<Tentative Translation>

RESPOSE

ABOUT PROMOTING INTEGRITY IN SCIENTIFIC RESEARCH

March 6, 2015
SCIENCE COUNCIL OF JAPAN

This Response is a result of discussion in meetings led by Science Council of Japan (SCJ) Exploratory Committee on Sound Scientific Research Subcommittee on Research Integrity.

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Summary

1. Background of Preparing This Response

The Ministry of Education, Culture, Sports, Science and Technology (MEXT) has been working on the issue of research integrity based on our special committee report entitled, "On Guidelines for Responses to Misconduct in Research Activities" (August 2006). However, facing several new research misconduct cases reported thereafter, MEXT formulated and published the "Guidelines for Providing Appropriate Responses to Misconduct in Research Activities" (August 2014, Decision of the Minister of Education, Culture, Sports, Science and Technology). In relation to the application of these new Guidelines, the Director-General, Science and Technology Policy Bureau of MEXT made a request of deliberation to the President of Science Council of Japan (Reference 1) on July 26, 2014.

2. Committee Deliberation

As per the deliberation request from MEXT, we have discussed the following topics:

- Scope of misconduct other than Specified Misconduct (fabrication, falsification and plagiarism) (such as duplicate submission and how to address the issue of authorship);
- Basic duty of care as a researcher, and period and method of storing experimental data, etc. (taking account of characteristics of research fields);
- Other matters for promoting research integrity;
- Reference standard for research ethics education; and
- Model internal rules of universities relating to responses to misconduct.

The Subcommittee on Research Integrity of SCJ Exploratory Committee on Sound Scientific Research had seven subcommittee meetings, and held the academic forum "Promoting Integrity in Scientific Research - Preparing for the application of the Guidelines for Providing Appropriate Responses to Misconduct in Research Activities -", where the subcommittee had Q&A sessions with peoples from research institutions and researchers all over Japan and collected written questionnaires from the participants. Then, the subcommittee reviewed the opinions from those people, and adopted them where appropriate.

3. Scope of misconduct other than Specified Misconduct (fabrication, falsification and plagiarism) (such as duplicate submission and how to address the issue of authorship)

(i) How to address the issue of authorship

One of the criteria for becoming an "author" of a publication (article) of research outcome is that the researcher has made a material contribution in the relevant research. But, interpretation of those criteria varies depending on the discipline, and decisions should be made reflecting the consensus of the researchers' community in the relevant discipline. In this regard, academic journals published by research institutions and academic societies should have their rules on authorship and publicly announce the same.

(ii) Prohibition of duplicate submission

Duplicate submission should be strictly prohibited not simply because it wastes other researchers time through unnecessary peer-reviewing, but because it misleads the others by creating such an appearance that there are many articles representing a specific idea. Academic journals published by research institutions and academic societies should develop their rules on duplicate submission in line with the above explanation and

publicly announce the same.

4. Basic duty of care as a researcher, and period and method of storing experimental data, etc. (taking account of characteristics of research fields)

Researchers are intrinsically motivated to store data and specimens generated in their own research activities for good, if circumstances allow. Since outcome generated in a public-funded research and data, etc. used as the raw materials therein also have the character of public assets, obligations and responsibilities to appropriately manage and store them and disclose as needed are imposed on researchers and research institutions.

Unless otherwise provided, research references such as experimental data from which the research outcome being published in the form of an article, etc. must be archived for a period of 10 years. Tangible materials such as specimens and samples must be stored for a period of 5 years, unless otherwise provided. However, these basic rules do not apply to the case where there is a socially-acceptable and compelling reason such as storing the materials is infeasible or extremely difficult or requires an enormous cost and/or space. Further, if there is any special institutional rule for handling data, etc. in such field as medical science or social survey, such rule must be complied with.

Researchers who have generated materials, etc. have the primary responsibility for archiving or storing the materials, etc. The leader of the laboratory unit and the head of the research institution are required to make efforts to develop an adequate environment for storing material, while enlightening their people on material storage as a part of research ethics education. In addition, if any researcher resigns the laboratory, current status of the stored object must be confirmed and traceability in case of a future need must be ensured.

5. Other matters for promoting research integrity

Besides those mentioned in the above sections, i.e., Specified Misconduct, authorship, duplicate submission and appropriate storing and archiving materials, data, etc. which have been used in research, and let alone compliance with legal and regulatory provisions and institutional internal rules, there are other matters to observe for the sake of ensuring research integrity such as appropriate responses to conflict of interest and fair evaluation of other researchers, namely, the issues of conflict of interest and evaluation of other research.

(i) Regarding conflict of interest

Conflicts of interest in research may form a bias in favor of one of the different interests, or may adversely affect educational activities. Also, research institutions may lose the public's trust because of inappropriate managing of conflict of interest situations. To avoid these negative consequences, in the context of joint efforts between industry and academia, if research that may involve a conflict of interest is to be carried out, it is required to clarify who carries out the research and take appropriate measures such as managing research outcome.

(ii) Regarding evaluation of other research

In reviewing a manuscript, a peer-reviewer may be a competitor of the author of the manuscript in the relevant discipline or may support a different theory or have a different thought or belief. Peer-reviewers must be strictly warned, such that they will not take an unreasonably harsh attitude against their competitor's manuscript or intentionally delay the reviewing process. Also, in the examination of competitive research funding, reviewers must comply with conflict of interest policies and rules, and in addition, if a reviewer has

any other relationship with an applicant which is not explicitly regulated but may affect the examination, the reviewer should recuse him/herself from the examination from the viewpoint of researchers' ethics.

6. Reference standard for research ethics education

For healthy development of science, it is necessary to establish research ethics education that is designed for researchers to develop self-discipline to control their own behaviors. In order to assure a certain quality standard for research ethics education that is carried out under the responsibility of each research institution, the reference standard is aimed to be the guidelines when they prepare education curriculum. All researchers who belong to a research institution (including leaders of laboratories, post-docs, etc.), students (graduate students and undergraduate students) and staff members are required to complete research ethics education, regardless whether or not funding source is a public subsidy, and are also required to learn appropriate and comprehensive contents in a systematic manner, in order to acquire research ethics of a higher standard which is not narrowly focused on a single discipline but has broader, general scope. Research institutions are also demanded to responsively design and provide research ethics education suitable for individual learners by actively utilizing an e-learning system, etc. and make creative efforts to increase educational effects by combining with an interactive educational program, etc. Further, research institutions are required to perform evaluation as evidence to ensure quality education, recognition of credit and/or issuance of certificate, and provide periodical (for researchers, at least every 5 years) learning opportunities. Furthermore, researchers are expected to fully understand effects and limitations of research ethics education to be provided by their research institutions and make efforts to maintain the public's trust.

7 Model internal rules of universities relating to responses to misconduct

We have prepared model internal rules based on these policies. "Model internal rules for prevention and response to misconduct in research activities" are to be used by universities as references when they create their internal rules as embodiments of the provisions of these Guidelines published by MEXT. Therefore, we drafted the texts to make them as consistent as possible with the standpoint of the Guidelines, and used same expressions with the Guidelines for key terms and numbers to specify a period of time, etc. In addition, since the deliberation request from MEXT was to prepare model internal rules relating to responses to narrowly-defined research misconduct, the present model internal rules do not include provisions to deal with misappropriation of research funds or conflict of interest.

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1. Introduction

(1) Background of Preparing This Response

Conventionally, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) had been dealing with the research integrity issue based on the publication entitled, "On Guidelines for Responses to Misconduct in Research Activities" (August 2006, by the Special Committee on Research Misconduct under the Council for Science and Technology). However, facing several new research misconduct cases reported thereafter, MEXT established a "taskforce on misconduct in research and misappropriation of research funds" in August 2013 to conduct intensive discussion for responses to any future cases and published the results of discussions in September 2013. Based on the discussions by the taskforce, a report of discussion was issued by the "Cooperator Conference on Revision, Improved Operation, etc. of the 'Guidelines for Responses to Misconduct in Research Activities'" (February 2014), and subsequently, MEXT published the "Guidelines for Providing Appropriate Responses to Misconduct in Research Activities" (August 2014, Decision of the Minister of Education, Culture, Sports, Science and Technology). These Guidelines will be effective from April 2015, and in relation to the application of these new Guidelines, the Director-General, Science and Technology Policy Bureau of MEXT made a request of deliberation to the president of Science Council of Japan (Reference 1) on July 26, 2014.

(2) Committee Deliberation

As per the deliberation request from MEXT, we have discussed the following topics:

- Scope of misconduct other than Specified Misconduct (fabrication, falsification and plagiarism) (such as duplicate submission and how to address the issue of authorship);
- Basic duty of care as a researcher, and period and method of storing experimental data, etc. (taking account of characteristics of research fields);
- Other matters for promoting research integrity;
- Reference standard for research ethics education; and
- Model internal rules of universities relating to responses to misconduct.

Science Council of Japan (SCJ) established the Subcommittee on Research Integrity in the Exploratory Committee on Sound Scientific Research for deliberation to respond to the request. The deliberation took place in seven subcommittee meetings, and the academic forum "Promoting Integrity in Scientific Research - Preparing for the application of the Guidelines for Providing Appropriate Responses to Misconduct in Research Activities -" (at the Science Council of Japan Hall) hosted by SCJ was held on February 5, 2015. In the forum, we presented a summary of our draft response and had a Q&A session with the people from research institutions and researchers all over Japan and collected their comments using written questionnaires. Then, the draft response was amended reflecting these comments, where appropriate.

2. Results of Committee Deliberation of the Requested Topics

(1) Scope of misconduct other than Specified Misconduct (fabrication, falsification and plagiarism) (such as duplicate submission and how to address the issue of authorship)

(i) How to address the issue of authorship

One of the criteria for becoming an "author" of a publication (article) of research outcome is that the researcher has made a material contribution in the relevant research. For example, authorship may be credited to a person who meets all of the following criteria: (i) who has made conception or design of the research or essential contributions to the performance of investigation or experiment, or substantial contributions to the research such as the acquisition, analysis, or interpretation of experimental or observational data or construction of the model; (ii) who has made contribution to the final product of the work such as drafting it or revising it critically with explicit comments for important content; and (iii) who has given final approval of the version to be published and being accountable for what is published[1]. However, there is no uniform interpretation of these criteria across disciplines. Determination as to who should be credited to authorship should be made based on the consensus of the researchers' community in the relevant discipline. If there are more than one authors, it is recommended to explicitly identify what role each of the authors has played in the relevant work.

On the other hand, if there are other contributors who have contributed to the performance of the research but do not "meet all of the above criteria" for authorship, it is appropriate to specify their names in the acknowledgement section. For example, such activities as acquisition of funding for the research or general supervision of a research group alone do not qualify a contributor for authorship.

Crediting authorship to a person who does not meet the criteria for authorship will be considered as "gift authorship". On the other hand, if a person who has made essential contributions to the research and meets all of the criteria for authorship is not identified as an author, such a treatment is seriously unjust. Also, if a person is listed as a co-author without permission of the person, such a treatment is also unjust.

Authorship confers credit to achievements of persons for the portions that they are in charge of in the relevant research outcome, but also responsibilities that they take for said portions. All people who have involved in the research should have a common understanding that who have contributed to and are responsible for which portion of the research outcome.

Under the conventional Japanese practices, authorship had been customary credited to those who have only provided equipment or facility for research or funding, or given authority to the work, or have taught a known theory or given a simple suggestion or advice and do not "meet all of the above criteria" for authorship, in some disciplines. One of the reason for such practice is that "acknowledgement" is merely a matter of formality in Japan. However, from now, Japanese researchers' communities should recognize the significance of identification in the acknowledgement section as their counterparts in Europe and North America do, and are required to separate contributors who are credited as authors and take responsibilities for the research outcome from those who are acknowledged. In addition, the order of multiple authors should be decided based on the consensus of the relevant discipline, as international customary practices are different among disciplines.

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[1] For this point, see the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" by the International Committee of Medical Journal Editors (ICMJE), April 2010 revision translated by toukoukitei.net. http://www.toukoukitei.net/i4aURM201004.html (last visited: October 13, 2014). In this Response, SCJ provides its own perspectives, using said material as a reference.

In addition, academic journals published by research institutions and academic societies should develop their rules for authorship in line with the above explanation and make public the same. For example, many academic societies explicitly state in their manuscript submission rules that "crediting persons who did not make direct contributions to the manuscript as coauthors constitutes misconduct and thus is prohibited". Authorship should be managed appropriately not only by those who were involved in the research, but also by the research institutions and academic societies who are the publisher of the academic journal. Also, it is recommended to explore possibility of taking into account the number of coauthors when evaluating research achievements of the researchers.

(ii) Prohibition of duplicate submission

Duplicate submission is, in print or in the form of electronic media, to submit substantially the same manuscript as an article which has already been published on or submitted to another academic journal, as the author's original article. Such a behavior should be strictly prohibited not simply because it wastes other researchers time through unnecessary peer-reviewing, but because it misleads the others by inflating the achievements and creating such an appearance that there are many articles representing a specific idea. In this regard, the "Revising the Guidelines for Providing Appropriate Responses to Misconduct in Research Activities" published by MEXT (August 2014) requires to address the issue of duplicate submission.

However, presentations at an academic conference are often done as a progress report in the middle of research. It has been widely accepted in many disciplines that an official presentation of research outcome is made by means of submission of a manuscript to an academic journal. Therefore, it is generally recognized that publication of a manuscript by means of proceedings associated with a conference presentation does not prevent submission of a final work to an academic journal, even from the viewpoint of prohibiting a duplicate submission. Also, when submitting a thesis for requesting a doctoral degree, candidates are often required to publish in a peer-reviewed academic journal, thus, in this respect, it is generally accepted to reprint the work from an academic journal to the manuscript to be submitted to request a doctoral degree. However, the reprinted work must explicitly indicate as such.

In addition, some academic societies and journals allow authors of a published English manuscript to republish the same contents as a Japanese manuscript, or vice versa, under certain conditions. In these cases, too, authors are required to comply with manuscript submission rules of both academic societies or journals and submit the manuscripts clarifying the relationship of the two, so that the principle of prohibition of duplicate submission will not be violated.

Academic journals published by research institutions and academic societies should develop their rules on duplicate submission in line with the above explanation and publicly announce the same. Duplicate submission should be managed appropriately not only by the authors but also by the research institutions and academic societies which publish the academic journals. Further, it is necessary to provide measures for allowing research institutions and academic societies to mutually manage duplicate submissions to different academic journals published by them.

As an example of rules on duplicate submission, "manuscript submission rules" set forth by Japan Society for Educational Technology (JSET) prohibit duplicate submission as follows[2]:

[2]"Japan Society for Educational Technology Manuscript Submission Rules (revised on 2014.04.01)" by Japan Society for Educational Technology.

(2) "Criteria for submission"

It is essential to meet the following criteria, and any manuscripts which do not meet these criteria will be returned. In particular, (i) and (ii) may be determined as duplicate submission, and, in that case, ethics of the authors will be questioned. Thus, authors should carefully check the situation before submitting their manuscripts. In addition, as for an English manuscript or translation, the following criteria will apply at the time that its Japanese manuscript is published on the JSET journal.

(i) Policies on papers that have already been published

Contents of the submitted manuscript have not already been or not to be published on an academic or other journal (including university bulletin), book, collection of papers on which papers for oral presentation at an international conference are peer-reviewed and published after the conference (proceedings paper) or a commercial journal, etc., or are not under submission or to be submitted to any of the foregoing.

(ii) Policies on relevant papers that have already been published

When the same author or another person has already published or will publish contents relevant to the contents of the submitted manuscript, such as when the submitted manuscript is a report of new knowledge, etc. which relates to a partially published contents, after conducting an in-depth analysis of the contents or further experiments, the earlier publication is identified as a reference with clear explanation of the relationship with and difference from the later publication.

(iii) Manuscripts, etc. presented at workshops or conferences of academic societies

In the case where neither the provision of (i) (policies on papers that have already been published), nor the provision of (ii) (policies on relevant papers that have already been published) applies, when the contents of the manuscript is partially or entirely published in any of the following forms and a translation thereof of a manuscript with additional texts thereto are to be submitted, such a case will not fall under duplicate submission as an exception. However, in order to clarify the relationship with the earlier publication, a note of explanation thereof must be added. In addition, when multiple publications of any of (a) to (f) relating to the submitted manuscript, etc. are combined, the note of explanation should identify only main publications among them:

(a) Collections of papers distributed for academic presentations such as workshops or conferences held by JSET or other academic societies, or in international conferences, etc. (presentation papers, research reports, technical reports, proceedings papers, etc.), etc.;
(b) Pre-print server relating to (a) above;
(c) Reports, etc. required under the scientific research grant program;
(d) University bachelor's, master's or doctoral thesis, etc.;
(e) Patent or patent application publications, etc.; and
(f) Newspaper articles, etc.

(2) Basic duty of care as a researcher, and period and method of storing experimental data, etc.

(i) Significance and necessity of storing or archiving references, etc. relating to research

It is a basic and important common practice for researchers to carry out research while recording their daily research activities. Notebooks to record research are used to keep experimental or observational logs (journal-like records) or record conditions under which data have been acquired, jot down key points of analysis, or write down discussions or ideas in the process of research. The traditional experimental research style in the field of natural science uses bound notebooks as laboratory notebooks, and researchers have been educated with a certain note-taking method to prevent subsequent modification, such as keeping records chronologically with date of entry and without leaving a blank line, and maintaining the history of correction, etc. when making any correction. These days, some conventional style laboratories use electronic means to keep research records, but the basic spirit remains the same.

Researchers are intrinsically motivated to store data and specimens generated in their own research activities for good, if circumstances allow. Also, it can be said that outcome generated in a public-funded research and data, etc. used as the raw materials therein also have the character of public assets, thus, obligations and responsibilities to appropriately manage and store them and disclose as needed are imposed on researchers and research institutions. As such, storing research data, etc. involves two aspects of "intrinsic motivation of researchers who carry out their research activities" and "obligations and responsibilities associated with research as a public activity".

After researchers publish outcome of their research, they may face allegation of research misconduct by any chance. Even in that case, if references and any other materials relating to the research are stored, researchers can clear up doubts by themselves. Thus, collaborators and their research institutions and funding agencies for the research are also responsible for appropriately storing and maintaining such references and materials.

In reality, among data, etc. that researchers have, determination of what to store and for how long should be based on the balance between the possibility of future use and usefulness thereof and the amount of resources (manpower, space and cost) to be invested for storing and archiving. Researchers who are transferred, change jobs or resign are likely to sort out or discard references and other materials before they leave, thus, their research institutions, etc. are required to develop guidelines setting forth a range of data, etc. which should be stored without discarding and necessary measures for that purpose, to prevent loss of data, etc. in those situations. Also, when research is carried out as a team effort, scope of responsibility of the leader of the laboratory unit and the head of a research institution should also be set forth in those guidelines, for the handling of data, etc. on the occasion of graduation of students or completion of academic terms or moving-out of members.

(ii) Categories and characteristics of objects subject to storage

When considering how data, etc. should be stored, it is reasonable to classify objects subject to storage into two categories: references, i.e., "information or data"; and objects with substance such as test specimens and experimental equipment, i.e., "tangibles". Then, start reviewing based on their characteristics. As to references (documents, numerical data, images, etc.), a specific method of storage may vary depending on the format thereof, in other words, whether they are electronic data or a hard copy of paper media, etc. On the other hand, "tangibles" such as specimens (test specimens, samples) and equipment, etc. do not fit to a general discussion, as their storage methods vary widely depending on the disciplines or the experimental

techniques. However, they may be roughly classified into some categories based on whether or not they need a special measures for storage, as shown in the table below (see Table 1).

These days, a large-capacity data storage device are available at a low cost, data stored in an electronic format will not create excessive burdens in terms of storage cost. All researchers are required to create a backup copy of important data and document files. Also, in case of any future needs, not only store files of data, etc., but also create metadata and securely manage the same.

As to paper media references, there are limitations in terms of storing capacities of filing or storing spaces. If the original format of a reference is a paper medium, it is recommended to convert it to an electronic file, wherever possible, to reduce storage cost and improve retrievability.

As for specimens, etc. (tangibles), spaces and costs for appropriate storage will be significantly large depending on the amount or characteristics of the tangibles to be stored. Thus, it is not wise to impose a general obligation to simply "store for the storage requirement". Research institutions are recommended to discuss development of rational guidelines suitable for the characteristics of the research. In particular, to store tangibles that require a special storage facility such as biological specimens, the research institution that stores such specimens should develop institutional guidelines and, at the same time, should proceed with development of infrastructure for appropriate storage.

Table 1:Categories and storage methods of research references/specimens

	Category of data, etc.	**Format/form**	**Storage method**	**Retrievability/ reusability**	**Storage space**	**Storage cost**
References (information, data)	Digital data	Electronic data	Recording media such as a hard disc	Easy if metadata is available	Small	Low
	Analog references	Paper media references, etc.	Filing, etc.	Depending on methods of organizing and storing	Depending on the amount	Relatively low
Specimens, etc. (tangibles)	Tangibles free from deterioration	Stable substances, samples, etc.	Simple storage	Depending on methods of organizing and storing	Depending on the amount	Relatively low
	Tangibles subject to deterioration, those requiring a special measure for storage	Unstable substances, reactive substances, biological specimens, rare samples, etc.	Storage under a special environment	Depending on the storage method	A special facility, etc. required	High

(iii) Scope of mandatory storage

In general, many data will be generated in the course of research activities, but only a small fraction of them will ultimately be used in papers, etc. to be published as research outcome. When data storage mandate is discussed in the context of ensuring research integrity, there should be such intention that, if research misconduct is doubted, researchers will be able to prove validity of their activities by themselves or those who are in charge of investigation will be able to validate the original data, etc. From that perspective, it may not be realistic to mandate storage of all data in general, including those that were not or will not be used in the publication such as a journal article. However, as mentioned earlier, researchers are intrinsically motivated to store all data, etc. generated in their own research activities including those that were not used in the publication of outcome, and many researchers have been actually storing all data. What is at issue here is what would be an appropriate scope of data storage mandated by official rules. Thus, it will not prevent anyone from voluntary storing all data or setting storage period exceeding the scope of mandatory storage, as

a matter of course.

In addition, if handling of particular data is subject to legal control or requires ethical considerations, such as survey data in the field of sociology, diagnostic data in the field of clinical studies and human genome information, or involves intellectual property rights, additional discussion for that purpose will be required for ensuring appropriate data handling.

(iv) Managerial responsibility of the leader of laboratory unit and the head of research institution

Regarding such issues as compliance with research ethics and code of conduct, assurance of safety and prevention of accidents and storage of references and specimens, etc., which should be practiced by each individual researcher, the leader of the laboratory unit and the head of the research institution are required to make efforts to provide appropriate education and instructions and environment from their positions, so that integrity of research activities can be maintained. As for the issue of specific method of storing references and specimens, etc., there are significant differences among disciplines due to characteristics of research activities and situations of research institutions. Thus, it is difficult to set forth a unified standard. Using the guidelines proposed in this Response as reference, and also referring to perspectives of researchers communities in the relevant discipline, research institutions should develop specific institutional rules and put into practice the same (see Table 2).

Table 2: Responsibilities of individuals in connection with laboratory operation

	Safety management	**Compliance with research ethics and code of conduct**	**Storage of references, etc.**	**Storage of specimens, etc.**
Individual researchers	Practice, Improvement proposal	Practice (if applicable, whistle-blowing)	Organized storage by organizing research records and metadata so that they are retrievable and extractable, creating an appropriate backup.	Storing whenever possible, recording and organizing metadata relating to specimens
Leader of laboratory unit	Education and instruction	Education and instruction	Education and instruction, managing metadata, creating a unified format of the lab, etc.	Education and instruction, securing storage method and space.
Head of research institutions	Creating an environment, education and training programs, safety inspection patrol, etc.	Creating an environment, education and training programs	Developing infrastructure such as by providing a backup server for data backup	Developing infrastructure for storing specimens that require special storage conditions

(v) Guidelines on storage of research references, etc.

Regarding the scope of mandate storage and storage period and method, the following guidelines may apply:

(A) In research activities such as experiments and observations, researchers are strongly recommended to keep records of the process thereof in the form of a laboratory notebook, etc. A laboratory notebook must be prepared in such a manner that does not permit subsequent modifications, and should describe logs of experimental manipulation, etc. and conditions under which data are acquired with enough information that can be used or validated at a later date. Laboratory notebooks must be appropriately stored as primary

information records of research activities.

(B) Research references (documents, numerical data, images, etc.) which are used as basis of publication of research outcome such as articles or reports must be stored in an appropriate form such that they can be used or validated at a later date.
When storing, it is important to be aware of importance of developing metadata and ensuring retrievability so that they can be used or referred to at a later date.

(C) A period of storing references (documents, numerical data, images, etc.) is, as a basic rule, for a period of ten years after publication of the relevant paper, etc. Electronic data should be stored in such a form that allows reuse of the data, such as by organizing and managing metadata and creating an appropriate backup. In addition, references of other forms such as paper media should also be stored at least for a period of ten years, but if there is a compelling situation such as a limitation of storage space, discarding those references may be allowed if it is within a reasonable extent.

(D) A period of storing "tangibles" such as specimens (test specimens or samples) and equipment is, as a basic rule, for a period of five years after publication of the relevant paper, etc. However, this does not apply to those that cannot be stored or archived by the nature thereof (e.g., unstable substances, specimens to be consumed by experiment itself) and those that require excessive costs for storage (e.g., biological specimens).

(E) The leader of a laboratory unit is required to, when any of the researchers in his/her group moves out or resigns, if there are any references that should be stored among those relating to research activities of the researcher, provide measures such as (a) storing such references by creating a backup, or (b) confirming the address of the researcher to ensure traceability. When the leader of the laboratory unit moves out or resigns, the head of the research institution provides similar measures. Additionally, in order to smoothly proceed with these measures relating to the storage of research references, each of the research institutions may develop institutional guidelines and mechanisms so that the institution and a researcher can exchange a memorandum at the time of employing the researcher.

(F) If handling of particular data such as personal data is subject to legal control or requires ethical considerations, such control and guidelines must be observed. Also, if there is any agreement or the like with the funding agency regarding handling of outcome of a specific research project, such agreement must be observed.

In addition, cases of a few disciplines which relate to characteristics of research references and specimens and conditions of storing and archiving will be given later in Reference 2 below.

(3) Other matters for promoting research integrity

Besides Specified Misconduct, authorship, duplicate submission, appropriate storage of references, data, etc. used in research discussed above, let alone compliance with legal and regulatory provisions and various institutional rules, there are other rules that must be complied with in order to ensure research integrity, such as appropriate responses to conflict of interest and fair evaluation of achievements of other researchers.

(i) Regarding conflict of interest

Conflict of interest is a situation where two opposite interests (benefit and obligation) confront with each other. There are several situations where a conflict of interest exists: personal conflict of interest (e.g., conflict between a personal gain and a duty as a university researcher or educator); organizational conflict of interest as a research institution (e.g., conflict between a benefit that a research institution gains and a social mission of the research institution); and conflict of obligations (e.g., conflict between an obligation of performing social duties as an individual and an obligation to perform professional duties within the research institution). These conflicts of interest may create bias in research due to difference of interests or may adversely affect educational activities, and, in some cases, may lead to lose the public's trust in the research institution.

For example, in clinical studies of an antihypertensive agent, "Diovan", which had been carried out by multiple universities, uncertain research funds and inadequate services were provided as a sales promotion based on an inappropriate conflict of interest, and data were manipulated intentionally. To avoid recurrence, when research takes place as business-academia collaboration, if the research has a possibility of developing a conflict of interest, it is required to clarify who carries out the research and take appropriate measures such as managing research outcome.

(ii) Evaluation of other research

For development of science, it is necessary to ensure fairness in the process of peer-reviewing, and researchers must perform peer-review with high ethical standards and wisdom. For example, in reviewing a manuscript, a peer-reviewer may be a competitor of the author of the manuscript in the relevant discipline or may support a different theory or have a different thought or belief. However, in such cases, peer-reviewers must be strictly warned, such that they will not take an unreasonably harsh attitude against their competitor's manuscript or intentionally delay the reviewing process. Also, in the examination of competitive research funding, reviewers must comply with conflict of interest policies and rules, and in addition, if a reviewer has any other relationship with an applicant which is not explicitly regulated but may affect the examination, the reviewer should recuse him/herself from the examination from the viewpoint of researchers' ethics.

(4) Reference standard for research ethics education

As reference standards when providing research ethics education, the following items can be given:

(i) Purpose of "reference standard for research ethics education"

For healthy development of science that can contribute to realization of the rich human society, it is necessary to establish research ethics education that is designed for researchers to develop self-discipline to control their own behaviors. Further, to nurture researchers to be able to perform responsible research activities regularly, they must be educated to voluntary comply with applicable rules and have trust in science. Furthermore, in order to maintain independence of science, it is necessary to provide uniform research ethics education throughout all disciplines. Therefore, a reference standard that enables to ensure such research ethics education must be developed. This reference standard aims to be the guidelines for preparing education curriculum, in order to assure a certain quality standard for research ethics education that is carried out under the responsibility of each research institution.

(ii) Scope of persons who receive research ethics education and basic skills to be developed

Scope of persons who receive research ethics education

Regardless whether or not funding source is a public subsidy, all researchers who belong to a research institution are required to receive research ethics education, including the leader of the laboratory unit. Also, education should also be designed to be suitable for graduate students who aspire to become a researcher and undergraduate students who are already at the stage of working in research, so that they can improve understanding of research ethics according to the stage of skill development they are at. In addition, staff members who are not researchers should also receive research ethics education in order to understand research activities that take place in their institutions.

Basic knowledge and understanding that should be acquired in research ethics education

Research ethics should be learned through appropriate and systematic contents of materials including specific case examples, rather than solely depending on an emotional appeal to researchers' common sense or learning through experiences. Also, curriculum should include code of conduct which defines appropriate behaviors as researchers and various guidelines and institutional rules. These materials should provide "knowledge" on research ethics, and, based on the acquired knowledge and understanding, learners should be able to develop "skills" to decide what ethical behaviors are by themselves and perform research activities in a just and fair manner. This learning process should be able to lead learners to fully understand the definitions and consequences of misconduct or other inappropriate behaviors as well as measures in response to allegations of research misconduct. Further, learners should contribute to promote responsible research activities and develop attitudes of respecting research subjects, and should be able to eliminate any possibility that may lead to research misconduct and be able to behave in such a manner that establishes a good communication that facilitates the research.

Examples of subjects in curriculum: what is research ethics?, why is research ethics education necessary?, what role should researchers play in the society? How should we deal with conflicts of interest?, how should research data be stored?, what are specified misconduct (i.e., fabrication, falsification and plagiarism)?, what should we keep in mind when drafting papers (e.g., the issues of duplicate submission and authorship)?, how should research outcome be published?, etc.

In addition, the contents of curriculum include contents that are considered important in certain specific disciplines (for example, how to handle personal information that has been obtained from questionnaires and interviews in a family budget survey or opinion survey in the field of humanity or social science, bioethics, informed consent, biosafety and research ethics on pluripotent stem cells, etc. in the field of life science and medicine, research safety in the field of science and engineering, etc.), however, these contents should also be learned as the issue of research ethics which should be acquired regardless of particular disciplines.

(iii) Basic policies on methods of leaning and evaluation of learning results

Institutional structure to provide research ethics education:

Research ethics education will be carried out under the responsibility of each of the research institutions. In addition, each institution should strengthen the structure of promoting responsible research activities, such as establishing a research ethics promotion office or consultation desk, and appropriately responding to

misconduct cases.

Method of education and timing of providing education:

Educational methods may be classified differently depending on the characters of the learners, and the following educational methods may be adopted. In addition, timing of providing education should also be arranged taking account of the specific composition of the learners.

〇University students:

- Enlightenment of basic research ethics in guidance at university entry.
- Enlightenment of research ethics which are required to engage in research in the introduction of the seminar work or graduation work (research ethics relating to drafting papers, informed consent, safety precautions, etc.).
- Providing research ethics education taking account of the characteristics of the area of expertise (discussions and lectures using case studies, etc.).

〇Graduate students:

- Enlightenment of research ethics required as researchers in guidance at university entry (comprehensive research ethics education including responsibility of authors of papers, formality of research ethics application form, conflict of interest policies, confidentiality obligation, etc.).
- Providing research ethics education taking account of the characteristics of the area of expertise (discussions and lectures using case studies, etc.).

〇Researchers who belong to research institutions:

- Regardless whether researchers are fulltime or part-time status, they should receive initial (at the time of employment or appointment) and periodical research ethics training (this should cover office regulations and relevant rules, legal provisions, etc.). These people should receive education at least every five years.
- Research ethics training actively utilizing e-learning, etc.
- Research ethics education training (this should cover contents to be provided in research ethics education for students) as a faculty development.
- Research ethics training taking account of characteristics of disciplines.

〇Staff members:

- Research ethics training at the time of employment (this should cover office regulations and relevant rules, legal provisions, etc.).

Besides lectures, trainings and e-learning as mentioned above, research institutions are expected to enrich the contents by providing or utilizing lecture meetings and seminars by the institutions or academic societies and enlightenment activities of research ethics using printed materials, websites, etc. In addition, academic societies are expected to provide important opportunities for researchers to complement contents of training that cannot be thorough only by their research institutions, by presenting guidelines on research ethics in specific disciplines. When creating e-learning modules, simple one-way learning should be avoided, and research institutions are required to make creative efforts to increase educational effects by combining with an interactive educational program such as arranging a subsequent group discussion session. Also, besides provision of research ethics education programs, research institutions are expected to promote development of guidelines for storing, disclosing, etc. of research data and give explanations to these points in training workshops or give lectures on the use of software capable of detecting similarity between texts (plagiarized text). Further, lectures and workshops dealing with research ethics should be designed to focus not only on

research ethics alone but also in combination with necessary knowledge and skills as researchers. Further, competitive research funding such as scientific research grant program (or Grant-in-Aids) should require candidates to complete research ethics education at the time of submitting an application (or by the time of issuing a grant).

Notes for curriculum guidance:

There are only a limited number of experts of "research ethics education", however, relating skills should be acquired by everyone in research institutions. Thus, education should also be given to graduate students and undergraduate students who have not yet started working in research. It is expected that quality of research ethics guidance to be given to such students should also be kept improved by the faculty development. It is expected that guidance to be given to undergraduate students and graduate students during lectures will be provided by a team-teaching method or a team of faculty members from various different disciplines. Also, research ethics education for foreign students may need to be arranged taking account of ethical views or morality to which those students are accustomed to. Further, research institutions are required to ensure compliance with research ethics among junior researchers (including post-docs, graduate students, etc.) through the mentor system utilizing researchers who have completed periodical research ethics education, and create places where students and researchers can communicate with and exchange their views on research ethics each other, etc.

Method of evaluation:

Evaluation plays an important role as evidence of assuring quality of research ethics education. Research institutions are required to issue a recognition of credit for undergraduate students and graduate students, or, in the case of a training course for researchers, a certificate (a certificate of education) after completion of the training course. Practice relating to evaluation method should take into consideration the specific learners and method of education. If research ethics education is provided to undergraduate students and graduate students in lectures as a part of curriculum, skills can be fixed by giving tests or requiring them to submit a report based on the contents of the lecture. Similarly, when providing training courses for researchers or e-learning modules, research institutions are expected to design a system in which learners do not simply attend the program but their understanding of the contents are confirmed, and submission of a statement of completion is required. Also, when designing training courses for researchers, researchers should not be treated as mere recipients of one-way lectures, and research institutions are expected to make such arrangements to help learners to fix knowledge and skills, such as arranging a subsequent group discussion session among attendants and requesting them to write a report individually.

(iv) Position of research ethics education in social context

Research ethics are the skills necessary for researchers to engage in research activities with a strong sense of responsibility, while voluntarily observing applicable rules. Although enlightening activities by research institutions have been increasing, conventional education of research ethics have been based on experience and social norms and there was no opportunity to receive education systematically. However, research ethics education from now should be designed to learn research ethics in the relevant discipline in a highly-sophisticated and systematic manner, so that researchers can acquire more general, high-level research ethics, much broader than those of their disciplines. On the other hand, researchers are expected to fully

understand effects and limitations of research ethics education that they learn at their research institutions, and make efforts to maintain the public's trust, by recognizing their relationships with the society, in nurturing and instructing junior members as well as in performing their own research activities.

(5) Model internal rules of universities relating to responses to misconduct

As model internal rules for preventing and responding to misconduct in research activities, the following provisions may be proposed. The provisions below are aimed to be referred to when universities embody the provisions of "Guidelines for Providing Appropriate Responses to Misconduct in Research Activities (published on August 26, 2014, Decision of the Minister of Education, Culture, Sports, Science and Technology; hereinafter, "Guidelines")" to develop specific internal rules, etc. Therefore, when drafting the model internal rules, we made great efforts to maintain coherency with the Guidelines and avoid conflict with them, and, matters that are explicitly described in the Guidelines as policies, etc., are reflected in the texts of the model rules. Also, we used same expressions with the Guidelines for key terms and numbers to specify a period of time, etc. In addition, since the deliberation request from MEXT was to prepare model internal rules relating to responses to narrowly-defined research misconduct which are subject to the Guidelines, the present model internal rules do not include provisions to deal with misappropriation of research funds or conflict of interest which relate to a wider sense of research misconduct.

Chapter 1: General Provisions

(Purpose)

Article 1

These Rules set forth necessary matters for preventing misconduct in research activities at XX (name of the institution) and for responding appropriately in the case that misconduct took place.

(Definitions)

Article 2

As used in these Rules, the following terms have the meanings given them below:

(1) Misconduct in research activities:

(i) Fabrication, falsification or plagiarism, which are caused by a willful act or gross negligence of basic duty of care as a researcher; or

(ii) Inappropriate acts in research activities other than (i), which are seriously deviated from researchers' ethics in view of code of conduct for scientists and social norms.

(2) Researchers, etc.:

Those who are employed by XX (name of the institution) and engage in research activities and those who are involved in research using a facility or equipment of XX.

(3) Office or department:

XX specified in the Rules on Administrative Organization of XX (name of the institution), a research organization established in XX Research Center and University Hospital.

(Responsibilities of researchers, etc.)

Article 3

1 Researchers, etc. shall not commit misconduct in research activities or any other inappropriate acts, and

shall endeavor to prevent others from committing misconduct.

2 Researchers, etc. shall complete training or subjects on researchers' ethics and laws relating to research activities.

3 Researchers, etc. shall secure means for proving validity of research activities, and appropriately store and manage experimental or observational notebooks, experimental data and other research references, etc. for a certain period of time in order to secure verifiability by a third person, and, shall disclose the same if such disclosure is found necessary and reasonable.

Chapter 2: Organizational Mechanism to Prevent Misconduct

(Chief Administrative Officer)

Article 4

XX (name of post) shall, for improvement of research ethics and prevention of misconduct, provide appropriate measures for promoting fair research activities, as a person who has the authority and responsibility to administer the entire corporation.

(Head of Office or Department)

Article 5

The head of office or department shall provide appropriate measures for promoting fair research activities, as a person who is responsible for improvement of research ethics and prevention of misconduct, etc. in the office or department that the person is in charge.

(Research Ethics Education Officer)

Article 6

1 XX (name of post) shall appoint a Research Ethics Education Officer as a person who has substantial responsibility and authority for research ethics education in the office or department, etc.

2 The Research Ethics Education Officer shall provide periodical education on researchers' ethics to researchers, etc. who belong to the office or department.

(Establishment of Institutional Review Board for Research Ethics)

Article 7

1 For preventing researchers, etc. from committing misconduct, an institutional review board for research ethics (hereinafter, "Institutional Review Board") having the following organizational structure shall be established in XX (name of the institution).

2 The Institutional Review Board shall consist of a Chairperson, a Vice-chairperson and members.

3 The Chairperson shall be selected from the members by XX.

4 The Chairperson shall administer operations of the Institutional Review Board.

5 The Vice-chairperson shall be appointed from the members upon designation by the Chairperson.

6 The Vice-chairperson shall assists the Chairperson, and, in the event that the position of Chairperson is vacant or the Chairperson is unable to perform its duties, lose its position.

7 Members shall be appointed from persons listed below upon designation by XX:

(1) XX of XX (name of the institution) (such as the head of XX (name of the institution), councilors, the head of office or department, etc. of XX): X person(s)

(2) Person(s) who have expert knowledge on scientific research: X person(s)
(3) Person(s) who have expert knowledge on code of conduct in scientific research: X person(s)
(4) External experts who have legal knowledge: X person(s)

8 The term of office of the members shall be two years; provided, however, that this does not prevent any member from being reappointed.

9 The term of office of a member appointed to fill a vacancy shall be the remaining term of office of his/her predecessor.

(Duties of Institutional Review Board)

Article 8

Institutional Review Board shall perform the following duties:

(1) Matters relating to planning and providing training and education on research ethics
(2) Matters relating to collection and dissemination of information on research ethics in Japan and abroad
(3) Matters relating to investigation of misconduct committed by researchers, etc.
(4) Other matters relating to research ethics

Chapter 3: Receiving Complaint

(Office Receiving Complaint)

Article 9

An office receiving complaint or consultation is set up in XX to respond to it quickly and appropriately.

(Procedures for receiving complaint)

Article 10

1 Anyone who believes that there is a doubt of misconduct in research activities may make a complaint to the complaint office by means of written document, facsimile, email, telephone or interview.

2 As a basic rule, a complaint shall be made identifying the name of the complainant, with clear identifications of name(s) of the researcher(s) or research group who have committed the misconduct in research activities, forms of misconduct in research activities and any other details of the case, and a rational reason for the doubt of misconduct.

3 The manager of the complaint office may, if finds it necessary, receive a complaint which does not identify the name of the complainant upon discussion with the Chairperson.

4 The complaint office shall, when it has received a complaint, promptly report thereof to the head of XX (name of the institution) and the Chairperson. The head of XX (name of the institution) shall notify the contents thereof to the head of office or department, etc. who are relevant to the complaint.

5 In the case where the complainant is not able to recognize whether or not the complaint has been received by the complainant office, such as when the complaint was submitted by post, the complaint office shall notify the complainant that it has received the complaint, unless the complaint was submitted without identifying the name of the complaint.

6 In the case where a doubt of misconduct has been pointed out by mass media such as newspapers or researchers' communities or via internet, etc. (limited to those which identify the case where name(s) of the researcher(s) or research group who have allegedly committed the misconduct in research activities,

forms of misconduct in research activities and any other details of the case), the Chairperson may handle it in the same manner as he/she handles an anonymous complaint.

(Consultation of Complaint)

Article 11

1 A person who believes that there is a doubt of misconduct in research activities and has concern about validity of complaint and/or procedures may consult the complaint office.

2 When the person consulted by the complaint office does not clarify his/her will to make a complaint, the complaint office shall, if it finds that the person's doubt is reasonable upon validation of the contents, confirm with the consulted person whether or not he/she has a will to make a complaint.

3 When the contents of consultation identify that misconduct in research activities is about to be committed or the consulted person is demanded to commit misconduct in research activities or the like, the consultation office shall report thereof to the head of XX (name of the institution) and the Chairperson.

4 Upon receipt of the report under Paragraph 3, the head of XX (name of the institution) or the Chairperson shall confirm the contents and, if finds that the doubt is reasonable, issue a warning to the persons relevant to the reported contents.

(Obligations of Staff Members of The Complaint Office)

Article 12

1 When receiving a complaint, staff members of the complaint office shall ensure protection of the complainant including secrets of the complainant.

2 The staff members of the complaint office shall, when receiving a complaint, use appropriate arrangements such as conducting an interview in a separate room if the complaint is made by means of an interview or providing measures for preventing other people from reading or listening the contents of the complaint if it is made by means of a written document, facsimile, email or telephone.

3 The provisions of previous two paragraphs shall apply mutatis mutandis to the consultation of a complaint.

Chapter 4: Procedures for Treating Concerned Persons

(Obligation to Protect Confidentiality)

Article 13

1 All persons who are involved in any operations under these Rules shall not divulge any secret which may have come to their knowledge in the performance of their duties. The same shall also apply after they have been relieved of their offices.

2 The head of XX (name of the institution) and the Chairperson shall ensure confidentiality of secrets including the complainant, the respondent, the contents of complaint, contents of investigations and progress of investigations, until when the investigation results are made public, so that these secrets will not be divulged outside the institution against will of the complainant and the respondent.

3 The head of XX (name of the institution) or the Chairperson may, in the event that information of the case of the complaint has been divulged outside the institution, upon approval of the complainant and the respondent, regardless whether the case is under investigation, make an official explanation on the case under investigation. However, the divulgence is due to the reason that is attributable to the complainant or

the respondent, approval of said complainant or respondent is not required.

4 The head of XX (name of the institution), the Chairperson or other concerned persons shall, when making a contact or notice to the complainant, the respondent, a cooperating individual or a concerned person, give considerations so that he/she will not infringe human rights, honor, privacy or the like of these people.

(Protection of Complainant)

Article 14

1 The head of office or department shall provide appropriate measures for prevent deterioration of workplace environment or discriminatory treatment against the complainant for the reason that he/she has made a complaint.

2 All persons who belong to XX (name of the institution) shall not treat disadvantageously the complainant for the reason that he/she has made the complaint.

3 The head of XX (name of the institution) may, if any person has treated the complainant disadvantageously, issue a sanction against the person in accordance with XX or any other relevant institutional rules.

4 The head of XX (name of the institution) shall not, unless it has been determined that a complaint is a bad faith complaint, fire, transfer, give disciplinary action, demote, pay cut or give any other disadvantageous treatments on the complainant simply because he/she has made a complaint.

(Protection of Respondent)

Article 15

1 No one who belongs to XX (name of the institution) shall give disadvantageous treatments on the respondent without a justifiable reason, simply because a complaint has been made against the respondent.

2 The head of XX (name of the institution) may, if finds that anyone has gave a disadvantageous treatment on the respondent without a justifiable reason, issue a sanction against the person in accordance with XX or any other relevant institutional rules.

3 The head of XX (name of the institution) shall not totally prohibit the respondent from carrying out research activities, fire, transfer, give disciplinary action, demote, pay cut or give any other disadvantageous treatments on the respondent without a justifiable reason, simply because a complaint has been made against him/her.

(Bad Faith Complaint)

Article 16

1 No one shall make a bad faith complaint. As used in these Rules, a bad faith complaint means a complaint that has been made based on a will solely directed to causing a damage on the respondent, such as for causing harm to the respondent or for obstructing the research carried out by the respondent, or for creating disadvantage for the organization that the respondent belongs to.

2 The head of XX (name of the institution) may, if a complaint has been determined to be a bad faith complaint, publicly announce the name of the complainant, give a disciplinary action and/or a criminal complaint or any other necessary measures

3 The head of XX (name of the institution) shall, upon taking a measure under the preceding paragraph, notify the contents thereof, etc. to the relevant funding agency and relevant government authorities.

Chapter 5: Investigation of Case

(Procedures of Preliminary Investigation)

Article 17

1 When a complaint under Article 10 has been made or when the Chairperson finds it necessary to conduct a preliminary investigation based on any other reasons, the Chairperson shall establish a Preliminary Investigation Board, and the Preliminary Investigation Board shall promptly conduct the preliminary investigation.

2 The Preliminary Investigation Board consists of three members who are designated by the Chairperson upon deliberation by the Institutional Review Board.

3 The Preliminary Investigation Board may request the persons who are subject to the preliminary investigation to submit relevant documents or any other written documents and the like which are necessary to conduct the preliminary investigation or respond to hearing, as appropriate.

4 The Preliminary Investigation Board may take measures for preserving relevant documents, laboratory notebooks, experimental references, etc. which can be used as evidence in the substantial investigation.

(Method of Preliminary Investigation)

Article 18

1 The Preliminary Investigation Board shall conduct a preliminary investigation on the possibility that the acts subject to the complaint took place, credibility of the rationale provided as a scientifically reasonable ground in the complaint, whether or not an investigation on the contents of complaint is warranted in the substantial investigation and any other matters that it finds necessary.

2 When conducting a preliminary investigation with respect to a manuscript which has been withdrawn before receiving the complaint, the Preliminary Investigation Board will, in the process of the preliminary investigation, also evaluate as to whether or not the case should be investigated in a substantial investigation as an issue of research misconduct, taking account of such matters as how and why the manuscript was withdrawn and any other relevant situations, and make a decision.

(Decision to Conduct Substantial Investigation, etc.)

Article 19

1 The Preliminary Investigation Board shall report the results of the preliminary investigation to the Institutional Review Board within 30 days from the date of receipt of the complaint or the date of receipt of instruction to conduct the preliminary investigation.

2 The Institutional Review Board shall, taking account of the results of the preliminary investigation, immediately decide whether to conduct a substantial investigation upon discussion.

3 The Institutional Review Board shall, when it has decided to conduct a substantial investigation, notify the complainant and the respondent that a substantial investigation will be conducted and request them to cooperate with the substantial investigation.

4 The Institutional Review Board shall, when it has decided not to conduct a substantial investigation, notify the complainant thereof with a reason why the substantial investigation will not be conducted. In this case, the Institutional Review Board shall preserve references, etc. relating to the preliminary investigation so that they can be disclosed upon request of the finding agency or the complainant.

5 The Institutional Review Board shall, when it has decided to conduct a substantial investigation, report the funding agency of the research funds of the relevant case and the relevant government authorities that a substantial investigation will be conducted.

(Establishment of Investigatory Board)

Article 20

1 The Institutional Review Board shall, when it has decided to conduct a substantial investigation, establish an Investigatory Board by a resolution at the same time as the decision.
2 The majority of the members of the Investigatory Board shall be external experts who do not belong to XX (name of the institution).
3 The members of the Investigatory Board shall be the following persons:
   (1) Member(s) of the Institutional Review Board who are designated by the Chairperson of the Institutional Review Board: X person(s)
   (2) Experts who are designated by the Chairperson after deliberation by the Institutional Review Board: X person(s)
   (3) External experts who have legal knowledge: X person(s)

(Notification of Substantial Investigation)

Article 21

1 The Institutional Review Board shall, when it has established an Investigatory Board, notify the complainant and the respondent of names of members of the Investigatory Board and their employers or offices.
2 The complainant or the respondent may, upon receipt of the notification under the previous paragraph, file an objection in writing on the members of the Investigatory Board to the Institutional Review Board within seven days from the date of receipt of said notification.
3 The Institutional Review Board shall, when an objection under the previous paragraph has been filed, review the contents of the objection and, when it determines that it is a valid claim, replace the members of the Investigatory Board subject to the objection and notify the complainant and the respondent thereof.

(Procedures of Substantial Investigation)

Article 22

1 The Investigatory Board shall commence the substantial investigation within 30 days from the date of decision to conduct the substantial investigation.
2 The Investigatory Board shall immediately notify the complainant and the respondent that the substantial investigation will be conducted and request them to cooperate with the investigation.
3 The Investigatory Board shall conduct the substantial investigation by scrutinizing papers, experimental or observational notebooks, raw data and other references relating to the research pointed out in the complaint and conducting a hearing of concerned people.
4 The Investigatory Board shall provide the respondent with an opportunity for explanation.
5 The Investigatory Board may request the respondent to prove reproducibility by conducting a same experiment, etc. Also, if the respondent voluntarily requests to conduct such an experiment, etc. and the Investigatory Board finds it necessary, the Investigatory Board will guarantee a necessary period and opportunity and the use of equipment for the experiment.

6 The complainant, the respondent and other persons who are involved in the complaint case shall be fully cooperative with the substantial investigation by the Investigatory Board, such as actively cooperating with the investigation and faithfully state the truth so that the investigation can be proceeded smoothly.

(Scope of Substantial Investigation)

Article 23

The scope of a substantial investigation may, in addition to the research activities subject to the complaint case, include other research projects of the respondent which are relevant to the substantial investigation, at the discretion of the Investigatory Board.

(Preservation of Evidence)

Article 24

1 The Investigatory Board shall, when conducting the substantial investigation, take measures for preserving references and any other relevant written documents which can be used as evidence relating to the research activities of the case subject to the complaint.
2 When the research institution where research activities of the case subject to the complaint took place is not XX (name of the institution), the Investigatory Board shall request the research institution to take measures for preserving references and any other relevant written documents which can be used as evidence relating to the research activities of the case subject to the complaint.
3 The Investigatory Board shall not restrict research activities of the respondent, unless it is necessary to do so for the measures under the preceding two paragraphs.

(Mid-term Report of Substantial Investigation)

Article 25

The Investigatory Board shall, if the funding agency which has distributed or took a measure for the budget of the research activities in question requests, submit a mid-term report of the substantial investigation to the funding agency even before the completion of the substantial investigation.

(Protection of Research or Technical Information in The Investigation)

Article 26

The Investigatory Board shall use a special care in carrying out the substantial investigation so that research or technical information subject to the investigation such as data and manuscripts before publication will not be disclosed beyond the extent that is just necessary for carrying out the investigation.

(Accountability for Doubt of Misconduct)

Article 27

1 In the substantial investigation carried out by the Investigatory Board, when the respondent intends to remove doubts over the research activities subject to the complaint, the respondent shall explain, under his/her own responsibility, that the research activities have been carried out in accordance with scientifically appropriate methods and procedures and the papers, etc. have been written based thereon using appropriate expressions, presenting scientific evidence that supports his/her explanation.
2 In the case of the preceding paragraph, if there is a need of conducting a same experiment, etc., the guarantee under Article 22, Paragraph 5 shall be given.

Chapter 6: Determination of Misconduct, etc.

(Procedures of Determination)

Article 28

1 The Investigatory Board shall complete documentation of the results of the investigation within 150 days from the date of commencement of the substantial investigation and make a determination as to whether or not misconduct took place, and, if it is determined that misconduct took place, shall further determine the details and maliciousness thereof, name(s) of person(s) involved in the misconduct, the degree of involvement of each person, the roles of authors of the manuscripts relating to the research activities being determined as misconduct in said manuscripts and in said research activities and any other necessary matters.

2 With respect to the period specified in the preceding paragraph, if there is a justifiable reason that makes determination within 150 days impossible, the Investigatory Board shall notify thereof with descriptions of the reason and an expected date of determination to the head of XX (name of the institution) and obtain approval thereof.

3 In the case where it is determined that misconduct did not take place, if it has been found that the reporting was bad faith through the investigation, the Investigatory Board shall make the determination of bad faith complaint at the same time.

4 When making the determination under the preceding paragraph, the complainant shall be given an opportunity for explanation.

5 The Investigatory Board shall, upon completion of the determination under Paragraph 1 or Paragraph 3 of this Article, immediately report the head of XX (name of the institution).

(Method of Determination)

Article 29

1 The Investigatory Board shall take into account the explanation given by the complainant and makes comprehensive evaluation of all evidence obtained by the investigation including physical or scientific evidence, testimonies and self-admission of the respondent, to determine whether or not misconduct took place.

2 The Investigatory Board may not determine that misconduct took place if the respondent's self-admission is the only evidence supporting the determination.

3 The Investigatory Board may, when a doubt that the misconduct took place cannot be reversed by the respondent's explanation and other pieces of evidence, determine that the misconduct took place. The same applies to the case where the respondent is unable to present sufficient evidence that reverses the doubt that the misconduct took place due to lack of basic elements which normally exist in research activities, such as lack of raw data, experimental or observational notebooks, test specimens or reagents and relevant documents which are in the range of mandatory storing period.

(Notification and Report of Investigation Results)

Article 30

1 The head of XX (name of the institution) shall promptly notify investigation results (including the determination) to the complainant, the respondent and person(s) other than the respondent who have been

determined to be involved in the misconduct in research activities. If the respondent belongs to an entity other than XX (name of the institution), said entity shall also be notified.

2 The head of XX (name of the institution) shall, in addition to the notification of the preceding paragraph, report the investigation results to the finding agency and the government authorities relevant to the case.

3 The head of XX (name of the institution) shall, in the case where a determination of bad faith complaint has been made, when the complainant belongs to an entity other than XX (name of the institution), also give a notification to said entity.

(Appeal)

Article 31

1 The respondent of the case being determined that misconduct in research activities took place may file an appeal to the Investigatory Board within 14 days from the date of notification of the results of the investigation. However, once an appeal is filed, another appeal based on the same reason cannot be filed even before the expiry of said period.

2 The complainant (including those who have been determined as making a bad faith complaint in the appeal proceedings initiated by the respondent) whose complaint has been determined to be bad faith may file an appeal against the determination, by applying mutatis mutandis Paragraph 1.

3 Review in the appeal proceedings will be handled by the Investigatory Board. If the review of the appeal requires a new determination based on expert knowledge, The head of XX (name of the institution) shall replace or add committee members or delegate the review to another body in place of the Investigatory Board; provided, however, that this does not apply to the case where the head of XX (name of the institution) finds there is no reasonable ground for requiring a change of the members of the Investigatory Board.

4 Article 20, Paragraphs 2 and 3 shall apply mutatis mutandis to the designation of the new members of the Investigatory Board under the preceding paragraph.

5 If the Investigatory Board determines that the appeal should be dismissed without the need of carrying out re-investigation of said case, it shall promptly report the head of XX (name of the institution) thereof, and the head of XX (name of the institution) will notify the appellant of said determination. In this case, if the Investigatory Board finds that the primary purpose of said appeal is to delay the conclusion of said case or to postpone the measures to be taken relating to a possible determination, the head of XX (name of the institution) shall also notify that a further appeal will not be received.

6 The Investigatory Board shall, when it has determined to carry out re-investigation in response to the appeal, immediately report thereof to the head of XX (name of the institution), and the head of XX (name of the institution) shall notify the decision to the appellant.

7 The head of XX (name of the institution) shall, upon receipt of an appeal from the respondent, give a notification to the complainant, or, upon receipt of an appeal from the complainant, give notification to the respondent, and also, give a notification to the finding agency and the government authorities relevant to the case. The same applies to the case where it has decided to dismiss the appeal or to carry out re-investigation.

(Re-investigation)

Article 32

1 When a determination to carry out re-investigation has been made regarding the appeal under the

preceding Article, the Investigatory Board shall request the appellant to submit reference materials that the appellant believes sufficient evidence to overturn the results of the earlier investigation and to cooperate with the re-investigation for prompt resolution of the case.

2 If the appellant is not cooperative, the Investigatory Board may decide to terminate the procedure without conducting re-investigation. In that case, the Investigatory Board shall immediately report the head of XX (name of the institution) of the decision, and the head of XX (name of the institution) will notify the appellant of said decision.

3 When the Investigatory Board has started re-investigation, it shall decide, within a period of 50 days from the date of commencement, whether or not it will overturn the results of the earlier investigation, and immediately report the results thereof to the head of XX (name of the institution). However, if there is a justifiable reason that makes it impossible to make a decision whether to overturn the investigation results within 50 days, the Investigatory Board shall notify thereof with a description of the reason and an expected date of decision to the head of XX (name of the institution) and obtain approval thereof.

4 The head of XX (name of the institution) shall promptly notify the results of the re-investigation proceedings based on the report under Paragraph 2 or 3 of this Article to the complainant, the respondent and person(s) other than the respondent who have been determined to be involved in the misconduct in research activities. If the respondent belongs to an entity other than XX (name of the institution), a notification shall also be given to said entity. In addition, the finding agency and the government authorities relevant to the case shall be reported.

(Public Announcement of Results of Investigation)

Article 33

1 The head of XX (name of the institution) shall, when a determination that misconduct in research activities took place has been made, promptly make public the investigation results.

2 Contents to be made public under the preceding paragraph shall include name(s) and office(s) of the person(s) involved in the misconduct in research activities, descriptions of the misconduct in research activities, descriptions of the measure(s) that have been taken by XX (name of the institution) by that time, names and offices of the members of the Investigatory Board, methods and procedures of the investigations, etc.

3 Notwithstanding the preceding paragraph, when the papers, etc. that have been determined to be misconduct in research activities had already been withdrawn before the receipt of the complaint, the name(s) and office(s) of the person(s) who were involved in the misconduct may not be disclosed.

4 When a determination that misconduct in research activities did not take place has been made, the investigation results may not be made public. However, the investigation results will be made public when it is found that recovery of honor of the respondent is necessary, when information of the case under investigation was divulged outside the institution, or when an unintentional mistake or a mistake that is not caused by gross negligence of basic duty of care as a researcher was found in a research paper, etc.

5 Contents to be made public in the case of the proviso of the preceding paragraph shall include descriptions that misconduct in research activities did not take place and there was an unintentional mistake or a mistake that was not caused by gross negligence of basic duty of care as a researcher, and descriptions of the name and office of the respondent, names and offices of the members of the Investigatory Board, methods and procedures of the investigations, etc.

6 The head of XX (name of the institution) shall, when it has been determined that a bad faith complaint

was made, make public the name and office of the complainant, the reason why the determination of a bad faith complaint has been made, names and offices of the members of the Investigatory Board, methods and procedures of the investigations, etc.

Chapter 7: Measures and Sanctions

(Temporary Measure during Substantial Investigation)

Article 34

1 The head of XX (name of the institution) may provide a necessary measures such as temporal suspension of payment of the research funds subject to the complaint to the respondent, for a period between when a decision to conduct a substantial investigation is made and when the head of XX (name of the institution) receives a report of the investigation results from the Investigatory Board.

2 The head of XX (name of the institution) shall, upon request of the finding agency to terminate the payment of the research funds relevant to the respondent, etc., provide measures in response to the request.

(Prohibition to Use Research Funds)

Article 35

The head of XX (name of the institution) shall order a person who has been determined to be involved in the misconduct in research activities, a person who has been determined to be materially responsible for the contents of the paper, etc. being determined to be the misconduct in research activities, and a person who has been determined to be responsible for the use of a part of or the whole of the research funds (hereinafter, "determined person") to immediately stop using the research funds.

(Recommendation to Withdraw Submitted Manuscript, etc.)

Article 36

1 The head of XX (name of the institution) shall immediately make recommendation to the determined person to withdraw or correct the paper, etc. being determined to be the misconduct in research activities or take other measures.

2 The determined person shall express his/her will to the head of XX (name of the institution) as to whether or not he/she accepts the recommendation within 14 days from the date of receipt of the recommendation under the preceding paragraph.

3 The head of XX (name of the institution) shall, when the determined person does not accept the recommendation under Paragraph 1, make public the fact thereof.

(Cancellation of Measures, etc.)

Article 37

1 The head of XX (name of the institution) shall, when it has been determined that misconduct in research activities did not take place, cancel the measures being taken in the substantial investigation, such as suspension of payment of the research funds. Also, the measure of preserving evidence shall be cancelled promptly after the lapse of a period for appeal without lodgment of an appeal, or after the result of review in the appeal proceedings has become definite.

2 The head of XX (name of the institution) shall provide measures to restore honor of the person who has

been determined that he/she did not commit misconduct in research activities and to prevent any disadvantage on him/her.

(Sanction)

Article 38

1 The head of XX (name of the institution) shall, when it has been determined that misconduct in research activities took place as a result of the substantial investigation, apply a sanction to the person(s) who were involved in the misconduct in research activities, in accordance with laws, employment rules for staff members and any other relevant internal rules.

2 The head of XX (name of the institution) shall, when the sanction under the preceding paragraph has been applied, notify the details of the sanction, etc. to the finding agency and the government authorities relevant to the case.

(Remedial Measure, etc.)

Article 39

1 The Institutional Review Board shall, when it has been determined that misconduct in research activities took place as a result of the substantial investigation, promptly make recommendation to the head of XX (name of the institution) to provide a remedial measure, recurrence prevention measure, or any other necessary measures for improving the environment (hereinafter, "remedial measures, etc.").

2 The head of XX (name of the institution) shall, based on the recommendation under the preceding paragraph, issue an order to the head of office or department relevant to the case to provide remedial measures, etc. Also, the head of XX (name of the institution) shall provide remedial measures, etc. in the entirety of XX (name of the institution), as appropriate.

3 The head of XX (name of the institution) shall report contents of the remedial measures, etc. being provided under Paragraph 2 to the finding agency and MEXT and other relevant government authorities.

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<Reference 1> Deliberation request from MEXT

26-MEXT-Science No. 161
July 24, 2014

To: Mr. Takashi Ohnishi, President of the Science Council of Japan

From: Nobuaki Kawakami, Director-General, Science and Technology Policy Bureau, Ministry of Education, Culture, Sports, Science and Technology

Deliberation concerning responses, etc. to misconduct in research activities (Request)

MEXT has published the "Guidelines for Providing Appropriate Responses to Misconduct in Research Activities" (Draft) on July 3, 2014, which are currently under public inspection. Upon receipt of public comments, we will decide the new Guidelines around the end of August 2014 to apply from April 2015.

In this connection, concerning the application of the new Guidelines, we would like to request that the following matters be discussed in your Council consisting of experts in various academic disciplines.

In addition, as we are planning to apply the new Guidelines from April 2015, we would be grateful if we could receive your reply by the middle of March 2015.

Note

1 Period and method of storing experimental data, etc. (taking account of characteristics of research fields)

2 Basic duty of care as a researcher

3 Scope of misconduct other than Specified Misconduct (fabrication, falsification and plagiarism) (such as duplicate submission and how to address the issue of authorship)

4 Reference standard for research ethics education

5 Model internal rules of universities relating to responses to misconduct

6 Other matters for promoting research integrity

<Reference 2> Examples of characteristics concerning storage of research references, etc. in different disciplines

For reference, examples of characteristics of research references and specimens and conditions of storage and archiving in several different disciplines are given as follows:

○Life science:

When storing "biological specimens" and "materials isolated or extracted from biological specimens", conditions concerning storage, namely, in what forms they are stored, are given depending on their characteristics and expected future use. Before storing samples, etc. they may be subjected to drying treatment or immersed in liquid for storage. Also, common practice for tissues and cells or "materials isolated or extracted from biological specimens" are storing them in a frozen state using liquid nitrogen. However, to store a large amount of specimens, it will require huge costs. In addition, measures required in connection with biohazard are taken in accordance with applicable regulatory standards.

○Substance and Material Science:

When it comes to the storage of stable substances, securing a storage space for specimens is the only issue. However, some of the substances having certain characteristics cannot be stored in the first place, and storage conditions may be given on some other substances. For example, *in situ* is essential for some of the research subjects in this area, such as nanomaterials on the surface, as these specimens are prepared in a ultrahigh vacuum condition and clean state can be maintained only for a very short period of time. In general, since a material phase in a non-equilibrium state is relaxed with the passage of time, it requires such a technique of preserving in an extremely low temperature in order to inhibit qualitative change of specimens. Also, to store reactive substances (e.g., substances which are reactive with oxygen or moisture in air), depending on the level of reactivity and the length of a storage period, they need to be stored in a desiccator or an arrangement of inert atmosphere or vacuum lock will be required. In addition, storage of specimens falling under radioactive materials or poisonous or deleterious substances must observe applicable regulatory standards.

○Relationship between open science and open data:

In such areas as high-energy physics, astronomy, earth and planetary science, environmental science, genome science and healthcare, experimental and observational data are often provided openly via the internet as common assets, so that researchers can freely access and analyze them. Such open data are provided in a different context from the issue of research integrity which is at issue here, however, these movements draw our attention, as they have certain relevance with organized storage and usage of scientific data and development of a technique relating to information science for handling an enormous quantity of electronic information.

<Reference 3> Deliberation history

2014:

Jul. 26:	A deliberation request to the President of the Science Council of Japan from Director-General, Science and Technology Policy Bureau of MEXT
Aug. 7:	Subcommittee on Research Integrity (1st meeting) ○Chairperson chosen by the vote of the members, etc. ○Deliberation request from MEXT ○Role of this subcommittee, how to proceed with the future meeting
Aug. 28:	Subcommittee on Research Integrity (2nd meeting) ○Response to the deliberation request from MEXT (Deliberation mainly on Items 2 and 3 in the request) ○How to proceed with the future meeting
Sep. 26:	Subcommittee on Research Integrity (3rd meeting) ○Responses to the deliberation request from MEXT ○How to proceed with the future meeting
Oct. 14:	Subcommittee on Research Integrity (4th meeting) ○A draft Response to the deliberation request from MEXT
Nov. 14:	Subcommittee on Research Integrity (5th meeting) ○A draft Response to the deliberation request from MEXT
Dec. 19:	Subcommittee on Research Integrity (6th meeting) ○A draft Response to the deliberation request from MEXT

2015:

Feb. 5:	Subcommittee on Research Integrity (7th meeting) ○Approval of the draft Response "Promoting Integrity in Scientific Research"
Feb. 5:	The academic forum "Promoting Integrity in Scientific Research - Preparing for the application of the Guidelines for Providing Appropriate Responses to Misconduct in Research Activities -" (at Science Council of Japan Hall)
Feb. 27:	Exploratory Committee on Sound Scientific Research (1st meeting) ○Approval of the Response "Promoting Integrity in Scientific Research"