



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-

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↑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.

ment at the Ministry of Health and Medical Education formally announced the death of the first patient with coronavirus-2019 in Qom on Wednesday February 19, 2020, and Iran's involvement was officially declared (1).

As the disease spread in the country, the headquarters for fighting Coronavirus convened on Thursday, March 1, 2020 in the presence of the Minister, his deputies, and other senior managers of the Ministry (2, 3).

Six days later, the Ministry published the first "Guidelines on the care, diagnosis, and treatment of Coronavirus."

What matters most in health-related crises is evidence-based decision-making. Conducting research to generate such evidences in epidemics, provided that ethical considerations are fully taken into account, is an undeniable necessity.

As one of the most renowned medical universities in the country, Iran University of Medical Sciences plays an effective role in providing educational, research, and medical services in Tehran province.

There are 17 hospitals — 11 teaching and 6 medical hospitals — affiliated to the university, covering over 5 350 000 of the population of Tehran province, with more than 12 million habitants. The university owns 3300 university hospital beds and there are about 7000 additional beds in the private covered centers. Thus, a total of 10 000 hospital beds, located in southwest, west, and northwest of Tehran, are supervised by Iran University of Medical Sciences. The university has more than 9000 students, about 1000 faculty members, 46 research centers, and 4 research institutes.

The university's Vice-Chancellor for Research and Technology established "IUMS COVID-19 research committee" at Iran University of Medical Sciences in early March, stressing that in this pandemic, research should play an essential role in providing scientific evidence as well as new technologies to support clinicians, nurses, health professionals, and wider range of policy-makers who should make important decisions in response to novel Coronavirus epidemic.

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.

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.

8. 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.

11. 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.

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

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

Table 1. Challenges and solutions of ethics reviewers

Research ethics criteria	Reviewer/committee concern	Recommended solutions
Scientific design	Previous scientific evidence is insufficient (Clinical information or pharmaceutical mechanism has not been fully disclosed). The objectives are hardly achievable with respect to available facilities	Evaluation of clinical information and pharmaceutical mechanisms by scientific reviewers of the research ethics committee Assessing the feasibility of proposed research procedures by the research ethics committee
Inclusion and exclusion criteria	Failure to meet appropriate inclusion and exclusion criteria	The criteria are to be explained in an objective and measurable way in both control and case groups.
Research procedures	Absence of adequate or appropriate expertise to perform the research procedures Not including procedures to monitor adverse events of the research interventions Absence of procedures for posttrial provision of research interventions, such as special psychological or educational training for the control group	Adding a researcher with relevant expertise to the research group Including procedures to monitor adverse events of the research interventions Employing procedures for posttrial provisions
Risk/burden and benefit	Failure to provide evidence on efficacy and safety required for therapeutic intervention Failure to balance the benefits / risks of unapproved interventions for patients The benefits to the patients or the future community are not clear.	Inserting and explaining scientific evidence on efficacy and safety of intervention in literature review After obtaining informed consent, the researcher is allowed to enter only those patients into the study whose clinical condition worsened, despite receiving treatment protocols notified by the Ministry of Health. Disclosing potential benefits for the community
Research subject compensation or reimbursement of costs	The PI/funder has not provided compensation to participants for the potential serious adverse events. Risk of coercion regarding the fact that patients participate only due to economic issues and reimbursement of costs	-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
Process of obtaining informed consent	Incomplete insertion of the process of obtaining informed consent	Writing down the time, place, and the person who explains information about the project to patients or their families. Stating the way how to get an alternative decision-maker to consent to patient participation in research, when the patient is not qualified to give informed consent.

consent document and recommended solutions in Table 3.

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 Guideline for Research on Iranian 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

Table 2. Workgroup and study type

Workgroup and study type	Number
Epidemiology and public health research	32
Clinical research	28
Basic science and virology research	16
Research into staff health maintenance, particularly mental and educational health	7

Table 3. Reviewer/committee concerns regarding consent document and recommended solutions

Criteria for consent document	Reviewer/committee concern	Recommended solutions
Purpose of research	Study information is stated in a way that therapeutic misconception may occur.	Providing the patient with ample opportunity to consult before making a decision
Study procedures	Participation stages are not clearly described. The type of intervention and how the patient cooperates are not properly stated.	The type of research intervention and patient collaboration should be clearly stated both in the proposal and in the informed consent.
Disclosure of potential risk/burden	The research risks are not fully explained. (Necessity to properly address the risks and possible side effects).	- The forms of informed consent and the report of adverse events will be examined by the ethics committee in research. -Accurate evaluation of the risks and possible complications of the research by experts
Disclosure of benefits	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	Accurate evaluation and scientific review of the suggested treatment by scientific referees collaborating with the research ethics committee

raising awareness and ethical sensitivity of all stakeholders toward ethical aspects of research. Also, they aim to provide, maintain, and improve mutual trust between researchers and research participants while conducting the research. Moreover, they maintain credibility and reputation of the research advocates as an ethical social institution and promote the concepts of professional commitment.

With regard to the importance of ethical decision-making in medical research, having basic solutions to solve researchers' problem is essential (4, 5). Ethical guidelines facilitate this by streamlining the decision-making process.

Using the right framework requires examining the specific conditions of the epidemic (6), which makes the decision-making much easier.

This article is a report of the performance of the ethics committees in the research of Iran University of Medical Sciences, which has been developed with the evaluation of common ethical guidelines in the world (7-9) and the experience of several years of ethics committees in research at Iran University of medical sciences. To achieve the above goals, and given that the country has been managing and fighting the Coronavirus epidemic, Iran University of Medical Sciences, through convening 6 specialized sessions and weekly professional sessions, has reviewed all the research proposals currently underway and has tried to tackle all the scientific and ethical challenges ahead.

The research team has presented some tables regarding ethical challenges encountered in proposals and has provided specialized strategies to tackle them. In these tables, the general ethical challenges associated with the proposals are presented along with the strategies; then, in a separate table, specific ethical challenges associated with informed consent are categorized and suggested strategies for addressing them are provided.

In addition, through more and better inclusion of scientific points and accurate and scientific evaluation of research, all research works are classified and evaluated in 4 groups: staff mental health maintenance and educational interventions, epidemiological and public health research, basic science and virology research, and clinical trials.

A similar study was conducted in 2014-2015 by govern-

ment agencies on the Ebola epidemic. That study also divided the research studies on the basis of clinical trial, vaccine production, diagnostic measures, and optimal treatment. In the next step, studies were categorized based on the vulnerable groups. Like pregnant women, they have reviewed quality studies and studies on extra blood samples and etc. (10).

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.

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