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For the Sound Development of Science

-The Attitude of a Conscientious Scientist-

Japan Society for the Promotion of Science

Editing Committee “For the Sound Development of Science”

Introduction

Scientific research is an activity in which we, motivated by intellectual curiosity and a desire for exploration, seek to understand truths about various phenomena surrounding us, how they happen, what causes them to happen. Scientific research is advancing through an accumulation of effort made by many who came before us. Today, scientific results are indispensable to people's lives, with science making extremely significant impacts on society, particularly over recent years. While proud of this fact, scientists also realize that it places upon them weighty responsibilities and expectations.

Meanwhile, scientific research has unfortunately seen cases in which the "pursuit of truth," science's most inherent value, is to one degree or another neglected. Should these cases continue to occur, trust in science may be lost, threatening its sound advancement.

Responsible scientists must, themselves, respond to these cases in appropriate ways: All scientists need to be perceptive of the true nature of scientific research and of the proper comportment of a principled investigator. They must also take proper care in guiding younger generations.

This book compiles essential points on how people engaging in research in all fields from the humanities and social sciences to natural sciences (hereafter referred to as "scientists") should conduct their research and communicate their results within the science community and to the larger society. To that end, the book begins with a section on "What Is a Responsible Research Activity?" Consisting of eight sections, it concludes with a section on "For the Progress of Society." The book contains what one should know while engaged in research, including ethical considerations, code of conduct, methods of presenting research results, appropriate uses of research funds, and other points to bear in mind as a scientist.

To advance science, it is essential that scientists treasure their intellectual curiosity, conducting research creatively in a free environment. While this book stipulates various restrictions and rules related to research, it is important to emphasize that, while scientists should learn from ethics programs and guidelines, they should not be overly constrained by them.

This book has been edited by the Japan Society for the Promotion of Science (JSPS), an agency that provides "*kakenhi*" Grants-in-Aid for Scientific Research, which established an editing committee in multi-faceted collaboration with the Science Council of Japan and experts affiliated with the Japan Science and Technology Agency and various universities. The committee receives advice from the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Scientific research is advancing day by day. While the most fundamental parts of this book will not change significantly in the future, it is possible that transitions over the passage of time will lead to minor adjustments in its content. When such cases happen, it may be necessary to revise the book's content as appropriate.

It is our hope that this book will be used at research sites all around Japan, and that it will contribute to the sound advancement of science.

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Editing Committee "For the Sound Development of Science"

Japan Society for the Promotion of Science (an independent administrative institution)

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Collaborators:
Subcommittee for Research Ethics Educational Program, Committee for Scientific Research Integrity, Science Council of Japan
Yuuji Kohara (Project Professor, National Institute of Genetics), Tetsuo Kidokoro (Associate Professor, The University of Tokyo), Hiromi Yokoyama (Associate Professor, The University of Tokyo), Hiroaki Aihara (Professor, The University of Tokyo), Tadashi Karube (Professor, The University of Tokyo), and Hideaki Kawabata (Associate Professor, Keio University)

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Section I: What Is a Responsible Research Activity?

1. Responsible Research Activity: Why Now?

Science is built upon a foundation of trust. Scientists believe that they and their colleagues "have gathered data carefully, used appropriate analytic and statistical techniques, and reported their results accurately."[1] The general public also believes that "scientific research results are an honest and accurate reflection of a researcher's work."[1] If such trust were to be shaken or lost, science itself would lose its foundation.

Unfortunately, there have been incidents of research misconduct such as data fabrication and falsification as well as improper use of research funds. Some of them have been reported in the media. Trust in science could have been shaken if no action were taken. The Science Council of Japan, the primary organization of scientists[2] in Japan, issued its "Statement: Code of Conduct for Scientists—Revised Version" in January 2013, followed by a declaration on "Measures to Prevent and Deal with Research Misconduct: Toward the Healthy Progress of Science" in December of the same year. In addition, MEXT has revised its "Guidelines for Responding to Misconduct in Research," and it plans to implement these new guidelines in 2015.

With this background, this book summarizes the standards that each scientist needs to understand and abide by to ensure the sound advancement of science. There are scientists who already know many of these principles, but it is beneficial for every scientist to gain a proper understanding of them, including some recent trends. To advance science, nothing is more important than freedom in carrying out research. While various rules and restrictions on research activities exist, research activities must not be impeded by these rules or by a misunderstanding of them. When scientists maintain these standards autonomously, it becomes possible for them to conduct their research freely and independently without incurring excessive external interference.

Such is the purpose of this book. Scientists should themselves take positive steps to learn anew the nature of principled research and to build upon that concept in fostering the next generation of scientists so as to soundly advance science and establish public trust in it.

2. Responsibility for Proper Research Conduct within Society

2.1. Science and Society

Let's consider again the relationship between science and society. A new discovery made through scientific research does not bring joy to the scientist alone. Scientific research is uniquely human, as only humans can carry out intellectual activities. A new discovery in science captures the interest of the general public and can bring great joy to society, not just to the scientists involved. What has allowed human society to overcome past hardships and difficulties and to obtain today's level of abundance is undoubtedly the system of knowledge science has strenuously built over the years. Challenges that must be tackled in building an even richer society are entrusted to the hands of current and future scientists. In addition, the impact that science has on society is growing larger, making the relationship between science and society even stronger.

It is the inherent responsibility of scientists to conduct their research activities in pursuit of truth in an ethical manner. As science and society are so closely tied, the sound advancement of science requires the society's trust and mandate. Accordingly, it is necessary for scientists to establish self-regulating ethical guidelines for research in order to maintain societal understanding.

Given the many details of each method, no ethics rule exists that can be universally applicable to all research areas. Specific methods for implementing research ethics may differ between research fields. However, there is a common set of values that all scientists need to possess in conducting ethical research. The following points of ethics undergird the autonomy of individual scientists: Responsibility to science and society, research integrity, and compliance with laws and regulations.

Responsibility to Science and Society

What are the responsibilities of scientists to society? Scientists are expected to use their knowledge and intelligence to make new discoveries and to solve various problems encountered by society. To respond to such expectations is one of scientists' responsibilities. In this process, scientists often use public research funds, so they must be aware of society's expectations reflected in such funding. Furthermore, scientists are expected to proactively explain the significance of their research and the role it plays in society in a way that is easy for the general public to understand. Scientists are also expected to objectively explain to the public possible impacts and changes that their research may exert on humanity, society, and the environment. This should be done from a neutral stance, while carrying out a constructive dialogue with society on the subject issues.

Science contributes to society in many different ways. Scientists are responsible for maintaining the level and quality of the specialized knowledge and technology that they produce, and for applying their knowledge, technology and experience to making contributions to the health and welfare of humankind, safety and peace within society, and the sustainability of the global environment. Accordingly, it is necessary for scientists to always apply honesty and integrity in their decision-making and behavior, to make effort to maintain and improve their expert knowledge, abilities, and techniques, and to do whatever they can to scientifically verify the validity and accuracy of the knowledge obtained through their research. It is also incumbent on them to understand the relationship between science/technology and the social/natural environment from wide perspectives and to behave in appropriate ways. Unfortunately, serious problems can arise when research results are maliciously used in spite of the ethical intent of the scientists. Each scientist must bear in mind this dual edge of research's sword.

2.3. Research Integrity

Scientific research is built upon the assumption that scientists can trust one another's research. Scientists must, therefore, exercise integrity in proposing ideas, making plans, submitting applications, conducting research, and reporting results. Scientists generally get recognition for their work based on the role they play in publishing or presenting their research results. Concurrently, scientists are also held accountable for the content of their papers.

Misconduct is not to be allowed in scientific research. Scientists must recognize that one of their responsibilities is to contribute to the establishment and preservation of an environment in which ethical research is conducted and misconduct prevented. They are expected to be actively involved in improving the quality of the research environment in their scientific communities, affiliated institutions and own research laboratories by ensuring principled research activities within them and providing related training and education.

Additionally, scientists need to evaluate correctly and respect the research results and work of other scientists. It is required of scientists to assess and/or critique the results of their fellow scientists while, at the same time, accepting humbly criticism of their own research, and to maintain an honest and constructive exchange of ideas. In this process, it is obviously important not to harbor biases based on nationality, gender, age, position, background, and other such factors, but to treat everybody fairly based on the scientific method. Occasionally, research can create a conflict of interest between an individual and institution, between two institutions, or among multiple missions of one individual—in such cases the scientist is required to make fair and equitable judgments.

Scientists also need to actively participate in mutual evaluations among peers within the scientific community, particularly in their areas of expertise. Only scientists in that particular field are equipped to do so.

2.4. Compliance with Laws and Regulations

In research activities where human subjects[3] are involved as participants, it is necessary to respect their individuality and human rights, to give them sufficient explanations, to respect all agreements, and to ensure that any disadvantages will not exceed the advantages. Similarly, when animals are involved, proper and thorough care must be taken so that their pain is kept to a minimum and that their contribution will not be wasted.

Not only in areas of research that involve human or animal subjects, but also in areas where the environment could be negatively impacted or where the research involves dangerous substances, laws, regulations and guidelines are stipulated for a variety of research activities. Scientists engaged in such research need to first acquire a thorough understanding of the regulations related to their research, get properly trained in the proper procedures, and take utmost care to comply with the regulations.

2.5. Role of Scientists in Society

Just as it is important for scientists to understand what society expects of science, it is also important that science be understood by society. To this end, scientists need to participate actively in dialogues and exchanges with the public. Toward solving various issues facing society and contributing to its well-being, another mission of scientists is to provide scientific advice that is helpful in formulating policies. While scientists must work to give advice based on scientific consensus, they must also be able to explain differences of opinion when multiple viewpoints exist.

We learned this lesson the hard way from the Great East Japan Earthquake of March 2011 and the subsequent nuclear accident at the Fukushima Daiichi Plant of Tokyo Electric Power Co., Inc. That disaster devastated the trust that people had in science. Using it as an opportunity, however, scientists learned the need for humility and for communicating with society as one of their duties. In 2013, the Science Council of Japan issued a “statement,” which included a renewed proposal for a “Code of Conduct” and added a section entitled “Science in Society.” This statement declares that it is not enough for scientists to just properly do their everyday research; rather, they need to bear in mind a concept of “science in society,” taking responsibility for making scientific contributions to society. Scientists are to be engaged in scientific activities advanced for the purpose of contributing to the welfare of the public and to provide appropriate advice based on objective and scientific evidence. Words spoken by scientists may have significant impact on the forming of opinions and policies; therefore, their authority should not be misused or misrepresented. The quality of advice given by scientists needs to be of the highest level possible, while uncertainties related to scientific knowledge or diversity of opinions must be explained clearly.

When advice based on scientific knowledge is presented to policy- and decision-makers, it should be respected; however, it must be understood that such advice is generally not the only grounds for policymaking. When a policy or decision is made contrary to the advice of the scientific community, it is the duty of scientists to request that the policy- and decision-makers provide an explanation to society, when deemed necessary. No one but scientists can play this role.

3. What Is Demanded of Scientists Today

In order for science conducted in Japan to maintain its trust both domestically and internationally and to make global contributions, maintaining research integrity is above all most important. Accordingly, each research institution is required to train and educate its members in research ethics, helping them to acquire a deeper understanding of integrity in scientific research. As stated above, it is only by scientists themselves working autonomously to establish and maintain research ethics that they can win public trust in science and achieve sound advancement, attained without debilitating their scientific efforts. It is our sincere hope that this book will be useful to scientists in achieving that goal.

Notes and References: -----------------

1. National Academy of Sciences. On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition. Translated by Satoru Ikeuchi, Kagakudojin, 2010.
2. The Science Council of Japan uses the term “researcher” to refer only to a person who does research as his/her job. In this book, however, we use the word “scientist” to refer more generally to all those who are involved in research, including “researchers” and graduate students.
3. “Human subject” (*hikensha*) is a term generally used in the medical field to refer to a person involved in an experiment or study, while the term “research participant” (*kenkyu taishosha*) is more generally used in the fields of psychology and human genetics, though these two terms refer to the same persons. In this book, we use the word “human subject” except when sentences are focused on psychology and human genetics, in which case we use the term “research participant.”

Column

Trends in Research Misconduct

The number of academic papers retracted from scientific journals due to fabrication (or suspected fabrication) has been on the rise in recent years in every country. This is not just because the total number of papers is increasing overall. In particular, some scientific journals, referred to as being first-class internationally and having powerful influence, have seen more than 40% of all their papers retracted because of falsification. Even in comparison with other reasons for retraction, such as plagiarism and duplicate publication, retraction by reason of falsification is clearly on the rise.

Under these circumstances, various international efforts are being made with a focus on nurturing a responsible research culture. *Responsible Conduct in the Global Research Enterprise: A Policy Report* (2012, InterAcademy Council/IAP—the Global Network of Science Academies) introduces some of these efforts. For other examples, the World Conference on Research Integrity (WCRI) has held three conferences (2007, 2010, and 2013). At the second conference, the “Singapore Statement on Research Integrity” was issued, defining what responsible conduct in research is. At their third conference, the “Montreal Statement” was issued. The European Science Foundation (ESF) and All European Academies (ALLEA) are also involved in defining exemplary practice, preparing research conduct standards (The European Code of Conduct for Research Integrity, ESF, 2010; ESF-ALLEA, 2011). In addition, the Global Research Council (GRC), a global funding organization that distributes research funds, is also reviewing challenges concerning research misconduct.

In the United States, the “Office of Research Integrity (ORI)” was set up within the Department of Health and Human Services (HHS), working to provide education on research integrity and conducting reviews of improper cases. As seen in these examples, a wide range of organizations and agencies all over the world are now involved in efforts to thwart research misconduct, bespeaking the need for “training programs to prevent research misconduct.”

Section II: Planning Research

1. Introduction

Research begins when a scientist makes a research plan.

First, there is a thought process, including what the scientist is interested in, what his/her goals and purposes are, and what lines of thinking and methods are to be used. Then, there is another process by which these ideas gradually grow and form a coherent research plan. There are cases when the interest of a scientist immediately leads to research activities, more generally, however, the scientist will encounter several variables influenced by his/her surrounding environment and purposes.

Let's consider what research constitutes and how it should be carried out looking at a case study in which a scientist finds "brain and neuroscience" interesting and engages in research in advanced technology fusion, which involves medicine, physical science, engineering, and other fields. The example below includes brain-machine interface (BMI), a technology that enables direct input and output between the brain and external information. This is an area of brain science research that is currently being carried out in various countries.

> Taro, whose major field of study is brain science, began working in the laboratory of Professor A in the Department of Brain and Neuroscience at a certain university as an associate professor, a position that has three-year term. Taro initially felt lost in a research environment that was totally different from the university where he received his doctorate. Attracted by the attitude towards research displayed by Prof. A, who energetically promoted interdisciplinary and international joint research, and by the invigorating atmosphere of his laboratory however, Taro was gradually able to steadily proceed with his own research. Then, Prof. A decided to apply for scientific research funding in the next fiscal year for a medicine-engineering research collaboration project that he had been conducting on a pilot basis over several years along with the laboratories of other universities and with support from corporations. He asked Taro to participate in the project as a co-investigator. This project involved controlling robotic arms using an electroencephalograph and the brain-wave patterns of a subject.
>
> Taro's own research was closely linked to this new project, so he gladly accepted the invitation. The professor then asked him to be actively involved from the initial stage of writing the grant application as this would be a good experience for him. Up to this point, although Taro had worked as a co-collaborator in a research project using a *kakenhi* grant, he had no experience in being involved in the initial preparation stage of writing or submitting a grant application. Taro immediately went to the *kakenhi* website and downloaded the documents necessary for the application. He noticed that one box to be filled on the purpose of the research had the following item in it: "Scientific characteristics, originality and expected achievements and significance of the proposed research in this area."

2. Value and Responsibility of Research

2.1. Purpose of the Research: What Research Is For

As one begins to prepare a research plan, his/her first and foremost question should be: “What is this research for?” Of course, all research activities are rooted in the scientist’s intellectual curiosity. Particularly in today’s world, however, knowledge and technology produced by research in virtually all field have the ability to impact society and the environment. The code of conduct issued by the Science Council of Japan states the following on this point.

> **(Basic Responsibilities of Scientists)**
> **1. Scientists shall recognize that they are responsible for assuring the quality of the specialized knowledge and skills that they themselves create, and for using their expert knowledge, skills and experience to contribute to the health and welfare of humankind, the safety and security of society, and the sustainability of the global environment.**

As a research plan is being prepared, the scientist needs to keep in mind that science and scientific research exist together with and for society and seriously consider how his/her research can contribute to the health and welfare of humankind, safety and security within society, and the sustainability of the global environment.

2.2. Appropriateness of Research

Every research project needs to be scientifically appropriate, be it for obtaining an academic degree such as a master’s or doctoral degree or for a large-scale international project. To validate the scientific appropriateness and originality of a research plan, a careful review and analysis must be made of what research has already been done in that area. It is also necessary to consider how the objectives of the planned research comply with the ethical standards and the code of conduct established by related academic societies and institutions.

> Taro’s research project theme was brain-machine interface (BMI). During an initial review process, Taro learned that proponents of research in this field agreed on the following four ethics principles:
>
> (1) BMI shall not be used for war or crime.
>
> (2) BMI technology shall not be used to read someone’s mind against his or her will.
>
> (3) BMI technology shall not be used to control someone’s mind against his or her will.
>
> (4) BMI technology shall be used only when its benefits outweigh its risk and cost and when the user can verify this fact.
>
> Taro incorporated these principles in his research plan.

2.3. Shared Objectives in Joint Research

> Prof. A also explained that, since this research project required discussions on the ethical, legal, and social implications of BMI, he wanted to invite the participation of departments

related to ethics and philosophy in his university and from overseas university research groups who are doing research in areas in which Japanese scientists were not yet engaged. In addition, it was decided that students in the doctoral program and international students in Prof. A's research laboratory should also be included.

As will be explained further in "Section V: How to Conduct Joint Research," when a number of scientists work together as a group or team to do research, it is important that the members have a common understanding of the research's purpose and objective, acquired by discussing fully what each wants to pursue via the project. In recent years, joint research transcending research laboratories, research institutions, and national borders has been on the rise, as have scientific joint research projects crossing various fields in ways that were unimaginable in the past. When one makes a research plan, it is essential to establish a common understanding among all parties involved.

When planning joint research, it is helpful to consult such references as the "Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations."[1] This statement points out the need for all participating partners of a joint research activity to come to an agreement after sufficiently discussing the objectives of the project from the beginning of the research, with the mutual understanding that there are differences in their fields of expertise, the nature and characteristics of their institutions, and the participants' own cultural and social backgrounds. In addition, it states that these objectives are to be aimed at increasing knowledge that is "beneficial to humankind." Whenever the objectives of a project need to be changed due to progress in the research, it is important that all parties involved meet and confirm a common understanding.

It is also important that all scientists involved agree at the initial stages of planning on the ownership of data and other intellectual properties, the decision-making method for presenting the results, and how to decide on issues related to acknowledgements, credits, and authorships, including the main authors and collaborating authors.

3. Freedom in Research and What Is to Be Protected—Safety, Health, and Welfare of Humankind and the Sustainability of the Environment

3.1. What Is to Be Protected

The contributions to human society that scientific research has made through its results are immeasurable, and today's scientists have the responsibility to promote and continue this research activity. In doing so, the protection of research freedom is a fundamental requirement.

However, this is not to say that anything should be allowed in the name of scientific research. One should never forget that freedom in research is to be guaranteed only so far as the research fulfills its responsibility of protecting those things that are to be protected. What then are those things?

Here again is the short answer. Science is expected to make contributions to the health and welfare of humankind, safety and security within society, and the sustainability of the global environment. Therefore, when conducting research these values are expected to be protected. In other words, planning to do research that may threaten the safety of society is not permitted.

The ultimate goals of the research project planned by Taro, et al. included enabling people who lost their ability to communicate normally (due to muscular atrophy, for example) to communicate through their brain waves and/or to use machines and other devices to communicate. However, to accomplish these objectives, the cooperation of many human subjects would be required. What is to be protected as this research is carried out?

For instance, the *kakenhi* application form has a section entitled "Protection of Human Rights and Compliance with Laws and Regulations" with instructions to "Describe the measures and actions that you will take if your research requires compliance with related laws and regulations (e.g. research requiring the consent or cooperation of other parties, research requiring consideration in handling personal information, and research requiring work involving bioethics and safety measures)." Objects to be protected by these measures include the following:

- Protection of human rights
- Informed consent
- Confidentiality of personal information
- Compliance with laws and regulations related to human life ethics
- Compliance with laws and regulations related to safety
- Approval of an ethics review committee

3.2. What Is to Be Protected in Research with Human Subjects

As can be seen from the example of the above *kakenhi* application form, whenever research involves human subjects, there are more "things to be protected" and stricter standards apply compared to research without human subjects. For example, the "Declaration of Helsinki" of the WMA (World Medical Association) has a section titled "Scientific Requirements and Research Protocols," which includes the following statement.[2]

> **"Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol."**

Today, academic journals in medicine and related fields contain a requirement that all submissions be based on research in compliance with the ethical codes of the "Declaration of Helsinki." Therefore, when writing a research plan in these fields, one must first and fully understand the principles laid out in the “Declaration of Helsinki” as things that must be considered.

Additionally, there is another document with more specific guidelines based on both the “Belmont Report” and the “Declaration of Helsinki”; it is the “International Ethical Guidelines for Biomedical Research Involving Human Subjects” (2002) issued by the Council for International Organizations of Medical Sciences (CIOMS).

3.3. Safety Consideration in the Research Environment

Another thing to be protected in research is the “safety of the research environment.” In the *kakenhi* application form, there is a box in which the applicant states what measures s/he will take in advance to ensure “Compliance with Laws and Regulations Related to Safety.”

> Because Taro had been mainly focused on research in brain and neuroscience, he had some knowledge and background on protecting the rights of human subjects and on safeguarding personal information; however, he had very little knowledge related to “safety.” In particular, he did not know much about safety issues in engineering research, so he decided to contact the Safety Committee of his university.

When writing a research plan, one must pay attention to the safety of not only oneself but also of the co-investigators and research collaborators including students. The subjects and contents to consider in terms of safety vary from field to field.

> One thing Taro learned from the Safety Committee was that, in this particular research project, he needed to consider the risk of injury (both to the subjects and researchers) caused by, for instance, malfunctions of a robotic arm, and the burden imposed on subjects even though brain-wave measurement is non-intrusive. In addition to these safety risks, what other risks must Taro consider?

There are many safety risks involved in conducting research. Scientists may handle materials or machines with which they are not fully familiar, particularly in carrying out an interdisciplinary joint research project. It is therefore necessary at the research planning stage to discuss all potential safety risks with members experienced in handling the materials/machines, including technical staffs, and to take appropriate measures to mitigate risks and accidents.

Many experimental research projects involve drugs and other chemical substances. Some studies have shown that more chemically related accidents occur in non-chemistry laboratories than in chemistry labs. To use chemical substances safely, one needs to fully understand the dangers associated with them and have knowledge of related laws.

Among chemical substances, of particular importance is the handling of radioactive materials, which requires special knowledge and caution. Not only does one need to have a fundamental knowledge of radiation, but also an understanding of its effects on the human body, critical exposure amounts, and other relevant facts. If not, one needs to acquire them before s/he can handle radiation and radioactive isotopes safely.

As life science research undergoes rapid advancement, more and more laboratories are handling organisms that are toxic to the human body and/or the environment. Concerning issues involving bio-hazards and bio-safety, members of research laboratories who actually handle organisms need to have sufficient knowledge, but so also do all those who work in nearby laboratories and related staff members of the university.

In addition, there are other points that need to be considered even though there may not be a legal requirement to do so, such as transportation and storage of heavy objects. Therefore, it is important to review the various related rules of the university or research institution.

4. Measures to Avoid Conflicts of Interest

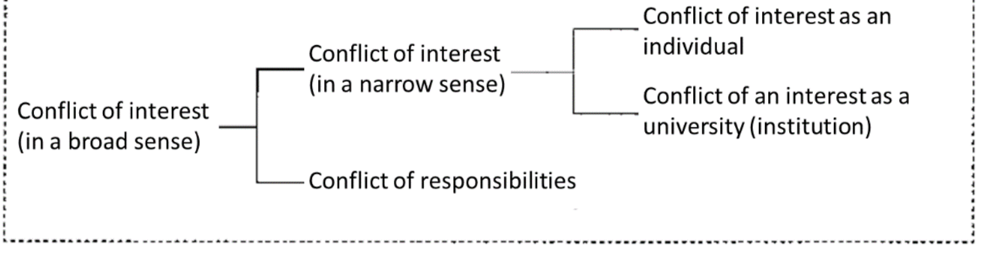
In Prof. A's background, he had worked as a consultant to a game manufacturer that utilizes the BMI technology; the university approved this side job. Now, that company expressed an interest in this project and was willing to donate 10 million yen annually as research funding if some of its employees were allowed to participate in the joint research. Would Prof. A be able to accept this proposal? If so, where on the *kakenhi* application should Taro state this fact?

In today's society where scientific research and industry are closely linked, scientists are expected to play multiple roles. For instance, a university professor may work as a consultant to a firm, while scientists may start up their own company and serve as its manager. When these multiple roles create financial consequences such as profits or losses, "objectivity," which is stringently valued in science, can be affected or can have the appearance of being affected. This is referred to as a "conflict of interest."

There are many schools of thought regarding conflicts of interest, among them the guidelines of the Ministry of Health, Labour and Welfare state the following.[3]

A conflict of interest specifically refers to a situation wherein, due to a financially profitable relation with an outside entity, for example, fair and appropriate judgment, which is necessary for public research, is compromised or appears to be possibly compromised to a third person.

When fair and appropriate judgment is blocked, data can be falsified, certain corporations could get special treatment, research could go on despite reasons to suspend it, and/or other results could follow.



There are two types of conflicts of interest: “Conflict of interest” in a narrow sense and “conflict of responsibilities.” While conflict of interest in a narrow sense involves economic profits or losses, conflict of responsibilities refers to situations “where a person is involved in various activities with responsibilities to carry out multiple duties, resulting in the loss of judgment in executing his/her main duty or the main duty not being attended to properly, including cases where such situations appear to be happening from the viewpoint of a third person.” One example would be a university professor who takes on multiple jobs outside the university, gets so busy that s/he slacks off in his/her main duty of teaching students and supervising their research. The guidelines of the Ministry of Health, Labour and Welfare state that “conflict of interest in a narrow sense of the term” includes “conflict of interest as an individual” and “conflict of interest as an institution.” The latter case includes university management and can occur, for instance, when a university invests in a corporation or when a university licenses a patent it owns.

Regarding “conflict of interest as an individual,” the Ministry of Health, Labour and Welfare defines a “financially profitable relation” within the context of a “conflict of interest as an individual” as follows.

> **“Financially profitable relation” refers to a relation in which a researcher receives compensations or other benefits from an institution other than the one he or she is affiliated with for research. Here, the term “compensation or other benefits” includes not just salaries but also service fees (consulting fees, honoraria, etc.), positions in industry-academic collaborative activities (contract research, technical training, visiting researcher positions, postdoctoral fellowships, research funding, contract experiments or analyses, machines or equipment), stocks (stock shares, stock option, etc.), and intellectual property rights (patents, copyrights, and royalties originating from these rights). This is not an exhaustive list; anything that has any monetary value is included here. However, honoraria, etc. paid by public organizations are not included.**

If Prof. A plans a research project related to the performance of a game console manufactured by the company to which he is a consultant, there will be a conflict of interest since that company makes a financial contribution to his university research project. No matter how the professor attempts to make his research results objective, a conflict of interest will still exist. When the objectivity of a research paper is questioned, it imposes a negative impact on society and other scientists. Therefore, when planning a research project, one must ensure that there are no conflicts of interest. Should a conflict of interest exist, appropriate actions must be taken such as to disclose that information in accordance with the rules and guidelines of one’s affiliated institution. This is to give sufficient information to those who will be reading a research paper for them to have the opportunity to decide for themselves its value. The types of conflicts of interest vary significantly from field to field. The humanities and social sciences do not generate as many economic conflicts of interest as science and technology, but conflicts of interest involving scientists in these fields occur more often than generally thought, including cases involving book endorsements and company evaluations.

Furthermore, according to the abovementioned guidelines of the Ministry of Health, Labour and Welfare, conflicts of interest can exist when there is a financially profitable relation not just for the scientist him/herself but also for his/her spouse, child, and/or parent(s). This also requires careful attention so as to not incur a violation.

Conflicts of interest involving research activities do not only include company-related financial profits and losses; they may also occur in peer reviews. Imagine, for instance, that you are asked to review a paper in your area of research. In such a situation, you, as a scientist, are expected to evaluate the paper fairly and appropriately. If the paper assigned to you for review is very close to your own research or in a competitive relation with yours, it is proper to refrain from reviewing it. Even if you assess it fairly, you must think about how others may view the situation. If you did not withdraw from review, suspicions could arise, such as claims that you intentionally reviewed the paper slowly to give your own unpublished research paper an advantage or that you incorporated knowledge or techniques acquired from a reviewed paper before it was published in your own research. If you are asked to review or evaluate a research application in a project that you, yourself, participate as a collaborator or a co-investigator, you should decline due to the clear conflict of interest involved.

Conflicts of interest like these are inherently bad, though some of them are impossible to prevent as science advances. For example, a particular research field may have very few scientists that are qualified to conduct peer reviews. In such a case, if a qualified scientist declines, the chance to conduct a peer review, which process is critical for scientific advancement, may be lost. In situations like these, it is necessary to disclose the conflict-of-interest related problems to the publication editors or research-funding agency so that they can decide how to handle it.

Today, increasingly more universities are setting up a dedicated department to manage conflicts of interest.[4]

5. Security Consideration

> When writing the research plan for the *kakenhi* application, Taro thought it might be a good idea to invite a student studying under an American research collaborator as an international visitor to the lab for a period of time. He took the idea to his professor, who replied, “I think that student is originally from a country of particular concern. You need to contact the Office of Conflict of Interest and Export Management about whether we can invite him or not.” Taro had never heard that there were countries of “particular concern” or that “export management” was required. He contacted that office.

5.1. Security Export Control of Subtleties and Other Technologies

International joint research will continue to expand in the future, not only for the promotion of scientific research and international exchange, but also for the education of graduate students and the training of young scientists. Exchange of research information and scientists is indispensable to successful joint research and should be encouraged in general. However, some information and technologies owned by a research institution or a university can possibly be applied to weapons of mass destruction (nuclear, biological, or chemical weapons, missiles, etc.) or to conventional weapons. If these somehow reach certain nations or get into the hands of terrorists, the consequence could be of tragic proportion in some part of the world.

Nothing saddens scientists more than to see their research results, originated with pure motives, used in terrorism. Some scientists may think, “My research is in areas of basic science, so it is not related to weaponry development.” As, however, it is possible for basic science to be used for developing weaponry in an unexpected manner, it may be subject to regulatory restrictions under the law.[5]

From the standpoint of international security, export of goods that can possibly be applied to weapons of mass destruction is subject to regulations in most countries around the world, including Japan, based on international agreements. Management of technology provision is also carried out under these agreements. This is referred to as “security export control,” and Japan has established and implemented a management system based on the “Foreign Exchange and Foreign Trade Act” (hereafter referred to as “FEFTA”). Originally, the system was aimed at managing exports of the commercial goods of manufacturers, but along with an increase in international industry-academic collaborations, much more security export control has been required of universities and research institutions since 2005.

There are still many who believe that “FEFTA is just for companies to comply with; that it does not apply to scientists at universities and other research institutions where ‘research freedom’ is guaranteed”. This is simply incorrect. This law applies to all goods or technologies subject to the restrictions of a country, even for research/education purposes. It even applies to providing a restricted technology within a country. Scientists and their affiliated institutions that violate these laws are subject to penalties. The Ministry of Economy, Trade and Industry (METI) has published a pamphlet entitled “That Export, That Technology, Wait a Minute!” It contains a clear warnings that technologies considered to be for consumer use, such as manufacturing equipment, valves, pumps, filtering devices, chemical materials, measuring devices, and advanced materials, incur a risk of being applied to weapons of mass destruction.[6]

Some specific examples of violations that could occur are as follows: Research training given to an overseas student or an international scientist, joint research done with a foreign university or company, taking research documents out of a lab, a foreign national coming to Japan for a plant tour or visit, a foreign scientist giving lectures that are not open to the public. Particularly in doing international joint research, there is a strong possibility that experimental equipment is loaned out, that data and technical information is sent/received via the Internet, and that scientists are invited and trained.

Some may also think that FEFTA does not apply to them because the collaborator in a joint research activity or the places that s/he will visit are not listed in the “End User List” (list of countries and companies feared to be involved in the development of weapons of mass destruction) published annually by METI, or because they think that their own research cannot possibly be connected to weaponry development and that all meetings will be held domestically. However, there are cases where laws are violated without the scientists’ knowledge. If there is any doubt at all, the judgment should not be made by the scientists alone; they should consult with appropriate offices of their affiliated institution.

5.2. Dual-Use Issues

> Taro was having lunch with a friend in the university cafeteria. The friend was a scientist in the field of synthetic biology, a lecturer at the same university. Taro shared with him some of the struggles he was experiencing in writing the *kakenhi* application. The friend then said to Taro, “It’s the same in my field! These days there is a lot of talk about the dual-use problem of scientific technology, triggered by research papers on bird influenza. Isn’t it possible that

the results of your project could be used in the future for military purposes or by terrorist organizations? The particular technology may not be subject to FEFTA right now, but I think you should really consider the problem of dual-use and indicate on your application that countermeasures are being carefully considered in your research planning stage.” For Taro, this was the first time he had ever heard the term “dual use.”

Originally, the term “dual use” in science and technology referred to the possibility that a particular technology could be used for both consumer (commercial) and military purposes. Dynamite is indispensable in civil construction, but it can also be used as a powerful weapon. Nuclear technology can be used peacefully for power plants and radiation treatment, but it can also be applied to atomic bombs, hydrogen bombs, and other weapons of mass destruction. Conversely, the Internet and GPS are good examples of technologies that were originally developed for military purposes but are now used for commercial purposes.

In recent years, the term “dual use” has a broader meaning; it pertains to usage ambiguity in science and technology, particularly in the fields of life science. What made this into a widely recognized issue in Japan was a 2011 discussion associated with the presentation of research project results on bird influenza in the United States, a project that included some Japanese scientists. It discovered that the H5N1 influenza virus—which was, while toxic, hardly infectious to humans—could become airborne-infectious to ferrets, a mammal, through genetic mutation. This result, which confirmed the ability to control the infectiousness of this disease, was important in that it could lead to improved public health. At the same time, however, it could also be used in biological weapons or in bio-terrorism, as it suggested the possibility that the H5N1 influenza virus could be artificially modified in a way to make it highly infectious to humans. Determined, therefore, to be a case containing societal and ethical problems, the presentation of the paper was restricted by a regulatory committee on bio-security in the United States. After discussions held at the World Health Organization (WHO), various organizations and scientific communities, the paper was finally released in 2012 in its entirety for benefit of the public.

The Science Council of Japan has been discussing the “dual use” of science and technology since the 1960s when it was dealing with issues related to the peaceful use of nuclear power. Taking the bird-flu case as an opportunity, the Council set up a committee to discuss the dual-use issue widely (not only in life science), and it prepared a report.[7] The report proposes “standards concerning ambiguities in science and technology use,” stating that it is the responsibility of scientists to ensure that their own scientific results are not used for purposes contrary to the welfare and safety of humankind.

It further requires that a wide and transparent discussion be advanced in both the expert community and society on the possibility of science and technology being misused or abused and on appropriate measures to take in preventing such usage. In the “Statement: Code of Conduct for Scientists—Revised Version,” the main points of this report are reflected in the following added paragraph.[8]

(Dual Use of Scientific Research Outcomes)
6. Scientists shall recognize that there exist possibilities that their research results, contrary to their own intentions, may be used for destructive actions, and shall select appropriate means and methods as allowed by society in conducting research and publicizing the results.

In life science, the Center for Research and Development Strategy of the Japan Science and Technology Agency have issued a specific proposal[9] on various measures to be taken by stakeholders involved in this issue, not just those participating in research but also ministries and agencies of the government, funding agencies, academic societies, and research institutions. Scientists who are in charge of their own laboratories are held to particularly higher standards, not only for having a proper understanding of dual use themselves, but also for strictly managing bio-safety and bio-security in their daily activities while teaching their laboratory staffs and students about such proper management. The document also states[9] the following: "(Scientists) are responsible for providing explanations as experts in documents used to apply for competitive research funding, in submitting papers and in presenting research results in accepted papers, under the guidance and support of their funding agencies and research institutions." Particularly when presenting a research result expected to have a significant societal impact, one should, after discussing the matter with related parties (members of the research group, funding agency, and the organization that conducted the research), use either an agreed upon, proper presentation procedures and deal with the media carefully.[9]

6. Compliance with Laws and Regulations

In conducting research, scientists must remember to comply with research-related rules including the law. Since the Act on Regulation of Human Cloning Techniques and the Guidelines for Handling of a Specified Embryo, for examples, regulate research leading to the production of clones, chimeras and hybrids, scientists must be aware that there are many laws, ordinances and rules regarding such research. There are also a variety of laws, regulations and guidelines on handling obtained data, such as the Act on the Protection of Personal Information; they too need be complied with. Concerning research involving animals, there is the "Act on Welfare and Management of Animals," and specific implementation points of this law in terms of laboratory animal use, proper breeding, care, and keeping of animals are stated in the "Standards Relating to the Care and Management, etc. of Experimental Animals" (Ministry of the Environment), "Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions" (MEXT), and "Basic Guidelines on Conducting Animal Research at Research-conducting Facilities" (Ministry of Health, Labour and Welfare) for matters within their respective jurisdictions.

Furthermore, scientists are required, in accordance with accepted social norms of modern countries, to refrain from exercising bias based on race, gender, position, ideology, belief, or religion in their research, education and organizational activities. They must rather treat everyone fairly based on scientific methods while respecting their individual freedom and human dignity.

Scientists must also pay close attention to avoid and properly deal with conflicts of interest between an individual and an institution, between two institutions, or among multiple missions of one individual where s/he does research, reviews, evaluations, selections, or gives scientific advice. As an example of such a conflict of interest, it was reported that a clinical experiment was conducted as part of a pharmaceutical company's sales promotion, with unclear sources of research funding and service contracting, to produce an outcome beneficial only to the company. To prevent such an incident, the Science Council of Japan proposed[10] the following regarding clinical experiments: Establish independent data management and statistical analysis, assure the appropriateness of research funding and funders, prevent conflicts of interest involving researchers, provide a management system that covers a project from beginning to end, and strengthen the review function by establishing linkage between an ethics review committee and conflict-of-interest committee.

Notes and References: -----------------

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9. Center for Research and Development Strategy, Japan Science and Technology Agency STRATEGIC PROPOSAL: Preparedness Framework and Its Governance of Dual Use Research of Concern for Promising Progress of Life Sciences (2013)

10. Clinical Trial Subcommittee, Committee for Scientific Research Integrity, Science Council of Japan, Recommendation: Issues in Clinical Trials Led by Japanese Researchers and Measures for the Future (2014)

Section III: Conducting Research

1. Introduction

The following April, Taro received a notice of informal decision that his *kakenhi* proposal had been accepted. The research would start soon. He had already obtained the approval of the campus ethics review committee, but its report pointed out that a review and approval would still be required at the other universities and institutions taking part in the joint research and that the group must obtain informed consent from each of the participants (subjects). Even with this BMI research that uses only non-intrusive interface devices, this request of the ethics review committee was appropriate as the research embarks upon new territory.

Then, a professor at another university taking part in the joint research sent a comment saying, "The ethics review committee at my university told us that the methods for obtaining informed consent from the subjects and for protecting personal information need to be more clearly defined. Our research has thus far involved only artificial objects, so I am not that familiar with such concepts as informed consent and personal information. Why do we need to get informed consent in the first place?" How should Taro respond to this question?

In carrying out responsible research activities, the principal investigator and other participating researchers are expected to conduct research with integrity; this is a scientist's responsibility. By fulfilling this responsibility, scientists can help maintain the relation of trust between the scientific community and society, which provides opportunities and funding for research, guaranteeing research freedom.

When a research project requires human subjects, scientists must possess a full understanding of their "responsibilities" as scientists. Research that involves human subjects spans a large spectrum of fields, including the humanities and social sciences, such as history and sociology, and engineering, such as information engineering and automotive technology. For example, the Society of Automotive Engineers of Japan, a public-interest incorporated association, issued "Ethical Guidelines for Research Involving Human Subjects" in 2012.[1]

Clinical research in medicine is the field having the most rigorous standards. It is helpful for scientists in other fields to consider these standards, instead of just saying, "Medicine and clinical research are not relevant to my research." Historically, medicine was the first profession (group of intellectuals) to be created; doctors and other groups of specialists in medicine-related fields established a research code of conduct, which can be applied to research in other fields. In particular, standards related to research involving human subjects can be used as reference in other fields, including the humanities and social sciences.

2. Informed Consent

2.1. Concept and Necessity of Informed Consent

The "Ethical Guidelines for Clinical Studies" established by the Ministry of Health, Labour and Welfare states that informed consent "means the consent that a person who is a candidate for inclusion as a subject of a clinical study, after having been fully informed of the design of the study by researchers or equivalent persons and having fully understood the significance, objective(s), method(s), etc. of the study, gives at his/her own discretion consent to participate in the study and approval of the procedures for handling the human specimens and equivalent materials."

The concept of informed consent and the process of establishing it were born out of deep regret and reflection over past experiments that ignored human dignity and human rights. In clinical sites, informed consent is also rooted in legal definition of patient rights in the United States and Germany. Instead of a one-way relationship from doctor to patient, which had been common, this is a relatively new, two-way concept and process through which the doctor, out of respect for the patient's dignity and autonomy, gives him/her the right to make choices. Today, this concept is widely accepted and practiced.

In the context of research ethics, informed consent applies three ethical principles (respect for persons, beneficence, and justice) in the Belmont Report[2] to research conduct. This is a concept and procedure to guarantee the dignity and rights of human subjects; it is not intended to give legal protection to the subjects.

The cornerstone of the discussion on life ethics leading up to the Belmont Report was the "Ethical Principles for Medical Research Involving Human Subjects" (1964, most recently revised in 2013) issued by the World Medical Association (WMA), the so-called "Declaration of Helsinki." It has undergone several revisions, but Article 1 of the most recent (2013) edition states that "The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable, human material and data." What is crucial here is that "identifiable, human subject and data" are all included as being subject to these principles and that they include data obtained by interviews and surveys without directly contacting a real person physically.[3]

The Declaration of Helsinki makes the point that "No matter how important the objectives of research may be to society, the research shall never violate the dignity and human rights of individual research subjects," and this is a fundamental principle shared with research in other fields. Informed consent is one of the specific processes necessary to protect this most important concept of "respect for persons." Based on various ethical principles included in the Declaration of Helsinki, international organizations and the governments of many nations have established legal restrictions, ethical policies, and guidelines. In Japan, the following are among the major documents in their respective fields.[4]

- *Ethical Guidelines for Clinical Studies* (entirely revised on July 31, 2008)
- *Ethical Guidelines for Epidemiological Research* (partially revised on December 1, 2008)
- *Guidelines on Genetic Tests and Diagnoses in Medical Practice* (February 2010)
- *Guidelines for the Use of Human Embryonic Stem Cells* (revised on May 20, 2010)
- *Ethical Guidelines for Human Genome/Gene Analysis Research* (entirely revised on February 8, 2013)
- *Guidelines on Research for Creating Reproductive Cells from Human iPS Cells or Human Tissue Stem Cells* (partially revised on April 1, 2013)

The importance of informed consent is clearly spelled out in all of these documents. For this discussion, we primarily look at the most comprehensive set of guidelines, *Ethical Guidelines for Clinical Studies,* issued by the Ministry of Health, Labour and Welfare.[5]

First, the objective of the Ethical Guidelines is to “set forth principles to be followed by all individuals involved in clinical studies from the standpoint of the dignity of the individual, human rights, and other ethical and scientific aspects, with an ultimate goal of promoting appropriate clinical research having the understanding and cooperation of the public.”[5] Obtaining the “understanding and cooperation of the public” is equally necessary in other research fields.

2.2. Components and Procedures of Informed Consent

> When Taro explained the necessity of informed consent to the inquiring professor, he replied, “Oh, I see. You are saying that informed consent is necessary in order to exercise respect for the dignity of human subjects; in other words, the concept of ‘respect for persons’ stated in the Belmont Report, and in order to maintain and strengthen good relations with the public, right? Indeed, if I or my dear family members ever become human subjects, we wouldn’t want to participate in the research unless our dignity was carefully considered. So I understand that it its necessity. But specifically what is required of us? For instance, if I recruit students at my university to be human subjects, what should I be careful to do?”

As clearly stated in the “Ethical Guidelines for Clinical Studies,” informed consent has three essential components: being “fully informed,” participation at one’s “own discretion,” and giving “consent.” These correspond with the three components of informed consent described in the Belmont Report[2]: information, comprehension, and voluntariness.

2.2.1. Information

Information necessary to being fully informed must be disclosed to the participant so that s/he can make an informed decision. Such information includes but is not only a “paragraph containing the order and methods used in the research, its objectives, expected risks and benefits, possibilities for other methods (if treatment accompanies the research), and the fact that the subject may, at any time, ask questions or terminate his/her participation.” It also is to include information on the method used in selecting the subjects and information on the principal investigator of the research project.

The “Ethical Guidelines for Clinical Studies” state that the following information must be disclosed as well.[5]

(1) Participation in the study is optional.

(2) Declining consent to participate in the study will not cause any disadvantage to the candidate.

(3) A subject or his/her proxy consenter or equivalent person may rescind informed consent at any time after giving it without sustaining any disadvantage.

(4) The reason why the individual was selected as subject candidate for the study

(5) The significance, objective(s), method(s), and duration of the study

(6) Name(s) and position(s) of researcher(s) and equivalent person(s)

(7) Outcome of the study, possible benefits and risks arising from participation in the study, unavoidable discomfort associated with participation in the study, and measures taken after completion of the study

(8) The possibility that the results of the study will be published after making the subjects unidentifiable

(9) Financial resources related to the study, possible conflicts of interest, and the relationship between the researchers or equivalent persons and the organizations related to the study

(10) Whether compensation will be provided for participation in the study (and details of the compensation, if any)

(11) Information on whom to contact if the subject has complaints, incurred inquiries, etc.

As the information that must be disclosed to obtain informed consent cannot have omissions, various organizations have prepared checklists. Nevertheless, it is important not to think of the items listed in the Ethical Guidelines as merely points to be "checked off." Scientists must themselves consider what information should be disclosed in order to guarantee the subjects' dignity and welfare in the best way possible.

2.2.2. Comprehension

Even if sufficient information is given, a subject candidate would not be able to comprehend the information or rationally exercise his/her free will if the way in which it is presented is complicated or confusing or if the items are listed in rapid succession. One should think of a way to explain the information in an easy-to-understand manner, considering the candidate's knowledge level and age. If the candidate is a foreign national, his/her cultural background and language should be taken into account. It is also important to be aware that the language scientists' use in their daily research is often very specialized and therefore difficult for the average person to understand. Even when these considerations are taken, quite often the candidate may not fully comprehend the explanation. Thus, one must pay close attention to verifying whether the candidate has understood all of the explanation: Testing his/her comprehension may be appropriate.

In situations where the candidate is a minor or cannot make a decision based on his/her free will, it is necessary to obtain the understanding of a "proxy consenter" such as a parent or guardian or another family member.

2.2.3. Voluntariness

Informed consent is established only when the subject voluntarily agrees to participate in research. Traditionally, Japan has had a cultural and social environment in which subjects are easily influenced by the status or authority of doctors and scientists; therefore, special care must be exercised in the case of Japanese subjects. In particular, scientists affiliated with a university or other educational institution should avoid using their own students, on whom they have strong influence, but rather try to find subjects who are other than their students. Should this not be possible, the scientist may approach his/her own students but only after a reliable method is used to confirm that they would participate at their own free will. Offering a big honorarium or presenting other benefits as compensation for the subject's participation would undermine the principle of "voluntariness." Obviously, hinting at giving a higher grade or promotion would clearly be an unethical practice.

2.2.4. Items to be considered in obtaining informed consent

As already mentioned, the necessity of obtaining informed consent is not limited to clinical research. One must be aware that this requirement applies to all research involving human subjects. So, scientists should consider anew whether it is necessary to obtain informed consent in their own research.

> The professor working with Taro as a researcher heard Taro's explanations and replied, "OK, I understand. It appears to be a process that takes time and effort, but is essential if we want our research to have any value. I was not familiar with this concept in my engineering department. I wonder if it is better understood in other fields." So, Taro decided to contact professors in the humanities and social sciences at his university to find out what type of procedures in their departments are carried out to obtain informed consent in areas of research involving human subjects such as in psychology.

In the field of psychology, the following points are germane to informed consent.[6]

In research involving human subjects, it is necessary to ask for the cooperation of those who will serve as human subjects. Regardless of the way that they are recruited, it is necessary to first clarify the type of research they are being asked to participate in and then recruit them. In the case of psychology research, disclosing certain information in advance to the participants may bias the research. In some cases, therefore, careful and detailed discussion of ethics is required, particularly when asking for participant's cooperation in research that necessitates not giving the subject certain information or even practicing deception (giving him/her false information).

Becoming a research participant and voluntarily participating in research may mean giving up one's private time. In some studies, the subjects volunteer without any compensation; in others, an honorarium or something else is given as a token of appreciation. This varies largely depending on the risk and duration involved.

Furthermore, in conducting research, it is necessary to carefully prepare safety measures, often including accident insurance in case some sort of health-related damage should occur.

Honoraria and accident insurance may also be necessary in fields other than psychology. Additional considerations and appropriate procedures may be required in certain cases, such as when the research participant's comprehension and decision-making ability is not sufficient to give voluntary consent (informed consent from a "proxy consenter") or when informed consent is not required, e.g. in observational studies. Even after informed consent is obtained once, the process of obtaining it may have to be repeated with detailed and proper explanations each time the situation changes; for instance, when the research participant's health changes or the research objectives change.

3. Protecting Personal Information

One of the points that should be explained when obtaining informed consent is how the subject's personal information is to be protected. Not only must this be considered sufficiently out of respect for the subject's dignity, in modern society leakage of personal information and privacy infringement can lead to dire consequences. Once information is leaked, it is impossible to contain it or to undo the leak. In some cases, the subject's character could be slandered or the subject could lose social credibility. Disadvantages could come in many forms. Genetic data obtained by research, such as in human genome projects, contains not only information related to the health and welfare of the subject, but as it is related to his/her family, leakage of such information could have enormous consequences far beyond anyone's imagination. Disclosure of personal information related to epidemiological studies can inflict harm on a large group of people.

Privacy and personal information protection have been actively discussed all over the world since the late 20th century (e.g. OECD's Eight Principles). In Japan, the Act on the Protection of Personal Information went into full effect in 2005. In clinically-relevant fields, the Ministry of Health, Labour and Welfare established the "Guidelines for Appropriate Handling of Personal Information by Medical, Nursing, and Related Businesses" (issued in December 2004, revised in 2010). This document urges that these guidelines be adopted by universities and other educational and research institutions that are exempt from the "Act on the Protection of Personal Information" so as to preserve their "academic freedom."

The guidelines contain the following ten points regarding personal information, related to provisions in the "Act on the Protection of Personal Information."[7]

(1) Identifying the purpose of its use

(2) Notification of the purpose of its use

(3) Obtaining personal information appropriately, ensuring its accuracy

(4) Measures for safety management: supervising employees, monitoring contractors

(5) Restrictions on providing personal data to a third party

(6) Public disclosure of items related to retained personal data

(7) Disclosure of retained personal data requested by the subject

(8) Amending information and suspending its use

(9) Procedures and fees for disclosure requests

(10) Explanation of reasons; responding to complaints

These laws and guidelines constitute fundamental rules to be understood by scientists. In particular, principal investigators must not only know these rules and guidelines themselves but must also ensure that every member (including students) participating in the research understands them, while promoting strict compliance.

3.1. Definition of "Personal Information"

In the "Act on the Protection of Personal Information," the term "personal information" is defined as "information on a living individual, which can identify the specific individual by name, date of birth or other description contained in such information (including information that can be compared with other information and thereby identify the specific individual.)"[8] Specifically, this includes not just information such as name, gender, date of birth, and other descriptions that can identify the specific individual but also "any information expressing facts, judgment, or evaluation concerning the individual's physical body, assets, occupation, position, or other attributes." This includes information already made public in addition to information known to a limited group of people, including information contained in images and sound. Even if such information is encrypted, it is still considered personal information.[9]

3.2. Linkable Anonymizing and Non-Linkable Anonymizing

In general, research involving human subjects includes a process of "anonymizing," in which information that can identify individuals is partially or entirely removed from their personal information and replaced with numbers or codes. If identification is possible by referencing the information with some other information (e.g. directories), then the information necessary for such referencing is also replaced with numbers or codes. This anonymizing process has two major types: linkable anonymizing and non-linkable anonymizing. The former is an anonymizing method in which the correspondence chart for codifying by numbers or codes is stored but not managed by the researchers. Its merit is that the subjects can be identified if necessary. The latter is an anonymizing method in which the correspondence chart is not stored but discarded. Any information processed by non-linkable anonymizing is no longer considered personal information.

3.3. Scientists' Responsibility for Personal Information in Conducting Research

What responsibility, then, does a scientist have in handling personal information while conducting research? The "Ethical Guidelines for Clinical Studies" list the following responsibilities related to the protection of personal information.[10]

(1) When presenting research results, the subjects shall not be identifiable.

(2) Personal information shall not be used beyond the scope necessary to accomplish the purpose of its use specifically explained to the subject when obtaining informed consent.

(3) Personal information shall not be obtained using an improper method.

(4) Effort shall be made to maintain personal information accurately and current within the scope necessary to accomplish the purpose of its use.

(5) Safety management shall be implemented to ensure that personal information is not leaked, lost, or damaged.

3.4. Handling Personal Information in the Humanities and Social Sciences

This discussion has been focused on clinical research thus far; however, research involving human subjects goes beyond clinical research. Some fields of the humanities and social sciences, such as history and sociology, can also involve personal information.

For instance, when one presents results while quoting unpublished documents or interview records, the following points need to be considered:

- In the original interview, to obtain consent from the interviewee concerning the objectives of the research, scope and format of disclosure, and whether or not his/her approval will be obtained before presentation.
- When quoting an interview record, to mention the interviewee’s name, position and occupation, date, time, and location of the interview within the scope agreed upon by the interviewee.
- When quoting a historical source or document publicly displayed in an archive or a historical library, to cite the name of the archive or library, title of the source/document, document number, and other details. When using a deposited document and the deposition agreement requires that the depositor be shown a rough draft of your presentation in advance, to be sure to comply with that requirement.
- If you have received special permission from an individual or a corporation to browse historical sources or documents, to obtain prior agreement and clarify the disclosure conditions, including to what extent you may disclose the actual resources/documents, their existence, and items containing personal information.
- When quoting historical resources or documents, to pay especially close attention to information such as an individual’s birth, lineage, economic status, death (including history of illnesses), and criminal history, because, while the individual may have lived in the past, such information may violate the privacy of his/her heirs or successors.

4. Collecting, Managing, and Processing Data

Taro’s research team has, with the cooperation of related offices of the university, completed the process of obtaining informed consent from all the human subjects, and is making preparations to begin their research. Just as they were about to begin their experiments, another professor said to him, “As we go about conducting our research, shouldn’t we decide in advance how we will share the data obtained among the collaborating researchers? The research plan does stipulate that the data will be shared in an appropriate manner, but provides no specific indication on how that is to be done. Besides, differences exist between the humanities and science researchers in the way they keep their research notes.” Taro decided to first discuss the experimental data and how they are recorded with the postdoctoral fellows and graduate students in his laboratory. He asked them, “As our group participates in this research, the way each of us keeps lab notes and maintains raw data may differ from one another. What rules has our laboratory followed thus far? When carrying out joint research with outside organizations, does anyone know how to handle lab notes and data?”

4.1. Data and Their Importance

Data comprise "all types of information based on facts, used for rational deduction."[11] The importance of data in research is obvious; without data, there could be no research. What constitutes data varies from field to field. In history, for example, data include not just printed materials and books but also hand-written letters, artifacts, and a wide variety of other things. In sociology and anthropology, survey results and interview records also make up crucial data. In the empirical world of science, data include measurement data and image data obtained via experiments.

To assure the reliability of data in scientific research, one must make sure

(1) that the data are obtained based on appropriate methods,

(2) that the data collection does not involve intentional wrong-doing or mistakes due to negligence, and

(3) that the data obtained are properly stored and their originality is maintained.

With the exception of few special circumstances, the quality of all scientific research is determined upon the assumption that the "data" were obtained using the utmost care and rigor available at the time. Accordingly, scientists must handle "data" with integrity in every phase of their research activities.

Collection of data differs depending on the research field, theme, objective, and other factors, so the procedures established for handling them in one's own field of specialization should be followed. However, at least in research involving experiments, there are some common factors on "record-keeping and the strict handling of research and investigation data." Let's take a look at them.

4.2. Purposes of Lab Notes

In experimental fields, data are generally recorded in the so-called "lab notes" (sometimes referred to as research notes or experiment notes). Well-maintained lab notes that contain data and ideas recorded in an appropriate manner serve at least three crucial roles. First, they prove that the research has been conducted fairly and properly. Second, when the research produces a result, the lab notes can prove its originality. Third, they make the data and ideas transparent in the laboratory and in the research group, serving as a tool for sharing and effectively applying the data, i.e., a tool for "knowledge management."[12]

The National Institutes of Health (NIH), a central agency for life-science research in the United States, states the following concerning the purposes of recording daily activities in lab notes:[13] First, if the experiment produces a result, information retained in lab notes can help a third party replicate the experiment. Further, in the context of research ethics, lab notes can validate the legitimacy of the research and prevent improper practices. There are situations where lab notes are legally required to fulfill contractual conditions, and for patents, lab notes can protect intellectual property rights. Furthermore, lab notes can establish effective research customs and practices within the research team, helpful in educating its members (including students). In addition, lab notes can provide evidence for recognizing accomplishments, i.e., how much each member has contributed to the research. With excellent lab notes, preparation for official reports, papers, and presentation can be made easy.

In private corporations, strict procedure may be applied to writing lab notes as they can be involved in intellectual property rights such as patents. Many firms have well-established lab notes management rules that stipulate their contents, recording methods, how to obtain witnesses' signatures to validate them as documents for evidence, and how to manage the notes. In the United States, where the industry-academic collaboration has been on the rise since the establishment of the Bayh-Dole Act of 1980, various issues associated with intellectual property have rapidly increased. Consequently, many universities have established and adopted policies on lab notes.[14]

In conducting responsible research activities, one needs to understand that lab notes are an indispensable tool and to establish and implement related rules after discussing them among the entire research group, including joint researchers (check the policies of affiliated institutions if they already have such policies).

4.3. What Makes the Best Lab Notes

So then, what do good and useful lab notes look like? According to F. L. Macrina, et. al., useful lab notes are those in which the scientist has clearly recorded

(1) what was done, why, how, and when it was done,

(2) where the experiment materials and samples are kept,

(3) what phenomena occurred (or did not occur),

(4) how the scientists interpreted the facts, and

(5) what the scientists will do next.

The best lab notes are stated to be

(1) easy to read,

(2) well organized,

(3) recorded accurately without omission,

(4) contain information sufficient for replication,

(5) satisfy the requirements set by funding agencies and affiliated institutions, and

(6) properly stored so that only authorized personnel can see them, and duplicates are made in case something should happen to the original notes.

Macrina et. al. conclude that lab notes are the "record that will ultimately validate the scientific contributions you have made."[15]

4.4. Lab Notes: Items to Record, Methods of Recording

Okazaki, et al. summarize important points for writing lab notes as follows: [16]

(1) Entries should be in chronological order.

(2) Notes should have no blanks. Cross out any blank spaces and completely avoid inserting sentences.

(3) Prior entries should never be corrected later. Any correction should be written on the page for the day when the correction is made.

(4) Entries should be managed according to “date” and “title” (convenient if they are linked to the table of contents).

(5) Abbreviations and special terms should be recorded with explanations for a third-party reader (good to add a “list of abbreviations” and “glossary” at the beginning).

(6) Objectives, logical reasons, and plans should be briefly stated for new plans and when the experiment is about to begin.

(7) Entries should be written in enough detail for a third party to replicate the experiment.

(8) Entries should be written so that (if they are separated) the reader can easily see the order in which the sections follow each other.

(9) Results and observation items should be recorded immediately.

(10) If a result (or something else) is attached, the person recording it, as well as the date and the signature of a witness, should be written on the attachment and the notebook page.

(11) If attaching a document is difficult, the location and the name of the attachment should be recorded in the notes and the attachment stored separately, with cross reference to each other.

(12) Facts such as data should be clearly distinguished in writing from ideas and conjectures such as observations.

(13) In joint research, entries should be written with an awareness of to whom ideas and proposals belong.

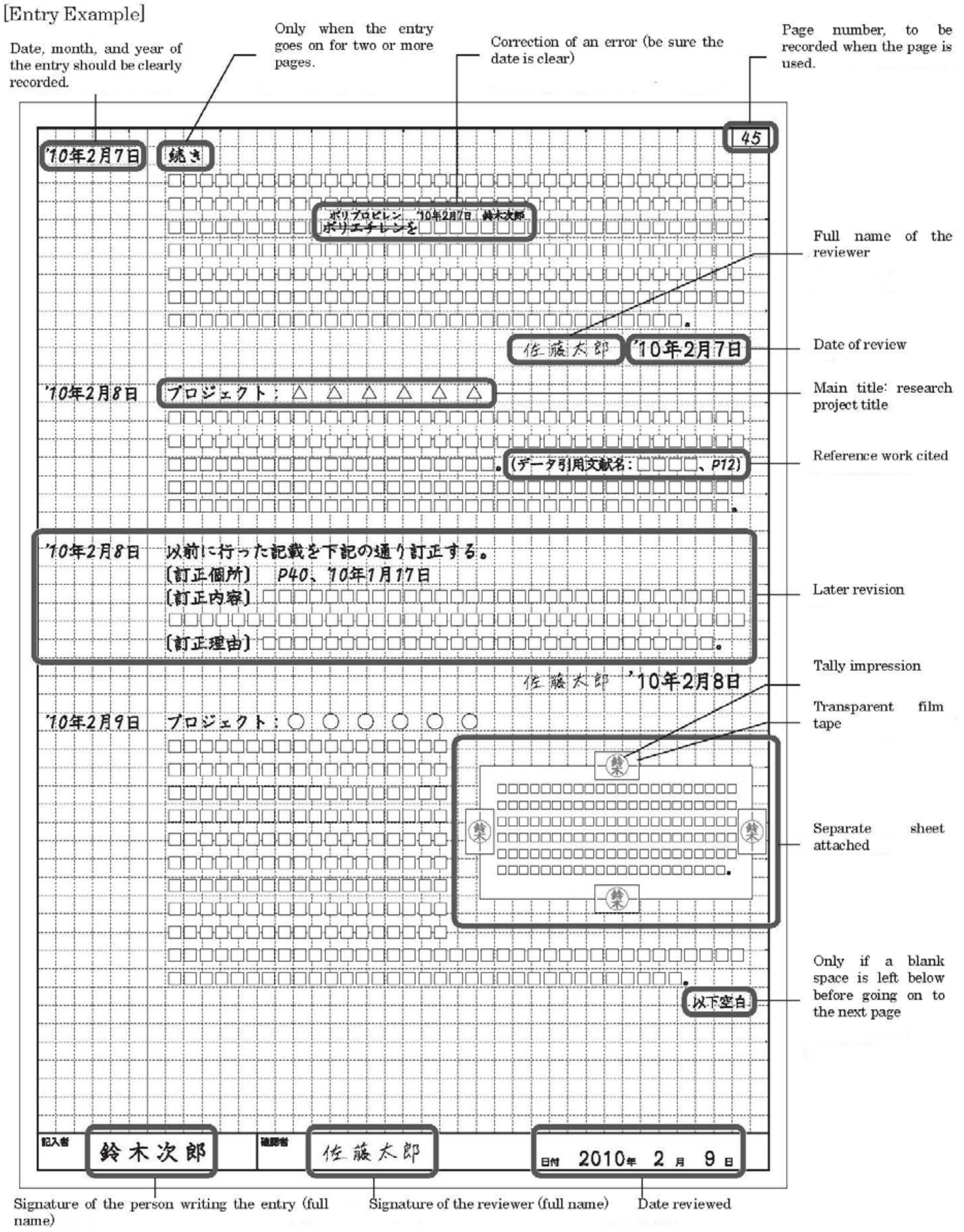
(14) Discussions in meetings should also be recorded.

(15) Each page should contain the name of the person writing the entry and a witness’s signature and date.

These are just examples; however, the quality of research will improve when these points are thoroughly discussed among the research team and checked on a regular basis throughout the research.

There are notebooks sold for lab notes. One example is the “Research Lab Notebook” developed jointly by Prof. Yoichiro Sada of Yamaguchi University and Kokuyo S & T Co. Ltd., a Japanese stationery manufacturer. Here is an example of an entry in it.

[Entry Example]



4.5. Managing Lab Notes (Data)

Even when lab notes are taken appropriately, clearly recording data and ideas obtained in the research, the reliability of the lab notes and their value as evidence could be lost if the notebook is poorly managed. For instance, if the notes are kept in such a way that one lab notebook can be completely replaced by another, the laboratory would be in a disadvantageous position when competing for a patent.[17]

Fundamentally, lab notes do not belong to an individual; they are considered to belong to the institution (e.g. research institution) that provides the research environment and funding. Therefore, they should be managed appropriately in accordance with the rules of that institution. Where the institution does not have a dedicated department or office that stipulates management rules, it is necessary for the principal investigator to initiate an effort to create such an office and to establish management rules by discussing them with the members of the research group. In institutions where the research members come and go frequently, such as universities, it will be necessary to create a management system that also includes training of new members. Particularly close attention should be given if the research involves data containing personal information. Access to the lab notes should be limited, and the notebooks should be kept in a locked cabinet. On the other hand, if the research is done by a team, the progress of the research could be hindered if the members' access to the data is severely limited. Therefore, discussion with the team members is necessary to obtain an appropriate balance.

As discussed above, lab notes are extremely important to scientists as a record of the experiments and research they have conducted. These notes are more than just an intellectual compilation of their own research processes and ideas. As lab notes can provide validation and evidence after a paper is presented, each research institution must establish policies on the method and duration of their storage.

Organizations that fund research are requesting that data be kept for a certain period of time after the subject research is completed. For research data related to patents, an exceptionally long period of 30 to 50 years of storage is considered desirable.[18] For such a long period of storage, the responsibility should not fall on the individual scientists or laboratories, but rather on the larger institution.

In joint research in which multiple institutions conduct research together, the ownership of lab notes and distribution of credit should be thoroughly discussed in advance. Even while the research is being carried out, discussions should take place often to ensure agreement.

Recently, it has become possible to store lab notes and data on electronic media. However, even in this case, it is still necessary for documents and data to be kept properly in such a way that correction, addition, and revision cannot be done after the date that an experiment was originally recorded. Research institutions must issue a clear statement on such a method as well.

5. What Is Research Misconduct?

5.1. Definition of Research Misconduct

Three types of conduct are defined as research misconduct all over the world, not just in Japan: They are fabrication, falsification, and plagiarism, sometimes abbreviated "FFP." Federal law in the United States adopts these three as the definition of research misconduct.[19]

However, internationally speaking, research misconduct is not limited to FFP; rather, the trend is toward questioning increasingly more deviant behaviors. The “European Code of Conduct for Research Integrity” lists many of them, including not explaining profit, violating confidentiality agreements, missing informed consent; deviating from clear, ethical, and legal requirements such as in abusing research subjects or misusing materials, attempting to hide misconduct, and taking retaliatory action against whistleblowers. Another item stipulated as misconduct by many academic societies in Japan and overseas is duplicate posting, which is prohibited and penalized. For example, the “Code of Conduct of The Physical Society of Japan” (issued on July 10, 2007) defines duplicate posting as misconduct.

MEXT formulated the new “Guidelines for Responding to Misconduct in Research” issued in August 2014, which defines FFP as especially grave research misconduct. However, it does not condone other forms of misconduct. On this point, please refer to section “6. Avoiding Questionable Research Practices.” These new guidelines stipulate that the following measures are to be taken against specific acts of misconduct in research activities.

3. Responding to Specific Research Misconduct

1. Applicable Types of Research Misconduct, etc.

The research activities, researchers, and research misconduct to which this section applies are as follows.

(1) Applicable research activities

The research activities to which this section applies are all those receiving competitive funding, administrative grants to national universities, corporations or independent administrative agencies under MEXT jurisdiction, private school subsidies or other funding for basic operating expenses, or other funding budgeted or specially allocated by MEXT.

(2) Applicable researchers

The researchers to whom this section applies are researchers who conduct the research activities defined in (1) above.

(3) Applicable misconduct (specific research misconduct)

The misconduct to which this section applies is the fabrication, falsification, or plagiarism of data or research findings, etc., contained in a submitted research paper or other published research results (hereinafter “specific research misconduct”), either willfully or due to gross neglect in the basic duty of care expected to be exercised by researchers.

(a) Fabrication

Making up data or research results, etc.

(b) Falsification

Manipulating research materials, equipment, or processes to change data or results obtained from research activities.

(c) Plagiarism

Appropriating the ideas, analyses, analytical methods, data, research results, research paper(s), or words of other researchers without obtaining the permission of the researchers or giving appropriate credit.

Note that in drawing up rules for responding to research misconduct in a research institution, there is no need to limit the applicability as in (1) to (3) above. For example, research performed on commission by another government agency or company should be included among applicable research activities regardless of the type of funding.

These guidelines also stipulate measures such as for cancelling the awarding of a grant or requiring a refund of the grant, depending on the circumstances involved, with respect to competitive funds used in research that involved fabrication, falsification, or plagiarism.

When research misconduct is confirmed, the scientist's eligibility to apply for further competitive funds will be restricted. [20]

5.2. Examples of Fabrication and Falsification

In 2002, a serious fabrication incident involving *Nature* and *Science* was uncovered. It originated at Bell Laboratories in the United States, a prestigious research institution that has so far produced 12 Nobel Prize winners. Using an innovative method, Hendrik Schön, a young German researcher, broke many records one after another in high-temperature super conductivity, attracting the attention of scientists all over the world. During a brief period of just three years (2000 through 2002), he published a total of 16 papers in *Nature* and *Science* combined, breaking his own record. At one point, he was said to be the scientist closest to winning the Nobel Prize.

However, questions arose when Schön continued to break his own records while the rest of world could not succeed in replicating his experiments. It became apparent that falsified experiment data was recycled in many of his papers. While each paper was supposed to be on a separate experiment individually performed, many of them used the same set of recycled experiment data. Bell Laboratories launched a review committee and concluded that 16 of his papers involved research misconduct. It was determined that many of the "experiments" were not actually done and that he had been falsifying and recycling experimental data from another experiment, thus "fabricating" the data as if breakthroughs and innovative results had been produced.[21]

Physics was a field in which research misconduct had been considered unlikely. Thus, when fabrication of such an enormous magnitude occurred, it became evident that research misconduct could occur anywhere, regardless of the field.

Another example of misconduct involving fabrication and falsification, in Japan this time, is the "Diovan" incident (2012). Multiple university hospitals participated in clinical research on "Diovan," a drug for treating high-blood pressure. It was alleged that, when each hospital conducted its own research, numerical data such as the subjects' blood pressure and statistics were manipulated in such a way that the conclusion would be advantageous to a certain pharmaceutical company. After the misconduct was exposed and made public, their research paper was retracted; however, the former hospital employee involved in the data fabrication and falsification and an employee of the pharmaceutical company, which used that invalid paper to advertise the medicine, were prosecuted for exaggerated advertisement prohibited by the Pharmaceutical Affairs Law.[22] In this case, another point that attracted public attention as a serious problem was the fact that, while the employee of the pharmaceutical company was engaged in the research group's statistical analysis, the publication of the research results listed him as an adjunct lecturer at the university. In this type of research, it makes a huge difference in the reliability of a paper whether the research was carried out by a university researcher who conducted the experiments from an objective, neutral standpoint, or whether it was carried out by an employee of the involved corporation. In this type of conflict of interest, full disclosure is required at the time of the paper's publication. In this case, however, the act of using his position as a university adjunct lecturer was done in a way to hide this conflict of interest and was thus deemed problematic.

Fabrication and falsification are fundamentally serious acts of betrayal against the very objective of scientific research: to pursue truth. One must recognize that such acts cause society to lose its trust in the scientific community, potentially even affecting the health and safety of the people. This type of misconduct wastes the time, efforts, and research funds of other scientists who try to replicate an experiment under the assumption that the data published by the scientist is trustworthy. When one scientist announces a new idea, other scientists try to verify and validate that result as well as to advance the idea together, even further. Fabrication and falsification are, therefore, acts that undermine the foundation of the community of scientists who, even while competing with one another, strive to work together to amass research advances toward the progress of science.

5.3. Examples of Plagiarism

Research presented by an author is his or her original work, and it is assumed that all its contents, i.e. information, ideas, and sentences, are those of the author. "Plagiarism" is an act that betrays this trust. Plagiarism is one type of false authorship; it suggests a lack of the ethical character "honesty" of the infringing scientist and is a serious violation of occupational ethics. Plagiarism can lead to a penalty as a violation of the Copyright Act (cf. "5.2. When Using Someone Else's Copyrighted Material of Section IV").

So then, what constitutes plagiarism? An obvious example is the act of using large parts of someone else's paper, without properly citing it, as if writing them as one's own work. But there are other forms such as a university professor looking at an unpublished paper of his graduate student and publishing an idea found in the preprint as his own idea; this constitutes plagiarism of an idea. In recent years, the widespread use of the Internet makes it possible for one to simply copy parts of a published paper or a website and paste them onto his/her own draft (referred to as "copy-and-paste"), possibly contributing to the rise in plagiarism. In the humanities and social sciences, while research misconduct involving fabrication and falsification has not been so common, it is becoming a significant problem.[23] In experimental research, a different type of problem exists: not citing sources of published papers when documenting materials and methods used in one's own experiments. Furthermore, original sources should be cited not only when using someone else's original description but also when adding changes and modifications to original descriptions.

5.4. Citing Sources

When using someone else's research results, one must cite that source so that the reader can reference it. Using someone else's results without citing the source constitutes plagiarism.

When citing sources, a scientist must clearly specify which parts belong to him/her, the author, and which parts belong to other scientists.

At times only citing a source is not sufficient. For example, suppose scientist A uses, without modification, a paragraph written by another author, scientist B, citing him only as reference. In this case, B is properly credited for the content, but the reader does not know whether the entire paragraph belongs to scientist A or B. When using just a part of some other scientist's paragraph without modification, the author must use quotation marks or different margins and clarify the source so that it will be obvious whether or not the entire paragraph belongs to another scientist.

Plagiarism is not limited to writing. When one uses an idea or technology obtained through reviewing a paper or a grant application, as in insider trading, such an act constitutes plagiarism. Even if one attends a public lecture and later uses an idea presented by the speaker without proper permission of the speaker, it may constitute plagiarism. In such a case, it is wise to clearly credit the speaker as the source of the idea or to obtain the speaker's permission in advance. When using a theory or an idea originated in discussions at a research workshop or a conference, a similar step should be taken from the standpoint of science ethics.

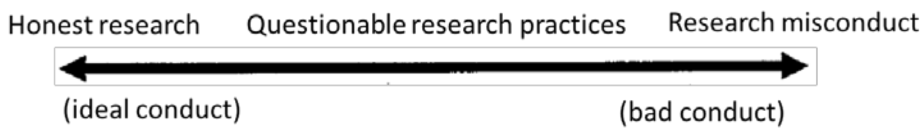
6. Avoiding Questionable Research Practices

In promoting integrity and responsibility in research activities, there are certain "values" shared by all fields of research. The "Singapore Statement on Research Integrity" (2010) lists the following four principles as these "values."

- Honesty in all aspects of research
- Accountability in the conduct of research
- Professional courtesy and impartiality in working with others
- Good stewardship of research on behalf of others

Misconduct such as fabrication, falsification, or plagiarism are on the opposite side of these principles.

Fabrication, falsification and plagiarism are not the only intentional misconduct in research, but they hamper the advancement of science and development of society. Situated between research integrity and research misconduct are so-called "questionable research practices" (QRPs), which are also feared to threaten the credibility of research.[24]



The National Academy of Sciences of the United States says following concerning “QRPs”:

“A questionable research practice is a practice that violates the traditional values of research activities, potentially resulting in harmful impacts on research process. These practices could damage trust in the honesty of the research process, threaten a variety of traditional customs of science, affect research results, waste time and resources, and weaken the education of young scientists.”[25] Specific examples of questionable research practices include the following:

- **Not keeping critical research data for a certain period of time**
- **Inappropriate management of research records**
- **Problems in the writing of the author of an academic paper**
- **Refusal to provide research materials and/or data**
- **Insufficient research training, exploitation of students**
- **Dishonest presentation of research results (especially to the media)**

According to a report on an empirical study on research activities, there are many scientists who have been involved in QRPs and/or have witnessed QRPs.[26] Just as fabrication, falsification, and plagiarism (FFP), QRPs must be recognized as misconduct that can waste research resources and damage the relationship of trust between society and the scientific community as well as within the scientific community itself.

Additionally, QRPs are not limited to practices during the implementation of research; they can occur at the planning stage of research. Examples include the following:[27]

(1) Inappropriate exaggeration of anticipated research results and their impact

(2) Proposing excessively biased research themes or research methods

(3) Not mentioning a conflict of interest that exists with the applicant or a related party

It is therefore necessary to consider whether QRPs may occur or not, both as an individual scientist and through an open discussion among the research collaborators, even while preparing an application for competitive funding or preparing to present a paper.

QRPs also include practices that are, while technically not misconduct, to be avoided because they are “not desirable.” Such practices as duplicate posting and inappropriate authorship are included within the definition of “research misconduct” in some nations and research institutions, so one must be careful regarding QRPs.

7. Duty of Confidentiality

> Taro was contacted by a staff member of the company involved in the joint research, who said, “In the joint research project we have been doing, we too are entering a new phase. I believe we need to sign a confidentiality agreement now. What do you think?” Taro replied, “Let me talk about it with Professor A. Please give me some time, and I will get back to you.” When Taro contacted the professor, he replied, “He’s right, it is probably necessary now. Let’s contact the Intellectual Properties Office of the university and ask them how to respond.”

When conducting research involving human subjects, there is a confidentiality requirement to protect personal information obtained in research; for doctors and other healthcare providers this is a legal requirement. The “Ethical Guidelines for Clinical Studies” of the Ministry of Health, Labour and Welfare state that similar requirements apply to parties involved in other fields and that principal investigators are responsible for ensuring that everyone on a research team understands the duty of confidentiality and for promoting compliance.

The area of intellectual property has another important duty of confidentiality. Since the enactment of the Japanese version of the Bayh-Dole Act (cf. Column “Japanese Version of Bayh-Dole”), results obtained in government-contracted research now belong to the institution (such as a university) with which the contracted scientist is affiliated. With this change, the number of patent applications originating from research conducted at universities is increasing. Prior to that, university faculty showed little interest in applying for patents; now, however, that their own results can be recognized in the form of patents, which in turn can generate licensing fees and royalties through the university, things are changing. Many universities have set up intellectual property offices and are attempting to commercialize inventions born out of research on their campuses.

There are at least three ways to generate profits from intellectual results produced in a university laboratory:[28]

(1) Technology transfer of an original result to industry (including patents)

(2) Joint research with a company, with the results used in a joint patent

(3) Launching a university-initiated venture company based on research results

In these processes, discussions are carried out by many people, including scientists, members of companies, and experts on intellectual property, in an attempt to find the best ways to generate profits. Of course, the disclosure of results obtained from the research is necessary in such cases. On the other hand, during these discussions, in which ideas and information that can be considered intellectual property are communicated to other parties, problems can occur, either intentionally or by accident, such as another party claiming the originality for an idea or information being leaked to the outside. To prevent such trouble, parties engaged in these discussions sign a “confidentiality agreement.”

As industry-academic collaboration is becoming more prevalent of late, it is necessary for researchers to pay closer attention to issues associated with intellectual property rights. Before starting a joint research project with a company, researchers should first consult with the intellectual property office in their institution and come to an agreement on property rights with the counterpart company.

Concerning the role of students in joint research between a university and a company, special attention must be paid even more than in normal joint research. Scientists hired by universities and research institutions are bound by many requirements including occupational confidentiality, in accordance with their employment agreements. However, students, who pay their own tuition and receive education and research supervision in return, do not have the same requirements placed on them. In the case of a student employed as a researcher using external funding, s/he shares the same obligations as the faculty members; however, consideration needs to be given whether it would be appropriate for him/her to sign a confidentiality agreement or to leave his/her status ambiguous. This is because the student may in the future seek employment in a rival company and a confidentiality obligation could potentially limit his/her freedom to choose an employer.[29] On the other hand, if a student signs a confidentiality agreement with the university, participates in the joint research, and then leaks some information subject to the confidentiality agreement to another company, the student could be held liable for damage compensation. Thus, there is a responsibility to educate students; and as the students' gains may not match perfectly with their participation in joint industry-academic collaboration, it is necessary for principal investigators to take both angles into account when determining the position of students in such projects.

8. Responsibilities of the Principal Investigator

Taro was worried when Professor A asked him to participate in the research management. He was easily able to complete the required procedures such as obtaining informed consent from the subjects and establishing a system to manage the lab notes; however, involvement in managing the research team would be a huge responsibility. Of course, since the professor was the principal investigator, Taro planned to continue his research and seek results according to the plan while checking the professor's instructions, but he felt that not all the members of the research team would sufficiently understand and share his ideas. In particular, postdoctoral fellow B appeared to be frustrated in his effort to produce a significant result before his tenure at this university was up. Recently, he had often been seen analyzing data by himself, and he seemed to be carrying out experiments on a tight schedule, at a rather unrealistic pace.

The principal investigator/scientist is responsible for conducting research activities appropriately and, therefore, also responsible for ensuring that all procedures are carefully followed according to various ethical policies and guidelines as well as for managing personal information, data, and intellectual properties.

Additionally, the principal investigator/scientist is responsible for achieving the project's goals (obtaining the desired results) while carrying out the research according to its plan as much as possible. For these reasons, s/he is expected to put forth maximum effort within the amount of time and effort assigned to him/herself when preparing the research application. However, it needs to be pointed out that some research may not go according to plan. In most research projects, at some stage a problem or an unforeseen situation will occur, and whenever this happens, the hypothesis or research method may be modified. Meanwhile, graduate students and young scientists may be doing research under tremendous pressure because they are required to produce a certain level of work, such as giving a presentation at a conference or publishing a journal article, within a fixed period of time in order to receive a degree or get a job. If joint research with a company is carried out, the company may try to find results that can be immediately applied to a patent. The principal investigator is required to conduct the research with a comprehensive understanding of all these demands and financial implications.

When research is conducted as a team, often the members will include young researchers and graduate students. The principal investigator needs to be aware that his/her conduct on the team can have a powerful influence on them, including influence in an educational sense. While it is important to maximize the research results of the team, the principal investigator should recognize that publishing a paper is not the only result/goal to be sought, but that fostering principled scientists and building a sound environment for scientific research are also honorable outcomes. Hence, the principal investigator should refrain from excessively rushing or pushing the team members. The Code of Conduct of the Science Council of Japan also states the following:

(Establishing Sound Research Environments and Thorough Educational Enlightenment)

8. Scientists shall recognize that establishing and maintaining fair research environments where responsible research can be conducted is one of their important duties, and shall work continuously to improve the quality of research environments in the scientific community and their own institutions, and toward educational enlightenment preventing misconduct. They shall also seek the understanding and cooperation of the public in achieving these goals.

These points are also related to the occurrence and prevention of research misconduct. An analysis of past research misconduct suggests that there are often excessive levels of emphasis centered on accomplishments/results throughout a laboratory or that some research members work under tremendous pressure. Given these reasons, the principal investigator is expected to promote an attitude that allows the entire research team to constantly perceive the real objective of scientific research. Establishing such an attitude is also an important factor in the implementation of a “research ethics program” at individual research sites.

Worried about the huge responsibility of being a principal investigator, Taro shared his thoughts with Professor A, who explained, “Sure, it may be really difficult at first, but as the editor of *Nature* says, a principal investigator is, as the researcher in charge, responsible for ‘teaching ethics and the code of conduct to younger generations by setting an example in his/her daily research activities.’ This is not just for one’s own satisfaction but it is for implementing a research ethics program that involves the entire research group in carrying out responsible research activities.” Hearing this, Taro thought that it would be important to create, not a system to catch and prevent research misconduct and other inappropriate practices, but an environment in which individual researchers would constantly perceive the significance and objective of research while engaging in their research and in which talented young scientists could freely conduct meaningful research. In the end, Taro, though young himself, decided to take on this role actively within the team.

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Column

“Japanese Version of the Bayh-Dole Act” (Industrial Revitalization Law, Article 30)

1. History

(1) Bayh-Dole Act of the United States

- As the international competitiveness of the Unites States economy dropped in the late 1970s, a bipartisan group of legislators led by Senator Birch Bayh (Democrat) and Senator Bob Dole (Republican) sponsored the “Bayh-Dole Act” (Patent and Trademark Law Amendments Act) in 1980 to promote commercialization of inventions resulting from research and development funded by the government. The central point of the act is to give patent and trademark rights resulting from government-funded research and development to private companies and universities.
- This act is credited for recovering the competitiveness of U.S. industry through patents obtained by universities, their technology transfers, and the creation of new venture businesses led by the accelerated technological development of companies.

(2) Legislation in Japan

- Meanwhile, in Japan, all patents resulting from research and development funded by the government belonged to the government.
- In 1999, as strengthening of the country’s industrial competitiveness was being discussed, the private sector introduced several proposals for improving the system in an Industrial Competitiveness Council meeting hosted by the prime minister. As a result, in June of the same year, a set of strategies for strengthening industrial competitiveness was adopted. It included a measure to establish a law similar to the U.S. Bayh-Dole Act.
- Based on this, the Industrial Revitalization Law, which includes a Japanese version of the Bayh-Dole Act, was adopted by the Cabinet on July 21 and then debated in and passed by the Diet. The Law was promulgated on August 13, with the Japanese version of the Bayh-Dole Act going into effect on October 1 of the same year.

2. System Objectives and Overview

(1) Objectives

The Japanese version of the Bayh-Dole Act has two objectives.

(i) to revitalize research activities in technology

(ii) to efficiently apply the results of such activities in business

(2) System Overview

The Japanese version of the Bayh-Dole Act gives contracted companies 100% possession of intellectual property rights on all contract research and development (including contracts through special corporations) funded by the government when the following three conditions are satisfied:

(i) Research results are reported to the government.

(ii) The intellectual property rights are licensed, free of charge, to the government if the government requires for the benefit of the general public.

(iii) The intellectual property rights are licensed, free of charge, to a third party, as requested by the government if they are not used for a certain period of time.

(Note) Prior to this act, the government had 100% possession of all the intellectual property rights obtained through research it contracted.

(3) Applicable Intellectual Property Rights

Laws stipulate the following intellectual property rights:

- Patent rights, the right to receive a patent (Patent Act)
- Utility model rights, the right to receive a utility model registration (Utility Model Act)
- Design rights, the right to receive a design registration (Design Act)
- Copyrights of computer program work, copyright for a database (Copyright Act)
- Layout-design utilization rights, the right to register the establishment of a layout-design utilization right (Act on the Circuit Layout of a Semiconductor Integrated Circuits)
- Breeder's rights (Plant Variety Protection and Seed Act)

Source: METI homepage (http://www.meti.go.jp/policy/innovation_policy/bayh-dole.pdf)

Section IV: Presenting Research Results

1. Presentation of Research Results

1.1. Importance of Presenting Research Results

The academic and research freedom given to scientists (Article 23 of the Constitution of Japan) is entrusted to them by society premised upon public trust.[1] The presentation of scientists' research results does not just lay the foundations for the next research topic. Academic papers and reports, which represent deepened knowledge of humankind in print form, become assets that can be preserved beyond the current generation. In addition, the modern scientist is expected to transmit, in response to public demands, a variety of knowledge and opinions for advancing discussions and promoting the sound development of society.

In transmitting research results to society, beyond the framework of the scientific community, we need to discuss not only how research is advanced and what types of results are obtained, but also what the nature of research should be and various ethical considerations.

It is also a responsibility of scientists to present research results in ways that are appropriate and will protect people and society. In the past, Japanese scientists studying Hansen's disease (leprosy) did not correctly report to the Japanese public the fact that overseas research had developed effective drugs and methods to treat the disease, which was believed to be incurable. So as to prevent the spread of infection, Japan was still quarantining patients, inflicting a cruel life on them and their families for a long period of time.[2] In addition, the history of pollution and drug-related harm in Japan bespeaks a lack social responsibility on the part of scientists. It is essential for today's scientists to be cognizant of such history.

1.2. Announcement Using Mass Media

The results of scientists' research are in general presented as papers published in academic journals, but in some fields it is fairly common to present research results in book form at an academic conference or research workshop.

On the other hand, presenting research results by way of an interview with a journalist or at a press conference brings with it special considerations that are different from publishing them in an academic journal or presenting them at a conference. Whether via print media such as a newspaper or a magazine, or an electronic media such as television, radio, or the Internet, the mass media have an enormous impact on modern society. Journalists doing science-related interviews or attending such press conferences are professionals expected to have some degree of scientific literacy. However, the scientist must consider the powerful influence that the media can exert and be very careful when presenting research results to them. More specifically, scientists must consider the character of the subject medium—its attitude regarding previous reports, the type of people who read, listen to, or watch it, and the personality of the interviewer—before attempting to establish communication with the mass medium and by extension communicating with society, which is the recipient of their report coverage. Above all, scientists must provide easy-to-understand explanations based on documents in order for the media to cover and report the research results accurately. Conversely, scientists must not go beyond that role and try to control the content or the tone of the coverage.

After the presentation, scientists should carefully check that the report does not contain any incorrect or inappropriate content and, if there is a problem, contact the media organization and ask them to take appropriate measures to fix it. Scientists must maintain firm governance of this series of steps while staying in contact with the PR office of their affiliated institution.

2. Authorship

2.1. Responsible Presentation

Research results presented in academic papers and books are normally shared not only within the scientific community but also with the public. If the results are not presented effectively, the achievements of the research cannot be shared.

To be responsible, research must be honest, accurate, efficient, and objective, all of which must also be maintained in the presentation of its results. The effectiveness of research presentations is evaluated based on what the scientist has clearly stated with respect to the following three points:

What the scientist did (methods)

What the scientist discovered (results)

Where the results will lead the scientist (discussion)

As standards to be satisfied in the responsible publication of research results, the Office of Research Integrity (ORI) in the United States lists the following three as "minimum" standards in its "ORI Introduction to the Responsible Conduct of Research,"[3] although it states that it is "not as easy as one might anticipate to meet these expectations."

A full and fair description of the work undertaken

An accurate report of the results

An honest and open assessment of the findings

2.2. Credit for Research Results

Recognition of a scientist's contribution to research is called "credit." This includes authorship, indicating who has written a given paper. Other ways of giving credit are "citations" of research by other authors and listing the scientists who contribute to a research study in the "acknowledgements." All of these are to recognize the contribution of named scientists. Such credit is also important for evaluating the contributing scientists and enabling other scientists to evaluate the subject research.

The authors of an original paper (the first published with the results) in an academic journal receive credit as the original inventors or discoverers. Receiving such credit implies that the scientists have made contribution to the advancement of research. The scientific community will then continue to advance that research based on the results presented by the scientist. This becomes a criterion for evaluating individual scientists, and can make a significant difference in their careers (e.g. getting jobs or promotions) and in securing research funding.

2.3. Authorship and Responsibilities

Being listed as a writer of a paper is what is referred to as authorship. Authorship is accompanied by duties and responsibilities. Authorship also implies that the writer guarantees that the research is free of errors and falsehoods and is of good quality. In other words, it is a guarantee that the presentation of responsible research results has met all the relevant standards as described in paragraph 2.1. In other words, authorship implies responsibility to meet requirements that are “not as easy as one might anticipate.” Disclosing any conflict of interest on the part of the author is also necessary to achieve that purpose.

2.4. Who Should Be Listed as Authors

Given the responsibilities of authorship, whose names should be listed as the authors of a paper is an extremely important question. Obviously, anyone who has made an important contribution to the research reported in the paper is entitled to be listed as an author, while those who did not are not so entitled.

The International Committee of Medical Journal Editors (ICMJE) has drawn up uniform requirements for manuscript submission,[4] which stipulate the following four criteria for one to be listed as a paper author.

(1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;

(2) Drafting the work or revising it critically for important intellectual content;

(3) Final approval of the version to be published;

(4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

These are the conditions that must be satisfied to be eligible for authorship; conversely, people who satisfy all of these conditions must be listed as authors.

People who do not satisfy these conditions are to be, for instance, included in the “acknowledgements.” A person who was only involved in acquiring research funding, supervising a research group, or doing overall coordination does not satisfy the requirements of authorship. It is appropriate for such persons to be included in the acknowledgements. For more details, see the below paragraph “4.4. Acknowledgements.”

2.5. List of Authors

Many papers list multiple names as their authors. In such cases, if a particular author only contributed to or is accountable for a specific part of the research, this fact must be disclosed. Unless such disclosure is made, it will be perceived that each author is fully responsible for the contents of the entire paper and can be held responsible for any research misconduct related to the paper, even if the misconduct is in a part of the research in which that author did not actually participate.

The “Guidelines for Responding to Misconduct in Research” issued by MEXT state the following: “An author, while not identified as a person involved in specific misconduct, is liable for the contents of a paper on research in which that misconduct was found to occur.” S/he could be subject to penalties such as restrictions in the applying for and receiving of competitive funding. Here, deciding on the author(s) who will be identified “liable” is determined on a case by case basis; however, preparing a proper list of authors is crucial to avoiding unnecessary misunderstandings.

There are various traditions regarding the order in which authors are listed. In some disciplines, authors are listed in order of their importance, while in others, the author having the most important role may be listed first or last—the order varying significantly from field to field with no clear rules. The order to be used in the author list should be discussed among the authors themselves, taking into account the tradition in that particular field of research. On this point, see Section V, paragraph “3(8) Rules on presenting results and authorship.”

Recently, prior to the publication of a paper, many academic journals are requesting confirmation from persons listed as authors as to whether they indeed did author the paper.

3. Improper Authorship

3.1. Gift Authorship

Gift authorship is a term referring to a practice in which a true author, out of kindness, gives authorship to someone not deserving it.

Someone who does not know or agree with the content of a paper cannot be accountable for the paper. Because the authors are persons held accountable for the research, it is not permissible to list someone as an author who did not actually contribute to the research. Such persons can be acknowledged for their cooperation, but should not be listed as authors.

There appear to be cases where persons in a more powerful position than a true author add their names as authors of a paper, taking advantage of their superior position. Conversely, there are cases where a true author adds to the list of authors someone close to him/herself or someone who can give the true author an advantage if listed as an author. Some people may want to add an authoritative figure in their field to the author list so that the paper will be more readily accepted. Not only is gift authorship improper, but both the persons who add and accept a gift authorship need to realize that such a practice violates research ethics.

3.2. Ghost Authorship

Opposite to gift authorship is the practice of ghost authorship, in which a truly deserving author is not given credit as an author.

There appears to be many problems of authorship when a professor and graduate student work together in carrying out joint research. Even when the graduate student’s experiments, data collection, and analyses were carried out under the guidance of the professor, the graduate student should be named as an author when s/he has made a substantial contribution to the research.

Some cases of ghost authorship are malicious, having the objective of hiding a conflict of interest. Take the case an employee of a pharmaceutical company carrying out clinical research and analysis of data but only university-affiliated researchers are listed as authors of the paper. If the employee were listed as an author, an appropriate measure to manage the conflict of interest would have to be taken and disclosed, which could greatly affect the reliability of the research results. Ghost authorship is thus sometimes used to avert a demerit to a company.

Ghost authorship also includes an act in which an author's name is correctly listed but his/her affiliation is not, hiding, for example, the fact that the author is an employee of a company having a close financial relationship with the research. In Japan, it is well-known that an employee of a pharmaceutical company was involved in the entire clinical research study on the Diovan drug to treat high-blood pressure while being listed not as the company's employee but as an adjunct lecturer at the university. This was the so-called "Diovan Incident" (2012).[5]

4. Improper Presentation Methods

4.1. Duplicate Posting, Duplicate Publication

Duplicate posting and duplicate publication are not acts of an author disclosing information already made available to the public. They are rather a practice of submitting (posting) and publishing identical information. When submitting a research paper, if an important part of the paper has already been presented elsewhere, that fact needs to be made clear. The editor of an academic journal decides whether or not to publish research results based on honest disclosure by the author.

Duplicate posting and publishing is problematic because the author is trying to make his/her accomplishment (the number of accepted papers) appear more impressive than it actually is. This also wastes other scientists' time and resources in undertaking unnecessary reviews and replication. Furthermore, these practices can endanger people's health and safety. If, for example, multiple epidemiological or clinical research studies show similar conclusions, scientists will focus their attention on them and conduct research along those lines. If these are duplicate publications of one research study, the conclusions reached by the misled scientists may guide public-health policies in the wrong direction.

As duplicate posting and publishing are not clear misconduct violations such as fabrication, falsification, and plagiarism, ethical standards regarding them have not been well-established among scientists. A Tohoku University report on a 2012 study of duplicate posting on its campus found that ethical standards regarding the problem were not sufficiently well-developed or widely accepted.[6]

Under such circumstances, in 2014, MEXT published "Guidelines for Responding to Misconduct in Research,"[7] which states that duplicate posting is a violation of research ethics and, as such, it is prohibited by many academic organizations and journals. It also requires the scientific community to come up with a policy to counter this practice when it occurs.

It should be pointed out that the publication of a doctoral dissertation is also subject to these presentation rules. In particular, Japan's regulations on academic degrees were revised in 2013, replacing dissertations printed on paper with dissertations presented over the Internet.[8] With this, it will be normal for a doctoral dissertation to appear on the Web within three months following the awarding of a degree. When one submits a paper based on a doctoral dissertation, this fact must be reported to the academic journal. In such cases, the author should not forget to mention, in the acknowledgement or quotation sections, anyone who has cooperated or provided guidance in the research or who is quoted in the paper.

4.2. "Salami Slicing" in Publishing

The act of publishing one research as multiple smaller studies (slices cut out from the main study) is referred to as "salami publishing" or "bologna publishing," after two types of sausages that are traditionally cut into thin slices before eating. Just as with duplicate posting and publishing, this practice not only artificially exaggerates one's accomplishment, but it is also problematic because it makes it difficult to grasp the overall significance of the research and unnecessarily wastes other scientists' time. The significance of the research would be much more easily understood by other scientists if the entire body of related information were published as one paper.

Implicitly, salami publishing may be encouraged by a tendency to evaluate a scientist's ability by the number of his/her research publications (or papers in which the scientist is the primary author) when applying for a grant, a job, or a promotion. However, one excellent research paper has a much greater impact than many sliced-up papers, and will contribute more to the advancement of science. To promote sound scientific advancement, it is necessary for people on the evaluating side to properly recognize that evaluating someone's ability merely by the number of papers s/he publishes, while it may be easy, is inappropriate and needs to be stopped.

4.3. Improper Referencing of Prior Research

Scientific research is built upon the accumulation of research results previously obtained by other scientists. When one conducts research, it is, therefore, important to carefully take into account prior research. The same applies when writing a paper. By studying and grasping prior research, a scientist can prepare a research plan that contains originality and clarifies the significance of his/her new work.

To give proper credit to research conducted in the past, it is essential to carefully investigate prior research and appropriately reference it when writing a paper. There are cases when a research group intentionally omits reference to prior research done by a competing research group. This sort of improper way of treating prior research should be recognized as a practice that can damage the objectivity and credibility of one's own scientific research.

4.4. Acknowledgements

When presenting a research paper, it is necessary to acknowledge those who cooperated with the author(s) and to recognize the research funding provided.

The uniform requirements for manuscript submission established by the International Committee of Medical Journal Editors (ICMJE), referred to above, state that it is appropriate for a related party who does not satisfy the requirements for being an author to be mentioned in the "acknowledgements." More specifically, this includes persons who secured funding for the research, laboratory supervisors, principal investigators, persons who provided advice and who helped the author in composing a draft or writing a paper in English (persons who are not eligible to be included as authors). In the acknowledgements, it is desirable to list each person's names along with the specific contributions s/he made to the research.

If the research was funded by a research grant, that fact also needs to be stated. This is not just to be accountable to the research-funding organization, but when funding is provided by a private corporation, a statement on the funding source is essential from a conflict-of-interest standpoint.

With *kakenhi* grants awarded to many researchers, it is required that the grant be acknowledged using MEXT or JSPS *kakenhi* Grant Number *****."[9]

5. Copyright

5.1. What Is a Copyright?

Copyright is a right granted automatically, without any required procedures such as application or registration, to a person who creates a work. A work is defined as a "production in which thoughts or sentiments are expressed in a creative way and which falls within literary, scientific, artistic or musical domains,"[10] but also includes, as examples, novels, music, art works, films, and computer programs.[11] Furthermore, it spans much more, including paragraphs, figures, charts, diagrams, photographs, illustrations, lectures, speeches, newspaper articles, and magazine articles, and articles in books and academic journals that scientists use on a regular basis.

5.2. When Using Someone Else's Copyrighted Material

When preparing and using a secondary work that copies or modifies someone else's work, generally one must first obtain permission from the owner of the copyright of that work.[12] The copyright of a work published in a journal or other publications normally belongs to the publisher, so an author may need to obtain permission from the publisher to use that article even if it was written by the author him/herself. When a scientist's research results are reported in a newspaper or other media, s/he may want to share the report or coverage by including it on a website. However, before the actual article or report is transferred to the website, the scientist must first obtain permission from the newspaper or media company. When a research paper is published in a journal, the author may want to include/transfer its summary or table of contents on/to his/her website; however, in this case as well it may be necessary to first obtain permission. Whenever someone makes secondary use of a work, it is necessary to look up the rules and guidelines stipulated by the owner of the copyright and use the work appropriately. A copyright infringement may result in a civil claim such as compensation for damages, injunction, and court-ordered ban, as well as a criminal penalty.[13]

5.3. Secondary Use When No Permission of the Copyright Owner Is Necessary

There are, however, situations where no permission is needed from the copyright owner for secondary use of a work.[14] In the following cases for example, no permission is needed unless transfer is expressly prohibited: Use of a work excluded from the protection of the Copyright Act by a national law or a local ordinance, duplication for a personal use, and use of a work whose copyright-protection period has expired. Also, as explained below, when "quoting" someone else's work or using part of someone's work for educational or examination purposes, no permission is necessary as long as proper procedures are observed.

5.3.1. Quotations

A practice whereby an author refers in his/her own work to a portion of someone else's work is referred to as "quotation." According to the Copyright Act, it is permissible to quote from a work "already made public" provided that it is "compatible with fair practice" and "to the extent justified by the purpose of the quotation such as news reporting or research critiquing."[15] The term "quotation" may be a bit difficult to grasp, but if the following requirements are satisfied, permission from the copyright owner is not necessary.

(1) the work being quoted has already been made public (including disclosure on the Web)

(2) the quotation is necessary (including, for example, using someone else's work to corroborate one's own theory)

(3) the portion being quoted is expressly indicated (the quoted portion is indicated by means such as quotation marks or a different font so as to be clearly distinguished from the author's own work)

(4) the work being quoted is not modified without permission

(5) the author's work is primary while the quoted portion is secondary

(6) the source is clearly cited.

One must pay close attention as any use of another's work without meeting these requirements constitutes a violation of the Copyright Act and could be considered plagiarism as research misconduct (cf. "4. Improper Presentation Methods" in Section IV).

5.3.2. Secondary Use of a Work for Educational or Examination Purposes

In schools and other educational institutions (excluding for-profit organizations such as private tutorial centers), use of duplicated work to the extent deemed appropriate for the purpose of lessons does not constitute a violation as long as the source is cited.[16] However, any act that unreasonably prejudices the interests of the copyright owner, such as making reproduced documents available on the Internet for downloading or distributing a reproduced volume of test questions, is a violation of the Copyright Act.

Use of a work already made public is permitted without permission for examinations, including entrance examinations, regular examinations, various certificate examinations, and employment examinations. This is to protect the confidentiality of examination questions.[17] However, when publishing a collection of past questions containing other work, it is necessary to obtain permission from the copyright owner(s) in advance.

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Section V: How to Conduct Joint Research

1. Rise in Joint Research and Background

Today, many research activities take the form of joint research with many scientists participating in them. There are several reasons for this expansion of joint research. Learning itself has become an increasingly more complex process, requiring a division of roles in carrying it out. Another factor is the widespread use and development of computers, which have enabled analyses of large amounts of data, resulting in more systematic research studies even in the humanities and social sciences. As segmentation of scientific research continues, more research activities involve collaboration among scientists in a variety of academic disciplines. In what is now referred to as "interdisciplinary research," studies are carried out by integrating information, data, methods, equipment, viewpoints, and theories from multiple research fields and systems of expert knowledge, allowing researchers to solve problems that would not be possible within a single field. Other factors include the rise of joint research between corporations and universities, reduced costs of research and development, and joint R&D projects that mutually complement the technologies of companies in different fields.

2. Challenges in International Joint Research

Transcending national borders has always been a characteristic of research activities, but with globalization, international joint research has been on the rise.[1] As joint research can involve many scientists from a wide variety of disciplines and backgrounds, it requires special considerations. In particular, international joint research brings together the traditions and behavioral customs of the various countries from which the scientists hail, so one must bear in mind that their ideas regarding research ethics may also differ.

In 2001, a Japanese researcher at the Institute of Physical and Chemical Research ("RIKEN") took out a gene sample from a private laboratory in the United States where he had previously worked. As this act was considered to be an attempt to advantage a foreign government by illegally taking away a corporate secret, he was prosecuted for violating the U.S. Economic Espionage Act of 1996. The researcher was under the false impression that the sample belonged to him because he had himself been awarded the research grant. This incident underscored the fact that Japan was lagging behind the times in its awareness of intellectual property practices. When participating in international joint research, one needs to know the research ethics and rules of the various countries and share that information within his/her research group.

3. Points to Remember in Joint Research

As scientific research works to maintain and develop humankind's intellectual assets and exerts a great impact on society, scientists have weighty responsibilities. With joint research, however, scientists bear not only individual but also collective responsibilities. The following points are important in conducting joint research.

(1) Deciding upon the principal investigator of the research group

One might think that it's not possible to have a research group without a principal investigator (a person in charge), but when the head of an institution is in name only made the principal investigator, it may be unclear who is actually in charge of the joint project, causing it to be a mere collection of individual researchers. In a research group made up of a variety of scientists, it is easy for the participants to act at cross purposes, so a principal investigator is needed to integrate the work of the entire team.

(2) Good communication and a culture of openness within the group

The larger a research body is, the more difficult it becomes to communicate ideas and opinions, potentially causing the sharing of information and issues to be neglected. When graduate students participate in joint research carried out between a corporation and a university, it is possible that the merits for them may not match the demerits, such as slippage in the timing for presenting their research results. As some of the scientists may themselves be in competition with one another, a conscious effort must be made to promote both internal and external communication among the members, particularly by the leading scientists including the principal investigator.

(3) Clarifying the division of roles and responsibilities and promoting mutual understanding among the members

The "ORI Introduction to the Responsible Conduct of Research" lists the following points as specific items upon which members of joint research must agree.

- the goals of the project and anticipated outcomes
- the role that each person in the collaboration will play
- how data will be collected, stored, and shared
- how changes in the research design will be made
- who will be responsible for drafting publications
- the criteria that will be used to identify and rank contributing authors
- who will be responsible for submitting reports and meeting other requirements
- who will be responsible for or have the authority to speak publicly for the collaboration
- how intellectual property rights and ownership issues will be resolved
- how the collaboration can be changed and when it will come to an end.

(4) Clarifying research goals

In joint research, the participating researchers are to communicate with one another right from the beginning stage of discussing the project's goals. The same is true when changing the research goals after the joint research has begun.

(5) Understanding laws and guidelines

With scientists from different disciplines participating, it is not always the case that the research guidelines are well understood. This is particularly important to consider when it comes to conducting international joint research.

(6) Methods of keeping research records and of keeping and using data

How research data is handled is a particularly important aspect of joint research carried out among various members. The ownership of research data depends on the research grant, the institution's rules, and the country. In the United States, for example, when research is funded by the National Science Foundation or National Institutes of Health, the data do not belong the scientists but to the institution. Other institutions have their own rules. In Japan, for instance, the Guidelines for Laboratory Researchers at The University of Tokyo (revised April 2014) state that even the experiment notes belong to the research laboratory and not to the individual.

(7) Handling intellectual property rights

If joint research involves a company, it is customary that a document be signed to state the ownership of intellectual properties that could lead to patents or commercialization. It is also possible for researchers engaged in joint research to apply for patents themselves, but care must be exercised as different institutions may have differing rules concerning the handling of intellectual properties such as patents based on research results.

Trouble could occur if rules are not laid out in advance of a presentation using research data after the completion of a joint research project. It is therefore necessary to come to an agreement at the beginning of the research project based on an understanding of the research institution and research-funding agency's rules.

(8) Rules on presenting results and authorship

Since authorship indicates a contribution to said research and is included among the scientist's accomplishments, it is very important to set up rules for authorship in joint research. Concepts of authorship may vary from field to field, so when scientists from different fields participate together in joint research, discussions must begin by sharing these concepts. The Montreal Statement stipulates that "collaborating partners should come to agreement, at the outset and later as needed, on how publication and other dissemination decisions will be made."

(9) Misconduct in research

It is important to make preparations which ensure that no deviant research practices or research misconduct will be committed or suspected (although they should not occur in the first place). Members of the joint research team should come to an agreement on items 6 through 8 above in advance as well as discussing rules for addressing issues if raised. Above all, it is important to create an environment in which the members can openly check on one another to prevent problems from occurring.

In joint research involving a company, it has become common to prepare an agreement clearly establishing the ownership of data and research results. However, such agreements may not necessarily include every item listed above. It is important to document these points in writing. Such a practice may not be a Japanese custom, but documentation is an effective way to maintain good mutual understanding by clarifying and formulating research ethics, which may have otherwise been considered implicit knowledge.

What is important in implementing this is to create a relationship of trust among the members of the joint research team. At the foundation of jointly conducting sound research activities are an open human relationship and trust among the members, so that, while their responsibilities and roles may vary, doubts and questions that arise can be resolved through mutual discussion.

4. Positions regarding Graduate Students and Joint Research

One of the difficult things in joint research is how to position participating scientists who are under the supervision of a faculty member, such as graduate students. A supervisor and student are often considered to be in a vertical teacher-learner relationship. Unfortunately, a teaching supervisor may push his/her own views unilaterally upon the student, leading to claims of academic harassment, or the supervisor may carelessly use in his/her own research some original research results obtained by the graduate student.

Depending on the discipline and laboratory, the position of graduate students varies. However, as described above, it is important for the supervisor and graduate student to talk with each other and create a relationship of trust with regard to the research objectives, contents, duties, and role division, and for the entire team (including the teaching supervisor) to share a common point of view with regard to fostering graduate students in their joint research project.

Notes and References: -----------------

1. National Institute of Science and Technology Policy, MEXT. Research Material 218: Benchmarking Scientific Research 2012—Bibliometric Analysis on Dynamic Alteration of Research Activity in the world and Japan (March 2012), Shibaura Institute of Technology. Investigation Research on the Development of Case Studies for Flexible and Rational Negotiations on Collaborative Research Agreement, Report on the Outcomes of the Industry-Government-Academia Strategic Coordination Program (2009) commissioned by MEXT (March 2010)

Column

Joint Research and the Anti-Monopoly Act

Another thing that must be kept in mind in conducting joint research is its relation to the Anti-Monopoly Act. It is possible for joint research to limit or restrict market competition, consequently resulting in monopolized sales of goods that use technology obtained by the research, thus interfering with fair competition. This may surprise many people, but because the very concept of patents implies a monopoly of intellectual results, the United States government, which has traditionally been for free-market and anti-trust policies, had taken a passive stance regarding patents and strengthening industry-academic collaboration. Hence, the establishment of the Bayh-Dole Act of 1980 marked a dramatic shift away from what was the long-term stagnation of the American economy.

Later, industry-academic collaboration and obtaining patents became a global trend, but the fact remains that joint research and development has the effect of limiting competition. For this reason, the Japan Fair Trade Commission established "Guidelines Concerning Joint Research and Development under the Antimonopoly Act" (revised Jan. 1, 2010). There was for example a case in which the Japan Fair Trade Commission discussed whether any potential violations of the Antimonopoly Act would occur when three construction material manufacturers decided to conduct a joint R&D project on construction material parts. The guidelines allowed such research if the market share of the participating businesses is 20% or less. If over 20%, they stipulated that the decision should be made holistically taking into account the nature of the research. In this case, the Commission concluded that the situation did not violate the law but added the following comment: "However, the total market share of the three companies in the applicable field is high at 30%, so it is necessary to ensure that their joint research and development does not result in any act that circumvents competition in the manufacture and sale of the product."

Section VI: Appropriate Use of Research Funds

1. Introduction

In conducting scientific research, “research funding” is indispensable, and scientists are expected to use it in appropriate ways. Certainly, such funding should be used in ways that enable the research to be carried out most effectively; however, this is not to say that the scientists can use it in any way they freely choose, and obviously it cannot be used for purposes other than research.

There are rules pertaining to the use of research funds; they apply not only to public research grants but also to subsidies from private foundations, donations and research contracts from private companies—virtually all funds used for research purposes. It is incorrect to think that one is allowed to freely use funds obtained by him/herself. Even donated funds are not the personal income of individual scientists; the rules of their institution must be followed in the use of these funds too.

Regarding research funds provided through a public system such as the *kakenhi* program, each system has its own usage rules based on its mission. This chapter deals with the appropriate use of research funds.

2. Responsibilities of the Scientist

2.1. Understanding Rules Concerning the Use of Public Research Funds

When research uses public funds, there are usage rules, required paperwork, management methods, and other aspects set in place to ensure that the funds are appropriately used to accomplish the objectives of the research.

First, organizations that provide public research funds (hereafter “funding organizations”) establish their own rules to ensure that their public research funds are appropriately used at the receiving research institutions. In Japan, these include MEXT, JSPS, Japan Society and Technology Agency (JST), Ministry of Health, Labour and Welfare, and New Energy and Industrial Technology Development Organization (NEDO).

In addition, there are rules established by research institutions themselves based on their nature and scale. Both of these rule sets must be followed when conducting research using public research funds.

Rules governing the use of public research funds vary due, in part, to differences in the funding organizations and the ways in which the funds are disbursed (e.g., grants, commissions). Even within one government ministry or agency, it is possible that a particular way of using funds may be allowed under one system but not another. For such reasons, it may be difficult for a scientist, who is not an administrative official, to grasp all the details of every rule. However, not knowing certain rules may prevent the scientist from carrying out his/her research smoothly.

Funding organizations and research institutions work to share information on their rules for using public research funds by holding briefing sessions and preparing pamphlets, especially regarding information that is absolutely necessary for scientists to know when conducting their research. It is important for scientists to attend these sessions and read the pamphlets so that they will at least understand the rules that must be followed when using public research funds. Some of these rules are revised every year, so what was allowed in the past may no longer be. The efficiency of research could be affected if it were implemented without an awareness of such information. Therefore, scientists need to attend these briefing sessions on a regular basis and to read the most recently issued pamphlets even if they had learned the rules a few years prior.

When there is something regarding the interpretation or implementation of a rule that a scientist does not understand, s/he should avoid making a judgment based on his/her own judgment or the customs of his/her research laboratory. That could lead to conducting research in ways that incur the improper use of funds. To avoid such situations, if there is anything that one does not understand concerning the use of research funds, s/he should contact an administrative official of his/her research institution.

Some may feel that it is too much trouble to contact administrative officials, but consultation can go easily if one maintains good communication with them. Consulting them prior to a problem arising allows the officials to handle the matter without affecting the research, though this is not the case if consultation is made after funds have been used improperly. That could incur a considerable burden: Referral to a misconduct review committee set up by the research institution, having to deal with the funding organization, and possible consequence for the research institution. Furthermore, such an improper use could jeopardize the research's continuation and threaten the career of the scientist(s). To avoid such consequences, scientists should freely consult with the administrative officers about anything they do not understand.

It is also important to ensure that rules on research funding allow scientists easy use of the funds. For instance, with the *kakenhi* system, which serves more scientists than any other funding system in Japan, enhancements are considered and made virtually every year in response to opinions and suggestions given by scientists. If a researcher feels that something is wrong with the rules on scientific funding, it is important for him/her to submit a request to the funding organization either in writing or via the administrative office of his/her research institution. It is not a proper attitude for a scientist, whose position obligates him/her to build a good relationship with the public, to simply not try to improve the system, thinking "whatever I say will not change anything," or to just go ahead and exercise his/her own interpretation of the rules.

2.2. Cooperation to Ensure Proper Use of Research Funds by Research Institutions

Each research institution is involved in maintaining a system for managing and auditing its research funds so as to ensure that they are properly used. Accordingly, each institution holds information briefings on the proper use of research funds for scientists affiliated with it, and it prepares pamphlets to explain various rules. It is important for scientists to be actively involved in these events at their research institutions.

To be more effective in implementing their systems for managing and auditing public research funds, some research institutions require their scientists to submit a signed statement pledging that they will strictly comply with the institution's rules and regulations and refrain from any misconduct.

In the rare event that a problem occurs in the use of research funds, scientists must cooperate positively in a review carried out by their research institution. Anyone who is not cooperative in such a review process may be deemed guilty of misconduct and penalized by the funding organization or research institution.

Additionally, MEXT has established its own guidelines, mandating each research institution to implement a variety of measures for managing and monitoring its public research funds.

Cooperation by scientists is essential for their research institutions to effectively implement these measures.

The main measures to be taken by research institutions according to the “Guidelines for Managing and Auditing Public Research Funds at Research Institutions (Implementation Criteria)”[1] (approved by the Minister on February 15, 2007 and revised on February 18, 2014) are as follows.

- To clearly state the rules on public research funds and notify all scientists
- To offer compliance training on public research funds to all scientists (including notifying them of the institution’s policies and rules on how misconduct is handled) and check their attendance and understanding
- To help scientists understand that it is their responsibility to comply with the contents of their compliance training and to have them submit a signed pledge to enhance the spread of such awareness
- To set up a contact desk for whistleblowers from within and outside the institution (reporting questionable or illegal use of funds, self-reporting, etc.)
- To make an open disclosure when improper use of public research funds has been verified, including the details of the improper use such as the names of the scientists involved, their affiliation, and the nature of the improper use.
- To ask each vendor doing business with the research institution to submit a pledge which states that the vendor will strictly comply with the institution’s rules and regulations, not get involved in misconduct, and report any improper request from scientists so as to preclude adhesion between them and commercial vendors
- To implement a risk-approach auditing process, including random inspections, so as to minimize the possibility that public research funds will be improperly used.

2.3. How to Process Private Subsidies

Rules established by universities and other research institutions need to be complied with, not just for the use of public research funds but also for the use of donations and commissioned research money from private companies. As long as a scientist is affiliated with a research institution such as a university, that institution is responsible for his/her scientific research, including how the research funding is spent. Even if money comes as a donation, it is not the personal income of an individual scientist, and must be managed appropriately under the responsibility of the research institution.

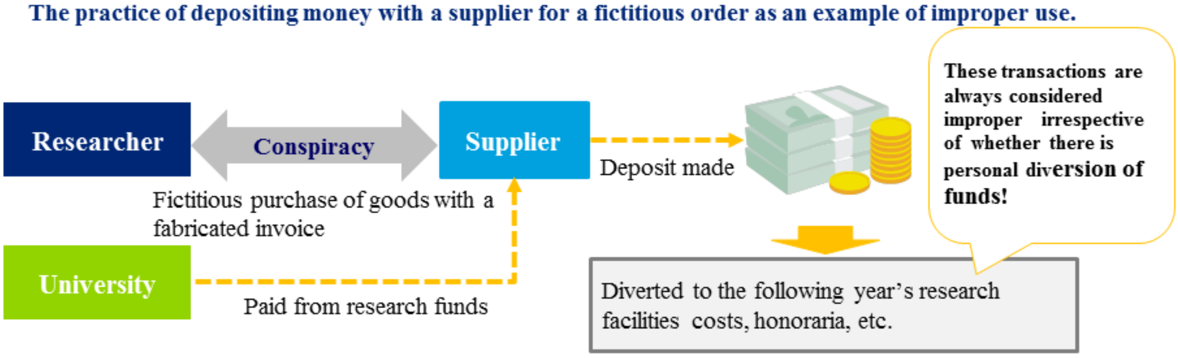
On the other hand, there are private funding groups that transfer or send grant money only into a scientist’s account, the money being given directly to the individual scientist. In such cases, it is a general practice for the scientist to re-transfer the money to his/her affiliated institution for it to manage. Even so, in some cases, this transfer is not made and the individual scientist privately manages the money. Some may be of the opinion that such private management is acceptable as long as it is carried out properly; however, the point here is not that problems may occur. Rather, as mentioned above, as long as a scientist is affiliated with a research institution while engaged in research activities, s/he must understand that the institution has the responsibility to manage the funds and that its rules must be complied with. Research activities are, of course, activities carried out by individual scientists; however, it must be understood that most scientists do so as members of an organization or society.

3. Examples of Improper Use of Public Research Funds

Let's take a look at some examples of improper use of research funds.[2]

Example 1: Impropriety through fictitious orders and deposits

The practice of depositing money with a supplier for a fictitious order as an example of improper use.



Analysis of impropriety factors

- Researchers wanted to use their research funds freely regardless of the fiscal year it was allocated for (motive).
- The system allowed researchers to control all steps of ordering from invoice to delivery and billing (opportunity).
- Researchers lacked awareness of the rules they must obey and that their funds are public money (justification).

Measures taken

- They were ordered to return the funds.
- They were banned from applying for and participating in research with competitive funding for the next 4 years (maximum of 5 years after the revision).
- The supplier involved was suspended from any transaction for a certain period of time.
- Some personnel measures were taken within the research institution, such as disciplinary actions.

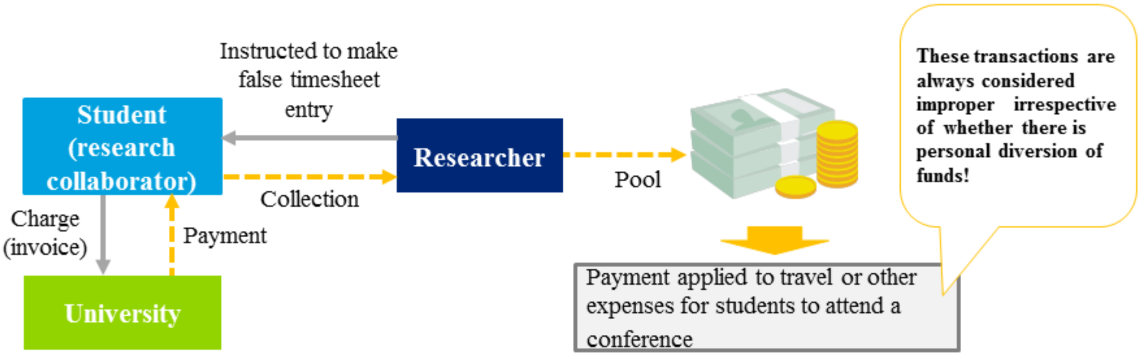
Important Point

It would have been possible to use the fund during the following year without any impropriety if the established carry-over system was appropriately applied with a valid carry-over reason.

In this example, the researchers pretend to purchase goods, which were not actually ordered, and send a deposit to the vendor to retain for use later to purchase something else. This type of violation occurs for various reasons. For example, the researchers may want to purchase goods not allowed to be bought with research funds; the process of purchasing goods is complicated and time-consuming; using research funds over multiple years involves a complex procedure. In the latter case, it would have been possible for the researcher to apply for multi-year funding under the "carry-over system," so the misconduct resulted from the researcher either misunderstanding or not knowing about the proper system. In fact, the *kakenhi* system has been improved by placing within it a Multi-year Fund that makes it possible to use grant funds from one fiscal year to the next, so that there is no need whatsoever to make deposits with vendors or commit other such acts of misconduct.

Example 2: Impropriety through fictitious labor costs (honoraria)

The practice of logging more hours than collaborators actually work and using the excess wages for improper purposes.



Analysis of impropriety factors

- Researchers wanted to use their research funds freely regardless of its specified purposes (motive).
- Worker attendance was managed solely by the research laboratory, and the administrative office did not check it (opportunity).
- Researchers lacked awareness of the rules they must obey and that their funds are public money (justification).

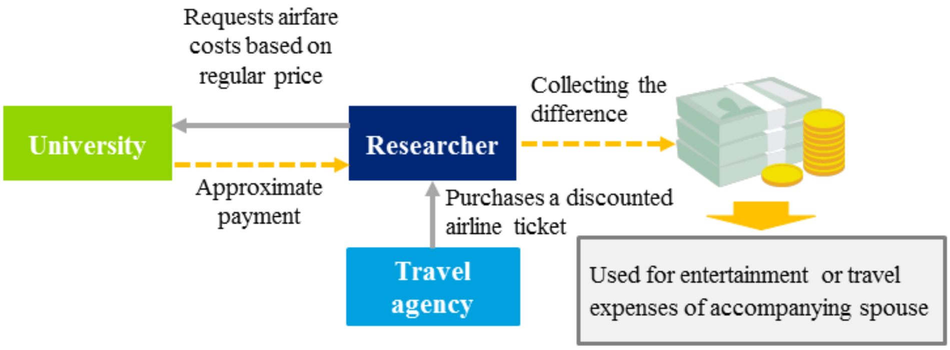
Measures taken

- They were ordered to return the funds.
- They were banned from applying for and participating in research with competitive funding for the next 4 years (maximum of 5 years after the revision).
- Some personnel measures were taken within the research institution, such as disciplinary actions.

In this example, fictitious honoraria are paid to university graduate students in a research laboratory, with the intent by the laboratory to pool the money to use for travel or other student expenses. Some may claim that this usage is not improper because the money will, after all, be spent for the benefit of the students. However, accumulating honoraria is an illegitimate means of pooling money; using the funds like this in the presence of the students is also undesirable from the standpoint of training them to be principled scientists. In fact, *kakenhi* money can be used to pay for the travel expenses of graduate students when deemed necessary for research purposes.

Example 3: Impropriety through fictitious travel and transportation expenses

The practice of charging research funds in an amount more than the costs, and using the over-charged for improper purposes.



Analysis of impropriety factors

- Researchers wanted to use their research funds for personal purposes (motive).
- There was no system to check whether the research-related trip actually took place as reported (opportunity).
- Researchers lacked awareness of the rules that they must obey and that their funds are public money (justification).

Measures taken

- They were ordered to return the funds.
- They were banned from applying for and participating in research with competitive funding for the next 5 years (maximum of 10 years after the revision).
- Some personnel measures were taken within the research institution, such as disciplinary actions.

Regarding travel-related expenses, each institution has a system in place to prevent misconduct, such as requiring researchers to turn in the stub of the tickets they used. If, despite such effort, misconduct still occurs by exploiting system loopholes, it would be considered an extremely malicious type of misconduct. Whenever this type of misconduct occurs, rules governing travel expenses get stricter, potentially causing an unnecessary level of restrictions and greater workload on scientists conducting research activities. One must realize that misconduct by a small number of scientists can have larger negative consequences on scientific research in general.

4. Measures Taken against Improper Use of Public Research Funds

4.1. Return of Public Research Funds Connected to Improper Use

When research funding is improperly used by a scientist at a research institution, the funding organization may request that the amount of money used improperly be returned. Such a request is made based on a final project report submitted by the research institution and on laws governing the proper execution of budgets related to grants and other funding and/or contract documents. If the misconduct occurred in the past, an interest charge, calculated according to rates established by law, is added. Even in cases when the entire amount of the improperly used money was not spent by the researcher—for instance, by a student in the laboratory—ultimately the principal investigator in charge of the publicly funded project is held responsible for returning the money. One must bear in mind that a refund may be ordered when a violation of the research-fund accounting rules occurs, even if no problem is found with the purpose for which the money was actually used.

4.2. Limitations on Eligibility to Apply for Competitive Funding

When funds from a competitive funding system are improperly used, the funding organization may ban the researchers involved from applying for other funds/grants from competitive funding systems for a certain period of time (from one to ten years), depending on the level of the misconduct. This measure is based on the “Guidelines for Proper Execution of Competitive Funds” (September 9, 2005), agreed upon by the government ministries and agencies administering competitive funding systems.

When the funds improperly used are MEXT’s *kakenhi* grants, this measure can ban the culpable scientists from applying for any funds/grants in all competitive funding systems, including those of other ministries and agencies.

Furthermore, the scientists involved in the improper use of funds are not the only ones subject to this limitation in application eligibility. Any scientist to whom research funds are disbursed is responsible for properly managing them (duty of diligence). If an assistant, for example, working in a support role under such a scientist is found to have used funding improperly, while the scientist him/herself is not guilty of any improper use, that scientist is still subject to this measure—that is, s/he could become ineligible to apply for a grant from a competitive funding system. In such a case, the funding organization bans the scientist from applying for a period of one to two years for neglecting his/her duty of diligence.

4.3. Disciplinary Actions within Research Institutions

When a scientist uses research funds improperly, not only can the funding organization limit his/her eligibility for application, but the research institution with which s/he is affiliated can also take disciplinary actions in accordance with its rules and standards. When the misconduct is particularly malicious, the research institution can even press criminal charges against the offending scientist, resulting in the court imposing criminal penalties. In the case, for example, of a scientist who pretends to purchase goods while actually using the money for another purpose, if the misconduct is considered to be very malicious, equivalent to his/her deceiving the research institution, it could constitute fraud.

Some research institutions disclose the names and other information on scientists involved in misconduct, applying their respective rules.

It should be borne in mind that any improper use of research funds can result in not only penalties, such as an order to return the funds and application eligibility limitations, but also in disciplinary actions taken by the research institution.

4.4. Miscellaneous

Guidelines for managing and auditing public research funds have been revised by MEXT, the Ministry of Health, Labour and Welfare, and Ministry of Internal Affairs and Communications, going into effect in April 2014. They mandate that when a research institution is found to have an inadequate system for managing and auditing public research funds, a certain percentage of their overhead funding will be reduced.

As systems to manage and audit public research funds do not govern scientists per se, an imperative exists for them to cooperate in the proper implementation of their institution's guidelines so that its overhead funding will not be cut due to rule inadequacies or failures.

[Note] Overhead funding

The term "overhead funding" here refers to funding necessary to manage a research institution for the purpose of carrying out research funded by a competitive funding system. It is provided to the institution as a fixed percentage of direct funding (30% of *kakenhi* funding). Overhead funding is a critical resource for improving the research and development environment of scientists who obtain competitive grants and for enhancing the overall performance of the research institution.

5. Conclusion

As public research funds come from the precious financial resources of citizens, their improper use can be extensively covered in media reports. Just as with research misconduct, improper use of research funds can damage the credibility and dreams of scientific research, potentially leading to reductions in scientific research budgets. It may be due to an act by a handful of scientists or just carelessness, but misconduct of any kind can have a tremendously negative impact on the entire Japanese scientific research community. Therefore, it is imperative to exercise constant care in the proper use of research funds.

Rules are not there to constrain research. There are reasons and backgrounds for them. Rules related to research funding should not be just memorized blindly; whenever one does not understand the meaning of a rule, s/he should ask an administrative officer or the funding organization for clarification. When rules are well understood, research will go smoothly. As described above, to carry out research activities more efficiently and effectively, it is important to engage in dialogue with the institution's administrative staff and, when it is felt that enhancements are needed, to request reviews of the rules by funding organizations. This too is the responsibility of a scientist.

Notes and References: -----------------

1. MEXT. Amendment of "Guidelines for Managing and Auditing Public Research Funds at Research Institutions (Implementation Criteria)"

http://www.mext.go.jp/a_menu/kansa/houkoku/1343831.htm

2. MEXT's Guidelines for Managing and Auditing Public Research Funds at Research Institutions (for Researchers)

http://www.mext.go.jp/component/a_menu/science/detail/__icsFiles/afieldfile/2014/08/05/1350202_2.pdf

Section VII: Contributing to Quality Improvement in Scientific Research

1. Peer Review

1.1. Role of Peer Review

"Peer review" plays a crucial role in guaranteeing and improving the quality of scientific research. Peer review refers to a process of "reviews" carried out by "peers," a process that is at the heart of all types of evaluation in scientific research, including the acceptance of research papers by academic journals, selection of research grants and subsidies, hiring and promotion of scientists, and the assessment of research institutions.[1] The system is based on a recognition that only scientists themselves can make informed judgments in these situations and that all types of decisions on scientific research should be made by the scientific community itself. Peer review is the cornerstone that undergirds the autonomy of the scientific community. Political interference in scientific research, such as support for a certain scientific theory based on a political agenda, can distort and misguide scientific research. Autonomy of the scientific community is indispensable to the sound advancement of scientific research. Peer review is indispensable for this reason.

1.2. Peer Review of Research Papers and Research Grant Applications

Peer review is called "*sadoku*" (review reading) in Japanese, and a peer reviewer is called "*sadokusha*" (review reader). Peer review is based on the assumption that it is the scientists in a special field of expertise who can most effectively evaluate the quality of scientific research in that field. From the standpoint of a paper submission, peer review may appear to the authors as the only part of the paper publication process; however, it actually plays the role of a gate keeper, checking for any problems contained in papers and introducing excellent papers to the world.

1.2.1. Peer Review of Research Papers

Normally, the following sequence of processes takes place before a research paper is published in an academic journal.[2]

(1) The author of a paper submits it to an academic journal.

(2) The editor and/or the editorial board of the academic journal (hereafter referred to as the "editor") examines the submitted paper and decides if it should be peer-reviewed.

(3) The editor asks scientists (normally at least two) in the specific field, qualified as peer reviewers, to peer-review the submitted paper.

(4) Each peer reviewer examines the submitted paper, prepares a peer-review report, and submits it to the editor.

(5) Having received the peer-review reports from the reviewers, the editor determines whether to accept or reject the paper. In many cases, the conclusion comes with conditions, asking for corrections.

(6) The editor reports the result of peer review to the author.

When the submitted paper is not in a field covered by the academic journal or does not comply with its editorial policies, or when it is determined that the quality of a submitted paper is clearly not worthy of publication, the editor often makes the decision, prior to the paper being sent for peer review, to reject its publication.

Each peer reviewer evaluates the paper and determines if it satisfies certain standards worthy of publication from an expert's standpoint, considering carefully such points as the paper's originality, significance, validity of the research methods used, the paper's organization, and the accuracy of its data interpretations. In the peer-review report, each peer reviewer states his/her review results, such as (1) recommending publication without change, (2) recommending publication with minor changes, (3) recommending publication with major changes, or (4) rejecting the paper. Each reviewer often adds comments pointing out problems and/or giving advice for improving the paper. The author, then, makes changes as necessary and the editor makes the final decision on whether the paper is to be published or not, based on the results received from the peer reviewers.

1.2.2. Peer Review of Research Grant Applications

Public research grants and subsidies such as *kakenhi* are also handled by peer review in order to guarantee the quality of the research projects to be funded and to maintain the integrity and objectivity of the selection process.

For *kakenhi* grants, the procedure includes (1) selection of the review committee members; (2) first-stage review (document review); (3) second-stage review (panel review); and (4) selection decision. At each of these stages, scientists in the specific field make decisions based on peer review. The review committee members are selected from among scientists registered in JSPS's database of reviewer candidates. They must meet certain standards[3] such as being well-informed of advances in their fields and possessing integrity and competence as evaluators.

Review standards for selecting topics for funding are determined based on discussions in an expert committee comprising scientists. Hence, the principle of peer review undergirds this entire selection system.[4]

Many research grants by private foundations are issued following similar selection processes. Therefore, scientists fundamentally play a central role in reviewing topics to be funded for scientific research.

1.3. Role and Responsibilities of the Reviewer

Peer reviewers have extremely important responsibilities. The Council of Science Editors, representing more than 800 scientific journals, lists the following points as guidelines for peer review.[5]

- **Confidentiality:** Contents of a paper to be peer-reviewed shall not be disclosed to a third party. The reviewer shall not keep the submitted paper after the peer review is completed, nor use the information obtained in the peer-review process for purposes other than peer review.
- **Constructive critique:** The reviewer shall laud the good points of a paper subject to peer review while pointing out problems from a constructive standpoint and suggest

ways to improve the paper. The peer reviewer is expected to make constructive comments.

- **Competence:** The reviewer shall accept a peer review assignment only if s/he has sufficient expertise in the field to appropriately evaluate the paper. S/he needs to avoid inappropriately influencing a publication decision due to not being qualified to evaluate a paper, because, for example, his/her field of expertise is different.

- **Impartiality and integrity:** The reviewer shall exclude any bias or preconceived notions and review the paper from an objective and impartial standpoint. The reviewer shall evaluate the paper solely on such grounds as its scientific significance, originality, organization, and the fields covered by the academic journal.

- **Disclosure of conflict of interest:** If any conflict of interest exists that could impact the objectivity of the review, the reviewer shall disclose that fact to the editor when the review is requested and, if necessary, decline to review the paper.

- **Timeliness and responsiveness:** The reviewer shall promptly respond to the peer-review request and submit the peer-review report by the deadline. If the reviewer cannot adhere to the deadline, s/he shall decline to review the paper or contact the editor in advance.

It is critical for a peer review to maintain impartiality and objectivity. For instance, bias exists when a supervisor reviews a paper or application of someone whom s/he has taught. Bias may also exist if a reviewer receives a paper submitted by a scientist with whom s/he is in competition or whose paper topic is closely related to the reviewer’s research, or if the publication of a paper could impact the reviewer’s own research activities. Whenever such a conflict of interest exists, the reviewer needs to deal carefully with the situation, including declining to review the paper.

Some academic journals use a system of anonymity to avoid bias. In the single-blind system, the names of the peer reviewers are kept anonymous while the reviewer is able to identify who the authors are; in the double-blind system, both the peer reviewers and the authors are kept anonymous. Both of these systems are used by academic journals. Meanwhile, to prevent their peer reviewers from being involved in misconduct while hidden under anonymity, BMJ (British Medical Journal) adopts an “open peer review” system, in which neither peer reviewers nor authors are anonymous.[6]

It is generally difficult to discover research misconduct when raw data are missing; however, it is important to check submitted papers for erroneous data usage, insufficient hypotheses or conjecture, conclusions based on invalid logic, and a lack of respect for other people’s work. Finding and commenting on such things is also important for improving the quality of papers. If there is any concern about possible misconduct, such as submitting a paper that has already been published in another academic journal (duplicate submission, duplicate publication) or submitting a paper containing someone else’s work without citing the source (plagiarism), it is important for the reviewer to verify the facts and endeavor to resolve the problem by working together with the editor.

1.4. Challenges in Peer Review

While peer review is a system to guarantee and improve the quality of scientific research, some problems with it have been raised. For instance, it has been pointed out that fresh, innovative research not falling within the current research framework has a hard time getting a good evaluation under the peer review system.

Furthermore, while peer reviewers are asked to maintain impartiality and objectivity, it's opined that, in reality, bias cannot be completely removed when one reviews a paper or research plan. Even the blind systems, designed to eliminate bias, do not work very well as the author of a paper can easily be guessed even when his/her name is kept anonymous, especially if the subject research community is small. Some feel that the anonymity systems have yet other disadvantages, and question their effectiveness.

In 2002, all the papers by Hendrik Schön published in *Nature* and *Science* were discovered to contain fabrications. He was conducting innovative work on superconductivity at Bell Laboratories in the United States, an institution that had produced many Nobel laureates. During the peer-review process, some reviewers raised questions about and opposed publication of his papers; nevertheless, they were ultimately published.[7]

These events hint at limitations in the peer review process. Currently, various attempts are being made to see whether some other review system would be better in guaranteeing and improving the quality of scientific research.[8] It can be concluded, however, that at present it isn't possible to conduct scientific research without peer review. Given its critical role, scientists must not be remiss in elevating the quality and ethical standards of the peer review process.

2. Guiding Younger Generations

2.1. Teaching Responsibilities as Mentors

Scientific research presupposes a succession of knowledge strenuously accumulated throughout history. To continue propelling that progress into the future, fostering younger generations of scientists is indispensable. Doing so is a critical responsibility of today's scientists. To that end, the relationship that students and young researchers (mentees) have with those who teach them (mentors) is a crucial aspect of universities.

For the scientific community to earn the trust of society and exercise its prerogatives, members of that community need to share common values (e.g., ethical standards and a code of conduct) and make ethical decisions while displaying behavior consistent with those values. Hence, it is not sufficient for mentors, who are supervisors and advisors, to simply hand down knowledge and skills in their fields of expertise. Mentors must continuously challenge their mentees with questions concerning the fundamental roles of scientists and their social responsibilities, such as "What is a scientist?" "What is the purpose of scientific research?" "How can scientific research contribute to the welfare of humankind?" Mentors also need to make an effort to share common values through dialogue with their mentees (e.g. graduate students), who will be the scientists of the future, and to teach them what it means to be a scientist. Their goal should not be simply "science" education but rather "scientist" education.

Since the 1990s, the method of disbursing research funds in Japan has largely shifted to systems of "competitive funding." To obtain research grants through these systems, scientists must spend a lot of time and energy amassing a record of accomplishments so as to write more persuasive grant applications. Moreover, due to a national policy that places emphasis on graduate education, the number of graduate students that need to be trained has increased rapidly. Under these circumstances, it is an unfortunate fact that the amount of time scientists have to spend on guiding and teaching graduate students how to "become a scientist" has declined.

Experienced scientists, particularly those affiliated with educational or research institutions, must possess a strong recognition that their role is not just to achieve good research results but is also (perhaps even more so) to fulfill their crucial role in teaching and supporting younger generations. While their "research methods" may vary by research site, the most important of a mentor's various roles is helping their mentees understand and comply with the code of conduct in their occupations.

In small laboratories, while mentors can provide individual instruction in a casual and free environment, they should maintain a tight grasp on their role as a mentor. In a large laboratory, not only should mentors train their mentees but their organization should also be systematically engaged in promoting its members' ethical behavior. In other words, the organization will need to continuously implement a research ethics program.

A research ethics program constitutes a "comprehensive effort" by a research institution to "share values" that reflect the purpose of its founding and organizational structure along with a "systematic line of activities" to set values and priorities for research carried out in it, and to establish principles and ethics guidelines in the form of rules and regulations, while delegating authority to assist its members in making appropriate decisions."[9] Concerning the components of such a program, the Science Council of Japan listed the following in its 2006 document "Code of Conduct for Scientists."[10]

(1) A code of ethics and code of conduct should be formulated and circulated

(2) Establish and implement an ethics program, get top-level commitment and leadership, set up a permanent dedicated division and system

(3) Need for education on research ethics

(4) Important points for research groups (e.g., create a relationship that maintains freedom, impartiality, transparency, and openness, and that promotes opinion exchanges on research ethics)

(5) Ensure that everyone observes the "Code of Conduct for Scientists"

(6) Establish and implement a system of consultation regarding suspected misconduct along with review procedures

(7) Establish rules governing compliance and conflicts of interest

(8) Establish a self-monitoring system

Not simply delegating the training of younger generations in the concepts and practices of this Code of Conduct to individual mentors, each research or educational institution must establish and operate a "research ethics program." Among its functions should be the transfer of values to be shared by researchers and the building and maintenance of a scientific community comprising a body of professionals that earn society's trust.

2.2. Guiding Doctoral Students and Reviewing Their Dissertations Responsibly

It can be said that doctoral students are at the most critical stage of their career as they enter the world of scientific research. Even for their future, original research, the antecedents often come from the ideas and research guidance they gained in their doctoral program. Therefore, it is necessary for advising supervisors to establish good communication with their doctoral students and to guide them effectively in ways that will help them mature as principled scientists.

Each doctoral student writes a doctoral dissertation as an overall summary of his/her research results. A doctoral dissertation is a type of research paper, but having it approved and receiving a doctoral degree is proof that the student has completed a program that produces competent scientists. This makes the doctoral degree something like the student's passport to his/her future life as a researcher. Since doctoral degrees are recognized all over the world, it is necessary to be very careful to "guarantee their quality." If not sufficiently guaranteed, trust could be undermined not only in the individual scientist but also in scientific research overall. Hence, it is important for the advising supervisor to be involved in the detailed instruction of the student from the stage when s/he is deciding on a dissertation topic, through the process of research, all the way to the completion of the dissertation. Furthermore, the faculty in charge of carrying out the dissertation review process must be fully cognizant of their responsibility to guarantee the graduate's quality as a principled scientist. How to "guarantee that quality" may differ from field to field, but transparency and impartiality are common elements in all.

3. Ways to Prevent Research Misconduct

To prevent misconduct and promote responsible research, it is not enough to just have a good mental attitude; one must also understand the systems that the government, academic societies and universities have established to maintain research ethics, and act accordingly.

3.1. Roles of Policies, Guidelines, etc.

Japan does not have a law that directly defines research ethics, as does federal law in the United States. Instead, guidelines and similar documents issued by ministries and agencies play a major role in setting the stage for research ethics. On February 28, 2006, the Council for Science and Technology Policy published the document "Appropriate Measures against Research Misconduct," requesting various organizations within the scientific community (including the Science Council of Japan), and related ministries and agencies, universities, and research institutions to establish their own ethical policies and rules regarding research misconduct. In response, MEXT, the Ministry of the Environment, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Internal Affairs and Communications, the Ministry of Health, Labour and Welfare, the Ministry of Land, Infrastructure and Transport and Tourism, and METI established definitions of misconduct and policies to deal with infractions in the administration of their respective research-funding programs.[11] These policies do not only deal with research misconduct; many guidelines have now been put in place for authorizing the initiation of research, taking into account basic human rights and life ethics. Moreover, since joint research with a company could obstruct fair competition through a market monopoly exploiting technology developed through the research, Japan Fair Trade Commission has established "Guidelines Concerning Joint Research and Development under the Antimonopoly Act" (January 1, 2010).

These guidelines take the form of notifications and, as such, have no binding power to impose criminal penalties when violated. However, they do define grounds for suspending grants for research affiliated with the ministries and agencies as well as for requesting the return of research funds. They also establish a basis for taking disciplinary actions by research institutions. Therefore, attention must be paid to these guidelines from a standpoint of maintaining research ethics.

Research institutions have also prepared their own codes of conduct and regulations for adhering to their guidelines. Most of the guidelines pertain only to research supported with research funds disbursed from ministries or agencies, but the basic principles of responsible research are the same regardless of the nature of the research funding. Scientists must, therefore, have a good understanding of the guidelines that the members of their research institution must respect and comply with.

3.2. Roles of Academic and Professional Associations

One stage for presenting research activities is academic conferences, and most scientists belong to academic associations while engaged in research. Some academic associations, both domestic and international, have established ethics guidelines and rules for paper submissions. As groups of experts, they work to maintain research ethics. According to a survey conducted in 2005 by the Science Council of Japan, only 12.1% of the responding academic associations had already prepared or were in the process of preparing ethics guidelines.[10] In another survey[12] conducted in 2013, approximately 43% of the responding academic associations said they were discussing whether or not to establish a code of conduct on research misconduct related to fabrication, falsification, and plagiarism, while about 33% were discussing whether to prohibit duplicate submission in their code of conduct. While not yet sufficient, various associations are beginning to work toward a shared undertaking of each having a code of conduct in the form of a written and explicit document.

The United States has many such statements, such as the “ASA (American Sociological Association) Code of Ethics” of the American Sociological Association (established in 1970 and revised in 2008), which details many guidelines, consisting of a total of 20 chapters and 30 pages, including basic principles.[13] There are also separate ethics rules for teaching sociology. One of the world’s largest academic associations, the American College of Physicians, with 137,000 members including 1,000 from Japan, has the “ACP: Ethics Manual” (6^{th} edition, 2012), a solid document of 32 pages, including detailed references. The National Society of Professional Engineers of the United States, which has 35,000 members, has set up an ethics review committee, which reviews and discloses incidents of ethics-related problems and promulgates principles of research ethics.[14]

3.3. Roles of Research Institutions

Institutions such as universities and laboratories are organizations whose responsibility is to conduct research, so they are also responsible for having rules and regulations to ensure that their affiliated scientists comply with research ethics and refrain from improper practices. They also establish whistleblower and review procedures and inform scientists of these procedures. In a 2013 study conducted by MEXT entitled “Current Status of Efforts by Research Institutions Such as Universities concerning Misconduct in Research,”[15] it was found that efforts were being made in 84% of all organizations surveyed to establish regulations and keep their members informed of them. However, a study done by another research group in the same year showed that, while 64% of universities had rules prohibiting fabrication, falsification, and plagiarism, only 29% of them explicitly prohibited duplicate submission.[12] All scientists are urged to learn and understand not only the code of conduct of their affiliated institution but also those of the academic associations to which they belong.

The “Guidelines for Responding to Misconduct in Research” issued by MEXT and revised in August 2014, stipulate that clarifying their management responsibilities is one of an institution’s operational pillars, and recommend that they do the following.

- Establish rules and regulations,
- Appoint a person in charge of research ethics education in each department and division,
- Set up a contact desk for whistleblowers and give members the contact information, and
- Ensure the promptness, transparency, and confidentiality of the review process.

The promulgation of research ethics is increasingly becoming an important role of research institutions.

4. Importance of Ethics Education in Research

4.1. Professional and Occupational Ethics

To maintain and improve the quality of scientific research, above all it is essential to prevent research misconduct and to promote responsible research practices. What plays an important role in accomplishing this is creating a research environment that promotes responsible research and that gives individual researchers the knowledge and skills needed to conduct such research.

Many have pointed out that research misconduct may be indirectly caused by today’s excessively competitive research environment. Two important points in establishing a research environment are whether the organization takes an initiative in bringing about responsible research and whether there is a robust system in place for managing and storing research data. In preventing misconduct and promoting responsible research, efforts made by research institutions play a crucial role.

This, however, is not to say that scientists should solely depend on their organizations such as universities and research institutions. The most influential environment surrounding a scientist is the research site and organization where s/he works daily, such as a laboratory or research center. What is important in these research sites, so closely as they are connected to the researcher, is an environment conducive to the scientists freely discussing research, while sifting through raw data, with colleagues in and outside their laboratory. When researchers can actively and candidly exchange ideas on their interpretation of research data, the validity of the research methods, the effectiveness of the research design (etc.), and when they are given opportunities to scientifically validate their own research results from a variety of angles, more dependable and trustworthy research results will follow. The ability to casually and informally engage other researchers in discussions regarding ideas, even simple questions raised during research, can contribute to the creation of an environment that promotes responsible research. It is the responsibility of each and every scientist to make contributions that accrue to creating such an environment.

4.2. Ethics Education in Research on the Rise

For each individual scientist, it is fundamental to acquire the knowledge and skills needed to conduct responsible research. Conventionally, it was thought that such knowledge and skills are acquired through instruction while a student at a research laboratory. In today's society, however, the atmosphere embedding responsible research is drastically changing.

It is now a general trend for researchers to change their affiliations, moving from one research lab to another, as they progress from being a student to a member of a university faculty. Many now go overseas as graduate students or postdoctoral researchers. An environment in which a student, who stays in one research laboratory, can obtain knowledge and skills through an apprenticeship is quickly disappearing. In addition, it has become more common to do interdisciplinary research with scientists from other fields, such as using a research method employed in another field. Compared to the past, there is more need to consider using research methods that transcend one's field and nationality. Concepts of authorship and of processing research data are also changing with the passage of time. Some practices that were not problematic in the past could now be considered so. Today, the eye of the public is much more stringent when it comes to research misconduct, requiring scientists to make a more serious effort than before in promoting responsible research from a viewpoint of science within society.

It is for these reasons that the importance of ethics education in research is attracting so much attention. An ethics course is not something that one should take once to just "get it over with." While scientists should try to acquire knowledge and skills needed for doing responsible research, they also need to routinely update that knowledge.

5. Prevention of Research Misconduct and Whistleblowing

5.1. Importance of Reporting Misconduct

When there is misconduct suspicion or behavior, only scientists can recognize it, so as scientists they need to deal with and correct the situation. As a place of contact for such scientists, research institutions need to establish a contact desk where research misconduct can be reported. Organizations that provide research funds, such as MEXT and JSPS, also have contact desks. When at a research site one encounters a situation where misconduct is suspected, ideally one should first bring it to the attention of a member of that research team or discuss it with other researchers. However, there are cases where such an action may be difficult to take, and may not work to resolve the issue. In such a case, one should not just leave the problem unresolved but should at least consult with the person at the contact desk.

Consultation and reporting with regard to an incident does not necessarily equate to research misconduct. The Office of Research Integrity (ORI) of the United States conducted a 5-year study from 1993, reviewing 150 cases. It found that 76 of those cases revealed misconduct while the remaining 74 cases did not. Whether or not misconduct has taken place is not a simple matter to determine. Out of 1,000 cases reported to the ORI, 4 out of 5 cases lacked sufficient information to call for a review, so not even preliminary reviews were carried out.[16] Misconduct needs to be reported along with scientific evidence. Scientists should not file irresponsible reports.

5.2. Protection of Whistleblowers

The most important point in reporting misconduct is the need to protect the reporter.

There have been cases where a report or an accusation was made, but the anonymity of the person who filed it was compromised, resulting in retaliation being taken against the person. In the 6th executive director-sponsored forum at the Annual Meeting of The Molecular Biology Society of Japan, entitled "What Shall We Do to Maintain Research Integrity?" (December 2013), examples from Japan and the U.S. were presented where whistleblowers became a victim and nothing was done to address the problem. In one case, a physician reported a colleague who had conducted a clinical study without the subject's consent. When the subject later died, the colleague falsified the patient's records. The physician was able to prove the misconduct but later was reported to have become a victim of obstruction in his business practice.[17]

Whistleblowers are important, and so is their protection. The principle that needs to be applied here is exactly what's stated in the Whistleblower Protection Act: Whistleblowers are to be protected when they report criminal behavior involving the safeguarding of a citizen's life, body, property, or other attributes. If misconduct is properly reported using scientific evidence but the person who reported it is not well-protected, allowing the misconduct to end up concealed or retaliation taken against the person who reported it, such an incident can arguably be called the worst kind of betrayal against science.

According to the "Guidelines for Responding to Misconduct in Research" issued by MEXT,

(1) Proper methods should be discussed to protect the content of the report and the identity of the person who filed it when misconduct is reported

(2) The duty of confidentiality among the staff should be strictly enforced

(3) The person who filed the report should not be subject to any disadvantageous treatment such as termination and demotion (unless the report is based on malice). Procedures at each university should be along the same line as MEXT's statements, having almost exactly the same content.

Researchers create knowledge and participate in research activities that make contributions to the society and the human race. They must also know the procedures for reporting misconduct. This is rather unfortunate, but it is only scientists who have the training and expertise to be able to examine research being conducted, check its validity, and preserve it. Intentionally distorted research not only contorts knowledge but also exerts negative impacts on society. Not only the creation of knowledge but also its preservation is the responsibility of scientists and the scientific community.

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Column

Ethics Education in Research: Efforts Made in the United States

In the United States, the “America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act of 2007” (“America COMPETES Act” for short) has made it mandatory for research institutions receiving funds or subsidies from foundations related to S&T education to require, in their application planning stage, all undergraduate and graduate students and postdoctoral fellows to take a training course on responsible research activities and ethics. In response, in January 2010, the National Science Foundation (NSF) requested that universities prepare a training course on responsible research activities when applying for research grants. The goal of the “America COMPETES Act” is to propel funding sources to promote innovation and train human resources toward higher industrial competitiveness. It also requires an organized effort toward ensuring responsible research activities. In addition, NSF, supported by the National Postdoctoral Association (NPA), has since 2007 been aiding postdoctoral fellows in their efforts to carry out responsible research activities at their respective universities. Then, NPA launched its “Project for Scholarly Integrity” in 2008. NSF is furthermore involved in supporting the development of an online center integrating ethics-related information in STEM (science, technology, engineering, and mathematics) fields and in supporting research and initiatives aimed at improving ethics education in all research fields. Hence, ethics education in research is being promoted nationwide in the United States.

Section VIII: For the Progress of Society

1. Role of Scientists

For human society faced as it is with a wide range of imminent problems in such areas as the environment, resources and population, science is an indispensable activity in helping to solve such challenges. It is also a two-edged sword as its abuse and misuse can cause difficult problems. Just before the dawn of the new millennium, in 1999 UNESCO and the International Council for Science jointly held a conference in Budapest to discuss what science should be in the 21st century. They adopted the "Declaration on Science and the Use of Scientific Knowledge," which lists the following four "meanings for science."[1]

(1) Science for knowledge, knowledge for progress

(2) Science for peace

(3) Science for development

(4) Science in society and science for society

This declaration, while reconfirming the importance of "science for knowledge, knowledge for progress," clearly states that scientific research, its results and dialogues based on objectivity and impartiality, should contribute to "peace" and "development." Furthermore, the part that science is to play in society is summarized as "science in society and science for society," identifying the roles and responsibilities of science as follows: "The practice of scientific research and the use of knowledge from that research should always aim at the welfare of humankind, including the reduction of poverty, be respectful of the dignity and rights of human beings, and of the global environment, and take fully into account our responsibility towards present and future generations." This declaration makes it clear that the role of science in the 21st century is not only played out in "experiment chambers," "laboratories," or a close-knit scientific community, but that the scientific community should widely execute roles and responsibilities within society. Strongly recognizing the importance of science's external responsibilities, the Science Council of Japan states the following in the preamble to its Code of Conduct for Scientists[2] concerning the relationship between science and society.

Science is a system of knowledge based on principles of reason and empirical proof that are assiduously built up over time, and constitutes an irreplaceable common asset of all humanity. Scientific research is an act that creates new knowledge by boldly pursuing the challenges of unknown fields. Science and scientific research exist both with and for society. Therefore, research activities based on scientific freedom and the subjective judgments of scientists only gain social recognition once they are premised upon public trust and the mandate of the people. (Some sentences omitted). . .

While scientists engaged in such intellectual activities enjoy the prerogative to pursue truth under academic freedom based on their own expert judgments, independent of the interests of specific authorities or organizations, as experts they also bear a grave responsibility to respond to the mandate given them by society at large. Especially in the modern world, where scientific activities and their results exert a vast and profound influence on all humanity, society demands that scientists always make ethical judgments and engage in ethical actions. There are also societal demands for science to play a role in the process of forming policy and public opinion.

More specifically, the societal roles of scientists are two-fold: First, creating knowledge through scientific research and passing it forward to future generations and, second, providing scientific advice to society. The results of scientific research are returned to society in the form of new knowledge related to materials, life, and other things and in the form of technology and information that helps society solve problems and address challenges. A majority of such scientific research receives public funding, while giving scientists the privilege of conducting their research autonomously. Scientists, therefore, have a weighty social responsibility. It can be said that scientists have entered into an agreement, a silent contract, with society that obligates them to conduct research with integrity and honesty.[3] Scientists are also responsible for teaching and instructing others in a process of handing down scientific knowledge to future generations. In recent years, scientists also play an important role in offering neutral, scientific advice in processes related to forming consensus and establishing policies for addressing major issues confronting society.

Regarding such challenges as energy, environment, food, medicine, education, pollution, drug abuse, and nuclear power safety, it is impossible for the public or the legislative and executive branches of government to make accurate decisions without scientific knowledge. In addition, the views of leading scientists are essential in choosing topics for science and technology research to be promoted through government investment. Their role is also critical in establishing methods to advance such research projects. Accordingly, scientific advice is regarded as playing an increasingly important role in forming social consensus and informing policymaking both in periods of peace time and during emergencies. On the other hand, it is not so easy to ensure that scientific advice is neutral, fair, and independent of specific ideas, beliefs, and values. In Japan there are organizations that formulate and propose scientific recommendations to the government and society, including the Science Council of Japan, many academic associations, and public think tanks. Some countries have a system whereby the government appoints scientific advisors who make recommendations directly to policymakers.[4]

Such changes in awareness over the external responsibilities and societal roles of science need to be accepted seriously by individual scientists. To enable scientists to make decisions and conduct themselves based on this awareness, various things need to be done in terms of education, systemization, and practical preparedness, all reflecting the “Code of Conduct for Scientists.” In the future, scientists themselves must take the initiative in carrying out concrete action.

2. Dialogue between Scientists and Society

Disseminating information to society by scientists and advancing dialogue (communication) between scientists and the public are essential to realizing the principle of “science in society, science for society.” In the Code of Conduct for Scientists,[2] revised by the Science Council of Japan after the Great East Japan Earthquake, a new chapter “III. Science in Society” has been added. It states the following.

(Dialogue with Society)

Scientists shall participate actively in dialogue and exchange with citizens to create better mutual understanding between society and the scientific community. Furthermore, in order to resolve various issues and enhance welfare in society, they shall also work to provide scientific advice effective for policy making to persons involved in the planning and formulation of policies. On such occasions, scientists shall aim to give advice based on consensus among scientists, and, when differences of opinion exist, shall offer explanations that are easy to understand.

In other words, scientists need to communicate, not just within the scientific community, but also with the people in society at large. In the past, these roles and responsibilities of scientists were not that emphasized, so insufficient consideration was given in nurturing scientists in these matters. In the present age, however, where science exerts significant impact on society in a variety of ways, scientists are required to make the necessary adjustments. Meanwhile, as scientific technology becomes larger in scale and complexity, it is less easy to give explanations that are readily understood on the uncertainties embodied in scientific knowledge or the benefits and risks inherent in science and technology.

In fact, communication should not be understood as unilateral explanations and lectures given by scientists in the first place. Scientists should not have the mistaken idea that communication, including explanation and persuasion, is a one-way street, rather they need to adopt a stance of mutual learning between the scientific community and society. After all, scientists are themselves members of society.

The brilliant progress being made in science and technology does not come without risks to society. Any scientific technology humankind has obtained can have both light and dark sides as seen with nuclear power, genetically modified food, and regenerative medicine. Physicist Alvin M. Weinberg refers to this dilemma as "trans-science."[5] This is the intersection of two domains: the domain that produces knowledge that can be rationally explained by science and the political domain in which decisions are made based on values and authority. It is defined as a "domain consisting of a group of questions that can be asked by science but cannot be answered by science." Although science can mathematically calculate that the probability is low of an accident occurring at a nuclear power plant, it cannot alone answer the question of whether people will accept a power plant as such a decision is made from a wide spectrum of perspectives including those related to society, economy, daily living, history, and culture.

In the future, the role played by science in forming national and global consensus will continue to grow. Along with the progress and globalization of science and technology, policy issues are becoming more complex, requiring ever-higher levels of expertise. An attempt to establish policies related to global warming (for example) requires the participation of scientists from a wide range of fields including science and engineering (e.g., meteorology, ecosystems, energy usage, and greenhouse gasses) and the social sciences (e.g., societal systems and international cooperation).

How then should a scientist be involved in these problems of trans-science? Scientists of the future need to begin by widening their viewpoints and by continuously pondering the societal significance of their own research activities. Furthermore, they need to participate actively in communicating with citizens while being fully aware that science has limits. Scientists need to recognize that their role in society is to provide information while advancing dialogue toward helping to solve various problems that society is facing. Every organization employing scientists should actively support their involvement in such efforts.

3. Scientists and Professionalism

“The Code of Conduct for Scientists,”[2] established by the Science Council of Japan, defines “scientists” as researchers or professionals who engage in activities for producing new knowledge or for using scientific knowledge in all academic fields irrespective of their affiliations. Now, let’s consider the posture of scientists as “professionals.”

Scientific research, as an activity aimed at satisfying the intellectual curiosity of individuals and organizations, has rapidly been systemized since the 19th century, giving birth to “scientists” as an occupation that plays an important role in society. At least in Europe and the United States, there is a tendency to think of scientists as professionals. For example, the U.K. has a professional qualification called “chartered scientist (CSci)”[6] while a textbook[7] on research ethics in the United States stresses “professionalism in science.” In a study conducted by the Office of Research Integrity of the United States on the learning objectives of the educational program “Responsible Conduct in Research (RCR),” every person on its expert panel responded that it is important that values as professionals be shared.[8]

The unique concept of “profession” strongly influences this Western way of thinking. This word also has the religious connotation of people “professing” their beliefs. Specializations such as theology, medicine and law have been established as learned professions within universities and institutes of higher learning that guarantee their quality. These occupations support the life of people in society. The clergy supports matters of the hearts through faith, physicians matters of the body through medical knowledge, and attorneys matters of social standing through law. All these occupations provide services indispensable to people’s welfare. They differ from other occupations in the long period of specialized education and training they require. Indeed, until the systematization of science and technology and popularization of higher education in the 19th century, the only subjects that could be studied in European universities were theology, medicine, and law. It is also widely recognized in society that these three professions are the antecedents of specialized education in universities.

Meanwhile, people in other occupations have begun making effort to raise their own occupations to a “professional” level, emulating the example set by these three traditional professions. Examples of such successful efforts include accountants, architects, and pharmacists.

As occupations become increasingly diversified, it becomes more difficult to assign the status of “profession” to them; from a sociological perspective, however, the following six attributes of a “profession” can be pointed out.

(1) An occupation based on theoretical or systematic knowledge

(2) Expert abilities gained through a long period of training and education

(3) Proof of abilities by examination

(4) Existence of systematized organizations/associations

(5) Maintenance of moral consistency through ethical standards

(6) Altruistic service to society.

Hence, a “profession” requires “ethical standards” (or a code of conduct), so that moral consistency (integrity) is maintained. Medicine, perhaps the oldest profession, has had a code of conduct called the “Hippocratic Oath” since the days of ancient Greece (B.C.). Even now, the preamble to the Principles of Medical Ethics of the American Medical Association states the following, reflecting the concept of this profession and its relationship to the code of conduct: “The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self.”

Therefore, to attain a profession, one must receive extremely rigorous education and obtain an even higher level of ethical awareness. One idea that supports this system is the “social contract” model growing mainstream in the English-speaking world in particular. According to this model, professions require a high level of expert knowledge and education to obtain that knowledge. Through this, professionals are qualified to own (monopolize) their occupation and are given high compensation and privileges (especially autonomy) that cannot be obtained in other occupations. This relationship can be thought of as a type of contract between a group of professionals and society at large. For their code of conduct, professionals devise their own ethical codes specific to their respective professions while they share the “Code of Conduct for Scientists” established by the Science Council of Japan.

The relationship between science and professionalism can be easily understood when one takes into account the history in which universities and the scholarly tradition they begot have prepared the environment that gave birth to modern science. In a textbook previously mentioned, the following five elements are listed as constituting professionalism.[7]

(1) Intellectual honesty

(2) Excellence in thinking and doing

(3) Collegiality and openness

(4) Autonomy and responsibility

(5) Self-regulation

In Japan’s scientific domain, there is a rather low perception of Western-type professionalism, except for in a few fields. The Science Council of Japan, through its Code of Conduct for Scientists, and many academic associations are stressing the importance of professional values. For Japan’s scientific community to make more impactful contributions to societal welfare and for scientists to be better trusted as true “professionals,” it will be essential for them to personify professional values in their daily research activities.

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