

Handbook for the Prevention of Research Misconduct



TOKYO MEDICAL AND DENTAL UNIVERSITY

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Introduction

Embarked upon with a view to preventing misconduct in research, including data fabrication and the disregard of matters concerning ethical compliance, this handbook has been written as far as possible in an easily understood format to build awareness of the nature of such misconduct. Its target readership includes this university's teaching staff and graduate students.

In recent years, a spate of incidents of research misconduct (including clinical research not in compliance with ethical principles or guidelines, data fabrication, and the misuse of research funds) has come to light in Japan. There have thus been ever stronger demands for educational research institutions to ensure thorough awareness of compliance and the proper use of research funds. The practicalities of the problem are, however, that there are inadequacies in the rules used among teaching staff, past habitual methods are being blindly adhered to and, even though they can possibly be said to have been unintentional, there have been constant cases recognized as misconduct due to such reasons as the complexities of administrative procedures. In response, we have therefore produced this handbook as part of our efforts to prevent misconduct in research activities.

Please note, however, that this handbook sets out the basic rules and other information and is not intended to be applicable to all systems. Especially in the case of research funds, please use this handbook in conjunction with verification of the rules and other factors that should be complied with under the funding system concerned.

I would like to take this opportunity to ask that all those involved keep in mind that the scientific community's autonomy is built on public trust and on a mandate from society. Please maintain a clear understanding of the social mission that educational research activities fulfill so that we can make increasing efforts in the development of our research activities.

Yasuyuki Yoshizawa
Tokyo Medical and Dental University, President



1. Vision

“Creating Professionals with Knowledge and Humanity, Thereby Contributing to People’s Well-Being”

Tokyo Medical and Dental University (TMDU) is located in the Yushima/Shoheizaka area, which is considered the sacred birthplace of scholarship and learning in Japan. As a comprehensive medical university, TMDU cultivates “professionals with knowledge and humanity” who embark on a lifetime of service, advancing the health and social welfare of people in the local community and spreading their wings to do the same in other communities across the globe.

● Education

We foster independent, creative, pioneering, and internationally minded leaders who have a broad range of knowledge, deep humanity, and a strong sense of ethics.

● Research

We seek to gather wisdom from every field of learning in order to advance interdisciplinary and cutting-edge research that will ultimately contribute to the greater public good.

● Medical Care

We provide high-quality medical and dental care that nurtures the heart, mind, and body, not only for the local community, but also for the world.

Guided by these basic principles, all TMDU students, faculty members, staff, and alumni endeavor to serve the diverse communities in which they work and study.

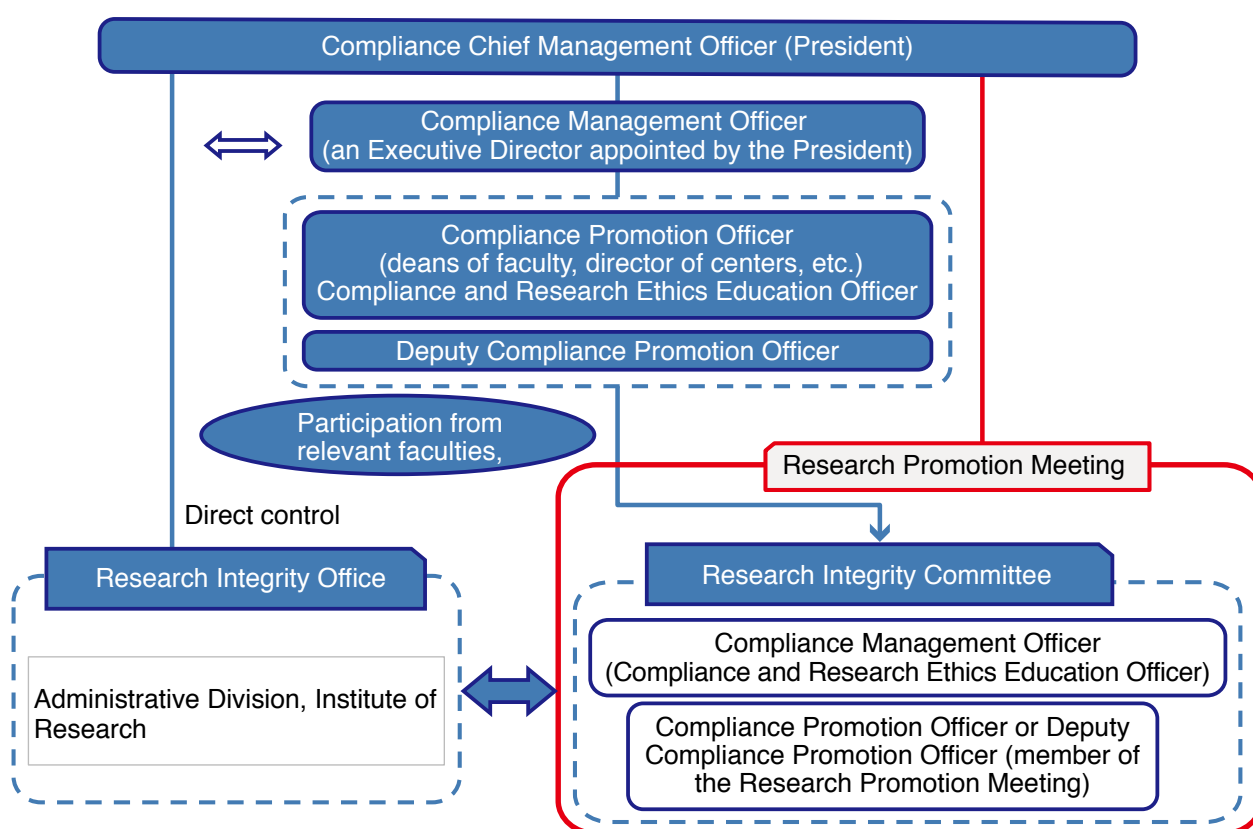


2. Obligations of University Staff and Graduate Students

- While maintaining high ethical standards and utilizing research funds in an appropriate manner, all university staff involved in research activities, including teaching staff, researchers, administrative staff and research support personnel (hereinafter “university staff”) as well as graduate students must not engage in any form of misconduct in the course of their research activities.
- Teaching staff, researchers, graduate students, etc. must record and save information regarding research proposals and plans as well as the research results. The latter must be made public.
- In conducting research and administering research funds, university staff, graduate students, etc. must obey the instructions of the person(s) responsible for conducting said research.
- University staff, graduate students, etc. must participate in education/training programs that cover the prevention of misconduct in research activities. These programs are conducted by the Compliance Management Officer (Executive Director of Research and International Cooperation in charge of industry-academia-government collaboration/research and development) and the Compliance Promotion Officer.
- University staff, graduate students, etc. must cooperate with any investigation into misconduct in research, as defined in the *Tokyo Medical and Dental University Research Misconduct Prevention Rules* (Rule 7, January 22, 2015, hereinafter “the Misconduct Prevention Rules”).
- In addition to the Misconduct Prevention Rules, all concerned must remain in thorough compliance with the stipulations contained in *Tokyo Medical and Dental University Research Misconduct Prevention Plan* (revised September 30, 2015).
- With regard to the ethical behavior of researchers, all concerned must remain in thorough compliance with the stipulations contained in the *Tokyo Medical and Dental University Code of Conduct Regarding Research Activities* (enacted October 16, 2007, revised October 1, 2014).

3. System for Taking Responsibility in Preventing Misconduct

Under the terms of the Misconduct Prevention Rules, the university president is deemed the **Compliance Chief Management Officer** for all research activities conducted at this university. An executive director designated by the president is named the **Compliance Management Officer**, and the deans of faculty, directors of centers, etc. are considered **Compliance Promotion Officers**. These officers enact and promote measures to prevent misconduct and deal with misconduct should it occur.



Note: The heads of the centers within the Institute of Global Affairs and the Institute of Information Technology, etc. do not attend Misconduct Prevention Project Promotion Committee meetings. It is assumed, however, that they will maintain close ties with the committee.

Under the direction of Compliance Management Officer, the compliance promotion officers cover wide responsibilities in that they:

- (1) Implement measures to prevent research misconduct in the respective schools, research institutes, centers, etc. under their supervision, while confirming and submitting reports on the status of implementation of those measures to the Compliance Management Officer.
- (2) Promote, oversee and observe the progress of compliance and research ethics training (such as training concerning rules for using research funds and the responsibility associated with that use, the code of ethics researchers are expected to follow, the kinds of behavior constituting misconduct, etc.) for all parties involved in research activities within their college, center, etc. in order to prevent misconduct.
- (3) Monitor whether all parties in their respective colleges, centers, etc. are conducting research appropriately, and when necessary, provide guidance on any areas in need of improvement.

(Article 4, Paragraph 5 of the Misconduct Prevention Rules)



4. Misconduct in Research

(1) Specific Types of Misconduct

Misconduct in research can be broadly classified into the following four categories:

Fabrication

Invention of non-existent data, research findings, etc.

Alteration

Manipulation of research materials, equipment or processes to create data or findings that are not accurately represented in the research

Plagiarism

Misappropriation of ideas, analysis/analytic methodology, data, research findings, theses or terminology from another researcher without the concerned party's consent or appropriate citations

Misuse of research funds

Using research funds for purposes other than those specified, either intentionally or through gross negligence; using or accounting for research funds in a manner that violates the details or conditions attached to the funding grant, or that conflicts with university regulations (e.g., billing for fraudulent compensation/wages or travel expenses, deposits paid to vendors for fictitious purchases, etc.)

The discovery of these kinds of misconduct can lead to the revision or retraction of theses, the forced return of research funds, restrictions on funding application eligibility, disciplinary action and even criminal prosecution.

(2) Other Misconduct

Duplicate submissions of theses

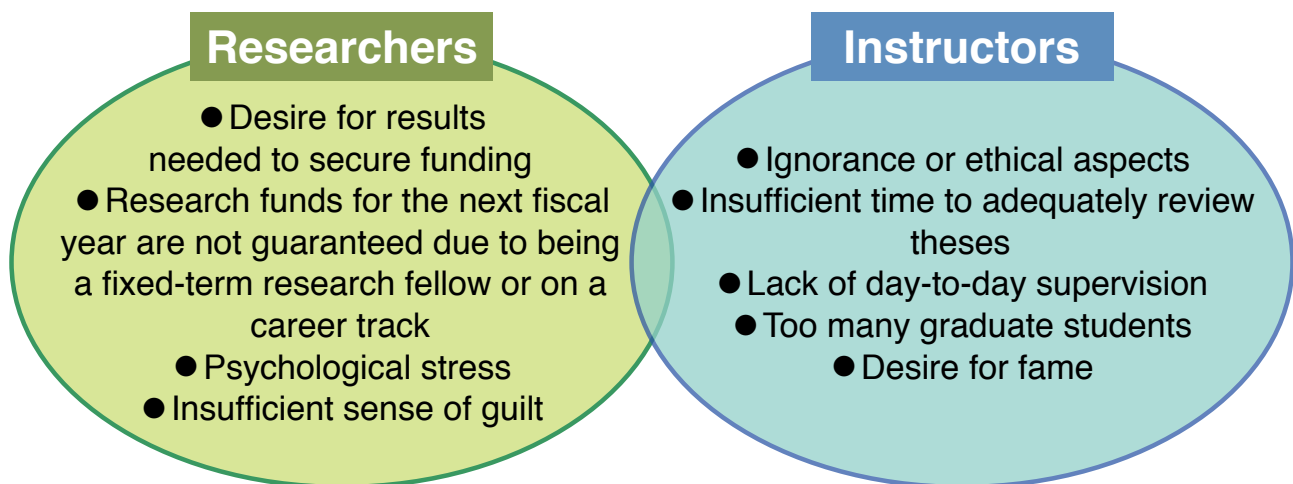
The submission of a thesis substantively identical to a thesis already published or submitted to another academic journal

Inappropriate authorship

The submission of a thesis without appropriate disclosure of the document's authors

Should the president, in his capacity as Compliance Chief Management Officer, deem them as having been committed with malicious intent, such cases may be treated as misconduct.

(3) Why Does Misconduct Occur?



Bearing in mind the important responsibilities that research related to medicine and dentistry bears in contributing directly to human health and welfare, it has become essential for each researcher to remain aware of the need for transparency and accountability under the highest ethical standards. At THDU, we believe that preventing misconduct in research also serves to safeguard the University's teaching staff and researchers. Consequently, believing prevention to be in the interests of science and academia, we are making the following efforts to that end.

1. Enhancing/Increasing Awareness of Research Ethics Education

Compliance and research ethics education geared toward university staff as part of faculty development (FD)

Lecture attendance within the initial research programs of graduate schools

This course is a requisite of the master's degree program credit course in the doctoral degree program

Attendance at e-learning (compliance and research ethics education) and submission of a written pledge

Please refer to pages 31,32 of this handbook.

2. Management of Research Data in Laboratories and Elimination of Closed-Door Policies

Obligation to store research data, notes and other materials for a 10-year period

Multiple advisor system for graduate students in the doctoral degree program

Cultivation of researcher ethics

3. Rigorous Response to Cases of Research Misconduct

We discourage any inclination toward involvement by having adopted a strict, no tolerance attitude with regard to research misconduct.

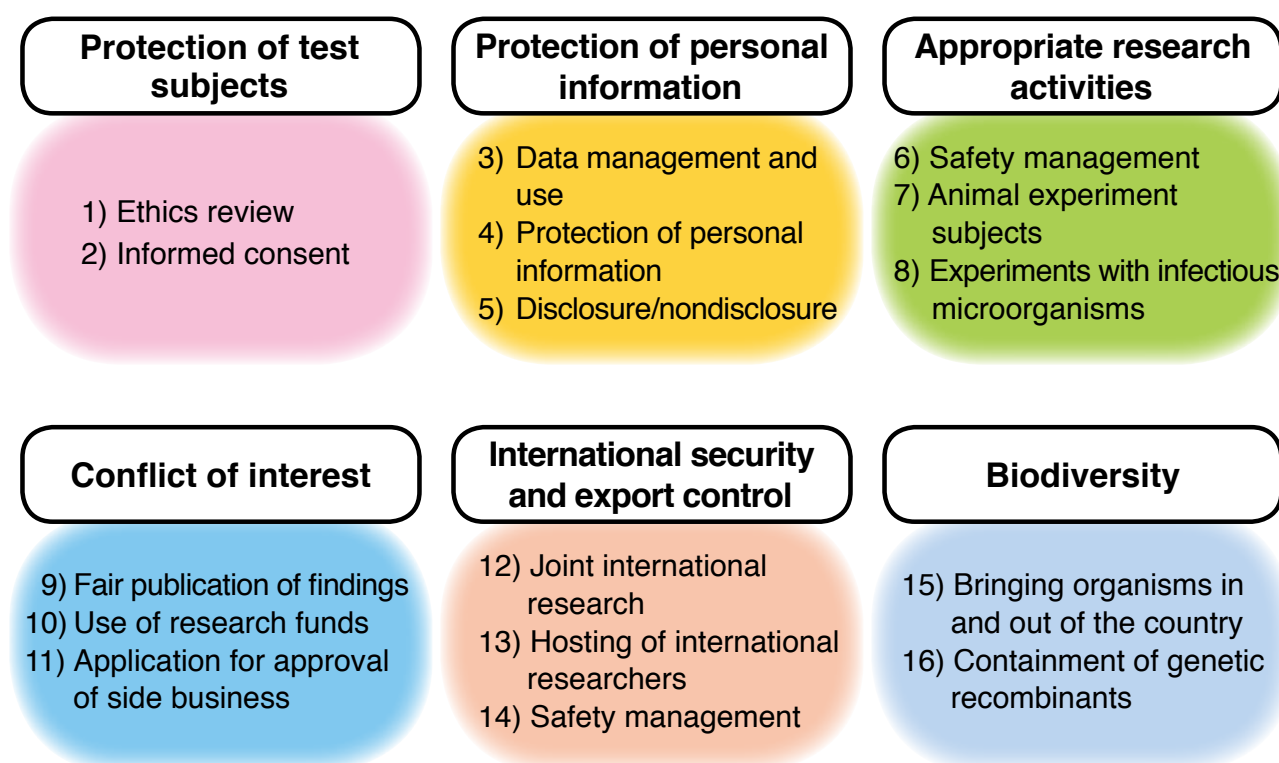
4. Protection of Whistleblowers and Discouragement of Misconduct Reports Submitted with Malicious Intent

Status of reports posted on TMDU homepage

Please refer to page 17 of this handbook.

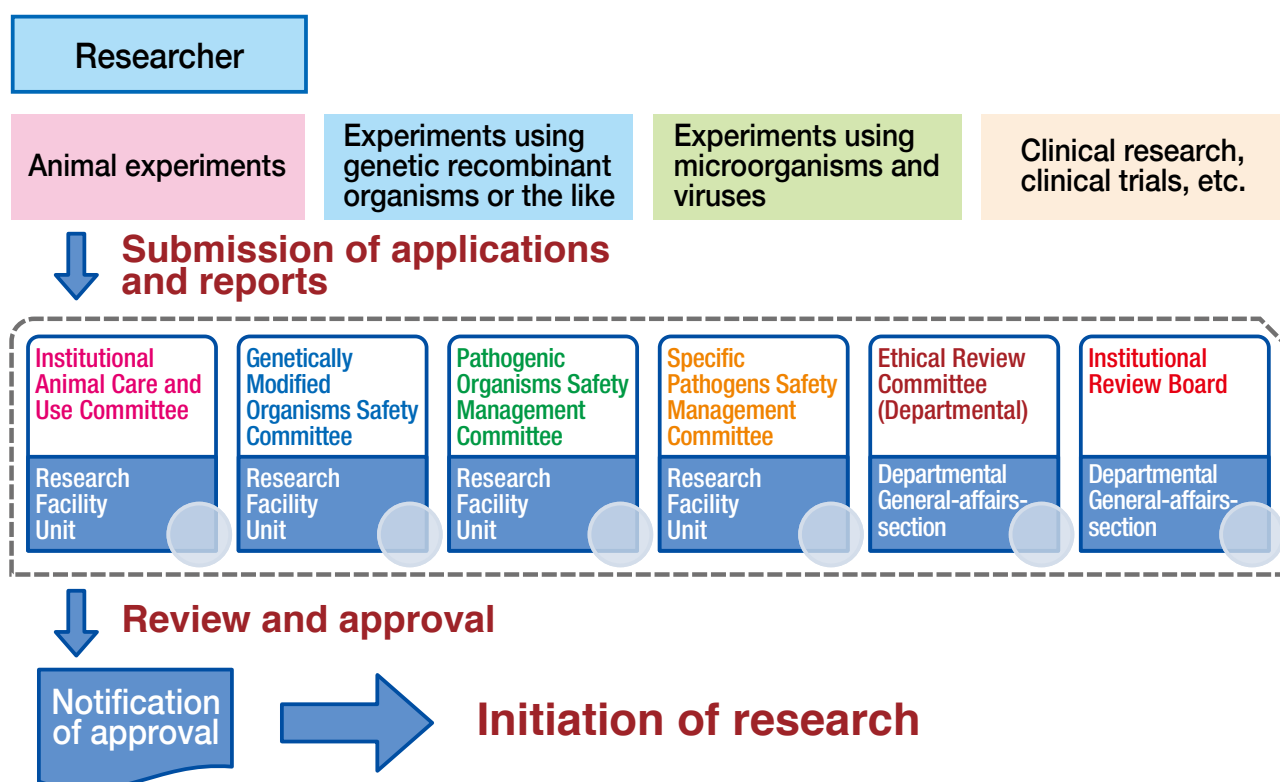
5. Ethical Issues and Misconduct That Arise during Medical and Dental Research

(1) Various Ethical Issues That Arise during Medical and Dental Research



Each teaching staff member and researcher needs to remain fully aware of the above points. Any action taken that contravenes them will be regarded as misconduct. For that reason, in addition to its Framework for Safe and Appropriate Experiments and, for research into security export controls, confidential information management, conflicts of interest, and research on humans (clinical research), its Framework for Research Ethics Evaluation, TMDU has set out structures for conflicts of interest relating to clinical research.

(2) Framework for Safe and Appropriate Research



- All university staff and graduate students concerned must attend workshops (education and training at the Center for Experimental Animals, research ethics workshops, training courses in safe and appropriate research) and receive a certificate number confirming workshop attendance.

Workshops	Period
Education and training at the Center for Experimental Animals	Every three years
Training course in safe and appropriate research	
Research ethics workshop	
Radioisotope(RI)-handling course	Every year

Note: Conducting research without the proper permits, reports and qualifications is regarded as research misconduct, and a researcher who does so may be subject to disciplinary action.

- The “safe handling workshop for radioisotope handlers (hereinafter “RI handlers”) is held every April and October. RI handlers must also undergo the “medical exam for persons engaged in radiation-related activities” at the Health Administration Center as a way to maintain health and safety. Please check for notifications regularly.
- The Office for Research Safety Management conducts safety management planning and coordination for each category of experiments to ensure that researchers conduct their research activities in a safe and appropriate manner.
- Depending on the experiment, multiple applications and material transfer agreements (MTAs) may be required. The Office for Research Safety and Management can answer all sorts of questions regarding safe and appropriate research by e-mail (using the question form). Please refer to page 25 of this handbook for more information regarding MTAs.

(3) System for Research Ethics Reviews of Medical Research on Humans

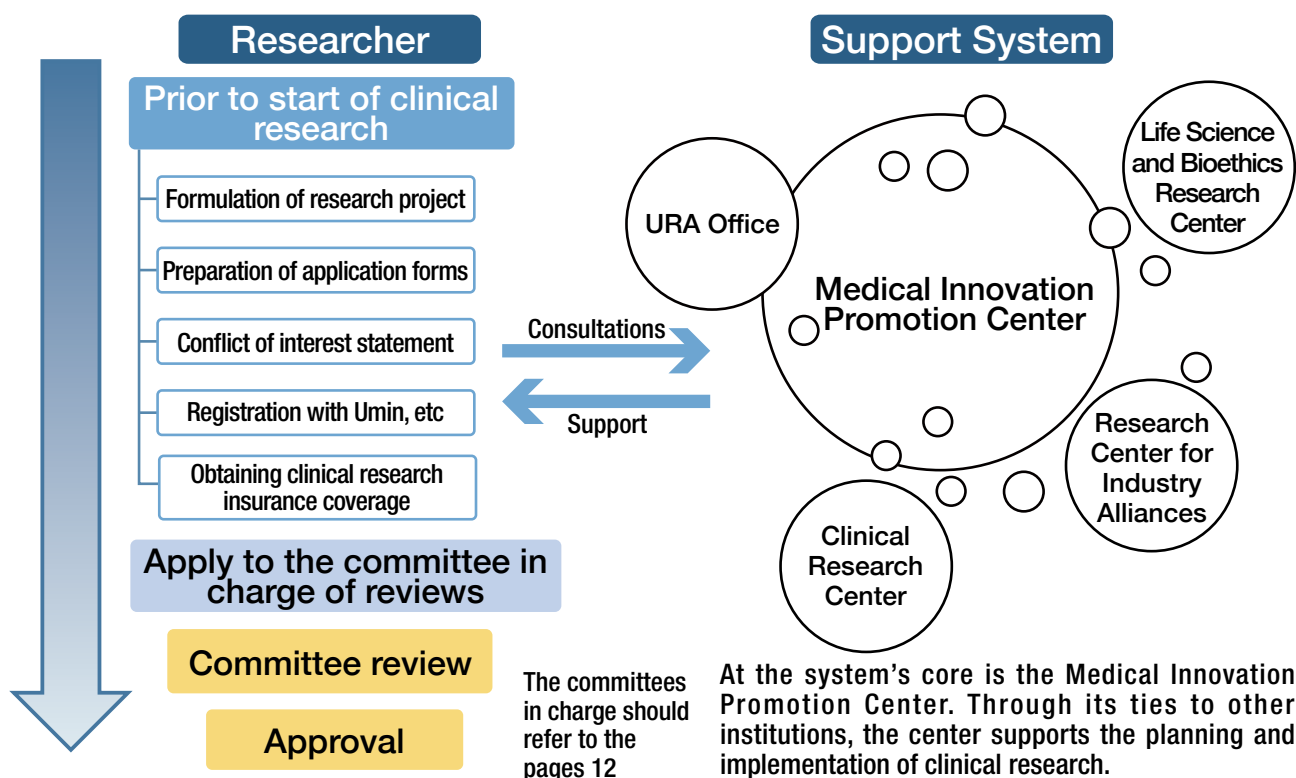
Research class	Content and subject of research		Applicable guidelines, etc.	Review committee		Place to apply at (provisional)
Clinical trial	Research regarding the approval of pharmaceuticals, medical equipment, regenerative therapies and other products		Good Clinical Practice	Institutional Review Board		(Medical Hospital) Clinical Research Center
Intervention studies (research that includes actions that exceed the breadth of normal medical care)	Specified Clinical Trials		Clinical Trials Act	The Certified Review Board		
	Research that includes the following actions in pursuit of research goals: ● Administration of drugs ◆ Approved drugs ◆ Unapproved drugs ◆ Off-label uses ● Puncture, incision, radiation exposure ● Questioning that touches on emotional trauma (including advanced medical treatment)		Ethical principles concerning medical research with human subjects	※Clinical Research Review Board (provisional)		
	Gene therapy research	Other than ex vivo	Gene therapy research principles	Designated and Regenerative Medicine Committee Clinical Research Review Board (provisional)		
		Ex vivo	Act on the Safety of Regenerative Medicine			
	Research in regenerative medicine					
	Noninvasive research: ● External diagnostic drugs ● Diet and exercise treatments, etc. Minimally invasive research (examples of minimal invasion) ● Tests comparable to those administered in normal check-ups ● Simple MRIs ● Simple anonymous questionnaires, etc.		Ethical principles concerning medical research with human subjects	Ethical Review Committee (Faculty of Medicine, Faculty of Dentistry, College of Liberal Arts and Sciences, Institute of Biomaterials and Bioengineering, Medical Research Institute) Note: In the case of joint research within the university, both committees will review the research.		
Observational research	Medical information, etc.					
Field research	Epidemiological surveys Questionnaire surveys					
Human genome/ gene analysis research	Research including the human genome or gene analysis		Human genome/gene analysis ethics principles	Human Genetic Research Ethics Committee		

With few exceptions, research projects that will involve clinical research must undergo an ethics review before research begins. The ethics review cannot be undertaken after research has begun or after research has been completed.

The Ethical Review Committee determines whether the submitted research program is suitable from both an ethical and scientific standpoint.

※As the Clinical Trials Act went into force on April 1, 2018, all specified clinical trials are subject to review by the Certified Review Board.

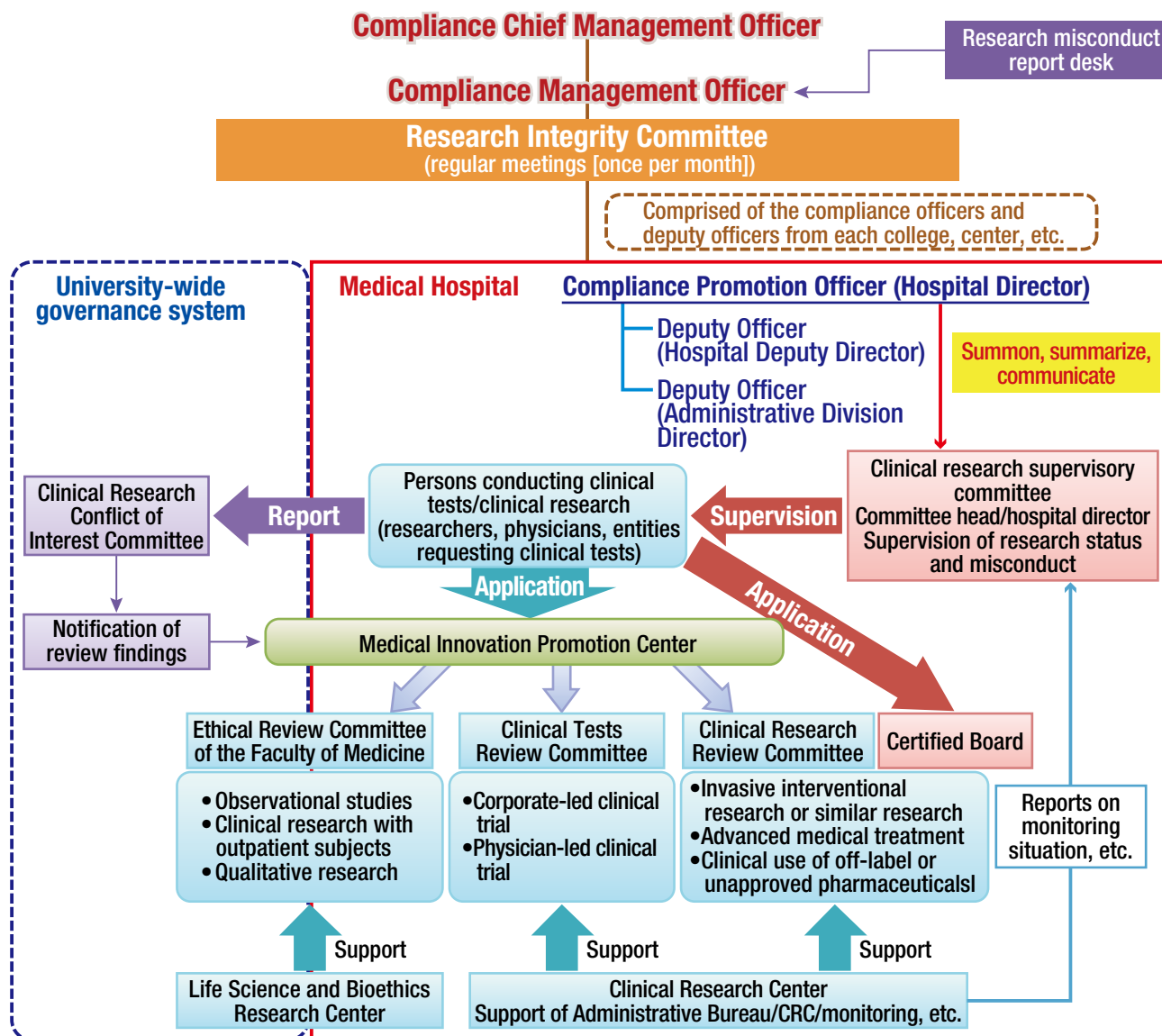
(4) Various Types of Application Procedures in Clinical Research (Support Systems)



Even clinical research for which informed consent seems unnecessary must undergo an ethics review. However, clinical case reports (case reports) released with the patient's consent do not require an ethics review.

(5) Governance System for Clinical Research (Medical Hospital)

The Medical Hospital has a governance system in place for the operation of clinical trials and clinical research, which falls under the university-wide governance system of the Research Integrity Committee and other committees.



※As specified in the Clinical Trials Act regarding conflict of interest management for specified clinical trials, it is required that a standard for the management of conflict of interest is established, a management plan is developed for overall conflict of interest in the study, and the initial plan submitted to the Certified Review Board, and the like.



6. Environmental Safety Office

(1) Overview and Tasks of the Environmental Safety Office

On a uniform, university-wide scale, this office manages the acquisition, storage, use and disposal of chemical substances, including toxic and hazardous substances.

Tasks of the Environmental Safety Office

Supervision of chemical substances or the like

- Training based on manual for creating database of chemical substances
- Listing stock and storage locations of chemical substances
- Tracking amounts of chemical substances used
- Regular inspection and guidance regarding management of chemical substances

Education regarding the handling of chemical substances or the like

- Training based on “Manual for Handling Toxic and Hazardous Materials”
- Inspection and guidance regarding usage records for toxins, hazardous materials and SDS
- Guidance regarding exceeding designated amounts of dangerous materials (Fire Service Act)

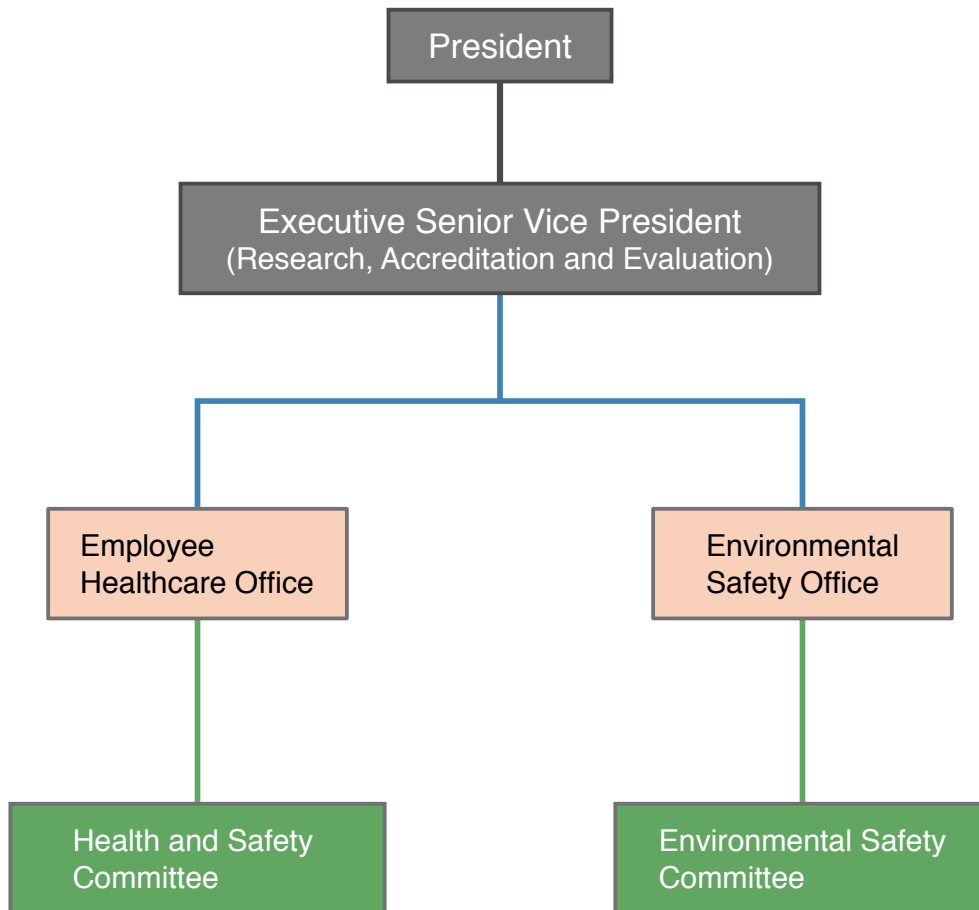
Education regarding the handling of waste from experiments

- Training based on the “Manual for Control of Liquid Waste, etc.”
- Transporting liquid waste or waste pharmaceuticals outside of the university
- Identification and disposal of unclaimed materials of unknown ownership
- Guidance on emitters that exceed effluent standards

Disaster prevention measures for chemical substances

- Receiving reports of emergency measures taken regarding chemical substances
- Gathering information regarding chemical substance incidents
- Sharing information from chemical substance stock lists with departments related to crisis control

Relationships between the various committees and the Environmental Safety Office



Inquiries:

Environmental Safety Office:

Ext. 5916

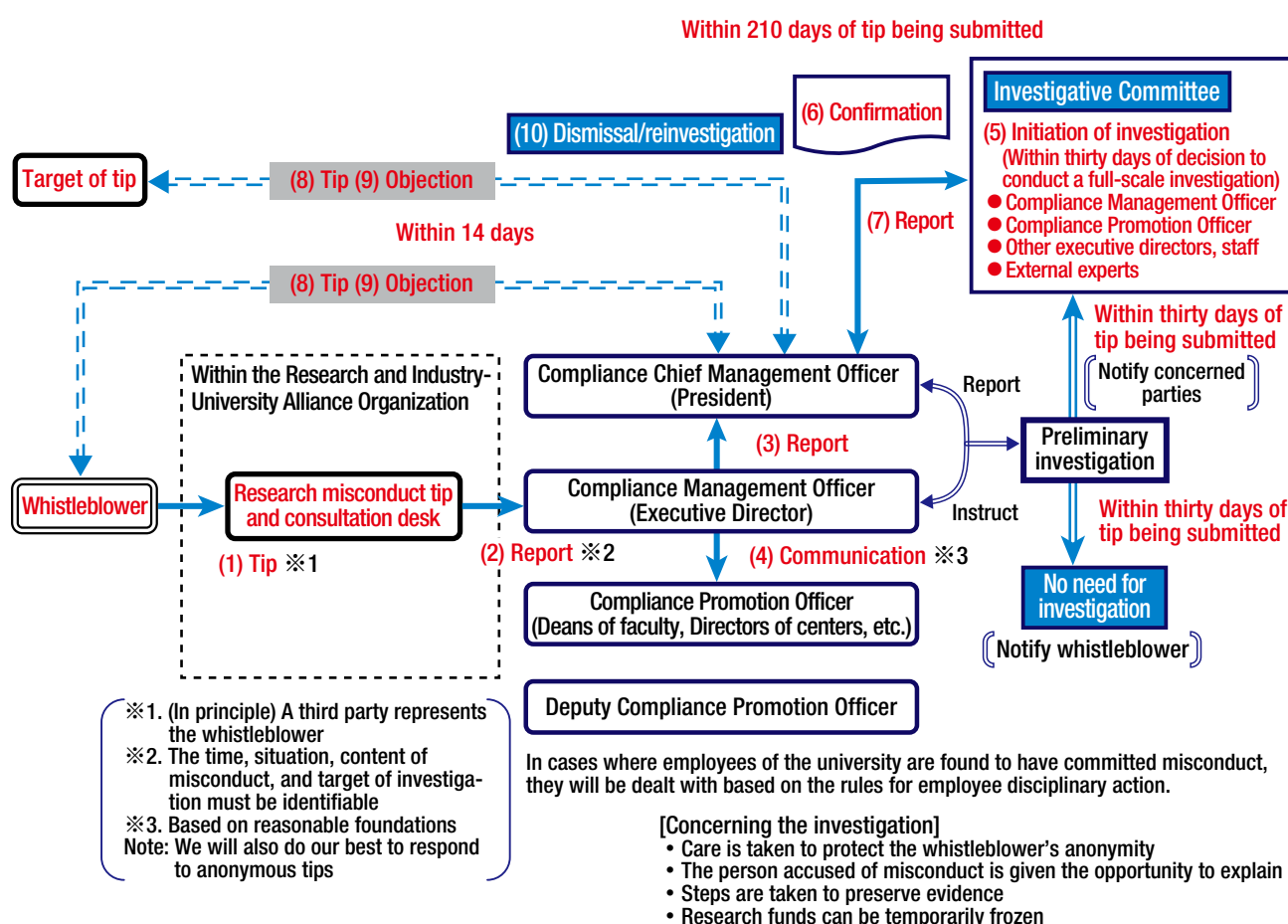
E-mail: kankyo.adm@tmd.ac.jp

7. Responses to Cases of Misconduct

(1) Procedures for dealing with suspicions of misconduct

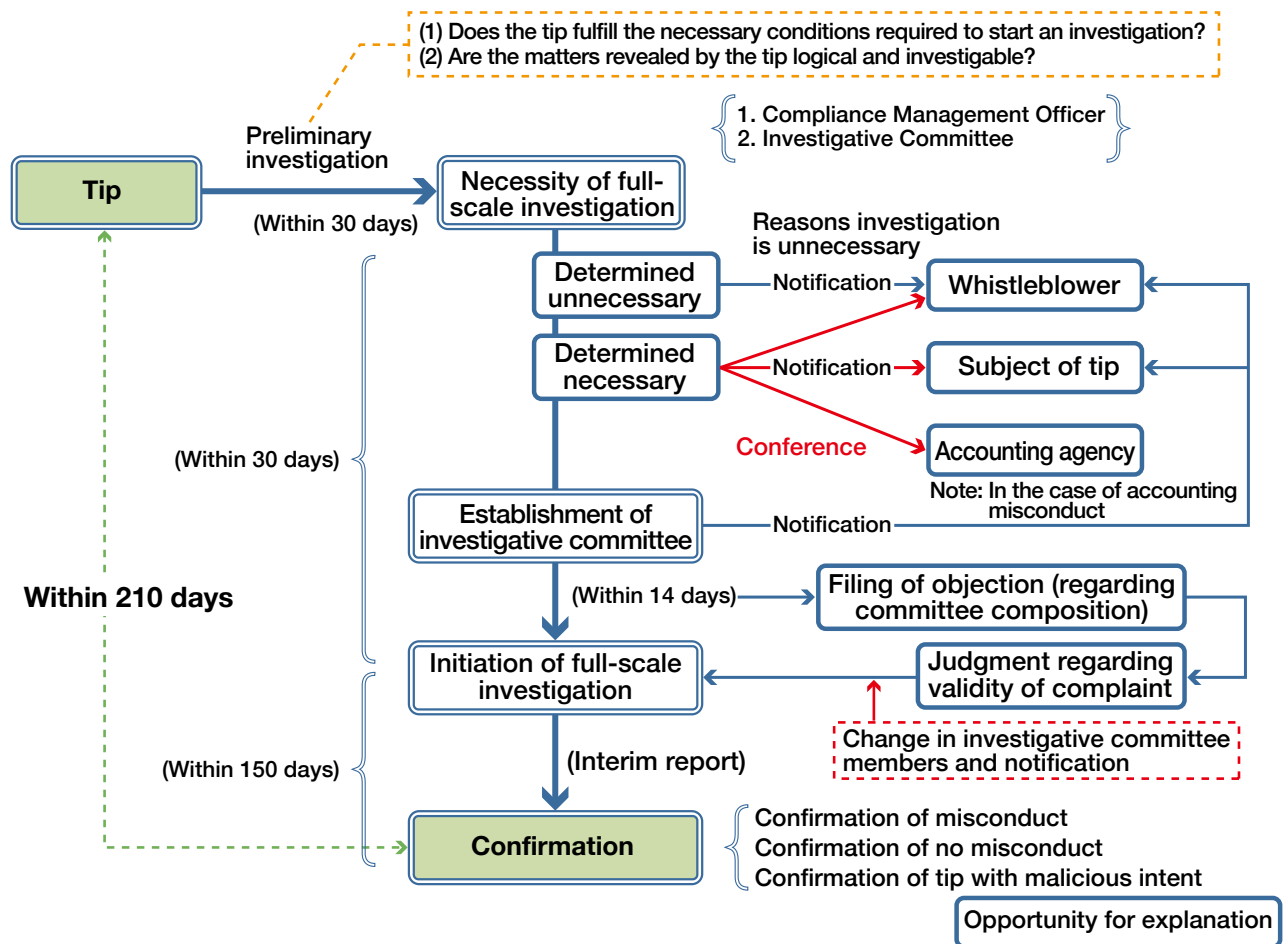
When a report regarding issues that satisfy certain conditions is received, a preliminary investigation that determines whether a full-scale investigation by the investigative committee should be held is conducted within 30 days. During this period, it will be determined whether the case meets conditions requiring an investigation, taking into account rationality, investigative potential, etc. If a full-scale investigation is warranted, it is initiated within 30 days of the decision to investigate. The whistleblower may file an objection regarding the members of the investigative committee within 14 days of the decision.

Whether there was misconduct and whether the report was submitted with



malicious intent are decided within 150 days of the start of the full-scale investigation. An opportunity for explanation is offered after the decision.

The timeline is as follows:



(2) Confirmed Cases of Misconduct

Confirmed cases of misconduct are treated in the following manner:

1. Return of improperly received (used) research funds (with interest)
2. Criminal prosecution in severe cases
3. Disciplinary action based on university regulations
4. Disqualification from applying for competitive funding

(3) Period of Disqualification from Applying for Competitive Research Funds

Under the “Guidelines regarding the proper execution of competitive funding (September 9, 2005 Agreement in the Liaison Committee of Ministries and Agencies Concerned with Competitive Funding),” persons who have committed misconduct regarding competitive funding are prohibited from applying for said competitive funding as well as other competitive funding, including that from other government agencies.

The following restrictions on applying for competitive funding were imposed in the revision of these Guidelines on June 22, 2017.

Use of research funds		Suitable period
Misuse Determined based on effects on society and degree of severity (in cases determined not to have been for personal appropriation)	(1) Degree of misuse of research funds determined to have had a major effect on society and the misconduct to have been severe	5 years
	(2) Degree of misuse of research funds determined to have had a minor effect on society and the misconduct to have not been severe	2–4 years
	(3) Effect on society and severity of misconduct determined to be other than (1) or (2)	1 year
Misuse Personal appropriation	(4) Funds used for personal economic gain	10 years
Improper receipt of funds Impropriety during the selection stage	(5) Selected as a research project based on deceit or other improper means	5 years
Breach in obligation to act as a prudent manager	(6) Cases where the offender wasn’t directly involved in the misuse of research funds, but misuse occurred due to the offender’s failure to act as a prudent manager	1–2 years

* In the following cases, instead of imposing an application restriction, a strong warning will be given.

- Cases where the impact on society is considered small, the maliciousness of the act is considered low, and the amount wrongfully used is small in (1), (2), and (3)
- Cases where the impact on society is considered small and the maliciousness of the act is considered low in (6)

Classification based on involvement in misconduct			Degree of misconduct	Suitable period
Persons involved in misconduct	(1) Particularly malicious persons, e.g. persons with improper intentions from the start of their research			10 years
	(2) Authors of scientific papers connected to research misconduct	Author responsible for the concerned scientific papers (supervisors, major authors or persons recognized to have similar responsibilities)	Judged to have a major effect on progress of research in the concerned field or on society, or to be highly malicious conduct.	5–7 years
			Judged to have a minor effect on progress of research in the concerned field or on society, or to be minor misconduct.	3–5 years
		Authors other than those listed above		2–3 years
	(3) Persons involved in misconduct except (1) or (2).			2–3 years
Authors that were not involved in misconduct but were responsible for scientific papers connected to research misconduct (supervisors, major authors or persons recognized to have similar responsibilities)			Judged to have a major effect on the progress of research in the concerned field or on society, or to be highly malicious conduct.	2–3 years
			Judged to have a minor effect on progress of research in the concerned field or on society, or to be minor misconduct.	1–2 years

Notes: Authorization to apply for competitive funding is revoked for competitive funding from the Ministry of Education, Culture, Sports, Science and Technology (MEXT) as well as competitive funding from other government agencies. Along with the researchers involved in improper accounting or misconduct, joint researchers and research directors will be penalized. In some cases, all research in a college/faculty or research institution may be temporarily put on hold.

(4) Points of Contact for Dealing with Misconduct Prevention

Reports regarding research misconduct at this university and consultations regarding misconduct (in cases that have not reached the stage of filing a report) are handled at the following location:

Research Integrity Office (Institute of Research)

1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510

Tel./Fax: +81 (0)3-5803-5024 (Hours: Weekdays, 8:30 a.m. to 5:15 p.m.)

E-mail: warning.adm@tmd.ac.jp

How to file a report or arrange for a consultation

- A) Reports can be submitted in writing (including by fax or e-mail) to the office listed above, or delivered by phone or in person.
- B) In principle, a third party representing the whistleblower must submit the report, and the following points must be specified:
 - Names of employees or groups suspected of misconduct
 - Detailed explanation of the misconduct
 - Scientific or rational basis for identifying the conduct as improper

In addition to TMDU's consultation points of contact, a portal for the receipt of reports of research misconduct—relating to competitive funding from the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the illegal use of research funding as well as the receipt of fraudulent payments—is located at MEXT, as detailed below.

Competitive Funding Adjustment Office,

Promotion Planning Division, Research Promotion Bureau,

Ministry of Education, Culture, Sports, Science and Technology (MEXT)

3-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8959, Japan

Direct Tel.: +81 (0)3-5253-4111 (Extension:3827,3862,3826)

E-mail: kenkyuhi@mext.go.jp

Phone calls received weekdays, 9:30 a.m. to 6:30 p.m.

8. Appropriate Use of Research Funds

(1) Categories of research funds

Research funds are funds necessary to execute research. Research funds can be roughly divided into the following five categories, and the rules regarding these funds differ based on the category. Furthermore, rules for research grants and subsidies differ according to the type of research project involved. In addition to public research funding originating from the Japanese taxpayer, there are corporate contributions and corporate-sponsored research. All types of funding include the obligation to reveal stakeholders. *Funds must be administrated with a clear understanding of all rules.*

Categories of research funds	Categories of rules	Examples of research types
Grants-in-aid	(1) Act on Regulation of Execution of Budget Pertaining to Subsidies, etc., and rules used by the researcher (grant terms) (2) University regulations such as accounting regulations	(Japan Society for the Promotion of Science) grants-in-aid for scientific research; (Ministry of Health, Labour and Welfare) grants-in-aid for scientific research
Sponsored research funds (for some joint research)	(1) Contracts Project manuals (2) University regulations such as accounting regulations	Ministry of Education, Science and Technology-sponsored research, such as JST's CREST and Sakigake, AMED-sponsored research, etc.
Joint research funds	(1) Contracts (2) University regulations such as accounting regulations	Joint research with corporations Joint research seminars
Endowments	(1) Endowment goals, endowment terms (2) University regulations such as accounting regulations	Endowments by corporations or individuals Endowment seminars
Grants to cover administrative costs	(1) University regulations such as accounting regulations	Basic research funds distributed within the university

The university's grant procedures must always be followed when directly receiving research aid from corporations or research support groups. If research grants are treated as personal accounting rather than taken in through the proper procedures, it could be prosecuted as improper accounting.

Sponsored research funding, joint research funding and grants-in-aid are specific to the research (project) noted in the research plan and contract, and their use is limited to the execution of said project and its directly required expenditures. Consequently, the rules surrounding these kinds of funding are stricter than those for general contributions and grants covering administrative costs.

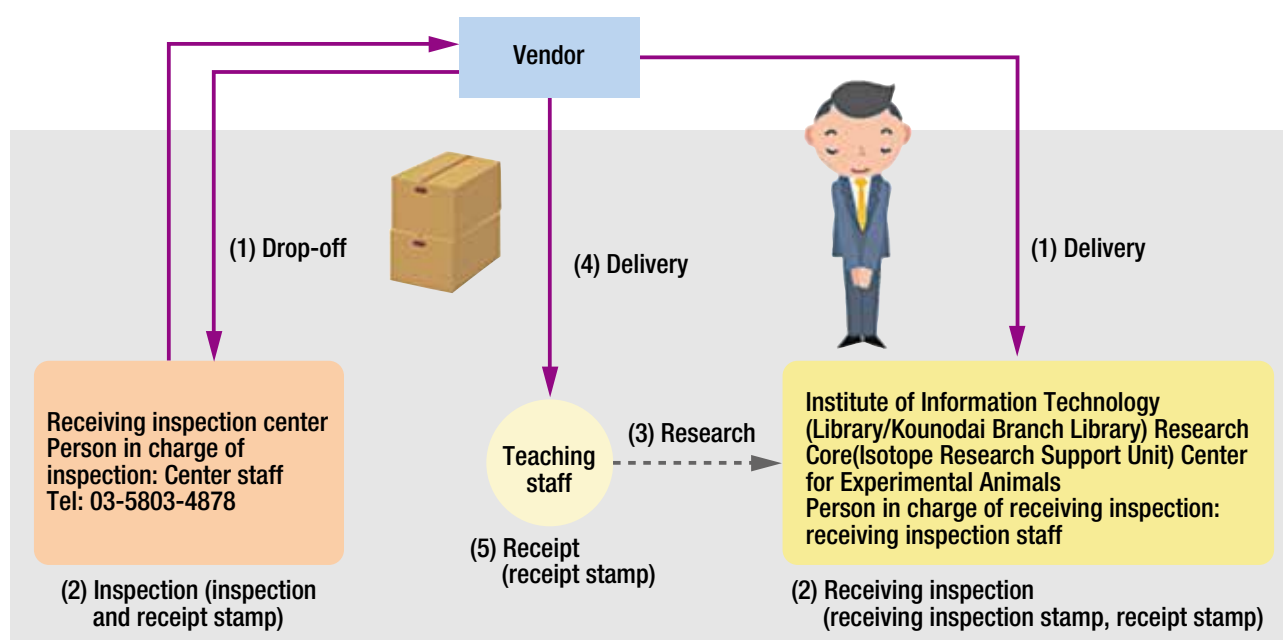
(2) Rules Governing Administrative Handling of Research Funds

In cooperation with the Financial and Facilities Division, General Affairs Division, and the Administration Division of each school/faculty, the Research Integrity Office has created the “Research Funds Administration Guidebook.” This guidebook explains the proper use of research funds to purchase supplies and equipment, procedures and considerations for travel expenses or hiring research support staff, and examples of misconduct. Please use it in conjunction with this *Research Misconduct Prevention Handbook*.

(3) Receipt and Inspection Center

The receiving inspection center was established to prevent the misuse of research funds.

Articles not inspected by the center will be regarded as improper procurements.



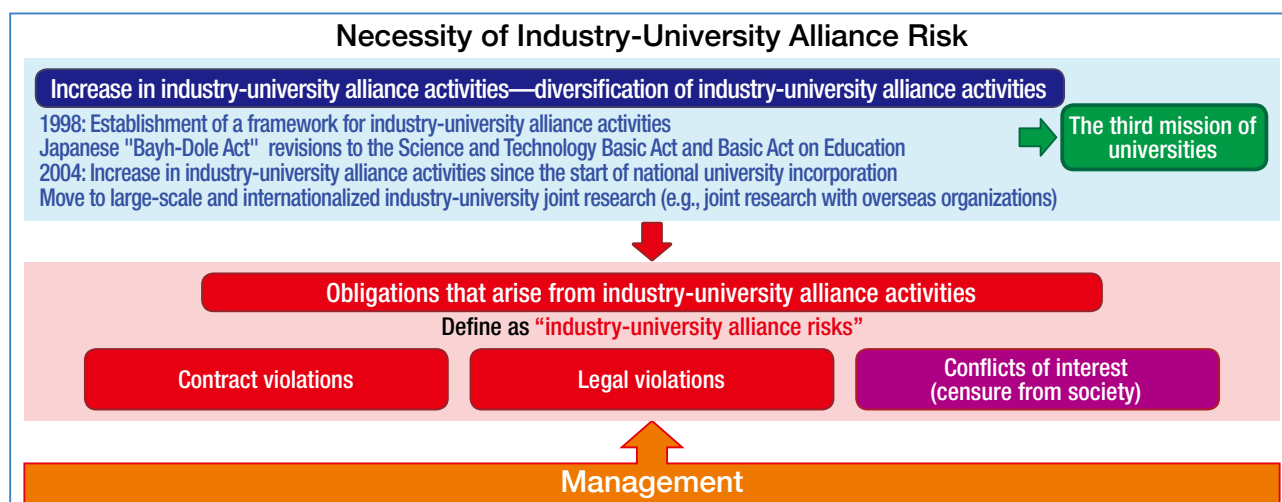
Note: Inspections for the Kounodai district are carried out at the receiving inspection center branch office (Administration Office, College of Liberal Arts and Sciences.) Please verify further details in the *Product Inspection Center Delivery Inspection Guidance* (<http://www2.tmd.ac.jp/cmn/keiri/buppinkensyucenter.pdf>)

9. Industry, Academia and Government Collaboration on Risk Management

(1) What Is Industry-Academia-Government Collaboration on Risk Management?

Many different contracts—joint research, sponsored research, nondisclosure, licensing, etc.—are executed in the course of activities involving industry-academia-government collaboration. Once a contract has been executed, there is an obligation to adhere to its terms and conditions. Likewise, there are myriad laws that must be obeyed in the execution of research activities and industry-academia-government collaboration.

If these contracts or laws are violated, the risk of civil or criminal liability arises. Industry conducts project development with a profit-making motive, while universities are motivated by the search for truth and/or the making of contributions to society. When industry and academia collaborate with government on joint projects, conflicts of interest are bound to arise. When such collaborative projects are undertaken, sound management guarantees, sound activities and conflict of interest management that increases transparency are crucial. The risk of contract violations and legal violations—as well as the risk of the perception of conflicts of interest—are defined as industry-academia-government collaboration risks.

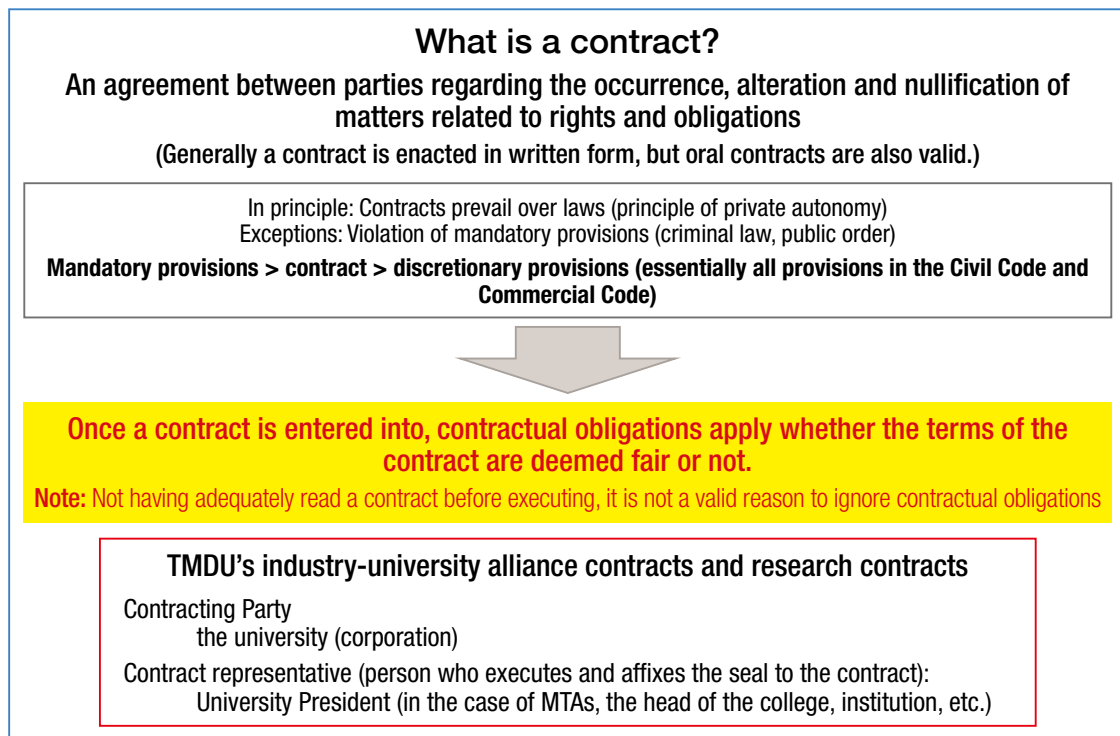


Here we set out the basic knowledge of contracts, laws and conflict of interest management needed when involved in research activities and industry-academia-government collaboration.

(2) Observance of Contracts

A contract is an agreement between parties regarding the occurrence, alteration and nullification of matters related to rights and obligations. Once a contract has been executed, all parties are obligated to adhere to it. Even if contract conditions are perceived as unfair, not having adequately read the contract is not a valid reason to fail to meet contractual obligations. Parties to a contract can be a person or a corporation. At this university, the university is the party to contracts related to university activities. In principle, it is the university president who executes and affixes his/her seal to the contract (in the case of MTAs, it is the head of the affiliated college, institution, etc.).

Note: If an individual executes a personal contract related to university activities and questions arise regarding liability for damages based on violation of contract obligations, the individual may be held personally responsible for payment of damages.



(3) Types of Systems and Contracts for Collaboration

This university has diverse systems for preparing contracts related to research activities and joint activities with external organizations (corporations, research institutions, etc.). They are designed to create the optimal, mutually desirable relationship between the parties involved. The Research Center for Industry Alliances is in charge of selecting the type of contract used and negotiating contract

terms, while the Administrative Division, Institute of Research takes charge of contract-related administrative procedures. The goal of this division of labor is the efficient execution of contracts.

Types of Contracts

Note: For more information, please visit the Research Center for Industry Alliances website:
<http://www2.tmd.ac.jp/tlo/gakunai/support/index.html>

Collaborative Research	A collaborative research system is a system for promoting the generation of high-quality research findings, where researchers or research expenditures are received from external organizations such as corporations, and teaching staff from this university join on equal terms with researchers from private and other external organizations to conduct collaborative research on a shared topic.
Commissioned Research	Commissioned research is research at this university that a corporation sponsors and is carried out by the university's teaching staff. The research findings are then reported to the sponsor. The sponsor pays all research expenses.
Joint Research Departments	Funding for the operation of a joint research departments is received from an external body such as a research institution or corporation. When necessary, researchers are also brought into the university. The university and external organization cooperate and work together continuously for a fixed period of time on a specific research topic. This system is set up with the goal of advancing and substantiating research at this university.
Academic Consulting Contract	Sponsorship is received from an external body such as a corporation, and employees of this university provide instruction and advice based on their teaching, research or specialized technical knowledge in support of the sponsor's business or activities. The sponsor pays the expenses for this support, and the university employees conduct the instruction (academic instruction) as a segment of their normal duties.
Non-Disclosure Agreement	This type of contract is used when undisclosed research data or findings are passed to external organizations or confidential information is received from an external body. For example, when investigating the possibility of cooperating on joint research, a nondisclosure contract is executed between the parties so that information can be exchanged.
License Agreement	This contract is used to give consent to a corporation or other external organization to use intellectual property rights the university owns, such as a patent, and establishes the compensation the university is to receive.
Material Transfer Agreement (MTA)	This contract establishes the rights and obligations of the concerned parties arising from material transfers. The <i>Guidebook Concerning Material Handling</i> (in Japanese) has been created to explain MTAs, so please refer to it (available by download): http://www2.tmd.ac.jp/tlo/resources/img/gakunai/notice/index/tmdu_mtaguide.pdf Note: Material transfer means the receipt of materials that are the results of research, such as cells, from other researchers (at external organizations), or the delivery of such materials to other researchers.
Joint Application Agreement	This type of agreement is used when jointly applying for a patent with an external organization, such as a corporation, to determine each party's ownership proceeds and share of the application expenses, as well as to decide management responsibilities.

(4) Legal Compliance

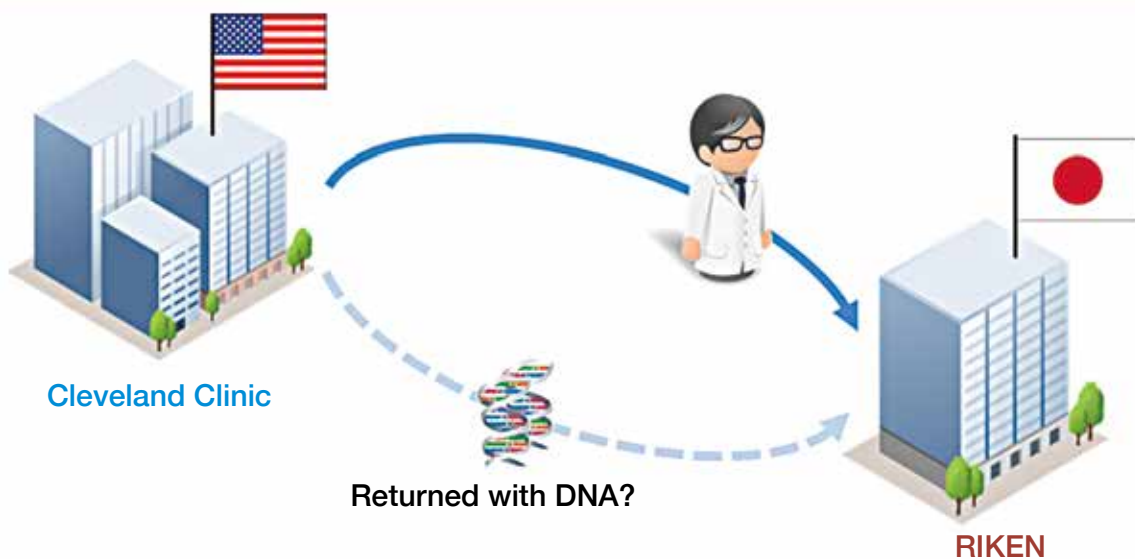
In some cases when conducting industry-university alliances there are laws and conventions that must be observed. When forming such alliances, check the relevant laws and conventions and act accordingly.

Examples

■ Unfair Competition Prevention Act (Handling of Trade Secrets)

The leaking of confidential information disclosed by another party can result in a maximum prison term of five years and a maximum fine of five million yen.

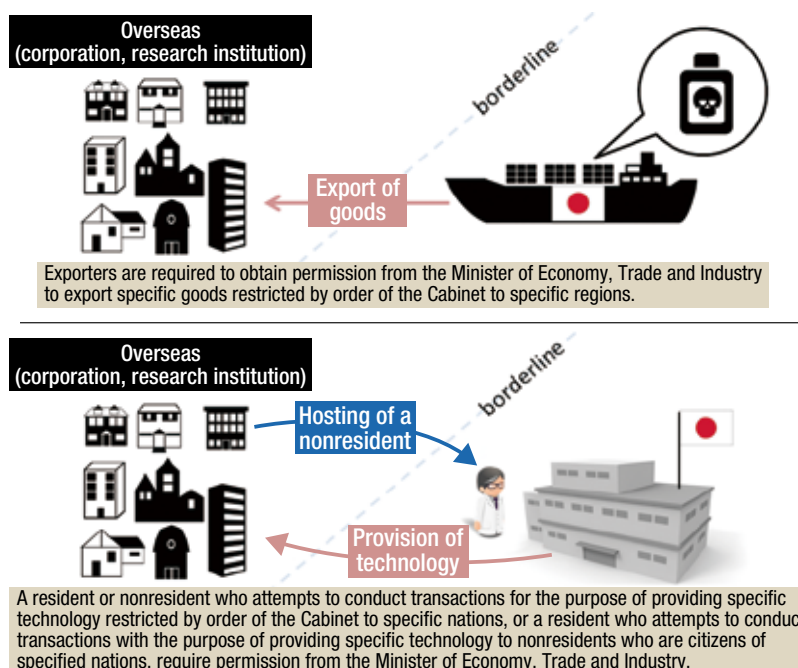
In July 1999, when Japanese Researcher A—who had been employed by the Cleveland Clinic in Ohio—transferred to RIKEN, he colluded with Japanese Researcher B, of the University of Kansas, to bring DNA related to the gene that causes Alzheimer's disease to Japan without permission. The U.S. government prosecuted the two for violating the Industrial Espionage Law. (One was arrested, and U.S. authorities demanded the other be handed over.) The two were charged with attempting to benefit a foreign government (RIKEN is a national research institution) by illegally obtaining a trade secret (the DNA).



■ Foreign Exchange and Foreign Trade Act (Security Export Control)

This act restricts the export of technology that could be put to use in the development of weapons of mass destruction or other weapons. It carries a maximum prison term of 10 years and a maximum fine of 10 million yen.

Whether transactions are considered foreign transactions is determined by both geographical considerations (whether the technology was supplied to a foreign country) and personal considerations (whether the technology was supplied to a nonresident). If one or both apply, then the transactions are considered foreign transactions subject to regulation.

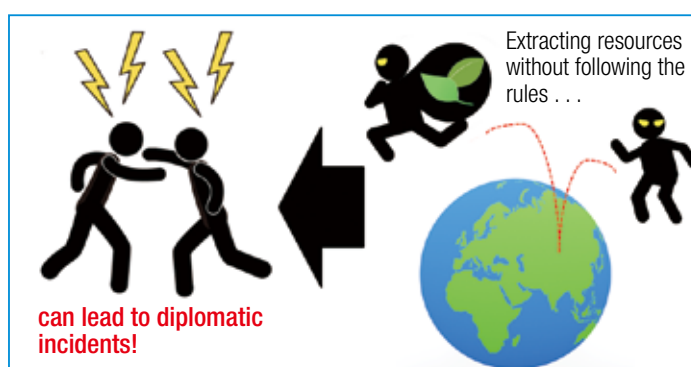


Note: For more details, please see the *Safe Guarantee Export Control Handbook*.

■ Convention on Biological Diversity

The purposes of this treaty are: (1) the preservation of biodiversity; (2) the sustainable use of the components of biodiversity; and (3) the fair and just distribution of benefits emerging from the use of genetic resources. The treaty recognizes the sovereign rights of nations regarding their genetic resources, and requires users of genetic resources to obtain prior informed consent (PIC) from the provider of said resources. The treaty also provides for the fair and just distribution of the benefits derived from the use of such resources to nations providing such genetic resources, based on mutually acceptable conditions.

For issues to keep in mind when dealing with biological or genetic resources, please refer to the *Guidelines on Access to Genetic Resources for Users in Japan* (in Japanese) put together by the Ministry of Economy, Trade and Industry and the Japan Bioindustry Association.



http://www.jba.or.jp/pc/archive/publication/admission/120312_guideline_access_to_gr_e.pdf

(5) Managing conflicts of interest

In specific terms, conflicts of interest (COI) refers to situations where the fair and appropriate judgment required in public research is impaired due to ties of economic interest to external entities, or situations which are apt to result in a third party expressing concerns of such an impairment of judgment.

Situations that can hinder fair and appropriate judgment include the falsification of data, preferential treatment of specific corporations and the continuation of research that should be halted.

(Note) A conflict of obligations refers to situations where side business activities result in obligations to perform multiple duties, leading to impairment of judgment regarding the primary business or neglect of the primary business. It also refers to the situation tending to result in a third party expressing such concerns.

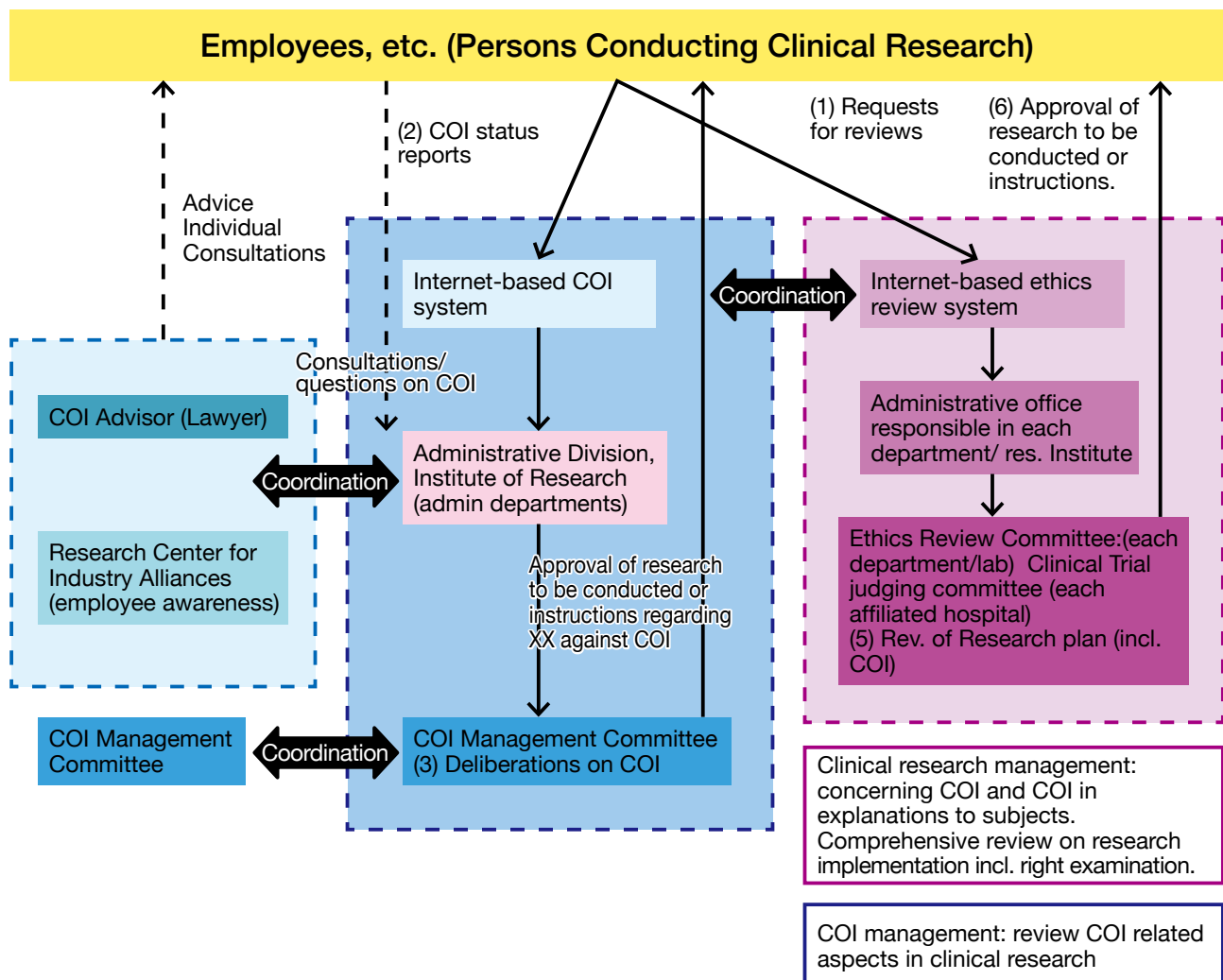
Source: *Guidelines for the Management of Conflicts of Interest in Health, Welfare, Labor and Science Research* (in Japanese)


The researchers (teaching staff and researchers) at TMDU declare any personal conflicts of interest once a year. Should the nature of industry-academia collaboration with a company fall within certain criteria stipulated in the regulations, the University has to disclose the content of the industry-academia collaborative activities with said company and the situation regarding any personal financial interests. In addition, a reason to make a disclosure that arises after the regular annual declarations have been made also requires the making of a declaration as needed.

Besides these fixed-interval declarations, when conducting clinical research, each researcher conducting research must also personally declare any conflicts of interest. The declaration of any personal conflict of interest is an essential prerequisite when applying for scientific research funds from the Ministry of Health, Labour and Welfare, the Japan Agency for Medical Research and Development (AMED) and other organizations.

(For more information, please refer to the *Conflict of Interest Management Handbook*, produced separately.)

Management System for Conflicts of Interest in Clinical Research (Introduction of Internet-based system planned for 2018)





10. e-Learning Course Attendance (Compliance/Research Ethics Education) and Submission of Written Pledge

TTokyo Medical and Dental University's Standard of Conduct for Research Activities states that "All members of the university shall actively participate in training and information sessions regarding research activities, including the administration and management of public research funds, and shall endeavor to acquire knowledge and understanding of all related laws and university regulations and shall obey them."

Furthermore, under the university's research misconduct prevention regulations, all persons who go through courses in compliance and research ethics education are required to submit a signed pledge stating that they will not commit misconduct, and that if they do commit misconduct in violation of the regulations they will be subject to discipline and legal liability from both this university and funding distribution agencies.

Compliance and research ethics education via e-learning

1. Teaching materials: APRIN e-learning program (CITI Japan)

Note: An exception is when participation in an e-learning program provided by the Japan Society for the Promotion of Science—an independent administrative institution—is regarded as equivalent to completion of the CITI program. Announcement of the course will be sent via an internal mass e-mail, so check it before taking the course.

2. Eligible participants: All members of the university involved in research activities (including teaching staff, researchers, research support staff, technical support staff, administrative staff, etc.)

Note: Master's course graduate students complete this course as part of their curriculum.

3. Course units: The unit of the course participants attend is determined based on occupation (teaching staff, researcher, research assistant, administrative staff, etc.)
4. Period: Announced through internal mass e-mail

The Administrative Division, Institute of Research will send user names and passwords

Access: <https://edu.aprin.or.jp>

Note: The course can be taken anywhere with Internet access.

Submission of a pledge

1. Target: All members of the university involved in the administration and management of public research funds (persons participating in research activities at this university, persons applying for public research funds, research administrative staff), including graduate students (with the exception of students who have already submitted a pledge in current academic year)
2. Where to submit: The section in charge of general affairs of your affiliated department
(General Affairs Section, Administrative Division)
3. When to submit: ASAP
(Can also be submitted at the time of university-wide faculty development [FD] or departmental FD)
4. Form: Attached at the end of this handbook
5. Fill out and submit a signed original

11. Q&A

Please refer to the following for information about what actions constitute research misconduct, and for typical questions and answers regarding research misconduct.

	Questions	Answers
1	A photograph of a cell is taken from another paper and used in one's own paper as a different photograph.	Since no experiment was conducted, this is an example of fabrication. It could also be an infringement of copyright.
2	An electrophoretic photograph is flipped using Photoshop and used as if it is the original photograph.	Since the photograph was used for an experiment that was not conducted, this is an example of fabrication and falsification.
3	Sought-after data are obtained through a single trial, and these data are published as a research finding.	The data have no integrity, since they were not obtained from multiple trials. This is a case of falsification.
4	After multiple trials, only sought-after data are published.	The data have no integrity, since they were not obtained from all trials performed. This is a case of falsification.
5	Since statistically significant data cannot be obtained, some data are ignored to obtain statistically significant results, and these are published.	The data do not have integrity, since they are not derived from all trials performed. This is a case of falsification.
6	Wording is copied from another person's paper for use in one's own paper.	Since another person's wording is copied, this is a case of plagiarism. It could also be an infringement of copyright.
7	Photoshop is used to darken the background, thereby creating an inauthentic photograph, which is published.	This is a case of falsification of data.
8	One's advisor cherry-picks supportive data from several trials and publishes them.	This is a case of falsification of data.
9	Clinical research is conducted with no review by the Ethical Review Committee.	This is regarded as conduct in violation of research ethics.
10	Specimens for research are acquired without the consent of test subjects.	This is regarded as conduct in violation of bioethics and research ethics.
11	A cell or organism received from an overseas university is transferred to another researcher.	If the material was transferred without permission, it is regarded as conduct in violation of the MTA contract.

	Questions	Answers
12	Inflated working hours are recorded for research assistants, etc. and submitted to the university.	This is regarded as misuse of research funds.
13	To cover expenses for the maintenance and administration of the research lab, students or the like are paid for fictional work and then asked to return the money, which is used to pay the expenses.	This is regarded as misuse of research funds.
14	Despite having received travel expenses from another institution, the university is billed for the same expenses and duplicate reimbursement occurs.	This is regarded as misuse of research funds.
15	Despite purchasing a discount ticket, a quote and receipt for the normal fare is obtained from the ticket vendor and travel expenses are reimbursed at the higher amount.	This is regarded as misuse of research funds.
16	Due to unused research funds in a given year, fictitious orders are placed with vendors. The payments are held by the vendors to be applied to supplies purchased in future years.	This is regarded as misuse of research funds.
17	Vendors are asked to create fraudulent transaction documents and are paid research expenses based on these documents. The payment is held as a deposit toward future purchases.	This is regarded as misuse of research funds.
18	See comment box above	

Details regarding the basic rules for administering research funds can be found in the *Research Funds Administration Guidebook*.



12. Code of Conduct and Misconduct Prevention Rules

Code of Conduct Pertaining to Research Activities at Tokyo Medical and Dental University

Enacted October 16, 2007

At Tokyo Medical and Dental University our educational philosophy is to train human resources in a wide- ranging education rich in humanity, to foster those who can both pose and solve problems and to produce medical personnel with an international mindset. This philosophy derives from a high awareness of our contribution to society through education and research activities.

Through research activities based on the achievements of those that have gone before, the individual will create new findings from his own results, building a system of knowledge and with the trust and mandate of the society be required to conduct research on a subjective and autonomous basis. Research fraud damages confidence in the whole scientific community, inhibiting the development of science based on justice and integrity and significantly damaging the trust of society and as such is not acceptable.

Research related to medicine and dentistry at our university is imbued with a critical responsibility as it directly contributes to the health and welfare of mankind and therefore researchers engaged in research activity should as a matter of course be aware of the need for transparency and accountability under the highest ethical standards. Based on the above, faculty staff, and in addition, researchers, research support personnel, clerical staff, etc. and all members involved in research activities including the administration and management of public research expenses (hereinafter referred to as ‘all members’) shall maintain the criteria pertaining to ethics and behavior as specified herein.

The code of ethics and behavior (‘Concerning the Scientist’s Code of Conduct’), formulated in response to the Science Council of Japan, was enacted on October 3rd, 2006 and revised on January 25th, 2013.

I. Responsibilities of Researchers

(Responsibility of Researchers)

1. Researchers have a responsibility to secure expertise that produces a quality of technology and furthermore, from their own technical expertise and experience, be responsible for and contribute to the safety and peace of mind of society and the sustainability of the

global environment.

(Attitudes of Researchers)

2. Researchers shall always be honest and exercise judgement in good faith and act striving to maintain and improve their own expertise and ability and will make their best efforts to show scientifically the accuracy and validity of the knowledge produced by their scientific research.

(The Researcher in Society)

3. The researcher shall understand that the autonomy of science is based on the mandate and trust of society and being cognizant of the relationship between science and technology and society and the environment shall act appropriately.

(Responding to the Expectations of Society)

4. Researchers have an obligation to meet the expectations of society with regard to achieving the clarification of the truth of various issues. In using research funds to implement and develop the research environment they shall maintain an awareness of the broad social expectations that exist pertaining to them and their activities.

(Explanations and Publicizing Findings)

5. Researchers shall explicitly explain the significance and role of the research they are engaged in and provide an evaluation of the possible positive impacts and changes that the research may bring to bear on human beings, the society and the environment. They shall publicize these results with neutrality and objectivity and seek to build a constructive dialogue with society.

(Ambiguities in the Use of Scientific Research)

6. Researchers shall maintain an awareness that the outcome of their research may be abused by forms of destructive behavior contrary to the intentions of the researcher themselves, and in conducting said research and publishing results shall select means and methods that are acceptable to society.

II. Impartial Research

(Research Activities)

7. Researchers shall act in good faith in the process of planning, application, implementation, and reporting of their research, etc. in accordance with the purpose of this Code. They are required to obtain recognition of their achievements in publishing their results in articles etc. and shall also assume responsibility according to their role in said research. They shall through thorough record keeping and strict handling of survey data avoid any complicity in fabrication or falsification and refrain from any illegal acts such as theft.

(Thorough Maintenance and Educational Awareness in the Research Environment)

8. Researchers shall be aware of the important responsibility they bear to establish and

maintain an impartial environment that enables them to carry out responsible research and to prevent fraudulent activities from taking place as well as to enhance the quality of the research community and environment of our university and in doing so continue to develop an educational awareness towards the deterrence of fraud. Moreover, they shall also strive to gain understanding and cooperation from society in order to achieve this.

(Considerations for Research Subjects)

9. Researchers should respect those who co-operate with them in their research and consider their welfare. Animals also should be treated with a sincere attitude.

(Relationships with others)

10. Researchers should appropriately evaluate and critique the results of others while at the same time extending this critique to that of their own research. They should listen humbly to other people and exchange opinions with a sincere attitude. They should honor the intellectual achievements of others and respect intellectual property rights. They should also actively participate in peer review with others in the research community, especially in their own specialized fields.

III. Science in society

(Dialogue with Society)

11. To encourage better mutual understanding between the research community and society, researchers should actively engage in dialogue and interaction with citizens. Also, in order to solve various problems of society and realize better welfare for all, they should endeavor to provide scientific advice which is effective for the formation of policy to policy and decision makers. In doing this, they should aim for advice that is based on the agreement of other researchers as well, and if there is a difference in these opinions they should seek to offer easy to understand explanations.

(Scientific Advice)

12. Researchers should give impartial advice on an objective scientific basis with the aim of contributing to public welfare. In doing so they should be cognizant of the seriousness of their statements in influencing public opinion and policy formation and not abuse their authority. In addition, they should make maximum efforts to ensure the quality of their scientific advice while at the same time giving explicit explanations where there is uncertainty in the scientific knowledge available and/or a diversity of views.

(Scientific Advice for Policy-making and Decision Makers)

13. While acknowledging that what researchers say should be respected, when giving advice to policy and decision makers researchers should be aware that in some cases scientific knowledge is not the only ground for policy decisions. In cases where there are decisions that are made which differ from the advice of the research community, we ask that researchers make their explanations to society as necessary.

IV. Compliance with Laws and Regulations.

(Compliance with Laws and Regulations)

14. In order to gain an understanding and comply with the rules and regulations on research activities including that of the administration and management of public funds for research activities, all members should actively engage in training and explanatory meetings etc.

(Proper Use of Public Research Funds)

15. All members should acknowledge that expenses provided in the manner of public research funds are from citizen's taxes and demonstrate accountability therefore in their use.

(Responsibilities of Clerical Staff)

16. Administrative staff, understanding the nature and characteristics of research activities being undertaken, should ensure proper execution and use of public research funds with expert knowledge and ability.

(Mutual Cooperation)

17. All members should cooperate with each other and strive to prevent in advance of their occurrence any misconduct in research activities (including the misuse of research funds).

V. Other

(Elimination of Discrimination)

18. Researchers shall not discriminate against any individual involved in research or education on the basis of race, gender, status, thought, religion or creed and shall respect all individual's freedom and personalities based on impartial scientific methodology.

(Conflict of Interest)

19. Researchers, as part of their research, examinations, judgments, scientific advice etc., have relations with individuals and organizations and should pay close attention to any conflicts of interest arising between themselves and these bodies while acting appropriately with consideration to the public.

Supplementary Provisions of this Code of Conduct shall come into effect as from October 16th, 2007.

Supplementary Provisions (revised, September 24th, 2014)

This Code of Conduct shall come into effect as of October 1st, 2014.

National University Corporation Tokyo Medical and Dental University Rules for the Prevention of Misconduct Related to Research Activities

(January 22, 2015)
Rule No. 7

Chapter 1. General Provisions.

Article 1: Summary

Hereafter are stated the applicable laws and regulations for the prevention of misconduct in research activities at the National University Corporation Tokyo Medical and Dental University (herein after referred to as 'the university'). These guidelines are pertaining to various research misconduct etc. related to research activities at the university in addition to what is specified in the Code of Conduct (hereinafter referred to as the Code of Conduct) which shall be dealt with according to these rules.

Article 2: Relevant misconduct

- 1 The research activities these regulations cover include all research activities undertaken at this university, including the administration and management of research funds (the same definition shall apply hereafter). Incidents of misconduct targeted by these regulations are as follows:
 - (1) Falsification, fabrication and plagiarism of data or results presented in published research findings, either intentionally or through gross negligence regarding the basic obligation of care expected of a researcher.
 - (2) Misuse of research funds (including inappropriate accounting) (the same definition shall apply hereafter).
- 2 In addition to the misconduct stipulated in the previous clause, conduct deemed by the Compliance Chief Management Officer to require handling as inappropriate research conduct (submission of duplicate scientific papers, inappropriate authorship, etc.) may be dealt with in the same way as the misconduct stipulated in the previous clause.
- 3 In these regulations, the following terms will have the definitions below.
 - (1) Fabrication: The creation of nonexistent data, research results, etc.
 - (2) Falsification: Manipulations that alter research materials, equipment or processes to create illegitimate data or research findings.
 - (3) Plagiarism: The misappropriation of ideas, analysis/analytic methodology, data, research results, scientific papers or terminology from another researcher without the concerned party's consent or without appropriate citations.
 - (4) Misuse of research funds: The use of research funds for extraneous purposes, either intentionally or through gross negligence, and the use of or accounting for research funds in a manner that violates the details or conditions attached to the funding grant or that conflicts with university regulations (e.g., billing for fraudulent compensation/wages or travel expenses, deposits paid to vendors for fictitious purchases, etc.).
 - (5) Submission of duplicate scientific papers, etc.: The submission of a scientific paper that is

substantively identical to a scientific paper already published in another academic journal or to a scientific paper already in the submission process.

- (6) Inappropriate authorship: The submission of a scientific paper without appropriate disclosure of the paper's authors.

Chapter 2. System for preventing misconduct

Article 3: Standard of Conduct

All university personnel (in addition to teaching staff and researchers, all persons involved in research activities, including research support staff, administrative staff, etc.; this definition shall apply hereafter) must abide by the Standard of Conduct.

Article 4: Framework of responsibilities

- 1 The University's President shall be the Compliance Chief Management Officer for all research activities conducted at this university, the Executive Director appointed by the president shall be the Compliance Management Officer, and the heads of schools, centers, etc. shall be Compliance Promotion Officers. As such, these officers shall draw up and promote measures to prevent misconduct (hereafter referred to as "research misconduct prevention measures") and respond to misconduct when it occurs.
- 2 The heads of schools, institutions, etc. mentioned in these regulations are listed in an attachment.
- 3 In addition to being responsible for drawing up and disseminating the Standard of Conduct and these regulations, the Compliance Chief Management Officer shall adopt the necessary measures to ensure that all university personnel abide by them, and exhibit appropriate leadership regarding the Compliance Management Officer and Compliance Promotion Officers.
- 4 The Compliance Management Officer shall take charge of putting together a cross-organizational system for the research misconduct prevention measures and shall draw up and implement concrete measures for all institutions within the university, while also confirming and reporting to the Compliance Chief Management Officer on the status of implementation.
- 5 Compliance Promotion Officers shall handle the following responsibilities under the direction of the Compliance Management Officer:
 - (1) Implementation of the research misconduct prevention measures in the schools, institutions, etc. they supervise, and confirmation and reporting to the Compliance Management Officer on implementation status.
 - (2) Implementation of compliance and research ethics training (education to ensure the understanding of usage rules for research funds and the concomitant responsibilities, ethical standards expected of researchers, kinds of behavior that constitute misconduct, etc.) for all personnel in their schools, institutions, etc. involved in research activities to prevent misconduct, and oversight of the status of participation.
 - (3) Monitoring of all personnel in their schools, institutions, etc. to ascertain whether said

personnel are conducting appropriate research activities and, when necessary, providing instructions for improvements.

- 6 The officers stipulated in the first clause must have an adequate understanding of their various supervisory responsibilities. If failure to adequately fulfill these supervisory responsibilities results in the occurrence of misconduct, the officer(s) may face disciplinary action.
- 7 The system of responsibility under Clause 1 is broadly disseminated within and without the university.

Article 5: Deputy Compliance Promotion Officer

- 1 Depending on conditions in the schools, institutions, etc., a Compliance Promotion Officer may appoint several deputy officers to handle compliance promotion and divide the responsibilities listed above in Article 4, Clause 5 among them. In such cases, naming an administrative staff member as a deputy officer responsible for the management and execution of research funds is allowed.
- 2 The Compliance Promotion Officer involved must report to the Compliance Management Officer when appointing a deputy officer.

Article 6: Research Integrity Committee

- 1 The Research Integrity Committee (hereafter referred to as “the Committee”) is established under the direction of the Compliance Chief Management Officer to deliberate on the university’s research misconduct prevention measures, and is composed of members named by the Compliance Management Officer from among the Compliance Management Officer, the Compliance Promotion Officer and Deputy Compliance Promotion Officers.
- 2 In addition to items stipulated in the above clause, other requisite items regarding the Committee are established elsewhere.

Article 7: Research Integrity Office

- 1 The Research Integrity Office (hereafter referred to as “the Promotion Office”) established under the Compliance Chief Management Officer as part of the Administration Office, Research and Industry-University Alliance Organization.
- 2 The Promotion Office conducts administrative business for the promotion of research misconduct prevention measures in accordance with decisions of the Committee.
- 3 Compliance Promotion Officers and Deputy Compliance Promotion Officers must cooperate with the Promotion Office to work toward misconduct prevention.
- 4 The Promotion Office shall maintain close contact with the Internal Audit Office and undergo internal audits by the Internal Audit Office.

Article 8: Research Misconduct Prevention Plan

- 1 The Committee must establish a research misconduct prevention plan (hereafter referred to as “the Misconduct Prevention Plan”) and disseminate it within and without the university.
- 2 The Compliance Chief Management Officer must conscientiously implement the Misconduct Prevention Plan.

- 3 Regarding implementation of the Misconduct Prevention Plan, the Compliance Management officer and the Promotion Office shall enact and implement concrete measures for the entire university and confirm the status of that project.
- 4 Compliance Promotion Officers must work to promote the Misconduct Prevention Plan within their own schools, institutions, etc., while also making progress reports to the Compliance Management Officer.
- 5 The Compliance Management Officer shall report on the state of the university-wide implementation of the Misconduct Prevention Plan to the Compliance Chief Management Officer.
- 6 The Committee shall regularly review the Misconduct Prevention Plan based on reports from Compliance Promotion Officers.

Article 9: Compliance and Research Ethics Education

- 1 Compliance Promotion Officers shall implement compliance and research ethics training—covering the contents of the Standard of Conduct and these regulations, as well as instances of actual misconduct—for all personnel involved in research activities in their schools, institutions, etc.
- 2 Those concerned must regularly attend the abovementioned compliance and research ethics training sessions.
- 3 The compliance and ethics training referred to in Clause 1 shall be carried out from the standpoint of the duties of the university staff—whether researchers, administrative staff, etc.—and disseminated in an easy-to-understand manner. It shall also be widely disseminated among research assistants and others involved in research activities as well as other students. The contents of the training sessions shall be regularly reviewed and new contents incorporated.
- 4 Compliance Promotion Officers shall monitor participation in the compliance and research ethics training referred to in Clause 1 as well as the level of understanding of the participants.

Article 10: Pledge

- 1 Compliance Promotion Officers shall ask those who participate in the abovementioned compliance and research ethics training to submit a signed pledge (Form 1) indicating that they will not commit misconduct and that they understand that if they do commit misconduct in violation of regulations they will be subject to discipline and legal liability from both this university and funding distribution agencies.
- 2 The University's President will not accept various experiment plans, competitive funding applications, research plan forms, etc., from persons who have not submitted this pledge.
- 3 Notwithstanding the stipulation in Clause 1, newly hired staff, transfer students/staff, graduate students, etc. shall be asked to submit the pledge.

Article 11: Preservation and dissemination of research data

- 1 Teaching staff, researchers and graduate students (hereafter referred to as “the researcher(s)”) must record research details in experiment and observation notes.
- 2 The researcher(s) must preserve the experiment and observation notes stipulated above

for ten years following publication of the relevant research findings in a scientific paper, etc. However, if said researcher(s) leaves the university during that period, the head of the field of education or research (hereafter referred to as “the relevant head”) must preserve copies of said experiment and observation notes for the remainder of the ten-year period.

- 3 The researcher(s) and the relevant head must release data on which a scientific paper is based, such as the abovementioned experiment and observation notes or copies thereof, at the request of the Compliance Chief Management Officer.

Article 12: Rules concerning administrative procedures

- 1 With the cooperation of related administrative units such as the Office of Research Safety and Management, Accounting Section and Personnel Section, the Promotion Office shall create a guidebook for the entire university that covers rules concerning administrative procedures related to the Research Misconduct Prevention Measures, Standard of Conduct, Misconduct Prevention System and research funding.
- 2 The abovementioned guidebook must be reviewed and revised as necessary
- 3 The guidebook stipulated in Clause 1 shall be disseminated to all university personnel involved in research activities at this university.

Chapter 3 Responses to Misconduct

Section 1 Receipt of reports

Article 13: Report desk

- 1 A report desk shall be established in the Promotion Office to deal with reports or consultations received from inside and outside the university regarding research misconduct at this university.
- 2 The report desk shall be named the Research Integrity Reporting Desk.
- 3 The address, telephone number and e-mail address of the abovementioned desk must be publicized and disseminated within and without the university so that reports can be received in writing, by phone, by mail or in person.

Article 14: Receiving and reacting to reports

- 1 Upon receiving a report at the abovementioned Research Misconduct Report and Consultation Desk, the Promotion Office shall quickly report to the Compliance Management Officer.
- 2 Upon receiving the abovementioned report, the Compliance Management Officer shall contact both the Compliance Chief Management Officer and the Compliance Promotion Officer of the affiliated school/faculty about the target of the report (hereafter referred to as “the targeted individual”). If the targeted individual is the Compliance Promotion Officer, the Compliance Chief Management Officer shall name a person to handle the duties of the Compliance Promotion Officer regarding this report.
- 3 Notwithstanding the stipulations in the two clauses above, if the targeted individual is the Compliance Management Officer, the Promotion Office shall report to the Compliance Chief Management Officer, who shall name a person to handle the duties of the Compliance

Management Officer regarding this report.

- 4 When the contents of the report require investigation by other research institutions, the report desk shall forward the report to the relevant research institutions. Reports forwarded to this university from other institutions shall be handled as reports at this university according to the three clauses above.
- 5 If suspicion of misconduct (including cases where the report desk has confirmed suspicions brought to its attention via the Internet) is brought forth by external organizations—such as academic societies or other scientific communities, the press or auditing agencies—it shall be treated as a report and handled in accordance with Clauses 1 and 2 above and Clause 2 of Article 15 below. In these cases, the targeted individual shall report immediately to the report desk.
- 6 Reports or consultations that misconduct is about to occur or misconduct is being called for shall be handled in accordance to Clauses 1 and 2 above. When the Compliance Promotion Officer who receives such a report determines that its contents are based on sufficient grounds, he/ she shall issue a warning in writing to the targeted individual.
- 7 In cases when a whistleblower provides a report in a manner in which the whistleblower does not know whether the report desk actually received the report, such as a written report, the whistleblower shall be notified that the report was received.

Article 15: Handling of whistleblowers and targets of reports

- 1 The person at the report desk who receives a report must protect the secrecy of the report's contents and the whistleblower's identity.
- 2 In cases where a preliminary investigation and main investigation are conducted, secrecy must be thoroughly preserved by those involved in the investigations (Compliance Chief Deputy Compliance Promotion Officer, members of the investigative committee, etc.) until the investigation findings are published. No confidential information shall be divulged against the will of either the whistleblower or the targeted individual to any persons other than those involved in the investigation.
- 3 As long as the report is not found to be based on malicious intent, the Compliance Chief Management Officer shall not dismiss or expose the whistleblower to other unfavorable treatment simply for having submitted a report.
- 4 Without sufficient cause, the Compliance Chief Management Officer shall neither ban the targeted individual either partially or totally from conducting research activities, nor dismiss or submit the targeted individual to other unfavorable treatment simply for having been the target of a report.
- 5 The Compliance Chief Management Officer shall institute measures to protect the targeted individual from slander.

Section 2 Report Investigative System and Methodology

Article 16: Cases of reports requiring investigation

- 1 To prevent the submission of reports with malicious intent—such as the entrapment of the targeted individual or obstruction of the targeted individual's research, which are aimed

entirely at damaging the targeted individual in some manner or putting the affiliated institution/organization of the targeted individual at some disadvantage (the same definition shall apply hereafter)—and to seek cooperation with the investigation when necessary, reports (including cases where indications of misconduct are brought forward by the scientific community [scientific society, etc.], the media or external organization such as auditing boards) that conform with the following items shall be treated as viable targets of investigation:

- (1) In principle, reports where the name of the whistleblower is known
 - (2) The particulars of the investigation—participants in the misconduct (researchers, vendors, etc.), the timing of the misconduct (fiscal year, etc.), mode of misconduct, details of the case, etc.—can be identified
 - (3) There is a legitimate basis for deeming the conduct misconduct
- 2 Even cases where all the aforementioned points are not fulfilled—such as anonymous reports—shall be subject to investigation to the extent possible.
 - 3 For reports related to the misuse of research funds, reports related to misconduct in past fiscal years for which the term for preservation of accounting records has expired shall be investigated to the extent possible.

Article 17: Preliminary investigation

- 1 Within thirty days of receiving a report, the Compliance Chief Management Officer shall have the Compliance Management Officer conduct a preliminary investigation to determine whether to conduct a full investigation.
- 2 During the abovementioned preliminary investigation, the Compliance Management Officer shall investigate the following points and report to the Compliance Chief Management Officer:
 - (1) Whether the case fulfills the conditions required to be considered a target of investigation
 - (2) Whether the report's contents are legitimate and possible to investigate
- 3 Notwithstanding the two clauses above, the Compliance Chief Management Officer may establish an investigative committee as provided for in the next Article, and begin a preliminary investigation.
- 4 If the Compliance Chief Management Officer decides not to conduct a full investigation, he/she shall notify the whistleblower of the fact and the reasons for the decision.
- 5 If the Compliance Chief Management Officer decides to conduct a full investigation he/she shall notify the whistleblower and the targeted individual of the fact. If the targeted individual is affiliated with an external research institution, the relevant institution shall also be notified.
- 6 If the Compliance Chief Management Officer decides to conduct a full investigation, he/she shall report to the research funding distribution agencies relevant to the case and to the Ministry of Education, Culture, Sports, Science and Technology.
- 7 Notwithstanding the stipulations above, for cases concerning the misuse of research funds, the Compliance Chief Management Officer shall report to the funding distribution agencies within thirty days of receiving the report whether or not the case is to be the subject of a full investigation.

Article 18: Establishing an investigative committee

- 1 When the Compliance Chief Management Officer decides to begin a full investigation based

on the results of the aforementioned preliminary investigation, he/she shall establish an investigative committee.

- 2 The investigative committee shall be composed of the following investigative committee members:
 - (1) The Compliance Management Officer
 - (2) The Compliance Promotion Officer from the affiliated school, institution, etc. of the targeted individual
 - (3) Other executive directors and employees
 - (4) Outside experts
- 3 The Compliance Management Officer shall serve as the chair of the investigative committee.
- 4 The number of committee members indicated in Clause 2, No. 4 must exceed half of the total number of committee members.
- 5 The investigative committee members must not have any conflicts of interest with the whistleblower or the targeted individual.

Article 19: Filing an objection regarding the composition of the committee

- 1 After establishing the investigative committee, the Compliance Chief Management Officer shall notify the whistleblower and the targeted individual of the names and affiliations of the investigative committee members.
- 2 The whistleblower and the targeted individual can file an objection to the composition of the investigative committee within fourteen (14) days of receiving the abovementioned notification.
- 3 When an objection is filed, the Compliance Chief Management Officer shall review its contents. If the contents are deemed valid, investigative committee members shall be replaced and the whistleblower and the targeted individual notified of the change.

Article 20: Main investigation

- 1 The investigative committee members shall initiate their investigation within approximately thirty days of the date of the decision to implement a full investigation.
- 2 In the case of investigations concerning misuse of research funds, the Compliance Chief Management Officer must report to and consult with the funding distribution agencies regarding the implementation of the investigation and its objectives, target and methodology.
- 3 During the investigation of a report, the Compliance Chief Management Officer must take care not to reveal the identity of the whistleblower to the targeted individual or any other persons other than those involved in the investigation, unless the whistleblower gives permission.
- 4 The investigative committee shall investigate through a close examination of all documents related to the research activities relevant to the report—such as scientific papers, experiment and observation notebooks, raw data, etc.—as well as through the testimony of concerned parties, requests for experiment duplication and review of accounting documents. During this time, an opportunity to hear the defense of the targeted individual shall be arranged.
- 5 When the investigative committee asks the targeted individual to confirm the reproducibility of findings or results through the duplication of experiments, or when the targeted individual voluntarily proposes such a process and the investigative committee recognizes the need for

such, experiments will be reproduced to the extent deemed legitimate by the investigative committee based on time constraints and opportunity (including equipment and expenses, etc.). In such cases, the experiments shall be conducted under the guidance and supervision of the investigative committee.

- 6 Relevant persons such as the whistleblower and the targeted individual must cooperate in good faith with the investigative committee's inquiries. Furthermore, this university shall cooperate in good faith regarding requests for cooperation in investigations from other research institutions.

Article 21: Measures to preserve evidence

- 1 Regarding research activities related to the report, the investigative committee shall take measures to preserve materials that could be used as evidence. In cases where the research activities related to the case were conducted at a research institute outside this university, requests shall be made to the relevant research institution to preserve materials that could be used as evidence.
- 2 The Compliance Chief Management Officer shall not restrict the research activities of the targeted individual as long as it does not influence the abovementioned measures.

Article 22: Interim reports, etc. on the investigation

- 1 In response to requests from funding distribution agencies and prior to the completion of the investigation, the Compliance Chief Management Officer shall submit progress reports and interim reports on the investigation to the relevant funding distribution agencies.
- 2 The Compliance Chief Management Officer shall respond to requests from funding distribution agencies for materials related to the relevant case and to inspect written materials as well as onsite inspections unless there are legitimate grounds for refusal, such as interference with the investigation.

Article 23: Temporary halt on funding during the investigation

- 1 When said prosecution concerns misuse of research funds, the Compliance Chief Management Officer may halt the administration and expenditure of research funding for research activities connected to the investigation until such time as the investigative committee's report is received.
- 2 When taking the abovementioned measure, the Compliance Chief Management Officer must carry out thorough consultations with the distribution agencies of the relevant research funds.

Section 3 Findings of misconduct

Article 24: Findings

- 1 The investigative committee shall complete its investigation within approximately 150 days of the initiation of the full investigation and determine whether misconduct was committed. If misconduct is found, the details of that misconduct, the participants, the extent of their participation and the amount of misused funds shall be identified.
- 2 If it is found that no misconduct was committed and the investigation determines that the

report submitted was based on malicious intent, the investigative committee shall confirm these facts.

- 3 At the time of the aforementioned finding, the targeted individual must be given the opportunity to defend him/herself.

Article 25: Considerations upon reaching a finding

- 1 The investigative committee shall confirm whether there was misconduct by comprehensively reviewing all evidence the investigation has gathered—including physical and scientific evidence, testimony, and the possible admission of wrongdoing by the targeted individual—while also taking into account the testimony of the targeted individual.
- 2 The investigative committee must not use the admission of wrongdoing by the targeted individual as the sole evidence for a finding of misconduct.
- 2 The investigative committee shall determine that misconduct has occurred when the targeted individual's testimony and other evidence do not overturn suspicions of misconduct.
- 3 The investigative committee shall determine that misconduct has occurred when sufficient evidence to overturn suspicions of misconduct is not available because the targeted individual cannot produce basic elements that should exist, such as the targeted individual's research data, experiment and observation notebooks, test samples and reagents.

Article 26: Notification of investigation results

- 1 When the investigative committee has reached a finding, it shall immediately submit a report to the Compliance Chief Management Officer.
- 2 Having received the abovementioned report, the Compliance Chief Management Officer shall quickly notify the whistleblower and the targeted individual (including persons other than the targeted individual found to have participated in the misconduct) of the results of the investigation. In cases where the targeted individual is affiliated with another research institution, said affiliated institution shall also be notified of these results.
- 3 The Compliance Chief Management Officer shall report the investigation results, factors that generated the misconduct, state of the auditing system, plans to prevent repetition of the misconduct, etc. to the distribution agency for the research funds relevant to the case and to the Ministry of Education, Culture, Sports, Science and Technology.
- 4 Notwithstanding the stipulations in the previous clause, in cases involving misuse of research funds, the Compliance Chief Management Officer shall submit a final report which includes the abovementioned investigation results to the funding distribution agencies within 210 days of the date of receiving the report from the investigative committee. If completion of the investigation within the time limit proves impossible, an interim report on the investigation shall be submitted to the distribution agencies.
- 5 If found that the report was based on malicious intent, external institutions to which the whistleblower is affiliated shall be notified.
- 6 Regarding investigations involving the misuse of research funds where even partial misconduct is confirmed, the Compliance Chief Management Officer shall immediately confirm the misconduct and report it to the distribution agencies.

Article 27: Appeal

- 1 A targeted individual found to have committed misconduct may file an appeal with the Compliance Chief Management Officer within 14 days of being notified of the investigation results. However, multiple appeals based on the same reason cannot be filed during that period.
- 2 A whistleblower found to have acted from malicious intent has the same appeal rights as above.
- 3 When a targeted individual found to have committed misconduct files an appeal, the Compliance Chief Management Officer shall notify the whistleblower.
- 4 When an appeal is filed, the Compliance Chief Management Officer shall report to the research funding agencies relevant to the case and the Ministry of Education, Culture, Sports, Science and Technology.
- 5 If the appeal is dismissed or a reinvestigation is initiated, the two clauses mentioned above shall apply.

Article 28: Examination of appeals)

- 1 The investigative committee shall examine any appeals submitted. If the substance of the appeal requires expert reinvestigation, the investigative organ shall replace or add members to the investigative committee or have a body other than the investigative committee carry out the investigation. However, when the Compliance Chief Management Officer determines that said appeal does not present a valid reason for requiring changes to the composition of the investigative committee, this shall not apply.
- 2 Regarding appeals from targeted individuals found to have committed misconduct, the investigative committee (or if, as in the aforementioned clause, the investigative committee has been replaced by another body, then that body) shall quickly determine whether to carry out a reinvestigation of the case, taking into consideration the substance of the appeal, reasoning, etc.
- 3 If it is decided to reject the appeal without a reinvestigation of the case, the investigative committee shall immediately report this to the Compliance Chief Management Officer, and the Compliance Chief Management Officer shall notify the targeted individual of said decision.
- 4 If it is decided to open a reinvestigation, the investigative committee shall ask the targeted individual to cooperate with the reinvestigation toward the rapid conclusion of said case, including the submission of materials sufficient to overturn the previous investigation's results. If such cooperation cannot be obtained, the examination of the appeal can be discontinued without conducting a reinvestigation. In such a case, the Compliance Chief Management Officer shall immediately be informed, and the Compliance Chief Management Officer shall notify the targeted individual of said decision.
- 5 Regarding a reinvestigation, the investigative committee shall decide whether to overturn the previous investigation results within approximately 50 days of initiating the reinvestigation, and immediately report the decision to the Compliance Chief Management Officer. Upon receiving the report, the Compliance Chief Management Officer shall notify the targeted individual, the targeted individual's affiliated institution and the whistleblower.
- 6 The Compliance Chief Management Officer shall report the abovementioned reinvestigation

results to the research funding distribution agency relevant to the case and to the Ministry of Education, Culture, Sports, Science and Technology.

Article 29: Examination of appeals when the report is found to be based on malicious intent

- 1 Upon receiving an appeal based on the stipulations in Article 27, Clause 2 from a whistleblower found to have acted out of malicious intent, the Compliance Chief Management Officer shall notify the whistleblower's affiliated institution and the targeted individual.
- 2 Upon receiving an appeal such as mentioned above, the Compliance Chief Management Officer shall report to the research funding distribution agency relevant to the case and to the Ministry of Education, Culture, Sports, Science and Technology.
- 3 Regarding appeals in Clause 1, the investigative committee (or if, as in the aforementioned clause, the investigative committee has been replaced by another body, then that body) shall conduct the reinvestigation within approximately 30 days of the appeal, and shall immediately report the results to the Compliance Chief Management Officer. Upon receiving the report, the Compliance Chief Management Officer shall notify the whistleblower, the whistleblower's affiliated institution and the targeted individual of said results.
- 4 The Compliance Chief Management Officer shall report the abovementioned reinvestigation results to the research funding distribution agency relevant to the case and the Ministry of Education, Culture, Sports, Science and Technology.

Section 4 Post-investigation measures

Article 30: Announcement of investigation results

- 1 The Compliance Chief Management Officer shall quickly announce the investigation results when the finding is one of misconduct.
- 2 The contents of the abovementioned announcement shall contain the following points:
 - (1) The names and affiliations of those involved in the misconduct
 - (2) The details of the misconduct
 - (3) Details of measures taken by the university up to the announcement
 - (4) The names and affiliations of the investigative committee members
 - (5) The methodology and procedures of the investigation
- 3 When there is a legitimate reason regarding the abovementioned, the names and affiliations of those involved in the misconduct may be withheld.
- 4 Investigation results shall not, in principle, be announced when no misconduct was found. However, the investigation results can be announced regarding cases where information regarding the case under investigation has been leaked or cases involving errors in scientific papers that were not intentional.
- 5 The contents of the abovementioned provisional announcement shall contain the following items:
 - (1) The name and affiliation of the targeted individual
 - (2) The names and affiliations of the investigative committee members
 - (3) The methodology and procedures of the investigation
- 6 When the report is found to be based on malicious intent, the investigation results shall be

announced.

Article 31: Measures regarding the targeted individual

- 1 When misconduct has been determined, the Compliance Chief Management Officer shall take the steps itemized below:
 - (1) Immediately order a halt on the use of relevant research funds by persons found to have participated in the misconduct, as well as by persons who—although not found to have participated directly—were found to bear responsibility for research activities where misconduct was found (hereafter referred to as “participants”).
 - (2) Based on the Tokyo Medical and Dental University Employees’ Rules of Employment (hereafter referred to as “Employees’ Rules of Employment”), the participants shall be dealt with appropriately according to prescribed procedures, and the withdrawal of scientific papers related to misconduct shall be recommended.
 - (3) In cases of serious wrongdoing—such as the misappropriation of research funds for personal use, or actions that greatly damage public confidence in the university—legal proceedings such as criminal prosecution and civil suits may be pursued in addition to the measures prescribed by various university regulations.
- 2 Participants involved in the misuse of research funds must repay said research funds.
- 3 Participants must repay expenses borne by the university to show reproducibility of experiments as stipulated in Article 20, Clause 4.
- 4 When investigation results find that misconduct has not occurred, the freeze on administration and expenditure of research funds put in place during the investigation shall be lifted. Measures in place to preserve evidence shall be promptly lifted when the appeal period expires without an appeal being made, or after the findings of the appeals examination are determined.
- 5 When investigation results find that a report was based on malicious intent, the whistleblower shall be dealt with appropriately based on the Employees’ Rules of Employment when the whistleblower is affiliated with the university or based on prescribed procedures in other cases. In such cases, the university may ask the whistleblower to reimburse the expenses borne the university incurred to show reproducibility.

Chapter 4 Administration and management of research funds

Article 32: Appropriate administrative and managerial activities involving research funds

- 1 Regarding administrative processing procedures surrounding research funding, the researcher who receives research funding (hereafter referred to as the “researcher responsible for research funds”) is responsible for them and must administrate the research funds appropriately based on the Misconduct Prevention Plan.
- 23To execute the above, the researcher responsible for research funds must regularly ascertain how the research funds are being used.
- 3 Regarding the above, an administrative staff person who is aware of the potential for a problem with funding administration may, when deemed necessary, confirm the

administrative problem with the researcher responsible for research funds, and when necessary request changes.

- 4 Compliance Promotion Officers shall adopt countermeasures for the schools, institutions, etc. they administer to prevent collusive relationships from forming between university personnel and businesses, in light of the fact that improper transactions tend to originate when relations between the two are overly close.
- 5 Regarding goods and materials, in cases of anomalous treatment where receipt and inspection by the receiving inspection center is curtailed, the officer responsible for accounting— as established in the Tokyo Medical and Dental University Accounting Regulations—shall establish appropriate methods and frequency for spot-checking such goods and materials in consideration of the number of such cases and the risk level involved, and shall implement after-the-fact checking through regular spot checks.
- 6 The receipt and inspection of special services (such as the development, creation of databases, computer programs, digital contents and the maintenance and inspection of equipment) shall be carried out in an appropriate manner based on content.

Article 33: Penalties for businesses involved in improper business transactions

- 1 The Compliance Chief Management Officer may conduct investigations and implement necessary measures through the Investigative Committee for Halting Transactions against businesses suspected of being involved in improper transactions, as provided for in the Tokyo Medical and Dental University's Essential Regulations for Fixed Assets and Material Procurements.
- 2 The Compliance Chief Management Officer shall require businesses with which this university does business to submit a pledge (Form 2).

Article 34: Personnel management of persons employed through research funds

Compliance Promotion Officers must regularly check the contents of personnel management documents and work details of persons employed with research funds in the schools, institutions, etc. they supervise. Spot-check inspection tours of the workplace of such employees must also be carried out based on a specific proportion of the total.

Article 35: Materials of great liquidity

Notwithstanding the Tokyo Medical and Dental University's Essential Regulations for Material Management, the researcher responsible for research funds must clearly demonstrate that materials with high liquidity have been purchased with the relevant research funds and must also manage them so that their whereabouts are known, irrespective of purchase price.

Article 36: Petitions for travel expense

The researcher responsible for research funds must understand and check the status of petitions for travel expenses by researchers, and request submission of reports to confirm the details of the business engaged in, destination, place of accommodations, persons met with, etc. He/she must confirm the appropriateness of the purpose of the travel business and the expenses incurred, including checking for duplicate expense receipts. When necessary, he/she

must make inquiries or fact-check the particulars of a researcher's business travel.

Article 37: Consultation desk

- 1 A consultation desk shall be established in the Financial and Facilities Division and the Administrative Division, Institute of Research to accept consultations from within and without the university regarding rules for use of research funds at this university.
- 2 The consultation desk shall be named the Research Funds Use Consultation Desk.

Article 38: Joint-possession of information by task managers and task manager training

- 1 The Promotion Office and the abovementioned consultation desk shall organize and analyze the cases that come before them and work to promote the joint ownership of information and mutual understanding among task managers.
- 2 The Promotion Office shall report to the Compliance Chief Management Officer regarding the results of monitoring and provide feedback regarding improvements to the Basic Plan and Internal Regulations as well as the contents of the compliance training.

Article 39: Internal audits

- 1 The Internal Audit Office shall conduct internal audits based on the Tokyo Medical and Dental University Internal Audit Regulations (2005 Regulation Number 25).
- 2 Internal audits of the administration and management of research funds shall be executed in keeping with the points listed below, in addition to points stipulated in the aforementioned clauses:
 - (1) Regularly during each fiscal year a certain number of audits shall be carried out regarding financial information, including whether all required forms for accounting documents have been filed.
 - (2) The systems for research funding administration and management for the prevention of misuse of research funds shall be verified.
 - (3) Samples shall be taken and prioritized based on risk of misuse and on-the -spot audits, including unannounced audits, shall be carried out (risk approach audits).
 - (4) There shall be close cooperation with the Promotion Office, including the provision of information on causes of misconduct.

Supplementary provisions

These regulations were enacted January 22, 2015.

Supplementary Provisions (Regulation No. 131 of May 21, 2015)

These regulations were enacted May 21, 2015.

Supplementary Provisions (Regulation No. 111, July 1, 2016)

These regulations were enacted July 1, 2016 and it will be applied from April 1, 2016

Supplementary Provisions (Regulation No. 108 of July 31, 2017)

These regulations were enacted July 31, 2017 and are applied from April 1, 2017.

Appendix (list of department heads etc.)

Department	Department Manager etc.	Remarks
Institute of Research	Director, Institute of Research	Includes each center of the organization
Institute of Information Technology	Director, Institute of Information Technology	
Institute of Global Affairs	Director, Institute of Global Affairs	
Graduate School of Medical and Dental Sciences (Medical), Faculty of Medicine	Dean, Faculty of Medicine	
Medical Hospital	Director, Medical Hospital	
Graduate School of Medical and Dental Sciences (Dental), Faculty of Dentistry	Dean, Faculty of Dentistry	Includes Dental Hospital
Graduate School of Health Care Sciences	Dean, Graduate School of Health Care Sciences	
College of Liberal Arts and Sciences	Dean, College of Liberal Arts and Sciences	
Institute of Biomaterials and Bioengineering	Director, Institute of Biomaterials and Bioengineering	
Medical Research Institute	Director, Medical Research Institute	
Student Support and Health Administration Organization	Director, Student Support and Health Administration Organization	
Sports Science Organization	Director, Sports Science Organization	

(University Personnel)

Pledge

Regarding research activities at this university, I pledge to observe the Standard of Conduct for Research Activities at the Tokyo Medical and Dental University (hereafter the “Standard of Conduct”) and all other regulations of this university, and not commit misconduct, including the misuse of competitive research funding.

Moreover, I pledge to execute proper research activities with the knowledge that if I do commit misconduct in violation of the Standard of Conduct or any university regulations, I will face penalties from the university and agencies distributing competitive funding as well as legal liability.

Date: _____

Employee number/student number:

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Affiliated school, institution, etc.
and field of study or research:

Name: _____ Seal

(Businesses)

Pledge

Regarding business transactions related to research activities at Tokyo Medical and Dental University, _____ pledges to act as follows:

- 1) Observe all regulations and rules of this university, including accounting regulations, and not participate in research misconduct
- 2) Cooperate with requests to peruse or submit transaction books for internal audits by this university or other investigations
- 3) Not object to any penalties imposed if improprieties are uncovered during investigations by this university, including the cancellation of business transactions
- 4) Notify the report desk of this university if a member of this university suggests or requests improper conduct

Date: _____

Corporation name: _____

Representative: _____ Seal

Handbook for the Prevention of Research Misconduct



TOKYO MEDICAL AND DENTAL UNIVERSITY

Tokyo Medical and Dental University Misconduct Prevention Planning & Promotion Division
(Administrative Division, Institute of Research)
Misconduct Prevention Planning/ Promotion Committee

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[Contact]

Misconduct Prevention Planning / Promotion department.
Ext. 5871 E-mail: warning.adm@tmd.ac.jp