# Handbook for the Prevention of Research Misconduct



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## Introduction

This handbook is meant to ensure that the teaching staff and graduate students of our university are aware of the nature of research misconduct. In so doing, we hope to prevent occurrences of misconduct in their research activities, such as the fabrication of data or ignorance of the rules of ethics.

Repeated instances of research misconduct have recently occurred in Japan, including clinical research that violates ethical principles and guidelines, the fabrication of data, and the misuse of research funds. Consequently, calls have grown even stronger for thorough compliance and awareness at academic and research institutions and the proper use of research funds. In reality, however, there are still many reported cases of misconduct attributable to the lax implementation of rules among teaching staff, the blind adherence to previous precedents, and unintentional misconduct due to cumbersome paperwork requirements.

This handbook was created to serve as one part of a campaign to prevent research misconduct. However, this handbook only presents basic rules regarding research misconduct, and is not meant to apply to every system. Especially in the case of research funds, please use this handbook while confirming the rules established for the respective funding system you are operating under.

With respect to all involved, our hope is that you will keenly realize that the scientific community's independence is built on the trust and mandate of the public. We ask you to continue to devote yourselves wholeheartedly to the development of research with a clear grasp of the social mission of academic and research activities.

> Yasuyuki Yoshizawa President Tokyo Medical and Dental University

# 1. Vision

#### "Cultivating Professionals with Knowledge and Humanity, thereby Contributing to People's Wellbeing"

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.

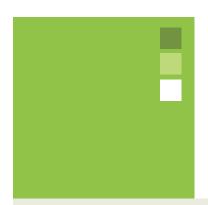
#### Research

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

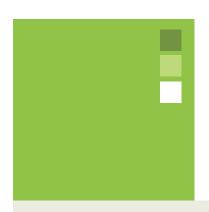
We provide high-quality medical and dental care that nurtures the heart, mind, and body, not only for the local community, but also for the world.

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



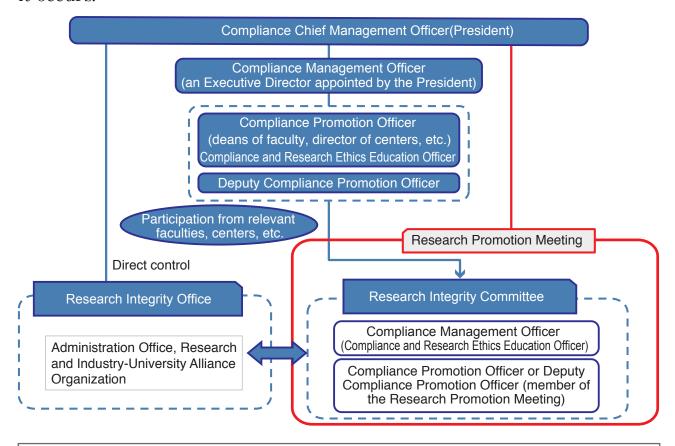
### 2. Obligations of the university staff and graduate students

- All university staff involved in research activities—such as teaching staff, researchers, office staff and research support staff (hereafter "university staff")—and graduate students must maintain high ethical standards, use research funds appropriately, and not commit research misconduct.
- Teaching staff, researchers and graduate students must keep and preserve records regarding research proposals, plans and research findings. Research results must be made public.
- University staff and graduate students must obey the instructions of the person(s) responsible for the research concerned on the execution of the research and the administration of research funds.
- University staff and graduate students must participate in education and training programs on the prevention of research misconduct implemented by the Compliance Management Officer (Executive Director of Research and International Cooperation) or the Compliance Promotion Officer.
- University staff and graduate students must cooperate with investigations regarding research misconduct as called for in the "Tokyo Medical and Dental University Research Misconduct Prevention Rules" (Rule 7, January 22, 2015; hereafter "Misconduct Prevention Rules").
- All concerned must closely observe the Research Misconduct Prevention Rules. They must also work according to the "Tokyo Medical and Dental University Research Misconduct Prevention Plan" (revised as of July 27, 2011).
- All concerned must closely observe the "Tokyo Medical and Dental University Standard of Conduct regarding Research Activities" (enacted on October 16, 2007, and revised on October 1, 2014), which establishes the rules of ethical conduct for researchers.



### 3. System of misconduct prevention responsibility

Based on the Misconduct Prevention Rules, the President of the University 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 when it occurs.

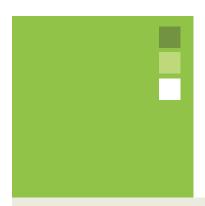


**Note:** The International Exchange Center, Center for Education Research in Medicine and Dentistry, Institute for Library and Media Information Technology, Student Support and Health Administration Organization, and Center for Interprofessional Education do not participate in the Research Integrity Committee. However, they must maintain close ties with the committee.

Compliance Promotion Officers handle the following responsibilities under the direction of the Compliance Management Officer:

- 1. Enforce research misconduct prevention measures in the respective schools, research institutes, centers, etc. under their supervision, and confirm and report the execution of such 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 for improvements.

(Misconduct Prevention Rules, Paragraph 5, Article 4)



#### 4. Research misconduct

#### (1) Specific types of misconduct

Research misconduct can be broadly classified into the following four categories:

#### **Fabrication**

Inventing nonexistent data, research findings, etc.

#### **Falsification**

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

#### **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 eligibility for applying for funding, 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

These cases will be handled as cases of misconduct if the Chief Supervisory Officer finds them to be malicious in nature.

#### (3) Why does misconduct occur?

#### Researchers

- Desire for results needed to secure funding
- Research funds for the next fiscal year are not guaranteed due to being a fixed-term research fellow or on a career track
  - Psychological stress
  - Insufficient sense of guilt

#### Instructors

- Ignorance or neglect of ethical aspects
- Insufficient time to adequately review theses
  - Lack of day-to-day supervision
    - Too many graduate students
      - Desire for fame

Researchers must realize that the ultimate purpose of medical and dental research is to directly contribute to the health and welfare of humanity. They must therefore carry out their research with transparency and accountability based on the highest ethical values. At our university, we believe that proactive prevention of misconduct protects our teaching staff and researchers, and leads to benefits for science and academics. To that end, we engage in the following measures:

#### A. Strengthening and spreading research ethics education

Compliance and research ethics training for university staff as part of faculty development Lectures within the initial research programs of graduate schools

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

Participation in e-learning (compliance and research ethics training) and submission of a written pledge

Please refer to page 32 of this handbook

### B. Manage research data in laboratories and eliminate closed-door policies

Obligation to preserve research data, notes, etc. for a ten-year period Multiple-advisor system for graduate students in the doctoral degree program

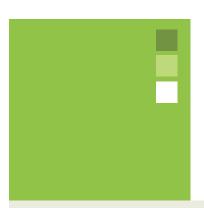
Cultivation of ethics in researchers

#### C. Respond vigorously to incidents of research misconduct

Squash any motivation to become involved in research misconduct by taking a rigorous stance against it

### D. Protect whistleblowers and discourage misconduct reports with malicious intentions

Accusations are filed through the university website Please refer to page 18 of this handbook



## 5. Ethical issues and misconduct that arise in the pursuit of medical and dental research

### (1) Ethical issues that arise in the pursuit of medical and dental research

#### Protection of test subjects

- 1) Ethics review
- 2) Informed consent

### Protection of personal information

- Data management and use
- 4) Protection of personal information
- 5) Disclosure/nondisclosure

### Appropriate research activities

- 6) Safety management
- 7) Animal experiment subjects
- 8) Experiments with infectious microorganisms

#### **Conflict of interest**

- 9) Fair publication of findings
- 10) Use of research funds
- 11) Application for approval of side businesses

### International security and export control

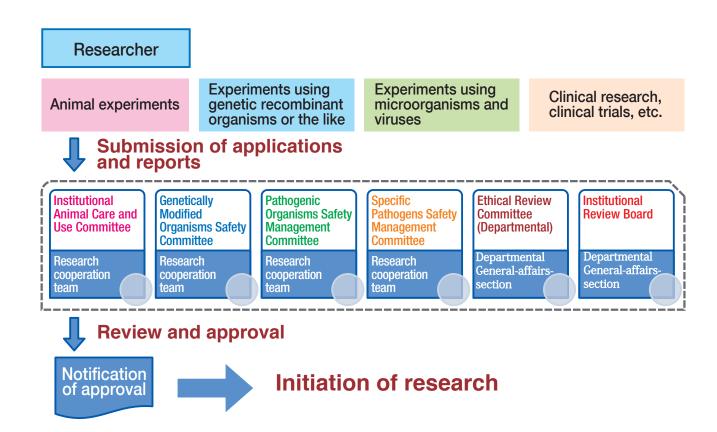
- 12) Joint international research
- 13) Hosting of international researchers
- 14) Safety management

#### **Biodiversity**

- 15) Bringing organisms in and out of the country
- 16) Containment of genetic recombinants

Each teaching staff and researcher needs to be fully aware of the above points. Actions in conflict with these points will be regarded as misconduct. Therefore, the university has instituted its "Framework for Safe and Appropriate Experiments" and "Framework for Research Ethics Evaluation" for research using human subjects (clinical research) as well as structures for conflicts of interest and security export controls.

#### (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
Training course in safe and appropriate research	three years
Research ethics workshop	F
Radioisotope-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.

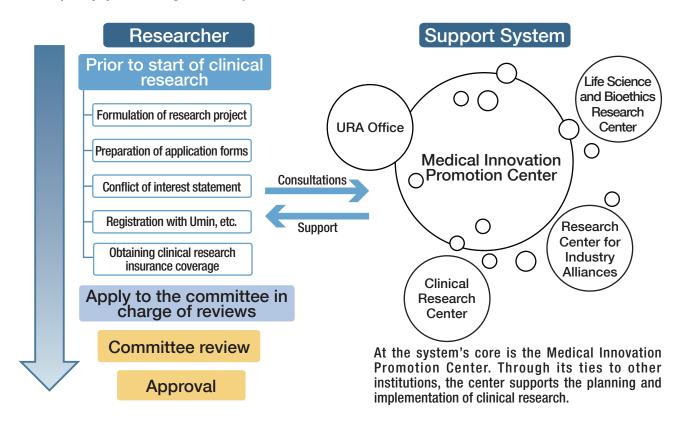
- The "safe handling workshop for radioisotope handlers (hereafter "RI handlers") is held every April and October. RI handlers must also undergo the "medical exam for persons engaged in radiation-related activities" at the Health Administration Center as a way to maintain health and safety.
  - Please 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. (Please refer to page 15 of this handbook.)
- 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 27 of this handbook for more information regarding MTAs.

### (3) Research ethics review system for medical research involving human subjects

Research class	Content and of rese		Applicable guidelines, etc.	Review co	ommittee	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
	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)		
Intervention studies (research	Gene therapy	Other than ex vivo	Gene therapy research principles			
that includes actions that exceed the breadth of normal	research Ex vivo		Act on the Safety of Regenerative Medicine	Designated and Regenerative	Clinical Research Review	
medical care)	Research in regenerative medicine			Medicine Board (provisional)		Medical Innovation Promotion Center (online application)
	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		
Observational research	Medical information, etc.			university, both committees will review the research.		
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.

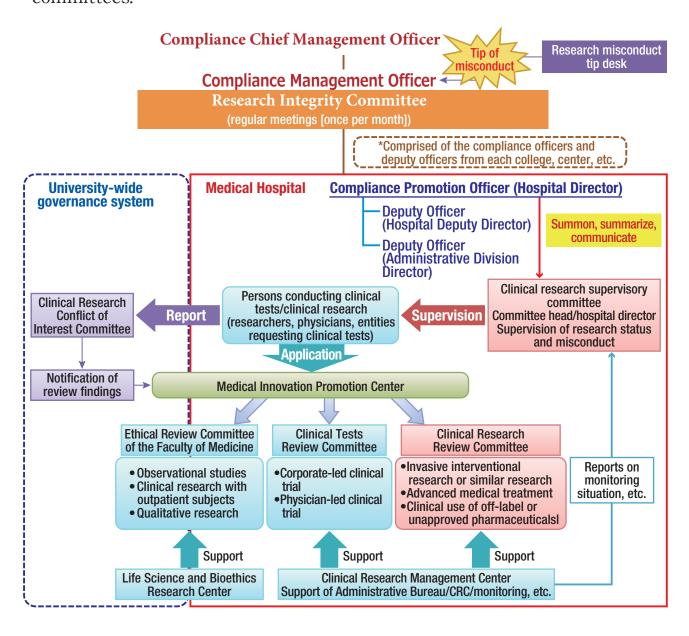
### (4) Various application procedures for clinical research (support system)

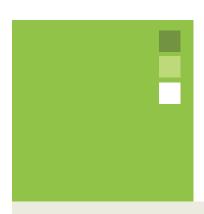


Even clinical research for which informed consent seems unnecessary must undergo an ethics review. However, clinical case reports (case reports) released with the patient's consent do not require an ethics review.

### (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.





# 6. Office for Research Safety Management and Environmental Safety Office

### (1) Overview and tasks of the Office for Research Safety Management

The Office for Research Safety Management is established within the Research and Industry-University Alliance Organization. The office primarily handles the tasks listed below. When pursuing any experiment related to medical or dental research, please contact this office with any questions or concerns regarding procedures.

(http://www.tmd.ac.jp/tmd-research/safety/)

- A) Creates manuals detailing the execution of all types of experiments
- B) Offers advice regarding the submission of application documents for all types of experiments
- C) Provides education and training regarding all types of experiments and coordination of annual schedule of proceedings
- D) Inputs information on all experimenters in a database
- E) Oversees discussions of policies regarding safe and proper execution of all experiments

### (2) Overview and tasks of the Environment 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

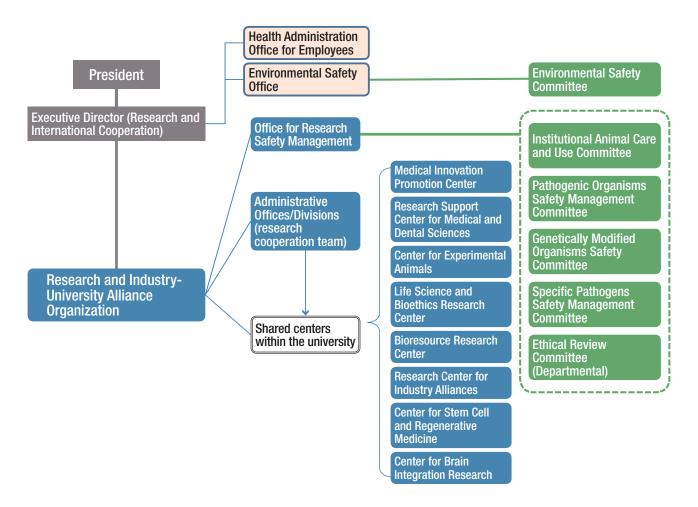
#### Disaster prevention measures for chemical substances

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

### Relations between the various committees, the Office for Research Safety Management, and the Environmental Safety Office



#### Inquiries:

Office for Research Safety Management:

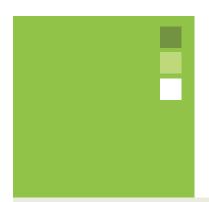
Ext. 5811

E-mail: info.saf.adm@cmn.tmd.ac.jp

**Environmental Safety Office:** 

Ext. 5916

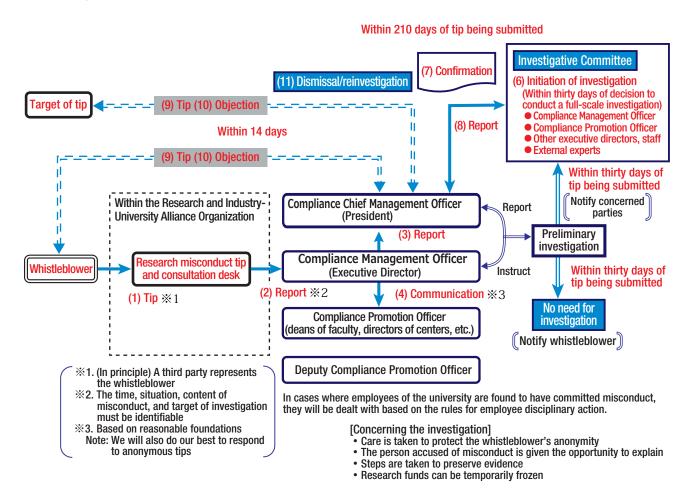
E-mail: kankyo.adm@tmd.ac.jp



#### 7. Research misconduct

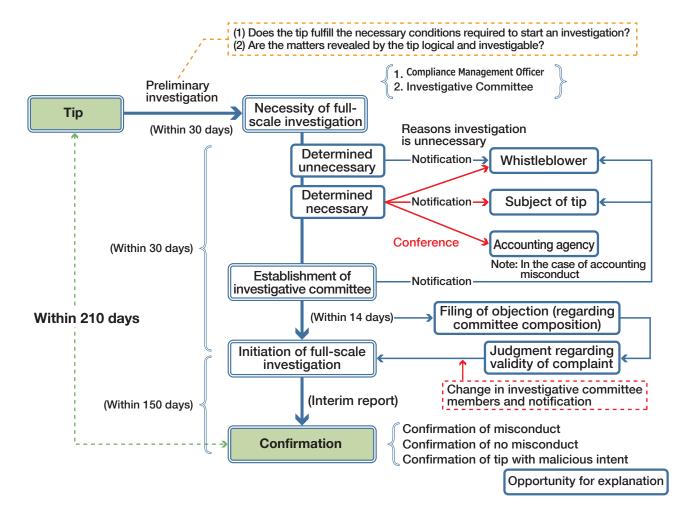
#### (1) Procedures for dealing with suspicions of misconduct

When a tip 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 thirty 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 thirty days of the decision to investigate. The whistleblower may file an objection regarding the members of the investigative committee within fourteen (14) days of the decision.



Whether there was misconduct and whether the tip 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) If misconduct was confirmed

Confirmed misconduct is 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 funding

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 this Guideline on October 17, 2012.

#### Misuse of research funds

Use of research funds		
Misuse Determined based on effects on society and degree of severity (in	(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
cases determined not to have been for personal appropriation)	(2) Degree of misuse of research funds determined to have had a minor effect on society and the misconduct to have not been severe	1 year
	(3) Effect on society and severity of misconduct determined to be other than (1) or (2)	2–4 years
Misuse Personal appropriation	(4) Funds used for personal economic gain, regardless of (1)–(3)	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

### Timeframe for restrictions on applying for and participating in competitive funding

Classification based on involvement in misconduct		Degree of misconduct	Suitable period	
Persons involved in misconduct	ed in with improper intentions from the start of their			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	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
	Authors other than those listed above	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	
				2-3 years
	(3) Persons involved in n	nisconduct 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

#### Note:

- A. Authorization to apply for competitive funding is revoked for competitive funding from the Ministry of Education, Culture, Sports, Science and Technology as well as competitive funding from other government agencies.
- B. 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) Response counter for misconduct prevention

Tips regarding research misconduct at this university and consultations regarding misconduct (in cases that haven't reached the stage of filing a tip) are handled at the following location:

### Research Integrity Office (Research and Industry-University Alliances Organization)

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

Tel./Fax: 03-5803-5024 (Hours: Weekdays, 8:30 a.m. to 5:15 p.m.)

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

#### How to file a tip or arrange for a consultation

- A) Tips 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 tip, 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

#### 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	<ul> <li>(1) Act on Regulation of Execution of Budget Pertaining to Subsidies, etc., and rules used by the researcher (grant terms)</li> <li>(2) University regulations such as accounting regulations</li> </ul>	(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)	<ul><li>(1) Contracts     Project manuals</li><li>(2) University regulations such as accounting regulations</li></ul>	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	<ul><li>(1) Endowment goals, endowment terms</li><li>(2) University regulations such as accounting regulations</li></ul>	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.

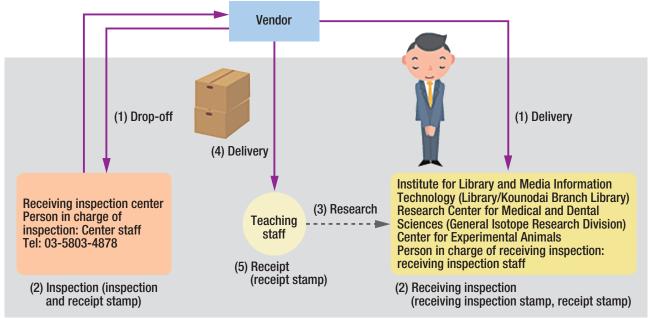
#### (2) Rules for the administration of research funds

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."

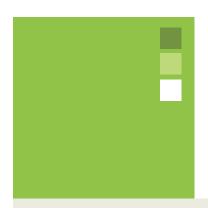
#### (3) Receipt and inspection center

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).



#### 9. Risk management of industryuniversity alliances

#### (1) What is industry-university alliance risk management?

Many different contracts—joint research, sponsored research, nondisclosure, licensing, etc.—are executed when executing industry-university alliance activities. Once a contract has been executed, there is an obligation to adhere to its contents. Likewise, there are myriad laws that must be obeyed in the execution of research activities and industry-university alliance activities.

If these contracts or laws are violated, the risk of civil or criminal liability arises. Industry pursues project development with a profit-making motive, while universities operate from motives of the search for truth and/or contributing to society. When these two work together on joint projects, conflicts of interest are bound to arise. When carrying out industry-university joint activities, sound management guarantees sound activities and conflict of interest management that increases transparency is crucial.

The risk of contract violations and legal violations—as well as the risk of the perception of conflict of interests—are defined as industry-university alliance risks. Let's explore the basic knowledge of contracts, laws and conflict of interest management, which is necessary when involved in research activities and industry-university alliance activities.



#### (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 (for 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.

#### What is a contract?

An agreement between parties regarding the occurrence, alteration and nullification of matters related to rights and obligations

(Generally a contract is enacted in written form, but oral contracts are also valid.)

In principle: Contracts prevail over laws (principle of private autonomy) Exceptions: Violation of mandatory provisions (criminal law, public order)

Mandatory provisions > contract > discretionary provisions (essentially all provisions in the Civil Code and Commercial Code)

Once a contract is entered into, contractual obligations apply whether the terms of the contract are deemed fair or not.

Note: Not having adequately read a contract before excuting it is not a valid reason to ignore contractual obligations.

TMDU's industry-university alliance contracts and research contracts Contracting Party

the university (corporation)

Contract representative (person who **executes** and affixes the seal to the contract):
University President (in the case of MTAs, the head of the college, institution, etc.)

#### (3) Types of systems and contracts for alliances

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 Administration Division of the Research and Industry-University Alliance Organization takes charge of contract-related administrative procedures. The goal of this division of labor is the efficient execution of contracts.

#### **Types of Contracts**

Collborative Research	A joint 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 joint research on a shared topic.
Commissioned Research	Sponsored 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 Course	Funding for the operation of a joint research seminar 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 <b>executed</b> 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 "Guidebook Concerning Material Handling" (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 contract is used when jointly applying for a patent with an external organization such as a corporation to determine each party's <b>ownership</b> proceeds and <b>bearing the</b> application expenses, as well as to decide management responsibilities.

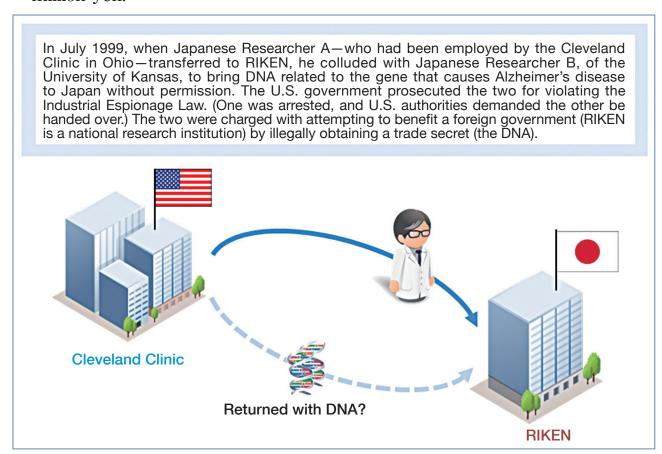
#### (4) Legal compliance

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.



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 ten years and a maximum fine of ten 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

Overseas
(corporation, research institution)

Export of goods

Exporters are required to obtain permission from the Minister of Economy, Trade and Industry to export specific goods restricted by order of the Cabinet to specific regions.

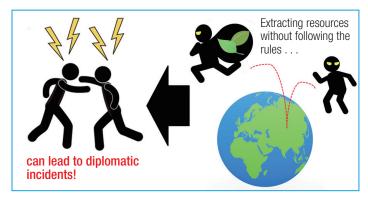
Overseas
(corporation, research institution)

Hosting of a nonresident who attempts to conduct transactions for the purpose of providing specific technology restricted by order of the Cabinet to specific nations, or a resident who attempts to conduct transactions with the purpose of providing specific technology to nonresidents who are citizens of specified nations, require permission from the Minister of Economy, Trade and Industry.

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) Conflicts of interest

Broadly speaking, conflict of interest includes both "narrow conflicts of interest" and "conflicts of obligations" (Note 1). "Narrow conflicts of interest" can be divided into "conflicts of interest at the personal level" and "conflicts of interest at the organizational level." In this handbook, we are mainly concerned with personal conflicts of interest.

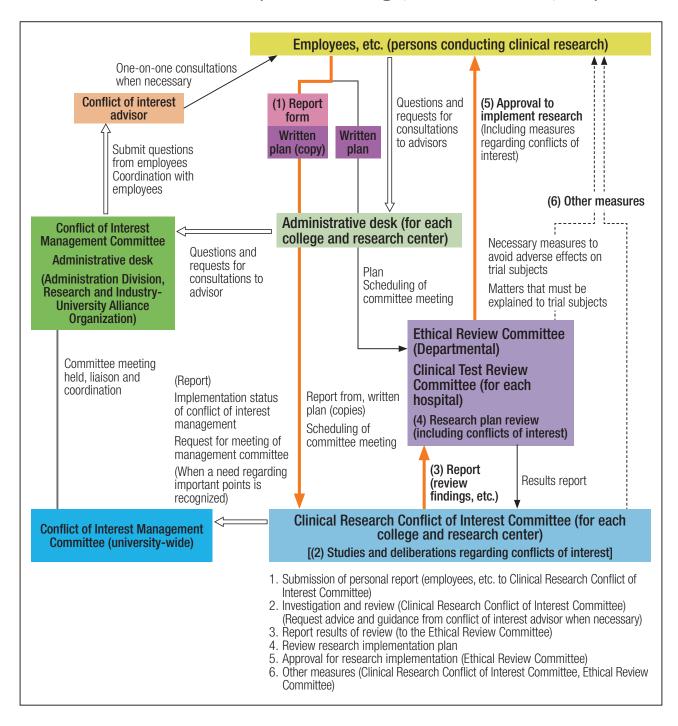
In concrete terms, conflicts of interest refers to situations where the fair and appropriate judgment required in public research is impaired due to ties of economic interest to external entities, or situations which are apt to result in a third party expressing concerns of such an impairment of judgment.

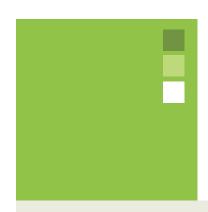
Situations that can hinder fair and appropriate judgment include the falsification of data, preferential treatment of specific corporations and continuation of research that should be halted.

(Note 1) 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)

### Conflict of interest management system "Conflict of interest management in clinical research (for each college, research center, etc.)"





# 10. Standard of Conduct and regulations for misconduct prevention

Tokyo 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: CITI Japan e-learning program

  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

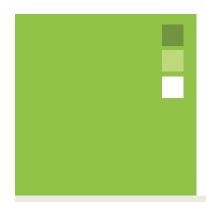
The Office of Research Safety and Management will send usernames and passwords

Access: http://edu.citiprogram.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 academic year 2014)
- 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. Excute the form and submit the original.



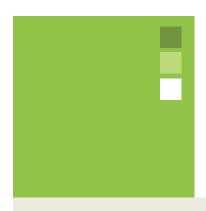
#### 11. Q and A

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	A personal computer or tablet is purchased with research funds, but is used for purposes not considered relevant to research expenses.	This is regarded as misuse of research funds.

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



# 12. Standard of Conduct and regulations for misconduct prevention

# Standard of Conduct Regarding Research Activities at Tokyo Medical and Dental University

Enacted October 16, 2007

Tokyo Medical and Dental University's philosophy of education is to foster creative human beings equipped with a broad-based education and a rich sensitivity who possess the ability to both pose and resolve questions of their own making, and medical professionals with a rich international perspective. This philosophy can only be realized through academic and research activities based on a strong awareness and understanding of the importance of contributing to society.

Research activities are activities that create new knowledge by building on the achievements of one's predecessors to obtain one's own findings. It is desired to encourage independent research by obtaining the trust and good faith of society. Research misconduct threatens to greatly damage trust in scientists as a group, hinders the development of science built on justice and integrity, and damages society's faith in science as a whole. Research misconduct can therefore not be tolerated.

Those that conduct medical and dental research at this university bear an important responsibility because such research contributes directly to human health and welfare. Researchers must be aware of transparency and accountability based on a strong ethical sense for every research activity in which they take part. The ethics and conduct standards regarding research activities are laid down here based on these points, and all persons involved in research activities—including the administration and management of public research funds (not only teaching staff and researchers but also research support staff and administrative staff—hitherto referred to as "all persons involved")—must adhere to them.

These ethics and conduct standards were created based in part on "On Standards of Conduct for Scientists" (enacted October 3, 2006 and revised January 25, 2013 by the Science Council of Japan).

#### I. Researchers' obligations

1. Researchers' responsibilities

Researchers have a responsibility to guarantee the quality of any specialized knowledge or technology that they create, and to use this specialized knowledge, technology and experience to contribute to the health and welfare of humanity, the safety and peace of society, and the sustainability of the global environment.

#### 2. Researchers' stance

Researchers shall always make decisions and act in an honest and conscientious way. They shall work to maintain and advance their own specialized knowledge, abilities and skills and work to their utmost to scientifically demonstrate the accuracy and validity of the knowledge their scientific research generates.

#### 3. Researchers in society

Researchers must be aware that the independence of science is built on the trust and good faith of society. They must also understand the relationship between science/technology and society and the natural environment from a broad perspective, and act accordingly.

#### 4. Research that responds to society's expectations

Researchers have an obligation to respond to society's expectations that they will elucidate truth and resolve certain issues. Researchers must always be cognizant of the existence of these broad social expectations when using research funds provided for the development of the research environment and the execution of their research.

#### 5. Explaining and publicizing findings

Researchers shall endeavor to publicize and clearly explain the significance and role of research in which they are involved. They shall evaluate the effects that their research could have on people, society and the environment and report their findings in an impartial and objective manner while maintaining a constructive dialogue with society.

#### 6. Ambiguities regarding use of scientific research

In recognizing that the results of their research could be misused for destructive purposes contrary to their own intentions, researchers shall choose appropriate, publically sanctioned means of executing their research and publicizing their findings.

#### II. Proper research

#### 7. Research activities

Researchers shall carry out the drafting, planning, application, execution and reporting phases of their research conscientiously in keeping with the intent of these standards. When publicizing their research findings in a scientific paper or otherwise, researchers are recognized for results achieved through the work of every member of the research team. At the same time, the researcher must take responsibility for the actions of all team members. Research and test data must be painstakingly recorded and preserved to avoid committing any misconduct—including fabrication, falsification and plagiarism—nor should researchers conspire in such conduct.

8. Development of the research environment and thorough education and enlightenment Researchers shall be cognizant that one of their important obligations is the establishment and maintenance of a proper environment that makes possible the execution of the research for which they are responsible as well as promoting the prevention of misconduct. Researchers shall work ceaselessly to qualitatively improve the research environment within their community of researchers and the university as a whole, and to educate and enlighten all regarding the prevention of misconduct. In addition, they shall endeavor to obtain society's understanding and cooperation in achieving these tasks.

#### 9. Concern for research subjects

Researchers shall respect the individuality and human rights of those who cooperate in research and show concern for their welfare. They shall also handle research animals with a sincere attitude.

#### 10. Relations with others

While appropriately evaluating and critiquing the findings of others, researchers shall listen carefully and humbly to evaluations and critiques of their own research, exchanging opinions with a sincere attitude. They shall fairly evaluate the achievements of others and their intellectual findings, and respect authority and intellectual property rights. They shall also actively participate in the peer review of fellow researchers within the community of researchers, particularly in their own specialty.

#### III. Science in society

#### 11. Dialogue with society

Researchers shall actively participate in exchanges with citizens to enhance mutual understanding between society and the research community. They shall endeavor to provide valid scientific counsel regarding policy formation to persons proposing and determining policy to resolve various societal issues and promote the realization of social welfare. At such times, researchers shall aim to present advice based on the consensus among researchers. If differences of opinion do exist in the scientific community, they should be presented in an easy-to-grasp manner.

#### 12. Scientific counsel

Researchers shall conduct research activities with the goal of contributing to the public welfare, and present impartial advice based on an objective scientific foundation. At such times, researchers shall be cognizant of the significant impacts that their statements could have on public opinion and policy formation, understand their responsibility, and not abuse their authority. They shall also do their utmost to ensure the quality of their scientific counsel, while at the same time clearly explaining the uncertainties of scientific knowledge and the diversity of opinions.

#### 13. Scientific counsel for policy formulators and policy decision-makers

When providing scientific counsel to policy formulators and policy decision-makers, researchers shall recognize that although scientific knowledge should be adequately respected as part of the policy formation process, it is not the sole basis for deciding policy. If a policy is selected that differs from the counsel the research community has given, it may be necessary to ask those who proposed and decided on the policy to explain their decision to the public.

#### IV. Legal compliance

#### 14. Legal compliance

All those involved in research shall actively participate in training and information sessions regarding research activities, including the administration and management of public research funds. They shall work to acquire knowledge and understanding of all related laws, university regulations and rules and comply with them.

#### 15. Appropriate use of public research funds

All those involved in research shall be cognizant that the source of public research funds is the taxpayer's money, and of the need for accountability in the use of those funds.

#### 16. Obligations of administrative staff

Administrative staff shall understand the uniqueness of this university's research activities and use their specialized knowledge and abilities to ensure the appropriate administration of public research funds.

#### 17. Mutual cooperation

All those involved in research shall cooperate and work to prevent research misconduct (including misuse of research funds) before it happens.

#### V. Miscellaneous

#### 18. Nondiscrimination

Researchers shall not discriminate against individuals based on race, gender, rank, ideology/creed or religion during research, education or social activities, and treat all persons fairly based on the scientific method, respecting personal freedoms and human rights.

#### 19. Conflicts of interest

In their research, evaluations, critiques and scientific counsel, researchers shall pay sufficient attention to the possible collision of interests between the individual and the organization or between different organizations, and respond appropriately in consideration of openness to the public view.

#### Supplementary provisions

This Standard of Conduct was put into effect October 16, 2007.

Supplementary provisions (revised September 24, 2014)

This Standard of Conduct was put into effect October 1, 2014.

# Regulations for the Prevention of Research Misconduct at Tokyo Medical and Dental University

January 22, 2015 Rule No. 7

#### Chapter 1. General rules

#### Article 1: Summary

The prevention of research misconduct at Tokyo Medical and Dental University (hereafter referred to as "this university") is based on these regulations, as well as all relevant laws, guidelines concerning the types of misconduct and the Standard of Conduct for Research Activities at the Tokyo Medical and Dental University (hereafter referred to as "the Standard of Conduct").

#### 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 shall be 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 tips

#### Article 13: Tip desk

- 1 A tip desk shall be established in the Promotion Office to deal with tips or consultations received from inside and outside the university regarding research misconduct at this university.
- 2 The tip 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 tips can be received in writing, by phone, by mail or in person.

#### Article 14: Receiving and reacting to tips

- 1 Upon receiving a tip at the abovementioned Research Misconduct Tip 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 tip (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 tip.
- 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 tip.
- 4 When the contents of the tip require investigation by other research institutions, the tip desk shall forward the tip to the relevant research institutions. Tips forwarded to this university from other institutions shall be handled as tips at this university according to the three clauses above.
- 5 If suspicion of misconduct (including cases where the tip 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 tip 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 tip desk.
- 6 Tips 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 tip in a manner in which the whistleblower does not know whether the tip desk actually received the tip, such as a written tip, the whistleblower shall be notified that the tip was received.

#### Article 15: Handling of whistleblowers and targets of tips

- 1 The person at the tip desk who receives a tip must protect the secrecy of the tip'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 Management Officer, Compliance Management Officer, Compliance Promotion Officer, 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 tip 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 tip.
- 4 Without sufficient cause, the Compliance Chief Management Officer shall neither ban the targetedindividual 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 tip.
- 5 The Compliance Chief Management Officer shall institute measures to protect the targeted individual from slander.

#### Section 2 Tip Investigative System and Methodology

#### Article 16: Cases of tips requiring investigation

- 1 To prevent the submission of tips 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, tips (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, tips 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 tips—shall be subject to investigation to the extent possible.
- 3 For tips related to the misuse of research funds, tips 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 tip, 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 tip'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/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 tip 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.
- <sup>3</sup> 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 tip, 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 tip—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 tip, 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 tip 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.
- 3 The investigative committee shall determine that misconduct has occurred when the targeted individual's testimony and other evidence do not overturn suspicions of misconduct.
- 4 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 tip 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.

- <sup>4</sup> 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 tip 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 tip 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 tip 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.
- 2 To 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 hrough the Investigative Committee for Halting Transactions against businesses tsuspected 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 Administration Office of the Research and Industry-University Alliance Organization 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 it of regarding 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 Provision

These regulations were enacted January 22, 2015.

### Attached chart (List of heads of schools, institutions, etc.)

Schools, institutions, etc	Dean	Notes
Faculty of Medicine and Graduate School of Medical and Dental Sciences (medical)	Dean of Faculty of Medicine	ncluding the Medical Hospital
Faculty of Dentistry, Graduate School of Medical and Dental Sciences (dental)	Dean of Faculty of Dentistry	Including the Dental Hospital
Graduate School of Health Care Sciences	Dean of the Graduate School of Health Care Sciences	
College of Liberal Arts and Sciences	Dean of the College of Liberal Arts and Sciences	
Institute of Biomaterials and Bioengineering	Director of the Institute of Biomaterials and Bioengineering	
Medical Research Institute	Director of the Medical Research Institute	
Institute for Library and Media Information Technology	Director General of the Institute for Library and Media Information Technology	
Center for Education Research in Medicine and Dentistry	Director of the Center for Education Research in Medicine and Dentistry	
Research and Industry-University Alliance Organization	Officer of the Research and Industry-University Alliance Organization	Including the Dental Hospital
International Exchange Center	Director of the International Exchange Center	
Student Support and Health Administration Organization	Director of Student Support and Health Administration Organization	
Center for Interprofessional Education	Director of the Center for Interprofessional Education	

### 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				
Employe	e number	/stude	ent nu	mber:		
Affiliated school, institution, etc. and field of study or research:						
Name:					Ç	Seal

## 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 tip 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





#### **Preparation and Editing**

#### Tokyo Medical and Dental University

Research Integrity Office (Administration Office, Research and Industry-University Alliance Organization)
Office for Research Safety and Management
Misconduct Prevention Plan and Promotion Committee

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