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<td>Inclusion and exclusion criteria</td>
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<td>Research procedures</td>
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<td>Risk/burden and benefit</td>
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<td>Research subject compensation or reimbursement of costs</td>
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<td>Process of obtaining informed consent</td>
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- According to chapter 2 of the ethics guidelines for clinical trials, the author is responsible for compensating patients. Thus, the author is supposed to commit to obtain the accident insurance policy from the sponsor of the project and submit it to the Research Ethics Committee.
- All clinical trial participants are covered by financial sponsors, which are usually pharmaceutical companies.
- Lack of conflict of interest of the researcher shall be ascertained by the committee.
- Review of ethical issues by ethics committee
- Making all treatments free of charge for patients with Coronavirus disease by the Ministry of Health

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<th>Table 2. Workgroup and study type</th>
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<td>Workgroup and study type</td>
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<tr>
<td>Epidemiology and public health research</td>
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<tr>
<td>Clinical research</td>
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<tr>
<td>Basic science and virology research</td>
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<td>Research into staff health maintenance, particularly mental and educational health</td>
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<th>Criteria for consent document</th>
<th>Reviewer/committee concern</th>
<th>Recommended solutions</th>
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<tr>
<td>Purpose of research</td>
<td>Study information is stated in a way that therapeutic misconception may occur.</td>
<td>Providing the patient with ample opportunity to consult before making a decision.</td>
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<tr>
<td>Study procedures</td>
<td>Participation stages are not clearly described. The type of intervention and how the patient co-operates are not properly stated.</td>
<td>The type of research intervention and patient collaboration should be clearly stated both in the proposal and in the informed consent.</td>
</tr>
<tr>
<td>Disclosure of potential risk/burden</td>
<td>The research risks are not fully explained. (Necessity to properly address the risks and possible side effects).</td>
<td>- The forms of informed consent and the report of adverse events will be examined by the ethics committee in research.</td>
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<td>Disclosure of benefits</td>
<td>Statement of the benefits can be subject to undue influence through persuading the individuals to participate in research to identify and discover new Coronavirus treatment without having sufficient evidence.</td>
<td>- Accurate evaluation of the risks and possible complications of the research by experts.</td>
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Acknowledgment
Thanks to the efforts of the research ethics committees at the university and considering the issues above, ethical scientific research will be performed with full protection of patients to promote treatment and management of the epidemic.

Conflict of Interests
The authors declare that they have no competing interests.

References

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