

## Feature 2 Promotion of Fair Research Activities

Research activities are intended to advance the quest for truth based on previous research outcomes and facts and data obtained from observation and experiments, create new knowledge and establish a knowledge system. The quest for knowledge is not limited to research, but research outcomes can help develop products which will improve people's lives and convenience. Misconduct, including the manipulation and falsification of data and research outcomes and plagiarism of research results by other researchers ("research misconduct" or "misconduct") contravene the true nature of science, prevent and blaspheme scientific and social progress and are absolutely unforgivable.

However, incidents involving such misconduct have come under the spotlight in Japan recently and the trust of citizens on science has been reduced. Having a sense of crisis, the government strived to take corrective actions. Recent cases of research misconduct and actions of the science community and government to prevent recurrence of misconduct in future are covered in this feature.

### 1 Recent Cases of Research Misconduct

#### (1) Overview

A series of incidents involving research misconduct have recently been reported. To be specific, STAP<sup>1</sup> research paper issue at the Institute of Physical and Chemical Research ("RIKEN" in this feature), clinical research into an antihypertensive drug at Novartis Pharmaceuticals ("Novartis") and the incident at the Institute of Molecular and Cellular Biosciences, University of Tokyo. The STAP paper and the clinical research into drugs to treat hypertension are described in paragraphs (2) and (3). The incident at the University of Tokyo relates to alleged mistrust of research papers involving former professors and others at the Institute of Molecular and Cellular Biosciences, University of Tokyo in FY 2012. The University of Tokyo investigated the allegation and admitted that manipulation and falsification were found in 33 papers and 11 people were found to be involved at the final report in December 2014. In addition, at least 10 cases of research misconduct were revealed by the investigative committee for research institutions nationwide in FY 2014<sup>2</sup>.

Some pointed out that such research misconduct was due to the excessive burden imposed on researchers, such as the increased number of researchers working on fixed term research projects and required to produce outcomes within a certain period of time. However, most researchers are honestly engaged in a quest for truth without misconduct. Whatever the reason, research misconduct should never be forgiven and scientists must always remain honest to science. In other words, scientists should always maintain inner discipline and act responsibly as professionals.

<sup>1</sup> STAP cells: Stimulus-Triggered Acquisition of Pluripotency cells

<sup>2</sup> 10 cases were identified by MEXT as of March 31, 2015. (12 cases occurred in FY 2014, including the STAP paper and the incident at the Institute of Molecular and Cellular Biosciences, University of Tokyo. Mistrust involving clinical research into the antihypertensive drug occurred in FY 2012.)

## (2) STAP paper issue

### 1) Outline and progress

Two papers authored by researchers at RIKEN and Harvard Universities, etc. presented in Nature magazine on January 29, 2014 caused a sensation. The papers reported a phenomenon whereby mouse cells were initialized and acquired pluripotency<sup>1</sup> simply by immersing them in acid solution. The authors named this pluripotential cell “STAP cell.” This phenomenon of animal cells being initialized without genetic manipulation but solely through immersion in an acid solution drew keen attention as a result exceeding the boundaries of common biological sense. Moreover, the main author was a young female researcher, which further stimulated public interest.

However, the presence of doubtful images, figures and tables in these papers was pointed out and RIKEN started investigating on February 13. It established an investigative committee on February 18 and the committee, upon completion of its investigation, confirmed two places of research misconduct (manipulation and falsification). RIKEN announced its verdict on April 1 and recommended that the authors retract two papers according to internal rules. The STAP cell papers were ultimately retracted from Nature at the request of the authors on July 2.

After the committee had completed its investigation, other incidents of scientific mistrust were pointed out and RIKEN resumed its preliminary investigation on June 30 and based on the result, established a new investigative committee comprising only external experts on September 3. The investigative committee approved two cases of misconduct (falsification) following investigation of the alleged mistrust and announced its conclusion that all samples based on which the STAP papers had been written were deemed to have originated from ES cells<sup>2</sup> or a mix of ES cells based on scientific evidence on December 26. RIKEN took disciplinary action against the persons involved.

While the committee was conducting its investigation, RIKEN started a verification test for a limited period on April 1, using highly accurate scientific methodology to clarify the scientific facts about the STAP phenomenon and fulfill its accountability to society. The author of the papers joined the verification test and the committee announced that the STAP phenomenon could not be confirmed in the verification test on December 19.

### 2) Actions taken by RIKEN to prevent recurrence of research misconduct

After research misconduct had been confirmed, RIKEN started seeking practical countermeasures by establishing internal reform office, headed by the chairman of the board and the Reform Committee for the Prevention of Research Misconduct (“Reform Committee”) comprising external experts on April 4, 2014 to prevent any recurrence of research misconduct and reestablish high standards.

On June 12, the Reform Committee suggested insufficient perception of the need to prevent research misconduct in the governance of RIKEN and the absence of a practical system to record and manage experimental data, and made eight recommendations to prevent recurrence, including establishing a head organization directly overseen by the RIKEN president to promote fair research and prevent research misconduct and a practical system to prevent research misconduct.

<sup>1</sup> Ability to differentiate various cells

<sup>2</sup> Embryonic stem cell: Artificial stem cell taken out from the embryo and cultured to pluripotent cells

Taking these recommendations seriously, RIKEN sought for advice from experts in various fields and decided on “Action Plans to prevent a recurrence of research fraud” (“Action Plans”) on August 27 to improve governance by setting a management strategy conference, reviewing the public relations system and drastically renewing the Center for Developmental Biology as well as reinforcing research misconduct prevention by comprehensive research ethics education and suitable management of experimental data. RIKEN implemented these measures in sequence (Table 2 consolidates the progress of Action Plans in relevant areas). RIKEN also established the “Management and Reform Monitoring Committee” (“Monitoring Committee”) comprising external experts to evaluate achievements and offer recommendations for review. The Monitoring Committee completed the confirmation and evaluation of the measures taken by RIKEN according to the Action Plans after nine meetings and two on-site inspections, agreed on the approach to reform, created an evaluation to recommend the steady execution of Action Plans and submitted the same to RIKEN on March 20, 2015 (Table 3)

Dr. Noyori, (then) RIKEN president received the evaluation and disclosed his decision to promote efforts based on the Action Plans, saying “I shall continue to do my utmost to regain public trust while seeking the cooperation of scientific society and related sectors, while learning a valuable lesson from this dishonorable incident.”

RIKEN has been tackling organizational reform for about a year after the STAP paper issue. As shown in the evaluation in Table 3, the Monitoring Committee wants RIKEN to accomplish the “RIKEN reform for society.” RIKEN must create a climate whereby all researchers are encouraged to raise their and colleagues’ awareness of research ethics and establish high standards of conduct as a model for other organizations, by effectively continuing efforts based on the Action Plans and helping society develop as the highest-ranking research institution in Japan, both in reality and in name.

**Table 1 / STAP Paper Issue and Responses**

<u>1. Investigation of papers for mistrust</u>			
2014	February	13	A preliminary investigation commenced upon receiving the external accusation on papers according to internal rules.
	February	18	An investigative committee was established to conduct a full investigation.
	March	14	The committee announced its interim report.
	April	1	The committee confirmed misconduct (manipulation, falsification) in two places in one of two STAP cell papers and RIKEN announced it.
	June	30	A preliminary investigation commenced into scientific mistrust pointed out by external sources on completion of the former investigation.
	July	2	Two papers were retracted.
	September	3	Based on the preliminary investigation, an investigative committee of external experts was established for full investigation.
	December	26	The committee confirmed misconduct (falsification) in two places in one of the STAP cell papers and RIKEN announced its conclusion of all samples potentially originated by ES cells or a mix of ES cells following analysis of the remaining "STAP cell" samples.
<u>2. Investigation of STAP phenomenon</u>			
2014	April	1	RIKEN announced a verification test plan.
	July	1	The author of the papers joined the test plan (till November 30).
	August	27	RIKEN announced an interim report (no trace of STAP cell like clusters)
	December	19	RIKEN announced the verification test result (STAP phenomenon not confirmed) and completion of the verification test.
<u>3. Measures for preventing recurrence</u>			
2014	April	4	RIKEN founded the Reform Promotion Headquarters for preventing recurrence of research fraudulent and a reform committee for preventing recurrence of research fraudulent by external experts.
	June	12	The reform committee announced its recommendations.
	August	27	RIKEN announced Action Plans and started implementing various plans
2015	March	20	The Management and Reform Monitoring Committee by external experts announced the Evaluation of the Action Plans.

Source: Created by MEXT.

■ Table 2 / Progress of RIKEN Action Plans in FY 2014

<p><b>1. Reinforcing governance</b>  → <b>Completion of system implementation and operation under reinforced governance</b></p> <p>(1) Establishment of a new management strategy conference  <b>Establishment of a Management Strategy Conference on September 5, 2014</b></p> <p>(2) Reinforcement of research compliance  <b>Establishment of the Research Compliance Headquarters on October 24, 2014</b></p> <p>(3) Addition of a new post for research policy councilor  <b>Addition of the Research Policy Councilor on October 24, 2014</b></p> <p>(4) Establishment of a system supporting the chairman and a structure for activating scientific discussion  <b>Assignment of a chairman's assistant on September 30, 2014</b></p> <p>(5) Reinforcement of auditing function and establishment of an audit office  <b>Establishment of the auditor and audit office on October 24, 2014</b></p> <p>(6) Establishment of a PR system suitable for press conference  <b>Establishment of rules for press conference on research results on October 23, 2014</b></p>
<p><b>2. Restructuring as the Center for Developmental Biology</b>  → <b>Restarting as a new center through operational managerial reform</b></p> <p>(1) Reform of research organization  <b>Restructured to the Center for Developmental Biology on November 21, 2014</b></p> <p>(2) Selection of new center manager  <b>Assignment of a new center manager on April 1, 2015</b></p> <p>(3) Reform of operation system  <b>System consolidation such as steering committee on September 30, 2014</b></p> <p>(4) Reinforcement of cooperation with external research institutions  <b>Cooperation with the Center for iPS Cell Research and Application, Kyoto University</b></p>
<p><b>3. Reinforcing measures to prevent research misconduct</b>  <b>Revision of rules to prevent research misconduct on October 30, 2014</b>  → <b>Commencement of new rules, further activation of research activities</b></p> <p>(1) Completely procedure-based research ethics education  <b>Introduction of research ethics education programs</b></p> <p>(2) Establishment of a dependable system to maximize the capability of young researchers  <b>Mentor Guideline on December 11, 2014</b>  <b>Guidelines for employment of researchers heading the research office on December 25, 2014</b></p> <p>(3) Establishment of a structure to ensure reliability of papers  <b>Establishment of rules for presenting research outcomes on October 23, 2014</b></p> <p>(4) Establishment and operation of a practical system to record and manage experimental data  <b>Introduction of a similarity search tool and establishment of research record management rules on October 23, 2014</b></p>

Note: The text in black is contained in the Action Plans and the text in red indicates the result.  
Source: Created by MEXT.

■ Table 3 / Points in the Evaluation by the Monitoring Committee (March 20, 2015)

- The system and rules specified in the Action Plans were established and efforts to operate the system appropriately started. This confirms the way to reform. Serious efforts of RIKEN for reform were ensured.
- Incomplete development of the integrated research environment and ineffective ethics education, etc. are behind the incident. The Action Plans should be steadily implemented.
- Create a climate for all researchers to raise their awareness on research ethics with respect to one another and prevent research misconduct. To do so, a highly effective implementation system is required. The committee proposed new approaches to improve the effectiveness of the Action Plans.
- RIKEN should strive hard to continue the Action Plans and reestablish high standards of conduct for achieving “RIKEN reform for society.” Accordingly, it is expected to be the “emergent RIKEN” to lead the world science community.

Source: Created by MEXT.

(3) Clinical research into the antihypertensive drug

1) Outline and progress of the incident

The antihypertensive drug Diovan (general name: Valsartan) of Novartis Pharma K.K. was approved in

Japan in September 2000 and large-scale clinical research was started at 5 universities to compare its effect with that of conventional depressor drugs from 2002. Consequently, Diovan was deemed to prevent diseases such as strokes and mimics angina compared with conventional depressor drugs and the result was posted and announced in famous international medical journals.

However, sparked by a question from medical doctors not involved in the clinical research in 2012, one after the other, related papers were retracted from prestigious medical journals from December 2012 onward and it was revealed that research data manipulated by researchers had resulted in a conclusion different from the truth. Misconduct in clinical research emerged at several universities. It was also revealed that former Novartis employees had been involved in the statistical analysis of the clinical research, preventing transparency and representing a Conflicts of Interest<sup>1</sup> among researchers.

This incident was not limited to data processing by researchers. The papers had been excerpted by the Japanese Society of Hypertension (JSH) to the “Guidelines for Management of Hypertension” of Japanese Society of Hypertension before being retracted and Novartis had extensively advertised its product using these papers. In fact, the retracted papers were widely known to medical practitioners and when retracted, patients having taken Diovan were worried, spawning national concern and damaging the reliability of clinical research.

In January 2014, MHLW made accusations against Novartis and related parties to the Tokyo District Public Prosecutors Office and Novartis as a corporation and former employees were accused of violating the Pharmaceutical Affairs Act (through exaggerated advertisements).

## 2) Government policy for clinical research and prevention of recurrence

Once the fraudulent behavior emerged, MHLW tried to get the bottom of the facts in cooperation with MEXT and established an “Investigative Committee for the Clinical Studies of Antihypertensive Drug” in August 2013 to prevent recurrence. The committee announced its report in April 2014, pointing out the possible causes of problem including: “clinical research is far from clarifying a medical research theme,” “acknowledged that the incident involved not individuals but rather Novartis,” “there is a problem of managing conflicts of interest at both universities and Novartis, such as a failure to ensure transparency in funding by Novartis to universities,” “it is doubtful whether university researchers were engaged in research according to their conscience as scientists,” “the ethical review board of universities did not function as a means to stop fraud” and “the clinical research infrastructure at universities and researchers is vulnerable.” It also made recommendations to restore public trust in clinical research by “taking measures to review the ethical guidelines for clinical research as required” and “considering the constitution of a legal system for clinical research.”

The ethical guidelines for clinical research designated in the report had been discussed before the incident was uncovered, from February 2013, by a joint meeting of MEXT and MHLW together with the ethical guidelines for epidemiology research, but based on the issue of the above report in April 2014, the ministries integrated both guidelines to establish new “Ethical Guidelines for Medical and Health Research Involving Human Subjects” in December 2014. According to these guidelines, research institutions

<sup>1</sup> Conflict or clashing objectives between social responsibility of individual researchers and personal profit accompanying industry-academia collaboration (especially monetary relations) (COI: Conflict of Interest)

developed a system assuring the reliability of research (conflicts of interest in management, storage of research materials and information, monitoring and audit), reinforcement of the authority of ethical review board and transparency of review and prepared provisions for the head of the research institution and the research leader to handle.

MHLW established a “Commission on Clinical Research Regulatory Systems” in April 2014 to discuss the constitution of a legal system. The committee made recommendations concerning the requirements for a legal system in addition to those imposed on researchers to comply with ethical guidelines for a certain range of clinical research in future while acknowledging differences between Japan and Western nations in terms of items subject to legal regulation, as shown in Table 4 in the report issued in December 2014. The commission concluded that the valid scope of legal regulation includes “clinical research using non-approved or unapplied drugs or clinical instruments” and “clinical research potentially used to advertise drugs or clinical instruments” taking this incident into consideration.

**Table 4 / Legal system in Japan and Western nations (difference in the regulated area)**

			Japan <sup>*Note 1</sup>	U.S. <sup>*Note 2</sup>	Europe <sup>*Note 3</sup>
Clinical trial	Drug		○	○	○
	Medical instrument		○	○	○
Clinical research	Drug	Non-approved, unapplied	×	○	○
		Approved, applied	×	×	○
	Medical instrument	Non-approved, unapplied	×	○	○
		Approved, applied	×	×	○
	Operation, procedure		×	×	×

Note 1: Clinical research is subject to ethical guidelines in Japan.

Note 2: Another law is applied to publicly funded research in the U.S. This includes those used for advertisements.

Note 3: Legal restrictions on clinical research using medical instruments in Japan are not strict compared with those for drugs in Europe.

Note 4: “unapplied” means using a drug or medical instrument outside the scope of approval of that drug or medical instrument, or approved items (e.g. direction, dosage, or efficacy, effect or performance).

Source: “Report on Clinical Research Regulatory Systems” (December 2014), MHLW

Practical efforts have been made in the field of clinical research. For example, various recommendations, mainly concerning ways to manage conflicts of interest, were made in the industry and science community to prevent any recurrence of inadequate clinical research.

In the industry, Japan Pharmaceutical Manufacturers Association (JPMA) revised its “Transparency Guideline for the Relation between Corporate Activities and Medical Institutions” in March and December 2013 to expand the scope of information disclosure based on the guidelines and the member companies decided the in-house “transparency guidelines” as the standards of conduct in reference to the guidelines.

Science Council of Japan (SCJ) made recommendation on the “Significance and transparency of COI management in clinical research” in December 2013 to clarify the responsibility and role of researchers involved in industry-academia collaborative clinical research. It also made recommendation on the

“Problems and countermeasures for investigator-initiated clinical trial in Japan” in March 2014 to indicate practical activities which may be required in future such as preparing guidelines for researcher-led voluntary clinical tests after the drug goes on sale.

The National University Hospital Director Conference established an “Emergency measures for ensuring reliability and managing conflicts of interest (COI)” in September 2013 to clarify the basic concept and policy of ensuring reliability as the responsibility of researchers and conflict of interest (COI) management as well as presenting a system for individual universities to establish and notified this plan to all university hospitals nationwide. It also decided on “Guidelines for disclosing funding by companies” in June 2014 (partly revised in September 2014) to ensure proper promotion and transparency of industry-academia-government collaboration. All national university hospitals publicized funding by companies according to the guidelines by November 2014.

The Association of Japan Medical Colleges determined the “Guidelines for COI management at medical colleges, research institutions and hospitals” in November 2013 (revised in February 2014). It also determined the “Guidelines for implementing investigator-initiated trials” in February 2015 and diffused among researchers through meetings.

The reliability of clinical research was damaged by recent inadequate clinical research, including misleading advertisements, inadequate involvement of companies or data manipulation in clinical research of antihypertensive drugs, leukemia curative drugs and Alzheimer’s disease.

As mentioned above, the government, industry and science community are engaged in discussing measures to prevent recurrence of misconduct in clinical research. These discussions should result in prompt and practical measures to conduct highly qualified clinical research based on adequate COI management to restore public trust in clinical research. Steady and prompt implementation of these countermeasures will contribute to the development of the medical care to relieve the sufferers in Japan and hold the key to Japan originating drug discovery as one of the growth strategies.

## **2 Prevention of Research Misconduct**

Various preventive actions have been taken by the science community and government to combat research misconduct. Following the recent occurrence of various misconduct cases, more stringent reform has been promoted to prevent any recurrence of research misconduct.

### **(1) Science community**

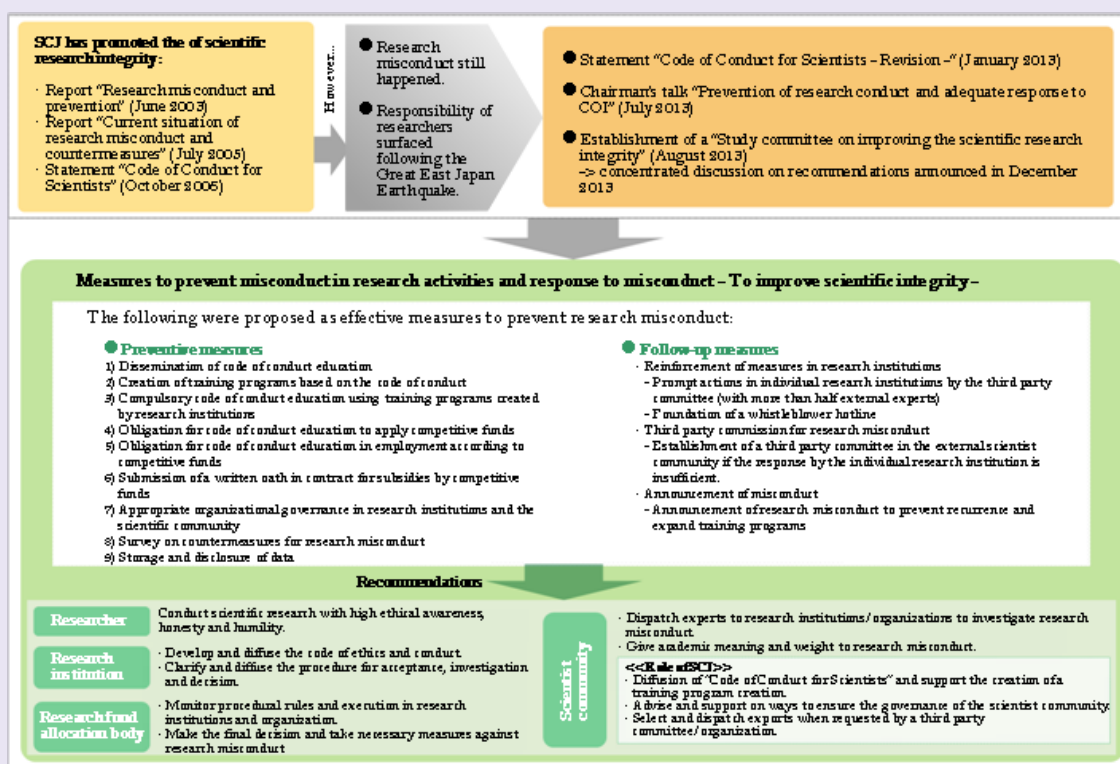
Research misconduct is a problem primarily resolved by the self-discipline of researchers, or autonomous self-purification of university research institutions or the science community.

From this perspective, Science Council of Japan (SCJ) implemented a “Code of Conduct for Scientists” in October 2006, as the basic code of conduct for all academic fields and for scientists to conduct scientific research voluntarily and autonomously, based on social reliability and funding and to accelerate the sound development of science. The “Code of Conduct for Scientists” was revised in January 2013 as the responsibility of scientists had surfaced following the Great East Japan Earthquake in March 2011 and research misconduct discovered. The revised code of conduct emphasizes the “promotion of fair research” and requirements for continuous education to prevent research misconduct.



SCJ announced its recommendations “Preventive and follow-up measures for research misconduct - To improve scientific integrity -” (Figure 5) in December 2013 following discussion at the SCJ “Investigative Committee on the improvement of scientific integrity” to cope with successive research misconduct, despite the issue of the code of conduct. The recommendations include: 1) Research institutions and academic conferences shall prepare training programs based on the code of conduct and all research institutions shall ask researchers and graduate students to join the training programs and 2) Potential research misconduct shall be investigated promptly through the 3rd party committee.

■ Figure 5 / Outline of SCJ recommendations “Preventive and follow-up measures for research misconduct”



Source: Created by SCJ

In December 2014, the chairpersons of the National University Association, Japan Association of Municipal and Prefectural Colleges and Universities and Private University Association jointly announced “Joint Statement for Enhancing the Integrity of Scientific Research” to declare an improvement in research integrity with concerted efforts of associations as the responsibility of academia in Japan.

Following the strong sense of crisis at the current research misconduct, the science community, mainly SCJ, took the initiative to promote countermeasures to restore public trust in science. Via a joint announcement, effective measures are expected to be taken for research misconduct with the cooperation of the research institutions.

## (2) Government approaches

### 1) Previous actions

In February 2006, MEXT established the “Proper Counteractions against Research Misconduct” in the Council for Science and Technology to investigate research misconduct and the committee consolidated the “Toward Guidelines to Respond to Misconduct in Research: Report of the Special Committee on Scientific Misconduct” (“2006 Guidelines”) in August. The guidelines suggest an operational flow from accusations of misconduct to approval and punitive measures for violators to allow the research fund allocation bodies and research institutions to take appropriate actions for misconduct on competitive funds.

The cross-ministerial action to prevent research misconduct has been promoted to some extent. The relevant ministries issued guidelines for misconduct in scientific research and the government, as a whole, imposes restrictions on researchers who commit any violation, rendering them ineligible for any ministerial competitive funds for a certain period.

### 2) Guideline response to research misconduct

MEXT took special notice of the research misconduct and misuse of research funds, which became a major social issue and established a “task force on research misconduct and misuse of research funds” led by Teru Fukui, then Vice Minister of Education, Culture, Sports, Science and Technology, in August 2013. The task force intensively discussed countermeasures for research misconduct and consolidated three basic policies; “action to prevent misconduct in advance,” “clarification of organizational management responsibility” and “government monitoring and support” in September.

“Action to prevent misconduct in advance” mainly comprises reinforcement of research ethics education, including the development of ethics education programs and obligation of applicants for research projects to take ethics education programs, disclose research misconduct in the form of a list and retain research data for a certain period.

“Clarification of organizational management responsibility” requires the assignment of a person responsible for ethics education to prove efforts made to tackle the issue as an organization and the establishment of system design to take corrective measures if problems emerge in the organizational management to develop and announce rules, or respond to misconduct.

“Monitoring and support by government” involves conducting government-led surveys to confirm the rules and system development conditions in research institutions, support for research institutions to conduct ethics education and the development of rules.

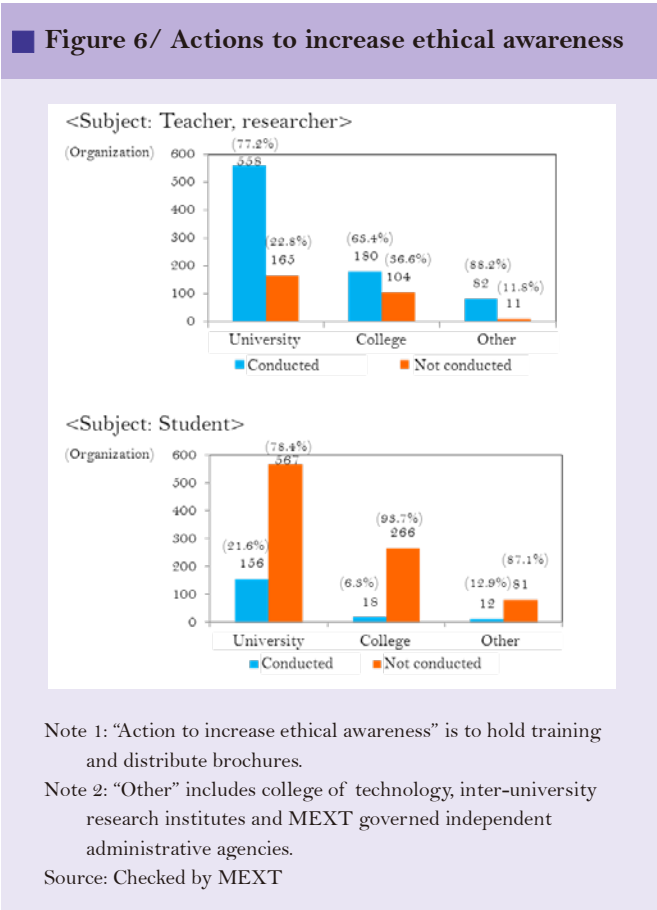
Based on discussion by the task force, MEXT founded a new conference dealing with research misconduct “Cooperative meeting to study ways of revising and improving the implementation of existing guidelines” (“cooperative meeting”) in November 2013 and integrated the discussions in February 2014.

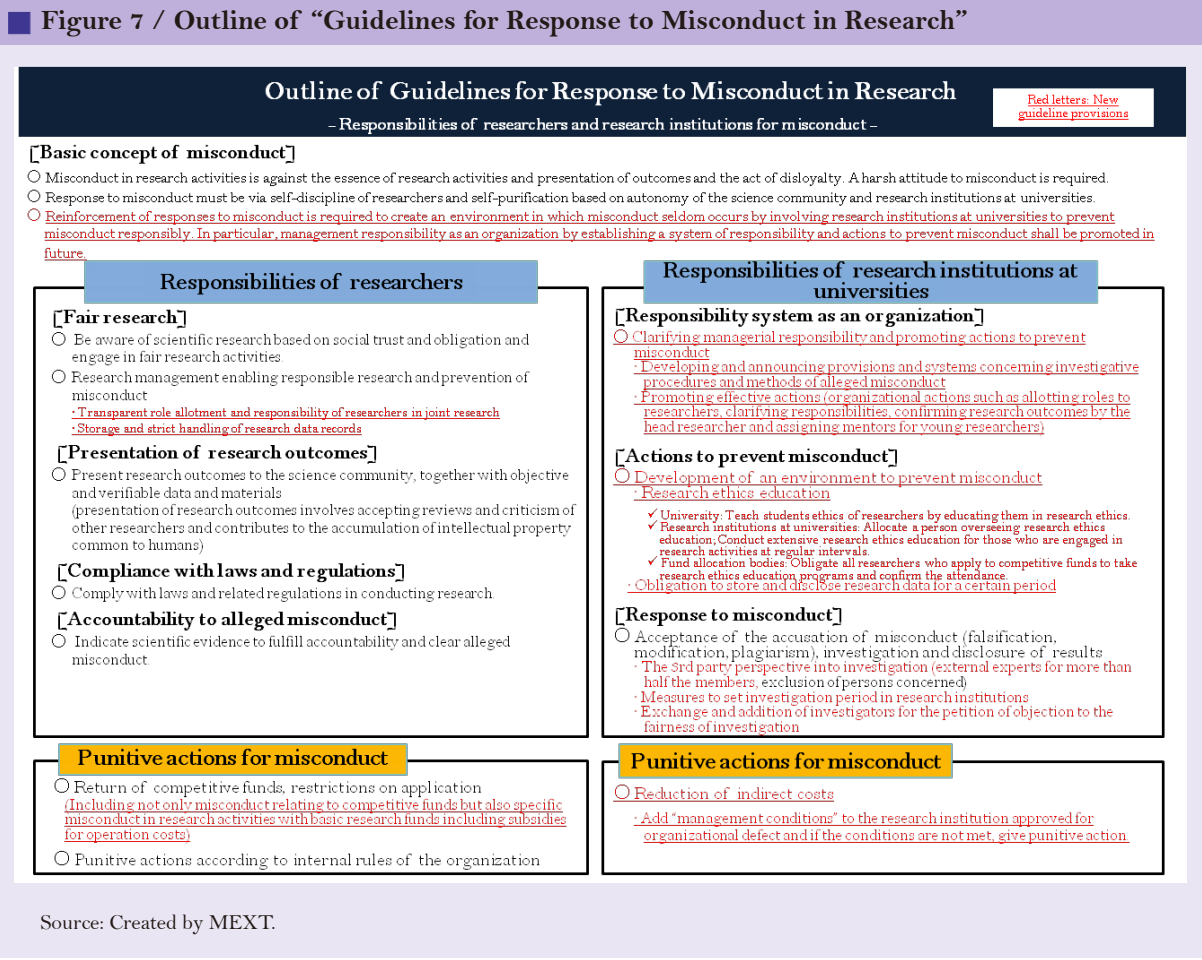
The integrated discussions included recommendations for the implementation of research ethics education, obligation of research institutions to keep research data for a certain period and punitive measures for research institutions (decrease in indirect cost). In particular, the focus was placed on research ethics education. In addition to the teachers and researchers in research institutions at universities, the importance of including doctoral students and other human resources for potential researchers in future in extensive research ethics education was emphasized to prevent misconduct and promote fair research activities.

The background to prioritize these matters was the insufficient research ethics education of students. According to a survey performed by MEXT in FY 2012, only 20% of all universities conducted initiatives to boost research ethics. Considering the importance of education in the early stages, promotion of research ethics education for students is a pressing issue (Figure 6).

MEXT drafted new guidelines based on the discussion in the cooperative meeting described above and lessons learned from the investigative reports of RIKEN on the STAP paper issue, conducted public comment procedures in July 2014 and finally implemented the “Guidelines for Response to Misconduct in Research” (“New Guidelines”) on August 26 based on the public comments (Figure 7).

In the New Guidelines, discussions of the task force and cooperative meeting were included as well as the basic concept of research misconduct in 2006 that misconduct is primarily resolved by self-discipline of researchers, or autonomous self-purification of research institutions of universities or science community. The basic policy is to put more focus on the role of research institutions to prevent misconduct responsibly to reinforce the response to misconduct in research, although it used to rely mainly on the self-discipline and responsibility of individual researchers.





MEXT started enforcing the New Guidelines from April 1, 2015. Prior to this enforcement, MEXT had strenuously promoted the New Guidelines for 7 months from implementation to enforcement and regarded this period as a time for intensive reform at agencies and for the authorities concerned to develop rules and systems according to the new guidelines.

The New Guidelines outline procedures for investigating research misconduct and the concept of preventive measures, but discussions by the science community are required for a more detailed response in individual research sites. MEXT therefore requested that SCJ discuss the following six subjects concerning the integrity of research activities in July 2014, while implementing the new guidelines: (i) Period and method of keeping experimental data, (ii) Basic precautions that researchers need to keep in mind, (iii) scope of misconduct other than specific misconduct (fabrication, modification, plagiarism), (iv) reference standard on research ethics education, (v) model rules for research misconduct at universities and (vi) other matters for sound research activities.

SCJ responded to the request from MEXT in March 2015 in “Enhancement of scientific research integrity”, including the following recommendations and presented model rules for research misconduct at universities (39 in all):

- Keep experimental data and other research materials, based on which the paper is written or the result presented, for 10 years from the presentation of paper in principle. Keep samples, specimens and other physical materials for five years in principle.
- Provide authorship provisions and publicize them in individual academic journals published by research

institutions and academic societies due to the wide fluctuation in the interpretation of “authorship” requirements for papers depending on research fields.

- Give researchers the opportunity to take research ethics education at least every five years.
- Individual research institutions should develop rules as specified while referring to the model rules.

The new guidelines require universities to promote research ethics education for students as well as researchers and instructors. With this in mind, the Graduate School WG of CSTP’s Subdivision on Universities has been discussing how best to promote research ethics education as of April 2015.

During this period, the Council for Science, Technology and Innovation (CSTI) issued “Addressing Research Misconduct” in September in response to comments submitted by executive members at the 119th Council for Science and Technology Policy held in April 2014. It defines two aspects of the CSTI role: One is to understand the whole situation, including the activities of individual research institutions and ministries concerned and taking appropriate actions as required and the other is to provide a cross-cutting perspective to collect and share a variety of information so that individual entities function comprehensively. The ministries concerned have also revised relevant guidelines for research misconduct.

### 3) Fair research activities

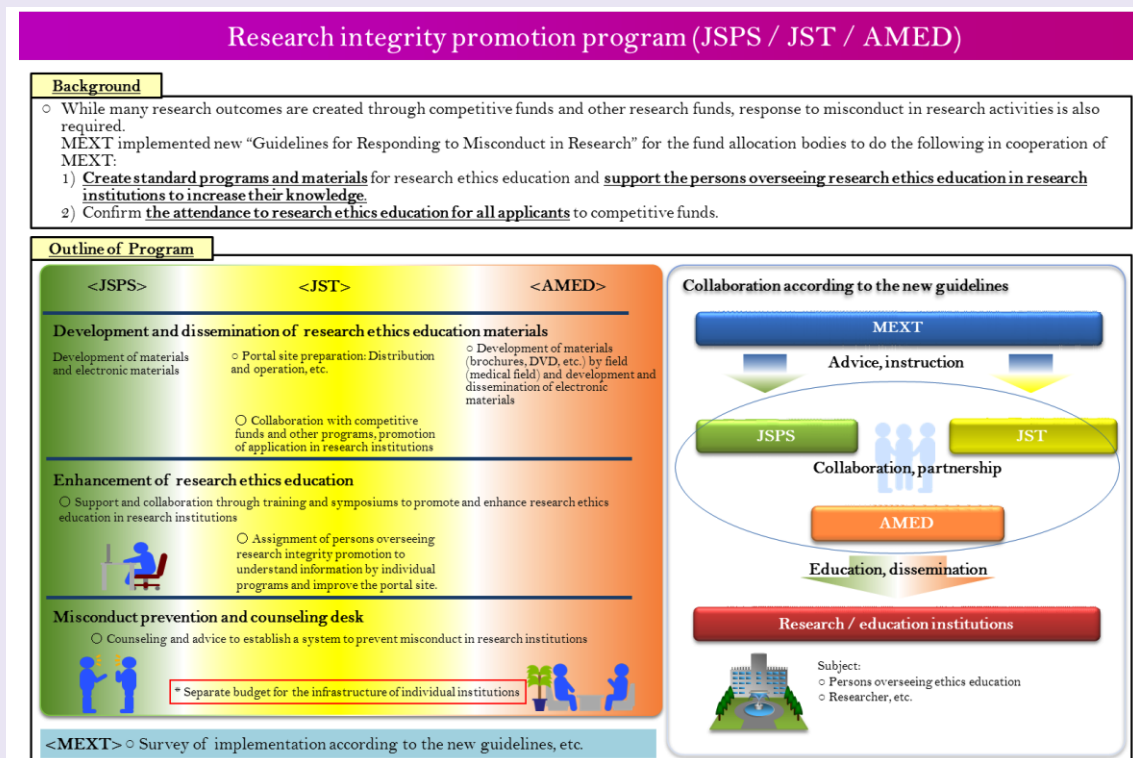
As mentioned above, it is important to ensure research ethics education in research institutions to prevent misconduct in research.

Since FY 2012, MEXT has supported the “CITI Japan Project”<sup>1</sup> to develop research ethics education programs for fostering the research ethics of those extensively involved in research activities, such as graduate students of medical departments and researchers. The Japan Society for the Promotion of Science (JSPS) published “For the Sound Development of Science - The Attitude of a Conscientious Scientist - (edited by the editorial committee for JSPS “For the sound development of science”)” in March 2015, assisted by MEXT and SCJ, as standard material for extensive research ethics education. MEXT started the “Research Integrity Promotion Program” in FY 2015 according to the new guidelines in collaboration with fund allocation bodies (JSPS, JST, Japan Agency for Medical Research and Development (AMED)) (Figure 8). This program aims to develop standard programs for research ethics and support every researcher to take research ethics education before participating in research by competitive funds.

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<sup>1</sup> A joint project of six universities, including Shinshu University, to develop research ethics education programs and e-learning materials suitable for the research site in Japan and meet international standards based on programs widely used in the U.S. and worldwide (CITI: Collaborative Institutional Training Initiative). Selected by “Program for Promoting Inter-University Collaborative Education” in FY 2012 and support planned for the period of FY 2012 to 2016.

Figure 8 / Outline of the Research Integrity Promotion Program




Source: Created by MEXT.

MEXT conducted a commissioned survey<sup>1</sup> in FY 2014 to understand the details of the present situation of research ethics education at the universities shown in Figure 6. In this survey, the following issues were identified in the survey of research ethics education in research institutions in future:

- Development of human resources capable of conducting research ethics education in an organization or department is required for continuing research ethics education.
- There is a need to keep materials up to date, create materials corresponding to the background of trainees, investigate their contents and format and evaluate the effects of materials and education for continuous and effective research ethics education.
- Coordination is required when it is difficult to gain consensus in a faculty or department for the systematic implementation of research ethics education due to differences in judgment or inappropriate scope depending on research fields and areas.

It is also suggested that education desirable for refining research ethics education should not be restricted to “preventive perspectives” of researchers and students such as “what to protect” or “what to follow” but also include an “intentional perspective” for mainly considering “how to respond.” MEXT plans to promote discussions concerning what to be confirmed in the implementation survey of the New Guidelines scheduled to commence after FY 2015 based on the above survey results. The research institutions must develop a system to discuss or conduct research ethics education to ensure the

<sup>1</sup> Survey and analysis report on research ethics education in research institutions (FY 2014 Commissioned Program for Development of Human Resources for Science and Technology, EY Advisory Co., Ltd., March 2015) ([http://www.mext.go.jp/a\\_menu/jinzai/1357901.htm](http://www.mext.go.jp/a_menu/jinzai/1357901.htm))



implementation of research ethics education under the “person in charge of research ethics education” required by the new guidelines while referring to the results of this survey and taking the current circumstances into account.

As suggested in the above explanation, actions have been taken mainly by the science community to prevent research misconduct in Japan, but research ethics education and managing conflicts of interest have not necessarily been satisfactory. Various investigations and development of rules, including the new guidelines, have been conducted in FY 2014 to accomplish fair research activities. Effective approaches in the research site based on these investigations and rules are strongly desired in future.

It is important for researchers to recognize that freedom of research activities is supported by adequate rules and ensure compliance with these rules and for the science community as a whole to promote “Responsible Conduct of Research” (RCR).

It should also be remembered that science, technology and innovation activities must be trusted by society and not only researchers but all stakeholders in areas of science, technology and innovation in Japan, including the government and industry, striving to engage in dialog and cooperate with society for “Responsible Research and Innovation” (RRI) to promote science, technology and innovation policies for the sustainable development of society in Japan.



## Approaches of Other Nations to Promote Fair Research Activities

Various institutions and organizations of the world have currently tackled fair research activities and the importance of “research ethics education” is emphasized in particular. Some principal examples are introduced below.

○ World Conference on Research Integrity (WCRI):

“Singapore Statement on Research Integrity (2010)” is the document agreed at the 2nd World Conference on Research Integrity held in Singapore from July 21 to 24, 2010.

It says “While there can be and are national and disciplinary differences in the way research is organized and conducted,” “there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.” It designates 14 actions, including compliance with rules, research records and authorship and response to research misconduct for responsible research activities.

○ Europe:

“European code of conduct for Research Integrity (2011)” is the document created after discussions by ESF (European Science Foundation) Member Organization Forum on Research Integrity from 31 fund allocation bodies and research institutions of 22 nations in the ESF and 53 academies (All European Academies) of 40 nations. It is a code of conduct in Europe concerning appropriate research practices in medicine, natural science, humanities and social sciences. Specifically, honesty in communication, reliability in performing research, objectivity, impartiality, independence, openness and accessibility, etc. are included in the code of conduct for researchers. In addition to falsification, modification and plagiarism, nondisclosure of interests and conflict of interest related matters such as breach of security are also designated as research misconduct. Principles ranging from data management to submission of papers are specified as responsible research activities.

○ The U.S.:

The National Institutes of Health (NIH) defined research misconduct in 1989 for the first time in the United States. NIH requested RCR education from 1989 and founded the Office of Research Integrity (ORI) in 1992. The America COMPETES Act passed in August 2007 obligates research institutions at universities etc. to have undergraduate students, graduate students and postdoctoral take training courses on responsible research activities and research ethics. The National Science Foundation (NSF) obligates universities to formulate research ethics education programs from January 2010.