

Research Article

Environment for Research Ethics in Japan

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Abstract

Research ethics entails various activities such as designing a system that promotes scientific research while protecting human rights and welfare of the research participants. Recently, in Japan, research ethics has been drawing increasing attention, with a number of fraudulent research studies becoming exposed.

This manuscript describes the environment surrounding research ethics in medical science in Japan: education about research ethics, support for research ethics, ethics committees, measures for researchers, tasks and countermeasures as organization, development of research ethics support specialists.

In conclusion, the present priority should be placed on the recognition of the authority and educational/research institutions regarding the true nature of research ethics so that they contribute further to its education and support. The human resource development of the research ethics specialist and research consultant is urgent given that it is the key for total research support.

Keywords: Research ethics in medical science; research ethics support; education about Research Ethics in medical science; ethics Committees; research consultant; Office for Research Ethics Support (ORES)

Introduction

Research ethics entails various activities such as designing a system that promotes scientific research while protecting human rights and welfare of the research participants. It is also an important concept that can be a point of contact between researchers and society. In fact, it is a sublime research theme, but it may also be a field that researchers who practice research ethics may find difficult to understand [1]. Recently, in Japan, research ethics has been drawing increasing attention, with a number of fraudulent research studies becoming exposed [2, 3]. Among the numerous issues discussed at present, educational and support issues particularly require urgent solutions.

In this context, this manuscript describes the environment surrounding research ethics in medical science in Japan.

Present Situation of Research Ethics in medical science in Japan

Although the exact percentage of medical professionals who engage in research is not known, it is clear that the enormous majority is not involved in any research but engages only in clinical practice evidently such as medical practitioners. This implies that generally, they have very few opportunities to encounter research ethics issues and perform routine practice without knowing any concept of research ethics, except those learned from educational/research institutions. Research ethics is a field that should be recognized widely among medical professionals, but in reality, its concepts are practiced only by a limited number of people who actually engage in research.

In fact, although research ethics is an essential concept for conducting medical/biological research for the development of medicine, medical equipment, or other technologies, researchers may find it difficult to handle research ethics and wish to avoid it; laypeople find it even harder to understand.

The original concept of research ethics started in the medical/life science domains with the aim of protecting the research subject. However, in Japan, research ethics is often associated with researcher frauds such as data fabrication and research fund abuse, and discusses a range of issues comprehensively including

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fraudulent research issues. By contrast, in Western countries, research fraud issues are generally discussed in the framework of research integrity instead of research ethics. For instance, in the United States, the governing authorities are the Office for Human Research Protections (OHRP) and the Office of Research Integrity (ORI) [4], indicating an environment different from the one in Japan.

Recent issues concerning fraudulent research in Japan have evoked awareness even among the general public, but they tend to be interpreted in a narrower sense that includes only the conventional stories of the so-called inappropriate relationship between pharmaceutical companies and healthcare professionals or attacks targeting particular researchers.

This bias seems to emerge because of media that tend to focus on criticizing particular researchers or pharmaceutical companies instead of the fundamental issue. In any case, researchers are losing social trust in this situation, and a more serious issue is the loss of credibility of the research conducted in Japan in the international society [5].

Therefore, government authorities have started to take measures to reinforce regulations, and various guidelines have been revised in recent years.

The related educational and research institutions are obliged to urgently address to these revisions at present.

Education about Research Ethics in medical science

We cannot say that adequate time is dedicated to providing education on research ethics in Japan, or even to that of clinical ethics. This is probably because we have conventionally had a general environment of believing that a physician's judgment is absolute and assumed that a physician naturally has a high ethical standard. We might have placed too much trust on the "quality of a physician" both in the clinical and research fields, resulting in the present lack of social consciousness about the requirement for an ethical education.

Currently, ethical education is limited to the academic level and is constrained by the time limits determined by the faculty, without any practical work. Besides the limited time, another reason for the lack of practical research ethics education is the reluctance to include the subject in the curriculum given that not every medical student aspires to be a researcher. Therefore, students receive practical education through e-learning programs such as CITI and Pharma Train after they begin to engage with research. Due to these reasons, practical education is delayed.

Support for Research Ethics

The Office for Research Ethics Support (ORES) of the Graduate School of Medicine of the University of Tokyo was established in 2009 with the primary purpose of protecting the rights, health, and dignity of research participants. Based on these

values, it supports researchers in performing their studies efficiently and in an ethically valid manner.

The primary tasks are the management of the Ethics Committee secretariat and the research ethics support services. ORES provides a wide range of services not only for individual needs including the pre-screening of research ethics review documents and consultation for researchers, but also examines the review contents of the Ethics Committee following the revisions of the ethical guidelines, prepares organ transplantation manuals for hospitals, coordinates views related to internal and external bodies, examines case documents in connection with high risk elective operations and medical treatments to be implemented for the first time at the University of Tokyo Hospital, and so on. All these are evaluated as indispensable efforts for the efficient implementation of ethically valid medical research. For approximately seven years since its inauguration, ORES has made efforts to shorten the time required for ethical review, enhance the review quality, and rationalize the review process. The efforts include specifically the reform of review system, implementation of local rules, construction of online application system of research ethics review, and introduction of an electronic conference, all of which enable a user friendly application system and ensure an accurate and rapid review process.

Regarding the main tasks of the management of the Ethics Committee secretariats and the research ethics support services, the number of applications submitted for research ethics review to the committee is increasing, and accordingly, the work volume is increasing almost to the capacity limit due to modification of guidelines and changing of recognition in researchers. The total number of the new and revised applications reached almost 1,200 in 2015 (Figure 1). This huge volume is processed daily by vigorous efforts of very limited human resources. During these years, major educational/research institutions are establishing a section providing research ethics support services respectively in different scales. Otherwise, there are many educational/research institutions which are establishing a section providing research ethics support services [6-10].

ORES also provides educational/training services including researcher education through consultation, planning/management of research ethics seminars, and development of secretariat staff.

Status Quo of Ethics Committees

At present, there are more than 2,000 ethics committees across Japan, but they are not centralized by systems that ensure review only by authorized committees, abolishing those who are unable to maintain quality, and grouping by region. They are not standardised in terms of review quality, which varies with institution or region. In addition, those ethical committees are not sufficiently coordinated, resulting in redundant reviews of a case. In this situation, review quality cannot be guaranteed. For these unstandardisation of review quality, the governmental authorities

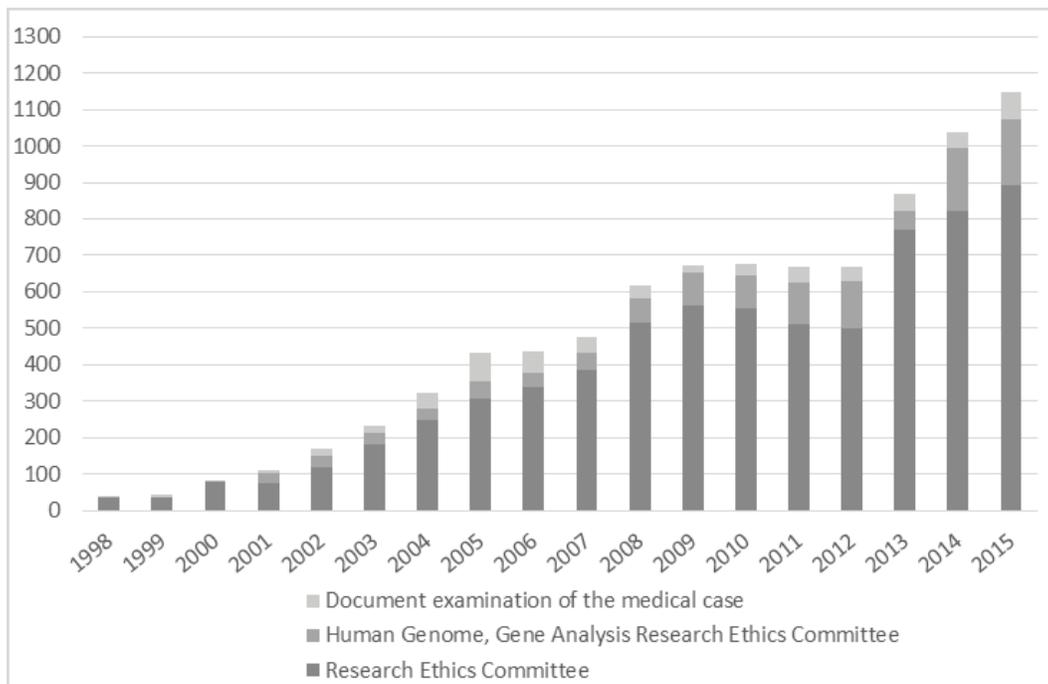


Figure 1. Total number of ethics reviews in Graduate School of Medicine and Faculty of Medicine, The University of Tokyo.

are leading the reforms. In addition, some committee members often have to deal with an overload of case reviewing without pay. Neither effective assessment system nor incentive systems exist for committee members. Not everyone but only individuals with a high ethical sense can handle the duties of the ethics committee. Considering the ever-increasing work volume at present, it is debatable if ethics committees can continue to fulfill their duties in the existing structure. Needless to say, the education of ethics committee members is indispensable to ensure the quality of the committee as well as that of their review.

Measures for Researchers

Although the number of researchers among healthcare professionals is not high at all, the research they conduct that are closely related to progressive medicine have enormous social impact in case anything goes wrong. The practical education of researchers must be reinforced particularly focusing on this aspect. It is undeniable that the literacy of research ethics among researchers is low, and this is not solely their fault. Research ethics should not be left unattended as a field that is difficult to understand and handle. Educational and research institutions should implement infrastructure that enables researchers to correctly understand and practice the concept of ethics. In addition to steady education, highly qualified ethical advisors should be allocated to for each unit of laboratory and department.

Tasks and Countermeasures as Organization

It is becoming more and more challenging for a manuscript

to be accepted by a journal with a high impact factor unless the research is large in scale. In this situation, total research support services which including ethics support should also be provided. However, organizations are often negligent and indifferent about the work evaluation or work volume of supporting services, which sets in motion a vicious cycle. Organizations should recognize that research will stagnate unless the support service is reinforced and proceed with drastic budgeting and recruitment. In Japan, where support services are generally complimentary, both service providers and users including institution executives lack seriousness, causing undoubtedly an adverse effect from being free of charge. Organizations should switch the support to a paid service to raise the quality of the support service department. At present, only a small number of institutions charge for the review service. In addition, the idea of regulatory science is not adequately widespread in Japanese medical research field. We may be rather lacking in terms of a habit of developing regulations. Organizational efforts may be required in the future to generalize regulatory science.

Development of Research Ethics Support Specialists

Few physicians aspire to be research support specialists, and fewer still research ethics specialists. Those who wish to become support specialists have no evaluation system, and their career path is difficult to predict. Therefore, the general impression is that failed researchers are obliged to become research support specialists. In fact, research support specialists often fall into a vicious cycle: hardly engaging in their own research activities, producing no

better results nor evaluation of their papers, and finding their motivation decline. With no organizational recognition, no budget allocation, and no human resource supplementation, research support specialists are obliged to resign. These merciless conditions suggest that no one should ever aspire to be a research ethics specialist unless there is a compelling reason. This is a pitiful situation and a serious problem. In reality, not everybody can be a research ethics specialist. Only those who have special skills can do so. Efficient researcher support can be achieved not only by physicians, but through the coordinated efforts of a team comprising various professionals. In particular, it is desirable that the manager of such a team is a physician when supporting medical and life-science research, but developing this type of human resource is extraordinarily challenging. A research ethics specialist should be among the most excellent human resources who can be successful as a researcher. The managers should particularly be in the same top class as clinicians and researchers.

Here, we consider the skills required of research ethics specialists. Researchers expect a lot from research ethics specialists and request for consultation regarding a wide range of issues related to research implementation. Specialists are expected to be able to guide researchers supportively but sometimes educationally as well. They also need to have skills to gauge the researcher's need and capacity correctly and offer necessary support as a service provider at an appropriate pace preferred by the researcher. Furthermore, they need to coordinate with other services and departments to support conducting of high-quality research. Communication and negotiation skills are of particular importance. They also need to develop self-consciousness given their location as support professional in the domain that can be a point of contact between researchers and society and always pay attention to the social response to relevant subjects. The most valued is the attitude to enhance their own personal quality as a negotiator as well as to develop their professionalism as a research ethics specialist.

What is the requirement to develop this type of a human resource? Again, we believe that an appropriate system should be implemented to recognize the research ethics specialist as a formal post that facilitates the practical application of academic achievements and then develop qualification and evaluation systems accordingly. Management consultant is socially recognized as a profession even though there is no relevant qualification system. Similarly, research ethics specialist and research consultant should be positioned as reasonable professions. Human resource for management should receive remuneration above a certain level, and an appropriate assessment system should be developed to make the post more attractive. Organizational initiative for these efforts will complete the basis to develop good human resources and promote its acceleration. The first step may be the action from

large-scale educational and research institutions to develop core specialists in research ethics and consultation to send them out to other institutions to popularize the profession and improve the environment surrounding the ethics committees and research/research ethics support sections.

Conclusion

The system should be reviewed and regulations should be reinforced, but the present priority should be placed on the recognition of the authority and educational/research institutions regarding the true nature of research ethics so that they contribute further to its education and support. The human resource development of the research ethics specialist and research consultant is urgent given that it is the key for total research support. Such an empowering system is certainly indispensable to raise the standards of Japanese research.

Competing interests

The authors declare that they have no competing interests.

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