

**Guideline for Conflict of Interest Management for Medical Research
and Related Reference Materials**

(Proposal for the Board of Directors of the Japanese Society of Pathology, Mar.28, 2011.)
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1. Guideline for Conflict of Interest Management for Medical Research

**The Japanese Society of Pathology
Medical Ethics Committee**

I. Introduction

In order to contribute to our society, through citizen educational programs, and by conducting educational programs for its members and providing its members with the opportunity to attend conferences and present the results of both basic and clinical research conducted by members, the Japanese Society of Pathology aims for improvements in the clarification of the etiology and pathology of diseases, as well as advances in the prevention, diagnosis and treatment of disease.

In Japan at the present, based on the policy of vitalizing the country through the establishment of Japan as a leader in the science and technology fields, there are a variety of programs and movements underway, being conducted as strategic government policies, and liaison between the industrial, academic, and government fields has been strengthened. The restoration of the results of research produced by universities, research organizations, and academic societies to society is of vital importance for the vitalization of the economy, as well as for ensuring security, safety and a good life-style standard for the citizens, and at the same time, it is significantly important for the vitalization of the source of those results, the education and research fields. In the local districts, as liaison between the industrial and academic fields increases, we have seen that the public organizations, such as universities and academic societies, develop deeper relationships with specific enterprises, and it is inevitable that the social responsibility of scientific organizations and foundations in the fields of education and research and the issue of personal benefit that arises along with liaison activities between the industrial and academic fields come into conflict. This situation is described by the phrase "conflict of interest" (COI), and there has been an increasingly strong demand for academic organizations and societies active in the fields of education and research to implement appropriate management of any latent COI situation for researchers employed at such organizations, in order to ensure that human rights and the safety of persons participating as the subjects of clinical studies are protected as part of the duties of those organizations.

The development of COI began in Japan in July of 2004, in a panel discussion sponsored by the Ministry of Education, Culture, Sports, Science and Technology (MEXT), titled "COI Measures for Clinical Research and Clinical Trials," where the importance of the COI issue related to clinical research was confirmed. Accordingly, MEXT established a commissioned study group entitled the "Study Group on the Theory of Clinical Research and Conflicts of Interest," and in March of 2006, a "Guideline for the Drawing Up of Policies Related to Clinical Research and Conflicts of Interest" was announced. The aim of this guideline was to define rules of conduct aimed at researchers engaged in clinical research in situations where the researchers were operating under conditions of an economic conflict of interest, and by establishing these rules at each of the universities, research organizations, hospitals and academic societies, etc., concerned, maintain the prestige and results of the organizations and individuals involved in research employing human subjects while ensuring the related social trust. Accordingly, the aim of this guideline extends to ensuring that the researchers involved could be confident that they were operating in a just environment, and concentrate on conducting their clinical research freely at a high level of quality. Thereafter, in 2008, the Ministry of Health, Labour and Welfare announced a document entitled "A Guideline for COI Management for Scientific Research Related to Health, Labour and Welfare," which expressly stipulated the duties related to COI management aimed at researchers receiving grants or other funds for the research concerned.

Recently, there has been a trend seen worldwide for nations to implement strategic promotion of translational research applied in a clinical setting, rather than basic seed research, and in the midst of this transition, the type of research targeted for COI management has not been limited to just clinical research or clinical trials employing human subjects (including treatment studies), but rather expanded to include basic life-science research conducted through liaison between organizations in the academic and industrial fields. In other words, the trend is for persons involved in basic research conducted by private organizations or profit-based foundations or other organizations through liaison between the academic and industrial sectors to submit a report on their personal economic COI situation. In view of this trend, the Japanese Society of Pathology decided to define the types of research that require COI management as "Medical Research," covering a wide variety of research fields conducted through liaison between organizations in the academic and industrial fields, such as research on the improvement of disease prevention, diagnosis, and treatment methods, the improvement of the clarification of the etiology and pathology of diseases, as well as the improvement of patient's daily life, including life science research, basic medical science research, clinical medical science research aimed at human subjects (including research that employs personal information or other data from which individuals can be identified), and clinical trials.

In consideration of its social responsibility and the demand for a high standard of ethics, the Japanese Society of Pathology determined to produce this Guideline for Conflict of Interest Management for Medical Research (hereafter, the Guideline). Through the provision of appropriate COI conditions for its members, the purpose of the Guideline was to ensure that our efforts to create venues for the presentation of research results, and promoting the spread of those results, as well as for member education, will be appropriately continued honorably in conditions of neutrality and thus fulfill our social responsibility to contribute to progress in the prevention, diagnosis and treatment of disease.

The main point of the Guideline is to inform the members of the Japanese Society of Pathology of the fundamental concepts related to COI, and when members of the organization are involved in a project conducted by the Japanese Society of Pathology, ensure that the members submit a public COI report in order to maintain the COI conditions appropriately. Members of the Japanese Society of Pathology must observe the policies shown below, and actively promote progress in medical research.

II. Basic concepts related to COI

A COI situation in a medical research organization can impact the rights of patients, their life or safety. In addition, when treatment methods are devised in basic research or in an onsite medical treatment setting, if the researcher is performing basic medical research, a clinical trial or treatment trial under liaison between academic and industrial organizations, and especially considering the special circumstances that venture companies are often involved in when producing new products based on these plans, the inevitable result is the rise of a COI situation. However, the appearance of an economic COI situation is not an issue in itself, rather it is important to construct a system providing for appropriate management at the institute, organization or academic society concerned in order to ensure that inappropriate medical research is not conducted.

In the field of medical research, in regard to clinical research and clinical trials aimed at human subjects, transparency reliability and specialty aspects have already been guaranteed by the use of appropriate COI management. In the "Guideline for Ethics in Clinical Research" issued by the Ministry of Health, Labour and Welfare, the explanation is "Under no circumstances whatsoever should the nature of the research become warped due to a conflict with the interest of the researcher concerned," but based on the situation in regard to clinical research in Japan, "If all research that had a reciprocal economical interest with a private organization was shut down, it may be considered that

this would be an obstruction to the development of pharmaceuticals and drugs, etc." As shown here, in the field of medical research, especially clinical medical research and clinical trials, the ethics and specialty aspects are very important, and as the research is differentiated because it is aimed at human subjects, there is somewhat of a different characteristic involved, compared to the usual COI issue. Therefore, it may be considered that the major prerequisite here is first to overcome that different characteristic in an appropriate manner, and in order to prevent any potential COI situation from developing into a serious issue, assure that medical research aimed at human subjects is conducted appropriately with a high degree of transparency.

In COI management related to medical research, information regarding the economic interests (funds, etc.) or other related interests (status or concessions) offered to the researchers involved by enterprises, public organizations engaged in profit-making endeavors, or foundations must be disclosed appropriately within the system. In the performance of basic medical research, clinical medical research, or clinical trials (including treatment trials), it is desirable that this information is offered and disseminated appropriately and that the information offered by the researcher concerned can be objectively judged and evaluated. Furthermore, individuals in positions performing medical research who conduct themselves in any manner that damages the reliability of the research concerned or that threatens the safety of the subjects participating in a clinical medical research project must not be allowed to reap any personal benefits or proprietary rights. In order to assure this stipulation, COI situations must be avoided or a third-party supervision committee employed to assure that the medical research is performed appropriately. Furthermore, in regard to academic societies, the personal financial benefits of the researchers concerned or related interests must be disclosed appropriately, and accordingly, all educational and research activities must be promoted based on the principles of impartiality, independence, objectivity, and rigorous scientific procedures.

III. Persons subject to the Guideline

The Guideline will apply to any person in the following list, when a COI situation may arise.

1. Members of the Japanese Society of Pathology
2. Executives of the Japanese Society of Pathology (Chairman of the Board of Directors, Directors, Auditors), Chairperson of the General Assembly, the Chairperson of the various committees, members of special committees (Academic Affairs Committee, Editorial Committee for the Society's Journals, Committee for Diagnosis Guidelines, Medical Ethics Committee, Guidelines Development Committee), and committee members of provisional work section meetings (subcommittees, working groups. etc.)
3. Persons giving presentations at the General Assembly of the Japanese Society of Pathology, persons appearing at scientific meetings sponsored by the Japanese Society of Pathology, and authors being published in the Society's bulletins or either of the Society's journals
4. Staff employees of the Japanese Society of Pathology

IV. Activities subject to the Guideline

The Guideline applies to all participants of all of the activities conducted by the Japanese Society of Pathology (hereafter, the Society) as enumerated below.

1. Academic meetings and conferences (including annual general assemblies), academic lecture meetings, and academic meetings sponsored by each of the Society's local branches
2. Bulletins, journals or books published by the Society

3. Diagnosis guidelines, the drawing up of manuals, and formulation of guidelines, etc.
4. Authorization of certified pathologists and in-service training facilities, etc.
5. Performance of research or studies
6. Promotion of research and public prizes for research results
7. Promotion of international research activities
8. Other activities, and duties necessary to accomplish the goals of the Society

Furthermore, even when members of the Society are engaged in activities not related to the activities of the Society, members must observe the Society's COI policies.

V. Items that should be disclosed and open to the public

When persons subject to the stipulations shown below as items No. 1 through No. 7 find that they meet or exceed the criteria, defined elsewhere, for a COI situation, it is their duty to use the prescribed form for a COI situation, and voluntarily file a report disclosing the situation accurately. In addition, it is also the duty of persons subject to these stipulations to file an accurate report on the situation to the Society when they find that either one's spouse, any member of their immediate family, or a joint owner of any earnings or property, as applies to items No. 1-3 below, exceeds the criteria defined elsewhere. Furthermore, the person filing the report is responsible for its content. Details on the disclosure method will be separately defined in the subsidiary rules and regulations for subject activities.

1. Persons employed as an executive or an adviser for a private enterprise or a profit-making organization
2. A stockholder of the organization concerned
3. Persons who receive a patent royalty from a private enterprise or a profit-making organization
4. Persons who receive a daily allowance paid for attending a meeting (giving a presentation at the meeting) or any allowance for time or effort expended by a researcher from a private enterprise or a profit-making organization
5. Persons who receive a manuscript fee for writing a pamphlet, etc. for a private enterprise or a profit-making organization
6. Persons who receive any research funds offered by a private enterprise or a profit-making organization
7. Other remunerations (not directly related to research, such as travel expenses or presents)

VI. Avoiding COI situations

1. Items all subjects should avoid

The presentation of the results of medical research should be based purely on scientific conclusions and conducted solely in the public's interest. In regard to decisions on whether or not the results of any medical research should be presented in a written paper or verbally at a medical conference and also in regard to the essential nature of any medical research results and the interpretation of those results, members of the Japanese Society of Pathology must not be influenced by the arbitrary intention of any person or organization providing financial support for the medical research, or enter into any contract that would make it impossible to avoid any such influence.

2. Items the person responsible for a clinical trial or clinical research should avoid

Persons selected to be responsible for a clinical trial with decision-making authority in regard to the planning and performance of clinical research, including clinical trials and treatment trials (not applicable to the principal physician in charge of each of the facilities at a multi-facility clinical research project) should be free of all of the COI situations listed below, and after they are selected, they should avoid these situations.

1. The assumption of office as an executive or advisor or being a stockholder for a company or person providing funds for the medical research (excluding a scientific advisor without compensation)
2. Ownership of patent rights or the reception of patent royalties related to medicines or medicinal supplies, treatment methods or study methods, etc. related to the clinical research themes concerned
3. The reception of payment of travel or accommodation expenses for participation in an academic meeting not related to or necessary for the research concerned from a company or person providing funds for the medical research
4. The reception of expenses far exceeding that necessary for the research concerned
5. The reception of payment or gifts exceeding that considered fair compensation for the time and effort spent on the research concerned

However, even if the person concerned is applicable under the conditions listed above, if the person concerned is considered absolutely necessary for the planning or performance of said clinical research, and the research is considered extremely important and significant from an international viewpoint, the person may be assigned as the physician in charge of the clinical trial for the research concerned.

VII. Implementation methods

1. Roles for members of the Japanese Society of Pathology

When members of the Japanese Society of Pathology present research results at academic meetings, etc., they must assume the duty of appropriate disclosure of their COI situation related to the performance of the research concerned. The disclosure must be conducted using the prescribed forms specified in the subsidiary rules and regulations. When there is a question in regard to a COI situation going against the items specified in the Guideline, the Medical Ethics Committee in Charge of COI Management (hereafter, abbreviated as the Medical Ethics Committee) will deliberate on the issue, and submit a report to the Board of Directors.

2. Roles for executives and members of the Japanese Society of Pathology

The Directors, Auditors and the Chairpersons of each of the various committees of the Japanese Society of Pathology play important roles in all of the activities of the Society, carrying a heavy responsibility, and in regard to COI situations related to the activities of the Society, they are obliged by duty to submit a report on their COI situations from the time they assume their various positions.

In regard to meetings of the Board of Directors, the executives of the Japanese Society of Pathology (Chairman of the Board of Directors, Directors, and Auditors) are responsible for the execution of all of the activities of the organization, and when a serious COI situation arises, or

when a report reveals an inappropriate COI situation, an inquiry will be submitted to the Medical Ethics Committee. Improvement measures, etc., can be indicated based on a report from the Medical Ethics Committee.

When members of the Japanese Society of Pathology present medical research results, the chairperson and members of the Program Promotion Committee will verify whether or not the presentation is in accord with the Guideline, and the Committee can order the halt of any presentation that is not in agreement with the Guideline. When this occurs, the person(s) scheduled to give the presentation must be notified immediately of the action, along with the main relevant reasons. Furthermore, the Medical Ethics Committee will deliberate on this issue, and submit a report to the Board of Directors, which must approve the action before it is implemented.

When the results of medical research will be published in one of the Japanese Society of Pathology's journals, the Editorial Committee for the Society's Journals will verify that the paper is in accord with the Guideline, and the Committee can order the halt of the publication of any paper that is not in agreement with the Guideline. When this occurs, the author of the paper must be notified immediately of the action, along with the main relevant reasons. When it becomes clear that the paper concerned is in fact not in agreement with the Guideline after it has been published, the publication concerned may publish a public notification to that effect under the name of the Chairperson of the Editorial Committee for the Society's Journals. Furthermore, the Medical Ethics Committee will deliberate on this issue, and submit a report to the Board of Directors, which must approve any action before it is implemented.

The Chairperson and committee members of other committees of the Society must verify that the various activities of the Society and their performance are in agreement with the Guideline, and when there is any doubt that either goes against the Guideline, they must immediately study improvement measures. Furthermore, the Medical Ethics Committee will deliberate on this issue, and submit a report to the Board of Directors, which must approve any measures before they are implemented.

3. Filing an objection against a prohibition order

Persons who receive a prohibition order against a publication or presentation according to stipulation No. 1 or No. 2 above may file an objection with the Japanese Society of Pathology. When the Chairman of the Board of Directors of the Japanese Society of Pathology receives any such objection, he will immediately establish an Objection Judgment Committee, which will deliberate on the issue and report to the Board of Directors. The Board of Directors will deliberate on the issue and notify the person filing the objection of the results of their investigations.

VIII. Measures taken against the indicated Guideline offender and the responsibility for explanations

1. Actions implement against Guideline offenders

The Japanese Society of Pathology reserves the authority to deliberate on behavior in violation of the Guideline as specified in the rules and regulations specified by the Society elsewhere. An inquiry regarding related matters will be submitted to the Medical Ethics Committee and a report issued by the Committee will be submitted to the Board of Directors. When deliberations conducted by the Board of Directors based on that report indict that there

has been a serious violation in conflict with the Guideline, actions may be implemented, in accordance with the seriousness of the violation as shown below, either all items or in part, as required.

1. All presentations at academic and lecture meetings sponsored by the Society will be prohibited.
 2. All publications of any paper in printed material issued by the Society will be prohibited.
 3. The assumption of office as a Chairperson at academic and lecture meetings sponsored by the Society will be prohibited.
 4. Participation in the Board of Directors, any committee or work section of the Society will be prohibited.
 5. The person will be removed from the position as councilor, or the assumption of the post of councilor will be prohibited.
 6. Suspension of the qualification for membership in the Society, expulsion from membership in the Society, or prohibition of becoming a member
2. Filing an objection

Persons considered in violation of the guideline can file an objection against the ruling with the Japanese Society of Pathology. When the Chairman of the Board of Directors of the Japanese Society of Pathology receives any such objection, he will immediately establish an Objection Judgment Committee, which will deliberate on the issue and report to the Board of Directors. The Board of Directors will deliberate on the issue and notify the person filing the objection of the results of their investigations.

3. Responsibility for explanations

When it is considered that there has been a serious violation of the Guideline related to the presentation or publication of the results of medical research at locations involved with the Japanese Society of Pathology, a meeting of the Board of Directors must be held immediately to deliberate on the issue and fulfill its responsibility to issue an explanation to the public.

IX. Establishment of subsidiary rules and regulations

The Japanese Society of Pathology reserves the rights to establish the subsidiary rules and regulations necessary in order to implement the Guideline.

X. Enforcement date and revisions to the Guideline

The Guideline will be implemented and in force on Mar.28, 2011

In order to assure that it will remain appropriate considering the variations seen in social factors and stay in agreement as new laws and ordinances are passed or revised, and further, maintain its viability with the various conditions surrounding medical treatment and research, it is considered that revisions to parts of the Guideline will be necessary in the future. The Medical Ethics Committee of the Japanese Society of Pathology, through decisions concluded at meetings of the Board of Directors, the Councilors, and the General Meeting, reserves the right to deliberate on and conduct revisions to the Guideline.

Furthermore, this document, the "Guideline for Conflict of Interest Management for Medical

Research," was drawn up based on the "Guideline for the Drawing Up of Policies Related to Clinical Research and Conflicts of Interest" announced in March of 2006 by the Ministry of Education, Culture, Sports, Science and Technology, "A Guideline for COI Management for Scientific Research Related to Health, Labour and Welfare," announced in March of 2008 by the Ministry of Health, Labour and Welfare, and the "Guideline Related to COI in Medical Research (proposal)," announced in December of 2010 by the Japanese Association of Medical Sciences.

2. Guideline Related Q&A

I. Q&A related to the purpose of drawing up the Guideline

Q1. I understand that in the original sense, COI management was conducted at the organization the researcher belonged to, so what type of management does the Japanese Society of Pathology do? (Related to Sections I – IV of the Guideline)

A1. Many of the members of the Japanese Society of Pathology belong to facilities conducting basic research or clinical research, and the results they obtain are presented at Society meetings. Please consider that COI disclosure is desired not only at the facility concerned, but also at the Society in both steps of the research process, the performance of the research and the presentation of the results of the research.

All of the researchers involved in the clinical research concerned must submit a research performance plan, and at the same time, submit a COI report to the head of facility the members belong to, and received COI management by the facility concerned, as suggested (Ministry of Education, Culture, Sports, Science and Technology and the Study Group for Ethics and COI Related to Clinical Research; "Guideline for the Drawing Up of Policies Related to Clinical Research and Conflicts of Interest").

In contrast, the "Guideline for Conflict of Interest Management for Medical Research" (hereafter, the Guideline) was drawn up by the Japanese Society of Pathology in order to protect the social and ethical position of members of the Society involved in all aspects of the Society's activities through the public disclosure of a COI situation report submitted by the members.

In other words, the Japanese Society of Pathology asks for disclosure through a report on the COI situation related to the subject of a presentation or paper related to medical research. In addition, in regard to executives of the Society and the chairpersons of the various committees, who have a large influence on the activities of the Society, an even more detailed public disclosure of the COI situation is requested. In regard to the Medical Ethics Committee, which is responsible for drawing up and making revisions to the Guideline, not only the chairperson of the committee, but also all committee members are required to submit the detailed COI situation disclosure.

Q2. Could you explain in easy-to-understand terms the basic concepts of COI management? (Related to Section II of the Guideline)

A2. In the field of medical research, there are many cases where the researchers at basic research or treatment on-site facilities devise new diagnosis or treatment methods, and the on-site researchers are involved in the performance of research, clinical trials or treatment trials conducted in liaison with academic and industrial organizations, and furthermore, there are also many cases where the results of that research are employed in product development conducted by a venture company with the involvement of the researchers concerned. This

special characteristic makes it inevitable that a COI situation will arise. The important point here is that there is no inherent issue in the rise of the COI situation itself, but rather the issue is whether the Society can construct a COI management system capable of implementing appropriate COI management or not, in order to ensure that inappropriate medical research is not conducted. In short, COI management is employed to assure that sufficient public disclosure of the financial benefit and related economic compensation for each of the individuals involved is enacted. Accordingly, this will ensure that the research itself or any presentation of the results of the research is not influenced by any economic interest, and for the Japanese Society of Pathology, the COI management system will function as a guarantee providing security for both the organization itself and its members.

- Q3. If we observe the articles in the Guideline and the stipulations of the enforcement subsidiary rules and regulations can we avoid legal responsibility?
- A3. At the utmost, the articles in the Guideline and the stipulations of the enforcement subsidiary rules and regulations were implemented as a self-purification measure, and just because one has observed these rules and regulations that does not mean that one is relieved of all legal responsibility. In addition, it is possible that legal responsibility may arise due to problems with the authenticity of the contents of the COI report in regard to profit obtained, issues arising after the period of custody for the report, or other reasons. In general, it can be said that you should be aware that the articles in the Guideline and the stipulations of the enforcement subsidiary rules and regulations issued by the Society are not effective in avoiding the applicability of the laws and ordinances, which take precedence over the Guideline and the subsidiary rules and regulations.

II. Q&A related to persons subject to the Guideline

- Q4. The Guideline stipulates that the COI situation report must include the COI situation for one's spouse, any members of their immediate family, or a joint owner of any earnings or property, but if any of these people refuse this public disclosure, what should I do? (Related to Sections III and V of the Guideline)
- A4. It is generally considered that the COI situation of one's spouse, etc., will heavily influence the COI situation of the person filing the COI situation report. In fact, there are many cases where relatives are involved in the startup of venture companies or their operation. There is no need for persons making a presentation at an academic meeting or contributing a paper for publication to include disclosure of the COI situation of one's spouse, etc. However, if the person concerned is an executive of the Society, etc., they must include disclosure of the COI situation of their spouse, etc. The purpose of this stipulation to include disclosure of the COI situation of one's spouse, etc., is to avoid any social sanctions that may arise if it was not included. Considering the actions necessary to protect the person filing the report, please try to convince your spouse, etc., to comply with the request. The Society does not have the authority, nor is it in any position to directly impose this request on one's spouse, etc. However, if the COI situation of one's spouse, etc., has a serious effect and the result is a social or legal issue, the Society cannot, regrettably, protect any person who did not include such information in the COI situation disclosure from social criticism. In addition, in such cases, the Society will treat such persons as being in violation of the Guideline and will be forced to implement the measures noted for such cases in the Guideline.
- Q5. I am employed as the head of the pathology department at a public hospital. I am participating

in a clinical research project being conducted on a nationwide scale with the chairperson of the Pathology Department at A University specified as the person in charge of the clinical trials. I am functioning as the physician in charge at my hospital. Am I required to file a COI situation report? (Related to Section VI of the Guideline)

- A5. The person in charge of clinical trials in a multi-facility clinical research project will have the authority to make important decisions in regard to the clinical research concerned, and accordingly, that person is required to file a COI situation report including any necessary information on the person or organization providing funds for the project, any private organization involved in the project, as well as any related financial relationship. As a physician in charge at a local district hospital participating in the multi-facility clinical research project, if you give a presentation on research results related to the project concerned at an academic meeting, you should use Form No. 1 and file a COI situation report.

III. Q&A related to activities subject to the Guideline

- Q6. Except for presentations at Society meetings, the publication of papers, and lectures open to the public, what are the other activities conducted by the Society that are subject to the Guideline? (Related to Section IV of the Guideline)
- A6. Activities conducted by the Society related to proposals submitted to the Japan Medical Association or the Ministry of Health, Labour and Welfare, etc., replying to inquiries from these organizations, commendation ceremonies for superior research results, and the drawing up of diagnosis guidelines are all subject to the Guideline. These activities are conducted under the name of the Society, but when a proposal is drawn up, an answer to an inquiry is written, a person is selected for commendation, or when a diagnosis guideline is drawn up, that action is taken by a Director or a committee member personally, so it is necessary for the person involved to submit a public disclosure of their COI situation.

IV. Q&A related to items that should be disclosed and open to the public

- Q7. What is the difference between disclosure and being open to the public?
- A7. In the Guideline, "disclosure" is defined as an action conducted for the Japanese Society of Pathology Office, Directors, Councilors, members of the Society, participants in meetings sponsored by the Society, or subscribers to the journals published by the Society. We use the phrase "open to the public" in regard to persons not directly related to the Society, or the public in general, with the meaning "to make available and clarify." The degree to which information in the contents of the COI situation report is disclosed and made open to the public varies according to the target person and duties or business.
- In regard to presentations at Society meetings or contributions to the Society's journals, the range of the disclosure report will be limited to only the relationship between the person involved in the presentation or contribution to a journal and the enterprises or societies related to the presentation or paper concerned. In addition, the act of filing a report is considered as disclosure.
- Executives of the Society are required to file a more detailed COI situation report. In addition, the detailed COI situation report filed by executives of the Society must include the COI situation for their spouse, any members of their immediate family, or any joint owner of any earnings or property. This report will be disclosed to the Society, and, in principle, the person submitting the report must swear that the contents may be disclosed. However, in view of the Act Concerning Protection of Personal Information (Japan Law No. 57, 2003), we do not

consider that the full actual disclosure to the public of the contents of the report should be allowed. The Medical Ethics Committee will deliberate on this issue, case by case, and the Board of Directors will determine the actual range of the disclosure, which will be the actual disclosure open to the public.

- Q8. Are stockholding and other compensations mentioned in the Guideline limited to the enterprises and societies related to the medical research (Related to Section V, items 2, 7 of the Guideline)
- A8. In regard to persons giving a presentation at a Society meeting or a contributing a paper to either of the Society's journals, the COI situation report will be limited to compensations received from the enterprises and societies related to the medical research concerned. In regard to executives of the Society, etc., the report must include all enterprises and societies related to the activities of the Society.
- Q9. I own stocks in a Pharmaceutical Company at a value of 200,000 yen. In addition, I received 70,000 yen for a lecture given at a meeting sponsored by that Pharmaceutical Company. Do I have to report all of these items in the COI situation report? Furthermore, do I have to file a report each and every time I have such income? (Related to Section V, items 2, 4 of the Guideline)
- A9. The concrete time period, report method, and limits for the values concerned will vary depending on the subject activities and person involved, and the details for these items are specified elsewhere. In regard to the time the COI situation report should be filed, if the enterprise concerned is involved in the presentation of research results, the COI situation report should be filed at the time the presentation is presented or the time of publication for a paper. In regard to executives of the Society, the report must be filed when the executive assumes his/her office, and thereafter, a report is required once every year. In regard to stocks, in principle, a report must be filed for yearly profit over 1 million yen, and the subsidiary rules and regulations specify that lecture fees amounting to 500,000 yen or more per year, per enterprise, must be reported.
- Q10. At the municipal hospital where I work, we received a sum of 2 million yen to be used as a scholarship grant from a medical instrument manufacturer, and it was addressed to me, as the researcher in charge. In fact, the funds are being employed impartially as a research grant by the whole municipal hospital. Should I include this scholarship grant in my disclosure of my COI situation? (Related to Section V, item 6 of the Guideline)
- A10. Even if the scholarship grant does not specify how the money is spent, it can be interpreted that this applies to Item V – 6 of the Guideline, and as the income from one enterprise per year exceeds 1 million yen, you should report this income as the person in charge of the research (for all of the researchers involved) in your COI situation report. This type of income should be reported when the total income exceeds 1 million yen a year, per enterprise, even if the person filing the report is a representative of the department or research laboratory. However, as shown in the subsidiary rules and regulations, in regard to COI situation reports for presentations or publications, if there is no relationship between the content of the presentations or publications and the enterprise or society providing the scholarship grant, this income is not subject to the disclosure. Executives of the Society must file a more detailed COI situation report for disclosure so all income must be reported.
- Q11. The Guideline states that we must report "any other compensation not directly related to the

research concerned," but should I report on winning a trip overseas as a prize on a TV program sponsored by a Pharmaceutical Company? (Related to Section V, item 7 of the Guideline)

- A11. Goods won in a quiz or lottery are free gifts, not remuneration. The Guideline specifies that "remuneration" must be reported. "Remuneration" is a payment in compensation for effort applied. Accordingly, free gifts are not subject to the report. As an example of the type of cases that would be applicable under the stipulations shown in Section V, item 7 of the Guideline, if an enterprise passes out free flash memory sticks to doctors as an expression of gratitude, this would fall under the items subject to the stipulations in Section V, item 7. In extreme cases, this may be interpreted as bribery, and be subject to criminal punishment, which is beyond the scope of this Guideline. Item 7 was included to provide a place for items that do not fit exactly in the categories outlined in Section V, items 1–6, but still may contribute to a COI situation. The subsidiary rules and regulations stipulate that any remuneration of more than 50,000 yen from one enterprise or society must be reported. Furthermore, travel or accommodation expenses paid for by an enterprise for participation in a society meeting not related to the research must be reported.
- Q12. Do I also have to report funds paid for a treatment trial? (Related to Section V, item 6 of the Guideline)
- A12. Research expenses that must be reported include entrusted research expenses, joint research expenses, scholarship grants, and treatment trial expenses. These must be reported if the total yearly amount received exceeds 1 million yen from one enterprise or society

V. Q&A related to avoiding COI situations

- Q13. Many research departments are operated with endowed funds donated by an enterprise, but does this mean that the Guideline's "Situations that all subjects should avoid" applies to professors and society members participating in research in one of these departments? (Related to Section VI of the Guideline)
- A13. This type of research department operating under endowed funds includes a high risk for the appearance of a COI situation, and therefore the Guideline does apply to this situation. You should file a COI situation report when you give any presentation or submit a paper for publication related to research results derived from research sponsored by an enterprise.
- Q14. In regard to the avoidance of a COI situation, doesn't stipulating an exception such as "if the person concerned is considered absolutely necessary for the planning or performance of said clinical research, and the research is considered extremely important and significant from an international viewpoint, the person may be assigned as the physician in charge of the clinical trial for the research concerned." weaken the principle of the Guideline? (Related to Section VI of the Guideline)
- A14. The purpose of the Guideline is not to deny the existence of any COI situation, nor is it to suppress clinical research when the researcher involved has a heavy COI situation. For society, it is a fact that the more important and significant the clinical research is, the COI situation will become heavier. It can be considered that it is important to provide the opportunity for talented researchers a path to participate in clinical research by supplying an exception regulation, as mentioned above. In contrast, as the researcher concerned in this exception regulation has assumed the position of the person in charge of the clinical trial involved, some third parties are of the opinion that an investigation is called for in this case. However, while

the Japanese Society of Pathology is in a position to manage COI issues for activities conducted by the Society, it is beyond our authority to exercise jurisdiction over clinical research conducted at the multitude of facilities and research institutions that exist in Japan. The Guideline does not include any COI situation or issue beyond our jurisdiction.

- Q15. According to the section on "Items the person responsible for a clinical trial or clinical research should avoid," the acquisition of patent fees (royalties) and patent rights should be avoided. However, while it is not included in protocol, is it necessary to renounce rights when extremely beneficial results are obtained (results outside of the enterprise's rights), or when a physician conducting clinical research independently is in a situation where intellectual property rights arise? (Related to Section VI of the Guideline)
- A15. We consider that it would be difficult to impartially supervise the research concerned for a person in charge of a clinical trial under conditions where the results are outside of the rights of the enterprise and where the person involved has intellectual property rights. If the person in charge of the clinical trial resigns, then he/she could avoid renouncing his/her rights.
- Q16. I am the Director of the Pathology Department at a private hospital cooperating in a clinical research project including 10 separate hospitals, and I have been asked to become the principal physician in charge of the clinical research at my hospital. However, I am also a Director at a Pharmaceutical Company that manufactures the medication employed in this clinical research, and I receive a yearly remuneration of 5 million yen. Can I accept this position as the principal physician in charge of the clinical research at my hospital? (Related to Section VI of the Guideline)
- A16. The principal physician in charge of the clinical research at each facility of a multi-facility clinical research project is not subject to Section VI of the Guideline, so we cannot deny that this Pathology Department Director can become the principal physician in charge of the clinical research at the facility concerned. However, if the COI Committee and Ethics Committee members, etc., of the facility concerned deem it inappropriate for the Pathology Department Director to assume the position of the principal physician in charge of that clinical research, in our consideration, that decision will take priority over our Guideline.

VI. Q&A related to the Guideline implementation method

- Q17. I want to give a presentation on research results obtained in a study on the effects of medication employing mice at the General Meeting of the Japanese Society of Pathology. Do I have to submit a disclosure report on my COI situation according to this Guideline? (Related to Sections I, II of the Guideline)
- A17. In principle, the Guideline includes medical research, and thus a disclosure report on the COI situation is required even for a presentation on the results of research employing cultured cells or the results of animal experiments.
- Q18. Is COI situation disclosure required for presentations at academic meetings other than those conducted by the Japanese Society of Pathology?
- A18. In regard to COI situation disclosure for presentations at academic meetings other than those conducted by the Japanese Society of Pathology, the academic society concerned has its own rules and regulations, and the Guideline is not applicable.

VII. Q&A related to the date the Guideline will be in effect and revision methods

- Q19. It is specified that the Guideline will become effective in November of 2011, but will violations of the articles of the Guideline be subject to measures from the day it becomes effective? (Related to Sections VIII, X of the Guideline)
- A19. The Guideline will become effective in November of 2011, but until it becomes common knowledge, violations of the articles of the Guideline will not be subject to measures for a period of two (2) years from the day it becomes effective. In addition, anonymous examples will be shown in the Society's journals and on its web site homepage, and we will promote the Guideline so that it becomes well known.

3. Guideline Related Enforcement Subsidiary Rules and Regulations (proposal)

Article 1. (Presentations at Society Meetings, etc.)

(Range of the disclosure)

The COI situation the principal author is obliged to disclose is limited to enterprises and profit-making societies related to the contents of the publication or presentation.

(When an abstract is presented)

Persons giving presentations made at Society meetings, symposiums, lecture meetings, or educational lectures open to the public, etc. must make it clear whether or not the principal author or presenter had a COI situation during the past year. This must be done when submitting the application for the subject of an address or when presenting an abstract of the address.

In regard to the COI situation to be disclosed for a presentation, items defined in Section V of the "Guideline for Conflict of Interest Management for Medical Research" as "Items that should be disclosed and open to the public" should be disclosed using the "Conflict of Interest Report for Principal Authors" (Form No. 1). Items that must be disclosed will be those that occurred in the one-year period prior to the time the abstract is presented. Furthermore, in regard to the various items that must be disclosed, the sums that require filing a COI situation report are as shown in the following list.

1. In regard to executives and advisors of enterprises and profit-making societies, a report must be filed when the yearly sum received as remuneration from one enterprise or profit-making organization exceeds 1 million yen.
2. In regard to the ownership of stocks, a report must be filed when the profit obtained from stocks during the period of one year from one enterprise or profit-making organization (dividends and the sum total profit obtained by disposal by sale) exceeds 1 million yen, or when the stock owned exceeds 5% of the total stock.
3. In regard to royalty fees for patent rights received from an enterprise or profit-making organization, a report must be filed when the yearly royalty fee for one patent exceeds 1 million yen.
4. In regard to compensation for the time and effort expended by a researcher in the form of a daily allowance (including lecture fees, etc.) received from an enterprise or profit-making organization for appearing at a meeting (presentation), a report must be filed when the yearly amount received from one enterprise or profit-making organization exceeds 500,000 yen.
5. In regard to manuscript fees paid by an enterprise or profit-making organization for writing pamphlets, etc., a report must be filed when the yearly amount of manuscript fees received from one enterprise or profit-making organization exceeds 500,000 yen.
6. In regard to research funds provided by an enterprise or profit-making organization, a report must be filed when the total yearly sum received from one enterprise or profit-making organization for one clinical research project exceeds 2 million yen. In regard to scholarship funds (incentive funds), a report must be filed when the total yearly sum received by one representative clinical researcher from one enterprise or profit-making organization exceeds 1 million yen.
7. In regard to other remuneration (remuneration not directly related to research, such as travel

expenses or presents), a report must be filed when the yearly amount received from one enterprise or profit-making organization exceeds 50,000 yen.

Article 2. (Papers published in the Society's journals, etc.)

(Range of the disclosure)

The COI situation the principal author is obliged to disclose is limited to enterprises and profit-making societies related to the contents of the publication.

(When the manuscript is submitted)

All authors who publish papers in one of the Japanese Society of Pathology's journals, the *Pathology International* or the *Japanese Journal of Diagnostic Pathology*, must file a disclosure report on their COI situation when they submit a manuscript for publication, using the Potential Conflict of Interest Report for Authors (Form No. 2), as specified in the rules and regulations for publications. Form No. 2 should be included and printed at the end of the manuscript, directly before the References section. When there is no COI situation as specified, the author should include the following sentence, or similar, in the same location, i.e., "The authors indicated no potential conflict of interest." The COI situation for items defined in Section V of the Guideline as "Items that should be disclosed and open to the public" should be disclosed when publishing a paper, etc. In regard to the various items that must be disclosed, the sums that require filing a COI situation report are the same as those shown above in Article 1 of the subsidiary rules and regulations. Items that must be disclosed will be those that occurred in the one-year period prior to the publication. In regard to publication in other printed material issued by the Society, other than the Society's journals, the same rules and regulations will be applicable, and a COI situation disclosure report must be filed.

Article 3. (Executives, Committee Chairpersons, and Members of the Medical Ethics Committee)

(Range of the disclosure)

The COI situation report that executives, committee chairpersons, and members of the Medical Ethics Committee are obliged to submit will be limited to any enterprise or profit-making organization related to the activities of the Society.

(When assuming office)

After assuming a new office, executives, committee chairpersons, and members of the Medical Ethics Committee must submit a COI situation report using Form No. 3, "Conflict of Interest Report for Executives, Committee Chairpersons, and Members of the Medical Ethics Committee" at yearly intervals. In addition, if a new COI situation arises during their term of office, they are hereby obliged to file a new COI situation report using Form No. 3 within a time period of six (6) weeks. In regard to the items that should be disclosed using Form No. 3, any COI situation defined in Section V. of the Guideline, "Items that should be disclosed and open to the public" must be reported. In regard to the various items that must be disclosed, the sums that require filing a COI situation report are the same as those shown above in Article 1 of the subsidiary rules and

regulations. Form No. 3 should be used to show the calculated sums for a one-year period. When assuming a new office, the COI situation report must include information for the prior two-year time period, starting on the day one assumes office. In this case, two Form No. 3 forms should be filled out and submitted, one for the one-year period immediately prior to the day one assumes office and one for the year previous to the year immediately prior to the day one assumes office.

Article 4. (Handling the COI report for Executives, Committee Chairpersons, and Members of the Medical Ethics Committee)

As required by these subsidiary rules and regulations, the Form No. 3 forms submitted and the COI situation thereby disclosed (COI information) will be processed at the Society's office, held in trust by the Chairman of the Board of Directors, and all personal information will be strictly held in custody and managed appropriately. This COI information is used to process the items specified in the Guideline, and therefore it may be used at any time at meetings of the Board of Directors or the Medical Ethics Committee. In regard to the COI situation of the person concerned, if there is any doubt involved or if a social or legal issue arises, the Medical Ethics Committee will deliberate on the subject, and after obtaining approval at a meeting of the Board of Directors, an appropriate range of the COI information will be disclosed within the Society, or to the public, as necessary. Submitted forms (Form No. 3) will be held in custody for two (2) years after the term of office for the executive, committee chairperson, or member of the Medical Ethics Committee concerned, and thereafter be disposed of by the Chairman of the Board of Directors. However, during the period in which the forms (Form No. 3) are held in custody, if there is any doubt involved or if a social or legal issue arises in regard to the COI situation of the person concerned, the disposal of the forms (Form No. 3) may be deferred.

Article 5. (Declaration and Announcement of handling rules, guidelines, etc.)

(Scope of disclosure)

COI situations that members of the Guidelines Development Committee are obligated to disclose are limited to those related to companies and commercial organizations connected with the contents of the presentation.

(At the time of disclosure)

At the time of disclosure in this scientific congress, COI situations must be disclosed according to the "COI Self-Declaration Form" (Form 1). Form 1 is provided on the inside of the back cover. In cases where no regulated conflict of interest exists, the provided space should be filled with words such as "COI (conflict of interest) Disclosure of Development Committee members: There are no potential conflicts of interests to disclose in connection with this provision content". The monetary amount for which self-reporting is necessary for a particular disclosure is the same as that has been defined in Article 1 of the Detailed Rules. All matters falling in time between 1 year prior to the establishment of the Committee and the time of disclosure must be disclosed. For a joint presentation with other scientific societies, etc., arrangements for the management of COI at each committee shall be made separately. Also in that case, the members of this society must submit the COI Self-Declaration form in the same format to the Society COI Committee.

Conflict of Interest Report for Principal Authors (Proposal)

Applicant's name _____

	Amount	COI situation	If "Yes," enterprise name, etc.
Executives, Advisors	1 million yen or more	Yes - No	
Stocks	1 million yen or more, or 5% or more of the total stock	Yes - No	
Royalty fees	1 million yen or more	Yes - No	
Lecture fees, etc.	500,000 yen or more	Yes - No	
Manuscript fees, etc.	500,000 yen or more	Yes - No	
Research funds	1 million yen or more	Yes - No	
Other remuneration	50,000 yen or more	Yes - No	

Potential Conflict of Interest Report for Authors

(Form No. 2)

These authors have the potential conflict of interest described below. The lower limits of funds that should be reported are specified in the JSP's conflict of interest policy.

	Leadership Position or Advisory Role	Stock	Royalty	Lecture Fees	Manuscript Fees	Research Funds	Other
Amount (Yen)	≥ 1,000,000	≥ 1,000,000	≥ 1,000,000	≥ 500,000	≥ 500,000	≥ 1,000,000	≥ 50,000
Author's Name							
Coauthor's Name							
Coauthor's Name							
Coauthor's Name							
Coauthor's Name							
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Note: Use the following symbols to indicate their respective amounts. *: 1,000,000-4,999,999 **: 5,000,00-9,999,999 #: ≤¥10,000,000

**Conflict of Interest Report for Executives, Committee Chairpersons, and
Members of the Medical Ethics Committee (Proposal)**

(Calculation period: Apr. 1, 20XX~Mar. 31, 20XX)

(Office use only)	Reception No.		
Reception date:	Year	Month	Day

To the Chairman of the Board of Directors of the Japanese Society of Pathology:

Name of the person submitting the report:

Name of the facility concerned (organization, department or clinic):

Name of the executive position:

Committee name at the Society: Member of the _____ Committee

A. Items concerning the reporter himself/herself

1. Have you received any remuneration as an executive or advisor from an enterprise or profit-making organization? If yes, enter the sum received. (Entry required if the yearly sum received from one enterprise or organization exceeds 1 million yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each enterprise or organization)
	Name of the enterprise or organization: Position (Executive, advisor, etc.): Amount of remuneration:
2. Do you own any stocks or have you received any earnings from stocks? (Entry required if the yearly earnings received from one enterprise exceed 1 million yen, or if the stock holdings exceed 5% of the total stock)?	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each enterprise or organization)
	Name of the enterprise or organization: Number of stocks owned: Stock value at the time of the report (per stock): Earnings from the stock for the previous year:
3. Have you received any remuneration as royalty fees from an enterprise or profit-making organization? (Entry required if the yearly royalty fees received from one enterprise exceed 1 million yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each patent)
	Name of the enterprise or organization: Patent name: Royalty fee:
4. Have you received any daily allowance (lecture fees, etc.) as remuneration for the time or effort involved in attending a meeting (presentation) from an enterprise or profit-making organization? If yes, enter the sum received. (Entry required if the yearly sum of the lecture fees	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each enterprise or organization providing the funds)
	Name of the enterprise or organization: Lecture fee, etc.:

received from one enterprise or organization exceeds 500,000 yen)	
5. Have you received any manuscript fees as remuneration for writing a pamphlet, etc. from an enterprise or profit-making organization? If yes, enter the sum received. (Entry required if the yearly sum of the manuscript fees received from one enterprise or organization exceeds 500,000 yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each enterprise or organization providing the funds)
	Name of the enterprise or organization: Manuscript fees:
6. Have you received any research funds for medical research from an enterprise or profit-making organization? (Entry required if the total yearly sum of the funds fees received for one medical research project exceeds 2 million yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each medical research project)
	Name of the enterprise or organization: Name of the medical research theme: Research funds received: Compensation received by the reporter:

7. Have you received any other remuneration (remuneration not directly related to research, such as travel expenses or presents)? (Entry required if the yearly sum of the remuneration received from one enterprise or organization exceeds 50,000 yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each medical research project)
	Name of the enterprise or organization: Remuneration content: Remuneration amount:

B. Items concerning the reporter's spouse, immediate family members, or persons sharing income/property

Name of the person concerned (and relationship to the reporter)

1. Have you received any remuneration as an executive or advisor from an enterprise or profit-making organization? If yes, enter the sum received. (Entry required if the yearly sum received from one enterprise or organization exceeds 1 million yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each enterprise or organization)
	Name of the enterprise or organization: Position (Executive, advisor, etc.): Amount of remuneration:
2. Do you own any stocks or have you received any earnings from stocks? (Entry required if the yearly earnings received from one enterprise exceed 1 million yen, or if the stock holdings exceed 5% of the total stock)?	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each enterprise or organization)
	Name of the enterprise or organization: Number of stocks owned: Stock value at the time of the report (per stock): Earnings from the stock for the previous year:
3. Have you received any remuneration as royalty fees from an enterprise or profit-making organization? (Entry required if the yearly royalty fees received from one enterprise exceed 1 million yen)	Yes or No (circle the applicable answer) (If Yes, fill out the content below for each patent)
	Name of the enterprise or organization: Patent name: Royalty fee:

Oath: I hereby swear that my COI situation is exactly as stated above, with no mistakes. There are absolutely no COI situations other than those stated above that could impact or obstruct any duty or function associated with the Japanese Society of Pathology. Furthermore, I hereby agree that the information supplied above may be disclosed to the public in the case where it is required to resolve any social or legal issue.

Report date: Year Month Day

Signature

4. Q&A Related to the Enforcement Subsidiary Rules and Regulations (proposal)

Q1. In concrete terms, exactly what should we do when we give a presentation at a General Meeting of the Japanese Society of Pathology, etc.? (Related to Article 1 of the subsidiary rules and regulations)

A1. At the present, in regard to presentations conducted at a General Meeting of the Japanese Society of Pathology, etc., it is necessary for the principal author to submit a COI situation disclosure report. The disclosure report is limited to the COI situation related to the content of the presentation concerned. When we were drawing up the subsidiary rules and regulations, we considered including the demand for submitting the COI situation for all joint authors, but in consideration of the load on the person submitting the application for the presentation, we decided to limit the demand to the principal author. Furthermore, the nature of medical research is such that, from an academic standpoint, we consider that the presentation of research results at an academic meeting alone is not sufficient, and that it is important to publish a paper on the subject. Accordingly, in regard to all important research results, a paper on the subject will be published, and at that time, not only the principal author, but also all co-authors must submit a COI situation disclosure report.

In more concrete terms, when submitting the application for the presentation to the Society, the principal author must fill out Form No. 1 (an example of a filled out form is shown below) to disclose his/her COI situation, seal the form tightly in a separate labeled envelope, and send it and the application by Post Office mail to the General Office of the General Meeting concerned. At the General Office of the General Meeting concerned the staff will handle the application and send the COI situation report, still in the sealed envelope, to the General Office of the Japanese Society of Pathology. Thereafter, the COI Committee will hold a meeting at the Office of the Japanese Society of Pathology, where the Committee will read and study the COI situation report (scheduled for a meeting to be held once every year in January). In addition, in the future, we plan to arrange matters so that the COI situation reports can be sent directly to the Japanese Society of Pathology.

When the actual presentation is conducted, at the beginning of one's slide presentation, or at the second slide, or the last page for a poster presentation, and regardless of whether or not there is any actual COI situation, the COI situation report must be displayed.

Conflict of Interest Report for Principal Authors (Example)**Principal author's name**

	Amount	COI situation	If "Yes," enterprise name, etc.
Executives, Advisors	1 million yen or more	<input checked="" type="checkbox"/> - No	A Pharmaceutical Co.
Stocks	1 million yen or more, or 5% or more of the total stock	<input checked="" type="checkbox"/> - No	A Pharmaceutical Co.
Royalty fees	1 million yen or more	<input checked="" type="checkbox"/> - No	B Pharmaceutical Co.
Lecture fees, etc.	500,000 yen or more	<input checked="" type="checkbox"/> - No	C Pharmaceutical Co.
Manuscript fees, etc.	500,000 yen or more	<input checked="" type="checkbox"/> - No	C Pharmaceutical Co.
Research funds	1 million yen or more	<input checked="" type="checkbox"/> - No	C Pharmaceutical Co.
Other remuneration	50,000 yen or more	<input checked="" type="checkbox"/> - No	C Pharmaceutical Co.

- Q2. What is the time period for the COI situation report, from when to when, for a person giving a presentation at the Japanese Society of Pathology? (Related to Article 1 of the subsidiary rules and regulations)
- A2. For instance, if the day you registered an application for a presentation was November 20, the time period would be the one-year period from November 21 of the previous year until the day you registered your application, and you should report any items that arose in that time period. If the actual presentation in this example was April 30, when the presentation is made, you should report any items that arose during the one-year and five month period from November 21 of the previous year until the day of the presentation. We included this requirement because we wanted to clarify any COI situation that may have arisen after you registered your application for the presentation.
- Q3. How should executives or chairpersons of committees go about submitting the report (Form No. 3)?
- A3. Executives and chairpersons of the various committees must submit a COI situation disclosure report when they assume office and thereafter once every following year. The report must be sealed in a separate envelope and sent to the Office of the Japanese Society of Pathology. After the General Meeting of the Society, a meeting of the Medical Ethics Committee will be held in June or July, and with all of the members present, the envelopes will be opened and the reports read. The Committee will report on the results of their study to the Chairman of the Board of Directors.
- Q4. How is the COI situation disclosure report submitted to the office kept in custody?
- A4. The COI situation disclosure reports submitted by executives or the chairpersons of committees (Form No. 3) are documents that contain important personal information. Accordingly, after the documents arrive at the office, they are kept in a locked safe, and are

held in strict custody until the Medical Ethics Committee holds a meeting to deliberate on the content. These documents can be viewed only by the members of the Medical Ethics Committee and only at a meeting of the Committee held at the Society's office for that express purpose. Furthermore, photocopies of these documents are strictly forbidden. After the Medical Ethics Committee deliberates on the content of the COI situation disclosure reports, these documents are resealed in envelopes and held in strict custody in a locked safe. Thus, strict management is employed to maintain and protect this confidential, personal information. After the term of office for an executive, etc., or after a member of a committee is asked to withdraw from the committee concerned, the documents are held in strict custody under the supervision of the Chairman of the Board of Directors of the Japanese Society of Pathology at the Society's office. After being held in custody a period of two (2) years, the documents are immediately disposed of under the supervision of the Chairman of the Board of Directors. However, with sufficient reason, if the Chairman of the Board of Directors determines that disposal is not appropriate, he may determine an extension time period for custody as required and defer the disposal of the COI situation disclosure report concerned.

In regard to the COI situation disclosure reports submitted at the General Meeting of the Society by principal authors (Form No.1), after the General Meeting of the Society concerned, the documents are immediately disposed of under the supervision of the Chairman of the Board of Directors.

- Q5. How should I fill out Form No. 2 for publication in either the *Pathology International* or *Japanese Journal of Diagnostic Pathology*? (Related to Article 2 of the subsidiary rules and regulations)
- A5. In regard to papers submitted for publication, all authors, including co-authors, must disclose their COI situation, but the content of the disclosure is limited to the COI situation related to the paper concerned. An example of a filled out Form No. 2 is shown below.

Potential Conflict of Interest Report for Authors (Example)

These authors have the potential conflict of interest described below. The lower limits of funds that should be reported are specified in the JSP's conflict of interest policy.

	Leadership Position or Advisory Role	Stock	Royalty	Lecture Fees	Manuscript Fees	Research Funds	Other
Yen amount	≥ 1,000,000	≥ 1,000,000	≥ 1,000,000	≥ 500,000	≥ 500,000	≥ 1,000,000	≥ 50,000
Ichiro Yama						CD Pharm. Co.#	
Jiro Kawa							
Saburo Ten							
Shiro Chi							
Goro Kaze							
Rokuro Hayashi							
Shichiro Aka		MR Co.*					
Hachiro Kuro		K Pharm. Co.*					
Kuro Ao							
Juro Shiro				G Ltd.*			
Ichiro Midori	A&B Pharm. Co.**						

Note: Use the following symbols to indicate their respective amounts. *: 1,000,000-4,999,999 **: 5,000,00-9,999,999 #: ≤¥10,000,000

- Q6. How long is the time period for the disclosure of the COI situation to be reported for the publication of a paper in the *Pathology International* or *Japanese Journal of Diagnostic Pathology*? (Related to Article 2 of the subsidiary rules and regulations)
- A6. For example, if the submission date is June 10, you should report items that arose during the one-year period from June 11 of the previous year. If the paper is "revised," and the publication is delayed, you should report items that arose during the period from June 11 of the previous year until the date of submission of the final revised version of the manuscript.
- Q7. If we observe the items in the Guideline and the subsidiary rules and regulations, a huge amount of personal information will be accumulated at the Japanese Society of Pathology, and I have my doubts that you can process that much information, and further, if there is a demand for the release of this information to the public at large, how does the Japanese Society of Pathology intend to respond? (Related to Article 4 of the subsidiary rules and regulations)
- A7. In accordance with Article 1 and 2 of the subsidiary rules and regulations, the obligation for disclosure of COI information by persons giving presentations at the Society is completed by the inclusion of the information in the slide show or poster used at the presentation. Accordingly, the COI information sent to the Society's office is disposed of immediately after the presentation under the supervision of the Chairman of the Board of Directors. In regard to papers published in the Society's journals, *Pathology International* or *Japanese Journal of Diagnostic Pathology*, the author's COI information is disclosed in the paper, so here also the disclosure is thereby completed. The only COI information remaining at the Society is only that of several tens of persons, limited to the Form No. 3 submitted by executives, the chairpersons of the various committees, and members of the Medical Ethics Committee. The custody period for this information is the two (2) year period after they complete their respective terms of office, and the information is disposed of thereafter. When these persons submit their Form No. 3, they sign an oath agreeing to the disclosure of that information to the public if it is considered necessary. However, in actual practice, if there is a demand for public disclosure, the issue will be deliberated sufficiently by the Medical Ethics Committee and at a meeting of the Board of Directors, who will determine an appropriate range for the disclosure, as clarified in Article 4 of the subsidiary rules and regulations.