Japan Gastroenterological Endoscopy Society
Guidelines Regarding Conflicts of Interest in Medical Research

The Japan Gastroenterological Endoscopy Society (JGES), originally established as the Japan Study Group of Gastroscopy in 1951, marked its 50th anniversary in 2008 and now has over 32,000 members. The goals of the JGES are to promote fundamental and clinical research in the field of Gastroenterological Endoscopy and to contribute to improvements in human healthcare not only in Japan, but also worldwide through extensive academic research. As a result of continued efforts, the JGES has become a Society with solid achievements and a strong reputation across a broad range of activities relating to the diagnosis, treatment, and prevention of various gastrointestinal diseases (primarily gastroenterological cancer), in addition to the development of endoscopic devices. Endoscopy is currently an essential component of daily medical practice and further developments of medical research led by JGES are expected in the future.

The research outcomes presented at academic meetings hosted by the JGES or in official JGES journals include medical research into the diagnosis, treatment, and prevention of various diseases, as well as research into the use of new drugs, devices, and techniques. To promote this research, joint efforts between industry (e.g. pharmaceutical or venture companies) and academia (collaborative research, funded research, transferring and assisting technology for use in clinical settings, and the funding of scholarships and study groups etc.) are of fundamental importance.

However, with greater collaboration between industry and academia in the field of medical research (including basic research, clinical research and clinical trial), it is inevitable that the involvement of public organizations (e.g. universities, research institutes, and academic societies) with specific private companies will increase. Consequently, potential conflict between the responsibilities of the academic institutions/organizations, whose primary responsibility is education and research, and personal profits arising from joint activities with private companies and organizations must be taken into consideration. This situation is generally described as “conflict of interest” (COI). Appropriate management of COI is extremely important for any academic institution or organization to properly promote collaboration with industry. In addition, medical research differs from collaborative research in other academic fields in the sense that medical research requires the participation of both patients and healthy volunteers. In medical research, serious COI resulting from financial and other types of support provided by private companies and corporations may lead to
compromises in patient safety and privacy. There may be serious concerns regarding human rights abuses and endangering of patient lives. Furthermore, the collaboration may result in biased research methods, data analyses, and interpretation of the outcomes. In some cases, even if the research outcome is appropriate, COI may mean that the outcome is not evaluated fairly or even that the study results are not published. However, the problems associated with COI that have surfaced in the past have been caused primarily by the management of COI, not by the existence of the COI itself. Thus, to promote appropriate collaborative research between industry and academia, many medical facilities and academic institutes both in Japan and abroad have created guidelines for the management of COI in medical research with the intention of maintaining justice and fairness in research, the transparency of academic presentations, and public confidence in the collaborative research undertaken by private companies and public organizations. Reporting the results of collaborative research publicly, with appropriate management of COI, is also essential to maintain public confidence in medical research.

In recent years, in the context of the national policy to promote a translational research from basic seeds discovery research to clinical research in each country, there is a global trend that an object of research in the management of COI has been extended to include a basic life-science research in collaboration between industry and academia, and has no longer been limited to the clinical research and clinical trial (including drug trial) on humans. With a background like that, basic researchers who conduct industry-academia joint researches with companies, profit-making corporations or organizations also tend to be requested to submit a self-declaration of financial COI. Therefore, JGES defines the researches from life-science research and basic medical research to clinical medical research on humans (including researches related to unmasked materials derived from humans or data with personal identifiers) and clinical trial, which are conducted in collaboration between industry and academia with the purpose of improving methods of prevention and diagnosis, better understanding of cause of disease and patient’s quality of life, as medical researches, and position them as objects of COI management.

To promote public accountability, the JGES has formulated the following guidelines to manage its members’ COI properly by disclosing any financial relationships with research sponsors when members present research findings at meetings, in publications etc.

**Article 1: Purpose**
As per the ethical doctrines for medical research on humans stated in the Declaration of Helsinki and the Ethical Guidelines for Clinical Studies (Ministry of Health, Labour and Welfare Notification No. 255, revised 2008), particular care should be taken when performing such research to ensure that subjects' lives and human rights are protected. Considering the social responsibility of JGES members and the high level of morality they are expected to display, the JGES has formulated the Guidelines Regarding Conflicts of Interest (COI) in Medical Research, hereafter referred to as the Guidelines. The purpose of the Guidelines is to properly promote research outcomes and related activities while maintaining neutrality and fairness and, at the same time, fulfilling our social responsibilities by contributing to advances in the prevention, diagnosis, and treatment of disease. The Guidelines contain the basic philosophy underlying COI for JGES members and request compliance by the voluntary disclosure of any COI when members present results related to various research activities.

Article 2: Persons Covered by the Guidelines
The Guidelines are applicable to any person listed below who may find themselves in a position of COI.
(1) Members of the JGES
(2) Presenters at academic meetings of the JGES
(3) The Board of Directors (President, directors, and inspectors), people in charge of academic meetings (chairperson etc.), committee chairpersons, and members of special committees or provisional working groups
(4) Administrative staff of the JGES
(5) Spouses, first-degree relatives, and anyone who shares the income and wealth of the people listed in (1)–(4) above

Article 3: Activities Covered by the Guidelines
The activities of the JGES listed below are subject to the Guidelines.
(1) Conferences and/or academic meetings (including Annual Meetings) hosted by the JGES and its branches
(2) The publication of in-house journals and academic books
(3) The implementation of studies and research
(4) Encouragement to undertake studies and bestowment of awards for research outcomes
(5) Implementation of certified-fellow systems (i.e. certification of specialists or qualified facilities etc.)
(6) Promotion of lifetime learning
(7) Communication and cooperation with related academic societies
(8) Promotion of international research partnerships
(9) Any other projects necessary to achieve the purposes of the JGES

The following activities in particular require strict compliance with the Guidelines.
- Presentation at conferences or academic meetings hosted by the JGES
- Presentation of research results in print publications, such as in-house JGES journals
- Formulation of clinical guidelines, manuals etc.
- Participation in investigation committees, sitting on advisory committees etc.

**Article 4: Matters Requiring Disclosure**
People falling into Categories (1)–(8) below shall report on their precise COI directly to the President of the JGES in case the benefits received exceed the criteria listed in the Detailed Regulations of the Guidelines. Specific steps for disclosure are given in a separate series of Regulations.

1. Those employed by, in a leadership position, and/or those who have an advisory role in private companies, institutions, or profit-oriented organizations
2. Those owning stock in companies
3. Those receiving patent royalties and/or licensing fees from private companies, institutions, or profit-oriented organizations
4. Those receiving daily allowances or honoraria (e.g. lecture fees) from private companies, institutions, or profit-oriented organizations as compensation for attending (presenting at) meetings
5. Those receiving manuscript fees from private companies, institutions, or profit-oriented organizations for writing promotional materials (e.g. brochures)
6. Those receiving funding for medical research (drug trials, funded researches, collaborative researches, clinical trials, etc.) from private companies, institutions, or profit-oriented organizations
7. Those receiving research funding (donations etc.) from private companies, institutions, or profit-oriented organizations
8. Study groups sponsored by companies, institutions, or profit-oriented organizations
9. Those receiving payment of fees for anything unrelated to research, education, or medical practice from private companies, institutions, or profit-oriented organizations
Article 5: Matters to be Avoided

5.1 Matters people subject to the Guidelines should avoid

The publication of the results of medical research or the formulation of clinical guidelines must be undertaken on a scientific basis and for the benefit of the public. In publishing and interpreting the results of medical research, as well as in formulating clinical and/or treatment guidelines and manuals, members of the JGES must not be influenced by the sponsors or companies that provided financial support for the study. JGES members should avoid any funding contract that may influence the results, outcomes, and publication of the medical research.

5.2 Matters people responsible for laboratory testing as part of the medical research should avoid

People in charge of the planning and implementation of medical research, especially clinical trials, drug trials, etc., must be researchers who have no COI with their clients according to the criteria listed below in Items (1)–(3) and must maintain this lack of conflict after being selected as the leader of the research project.

(1) Owning stock in companies providing funding for medical research
(2) In a position to receive patent royalties and/or licensing fees for products and/or techniques developed as a result of the medical research
(3) Being employed by, in a leadership position, and/or having an advisory role in private companies or profit-oriented organizations sponsoring the medical research (excluding those with an unpaid position as a scientific advisor)

If, however, a person falls into one of the three categories listed above, he or she can still lead a medical research if he or she is indispensable to the planning and implementation of the medical research and if the medical research is of considerable social importance in the field, provided that the person’s fairness, equity, and transparency in terms of both judgment and action are clearly maintained.

Article 6: Means of Execution

6.1 Member responsibilities

When presenting the results of medical research at conferences or academic meetings, JGES members shall disclose COI related to the research in question according to the Detailed Regulations of the JGES and using a designated form. If
any violations of the Guidelines occur in connection with the presentation, the Board of Directors shall request the committee that manages problems associated with COI (hereafter referred to as the COI Committee) to discuss the matter and make recommendations. The Board of Directors will then take reasonable measures based on the COI Committee’s report.

6.2 Directors’ responsibilities
The Board of Directors (President, directors, and inspectors), people in charge of academic meetings (chairperson etc.), committee chairpersons, and members of special committees or provisional working groups have crucial roles in all JGES activities and shall voluntarily disclose any COI at their inauguration using a designated form. In addition, directors are required to conduct hearings, investigations etc. to manage any COI problems that arise and to report back to the President.

6.3 Role of the COI Committee
When a serious COI arises among members or when the COI reported renders member participation in JGES activities inappropriate, the COI Committee shall inform such members accordingly and provide proper guidance to them. If questions and problems regarding COI are reported, the COI Committee will conduct hearings, investigations etc. to manage the COI and will report back to the President.

6.4 Role of the Board of Directors
When a serious COI occurs among board members or when the COI reported for board members renders their participation in JGES activities inappropriate, the Board of Directors has the right to ask the COI Committee’s opinion and to call for remedial action in accordance with the Committee’s report.

6.5 Role of people in charge of academic meetings
When the results of medical research are presented at conferences or academic meetings, the people in charge of such meetings (chairpersons etc.) shall verify the presenters’ compliance with the Guidelines and, if any violations are found, those in charge of the meeting have the right to take necessary measures, including suspending presentations, with prompt notification of the reasons to the presenter. These measures are to be reported to the COI Committee, and the Board of
Directors may call for remedial action in accordance with the Committee's report.

6.6 Role of the editorial board
When clinical results are published in Society journals as original articles, reviews, clinical guidelines, editorials, or opinions, the editorial board shall verify compliance with the Guidelines and, if any violations are found, may take necessary measures, including suspension of publication with prompt notification of the reasons to the authors. If violation of the Guidelines is detected after publication of the material in question, the editorial board may announce that fact in the journal under the name of the Editor-in-Chief. The Editor-in-Chief shall report to the COI Committee and may call for remedial action in accordance with the Committee's report.

6.7 Others
Other chairpersons and members of committees involved in Society activities shall verify their compliance with the Guidelines and, if there are any violations, may take prompt remedial action. These measures are to be reported to the COI Committee, and the Board of Directors may call for remedial action in accordance with the Committee's report.

Article 7: Actions in Case of Guideline Violations and Accountability

7.1 Actions to be taken against violators of the Guidelines
The Board of Directors of the JGES has the right to discuss any violations of the Guidelines according to separate rules. If the violation of the Guidelines is deemed to be crucial after the opinions of the COI Committee, Ethics Committee, and any other relevant committees have been sought, the matter shall be discussed at a Board of Directors meeting and the board members shall take punitive actions depending on the degree of the violation.

7.2 Filing of complaints
The person who is the object of the accusation has the right to file a complaint against the JGES. When such complaints are received, the President of the Society is required to set up an administrative review board (interim advisory committee), refer the complaint for examination, discuss the report of the review board at a Board of Directors meeting, and notify the complainant and any other
relevant people of the results.

7.3 Accountability
When the Society discovers significant violation of the Guidelines in the results of medical research presented at JGES-related meetings etc., the Society is required to fulfill its obligations after discussion of the matter at the Board of Directors meeting.

Article 8: Coordination with Related Societies
The Society works closely with many other internist and surgical societies and provides information regarding any amendments to these Guidelines or the formulation of the Detailed Regulations.

Article 9: Formulation of Detailed Regulations
The Society may formulate Detailed Regulations for the execution of the Guidelines, if necessary.

Article 10: Amendments to the Guidelines
The Guidelines shall be reviewed periodically and amended if necessary to take into account societal changes, amendments to Acts related to collaborations between industry and academia, and changes in medical treatments and/or research.

Supplementary Provisions
The Guidelines will come into effect on March 1, 2012.

Partial amendments: Made on October 1, 2013 (“clinical research” was changed to “medical research” with changes in related particulars.)
Japan Gastroenterological Endoscopy Society
Detailed Regulations of the Guidelines Regarding Conflicts of Interest in Medical Research

The Japan Gastroenterological Endoscopy Society (JGES) has formulated Guidelines Regarding Conflicts of Interest in Medical Research to appropriately manage members’ conflicts of interest (COI) arising from involvement in a collaboration between industry and academia to undertake medical research. The Guidelines relate the basic philosophy of COI and ask that Society members voluntarily disclose any COI when making presentations at JGES conferences or academic meetings.

The regulations required for the execution of the Guidelines such that, in accordance with the aims of the Guidelines, the fairness of the process, ethical transparency, and the integrity of the results of medical studies and the Society’s activities are maintained are listed below.

**Article 1: Disclosure of COI at JGES Conferences or Academic Meetings**

1.1 Any lead presenter or speaker at conferences and academic meetings held by the JGES (including Annual Meetings, lecture presentations, and seminars) or by its branches (including Annual Branch Meetings and seminars) shall voluntarily disclose the existence or nonexistence of any financial relationship and/or COI over the past year with companies and profit-oriented organizations in connection with the medical research presented, regardless of whether they are a member of the JGES or not, at the time of Abstract registration using Form 1. This disclosure extends to the presenter’s spouse, first-degree relatives, and anyone who shares his/her income and wealth.

The head presenter or speaker shall disclose any COI at the beginning of his/her presentation or on the slide profiling the presenters involved in the study using Form 1-A (if he/she has any COI to disclose) or Form 1-B (if he/she has no COI to disclose). Alternatively, for poster presentations, any COI shall be disclosed at the bottom of the poster using Form 1-C.

1.2 The definition of companies and profit-oriented organizations that are related to the medical research referred to in Section 1.1 are defined below.

1. Company or organization that requests the medical research to be undertaken or collaborates in it (regardless of compensation received)
2. Company or organization that shares the rights to the medical research, including any patents in connection with treatments, drugs, or equipment
evaluated in the study
(3) A company or organization that provides drugs or equipment used in the medical study without charge or at a reduced price
(4) A company or organization that provides financial support for or donates funding to the medical study
(5) A company or organization that provides unapproved drugs or medical equipment for the medical study
(6) A company or organization that sponsors study groups

1.3 “Medical research related to the presentation” refers to basic and/or clinical research conducted with the aim of improving disease prevention, diagnosis, and treatment methods, to better understand disease etiology and conditions, to enhance the quality of life of patients, and that in which the study subjects are human. Clinical research in which the study subjects are human includes research that uses anthropogenically derived material and that can identify personal data. The definition of that data and those materials is as given in the Ethical Guidelines for Clinical Studies provided by the Health, Labor and Welfare Ministry of Japan.

**Article 2: Criteria for the Disclosure of COI**

The criteria and monetary values for the disclosure of COI are as follows.

(1) When the compensation for employment, a leadership position, and/or an advisory role in one company or organization exceeds one million yen per year

(2) When the profit from stocks (total dividend and gain-on-sale) in one company or organization exceeds one million yen per year, or when the ratio of stock held exceeds 5% of all shares in one company or organization

(3) When patent royalty and/or licensing fees for one patent and/or license from one company or organization exceeds one million yen per year

(4) When the daily allowance or honoraria (e.g. lecture fees) paid by private companies, institutions, or profit-oriented organizations for compensation to attend (or present at) meetings paid by one company or organization exceeds one million yen per year

(5) When the total of manuscript fees for writing promotional materials (e.g. brochures) paid by one company or organization exceeds one million yen per year

(6) When the total research funding (including funding for drug trial, funded research, and collaborative research) paid by one company or organization exceeds two
million yen per year

(7) When the total of contributions for scholarships provided by one company or organization to a presenter, his/her department (including course and class), or a representative of his/her laboratory exceeds two million yen per year.

(8) When a presenter belongs to a study group sponsored by a company or organization

(9) When the total amount paid by one company or organization for anything unrelated to research, education, or medical practice exceeds fifty thousand yen per year

Among the above items to be disclosed, parties to accept donations to fund scholarships from a company or organization are divided mainly into two, a head of an organization (principal or director of hospital) or a head of a course/class. In the former case, donations tend to be considered as not related to the individual researcher, but if such scholarships are delivered to individual presenter, or to his/her department (course or class) or laboratory from company or organization through the head of the organization, the amount of such donations should be disclosed.

Also, financial supports (funded research and research grant) from company through non-profit corporation (such as NPO) or public-interest corporation (such as foundation) is likely to raise question, but should be disclosed. The higher the amount of financial support, the more people tend to receive an impression that objectivity and fairness of research results are impaired, so in case the indirect research supports from related company are envisioned, it is desirable to voluntarily disclose his/her COI in order to prevent any doubt or question from society.

Article 3: Disclosure in Journals, Including Official JGES Journals

To meet the requirements of the Author Guidelines, all authors who publish their articles (e.g. review or original articles) in in-house JGES journals (Digestive Endoscopy and Gastroenterological Endoscopy) are required to report any COI with a company or organization prescribed in Article 1.2 of the Guidelines over the past two years to the JGES administrative office in advance if the authors have economic ties with a company or organization that is related to the content of the published articles using Form 2-A “Disclosed Potential Conflict of Interest” (JGES Conflict of Interest Disclosure Statement) or Form 2-B “Gastroenterological Endoscopy: disclosure statement of COI”). A statement of “Disclosed Potential Conflict of Interest” will be published at the end of the article or immediately before the Acknowledgments or References. If authors do not have any COI, the phrase “No potential conflicts of interest were disclosed.” shall be
published instead. What kind of COI has to be disclosed when submitting an article for publication is prescribed in Article 4 of the Guidelines Regarding Conflicts of Interest in Medical Research. The criteria for disclosure are prescribed in Article 2 of Detailed Regulations of the Guidelines Regarding Conflicts of Interest in Clinical Research. Any article published in a JGES publication other than Digestive Endoscopy shall conform to these regulations. Any “Disclosed Potential Conflict of Interest” reported by presenters will not be disclosed to the referees. As to Digestive Endoscopy, however, many of the submitted articles are written by overseas researchers (non-members) with different systems of industry-academia collaboration from country to country, so matters including 1) scope of subjects to disclose COI, 2) items to be disclosed, 3) evaluation method for disclosure and 4) ways to measure, shall be defined in the disclosure policy of the journal separately.

Article 4: Submission of COI Statements by the Board of Directors, chairpersons, and committee members

4.1 The Board of Directors (President, board members, and inspectors), councilors, people in charge of academic meetings (conferences, seminars, lecture meetings hosted by branches and annexed workshops), committee chairpersons of all committees, Editors-in-Chief of in-house journals, members of pharmaceutical and healthcare committees, academic workshops, award selection committees, and ethics committees, and administrative staff of the JGES are required to voluntarily submit their COI statement over the past year, as prescribed in Article 4 of the Guidelines, to the Board of Directors when they first come into office and annually thereafter. However, submission is not needed if any COI have already been reported to the board. Disclosure of COI is limited to companies and organizations related to JGES projects.

4.2 COI to be disclosed in Form 3 are prescribed in Article 4 of the Guidelines. The criteria or monetary values for each disclosure are prescribed in Article 2 of the Detailed Regulations of the Guidelines. People who come into office shall disclose any COI over the past year and report a calculated amount received and the period of time over which the funds were received using Form 3. During their service to the JGES, directors are required to disclose any newly occurring COI within 8 weeks of its occurrence using Form 3.

Article 5: Handling of COI Disclosure Statements

5.1 Any COI Disclosure Statements submitted at the time of registration of Abstracts
for conferences and/or academic meetings or at the time of submission of manuscripts to JGES journals shall be kept on file for 2 years after their submission under strict supervision of the President at the JGES administrative office. Similarly, COI Disclosure Statements of retired executives and committee members shall be kept on file for 2 years after their retirement under the strict supervision of the President at the JGES administrative office. After 2 years, these statements will be promptly deleted or destroyed under the supervision of the President. However, in cases in which the Board of Directors deem that the deletion or destruction of specific statements is not appropriate, the statements may be stored for a predetermined period of time. The COI Disclosure Statements of people in charge of academic meetings (conferences, seminars, lecture meetings hosted by branches and annexed workshops) shall be treated the same as statements from JGES directors.

5.2 The JGES Board of Directors and related officers, following the Detailed Regulations, have the right to use the disclosure statements submitted if they find themselves in a position of needing to evaluate the COI situation for any member/person and to supervise, or take necessary measures. However, such access will be limited to those people who need the information in order to carry out the necessary investigations.

5.3 In principle, COI information will not be disclosed, except for the events defined in Article 5.2. However, sections of the information provided on the COI disclosure forms that are related to the activities of the Society (including annexed subcommittees) and regular or temporary meetings may be revealed internally and externally of the JGES after deliberations at a Board of Directors meeting if required for social and ethical accountability. The decision to disclose relevant information may be delegated to specific board members who are responsible for these issues after consultation with the COI Committee or the Ethics Committee. In such cases, the person whose COI will be disclosed has the right to state his/her opinion to the Board of Directors or specific board members. (Note, cases requiring urgent disclosure are excluded from this process.)

5.4 When nonmembers request disclosure of COI for specific members with proper justification (including legal demands), the matter shall be sent to the COI Committee to handle appropriately, protecting members’ personal information, after consultation with the President.

If the COI committee determines that the matter cannot be handled by the committee, the president shall promptly appoint several members of JGES and at
least one outside expert as members of a new COI Investigation Committee. The newly appointed COI Investigation Committee must hold a meeting within 30 days after the request and discuss the matter to resolve the problem.

Article 6: The COI Committee
The JGES will set up a COI Committee comprised of society members nominated by the President and more than one nonmember. The members of the COI Committee will choose a chairperson for the committee. Members of the COI Committee are obliged to maintain confidentiality regarding any information gleaned through the course of the Committee’s activities. The aim of the COI Committee is to preclude potentially serious COI problems for members and to handle any violations of the Guidelines in cooperation with board members and members of the Ethics Committee according to the COI policy and these Detailed Regulations. Article 5 is to be applied for the reporting and handling of COI information for members of the COI Committee.

Article 7: Actions Following Violation of the Guidelines
7.1 When any doubts or matters related to social and ethical issues are raised concerning the COI Disclosure Statements submitted by authors to all in-house journals (Digestive Endoscopy and Gastroenterological Endoscopy) or by presenters at JGES conferences and/or academic meetings, the Society will take appropriate measures after sufficient investigation and a hearing convened by the COI Committee to ensure proper societal accountability. If the COI is serious enough that it is impossible to achieve proper societal accountability, the President may take any measures deemed necessary, such as banning of the planned presentation and/or publication following a recommendation from the COI Committee. In addition, when doubts are raised regarding past presentations or publications, the President will investigate the matter and will take any measures necessary, including withdrawal of the presentations or articles concerned. In cases in which the violation seriously undermines the public’s trust in the JGES, membership of the JGES may be suspended, as allowed in the JGES constitution.

7.2 If a problem arises concerning the COI disclosure of JGES directors, chairpersons of various committees, or committee members, including their candidates who are required to disclose any COI, the chairperson of the COI Committee shall report the issue to the President in writing. The President shall promptly convene a Board of Directors meeting so that the Board can decide whether to accept or deny
the allegation. If the allegation is accepted, the directors or candidates for director positions in question shall immediately resign their position; in the case of other committee members, the committee may withdraw their commission after consultation with other committee members and candidates.

**Article 8: Petition of Objection**

8.1 Filing a claim

A person who has been notified of violating the COI Guidelines under Article 7.1 or asked to resign their position or withdraw their commission under Article 7.2 may submit a written claim to the President of the Society via the JGES administrative office within 7 days of notifying the President of their disagreement with the decision. A concrete counterargument/opinion against the allegation must be included in the written claim. Along with the counterargument, additional information supporting the argument should be provided in the written claim.

8.2 Procedure for examination of a filed claim

1. Once a claim has been received, the President shall promptly set up a Claim Review Committee. The Committee must comprise several Society members nominated by the President and more than one external nonmember. The members of the Claim Review Committee will nominate a chairperson for the committee. Members of the Ethics Committee cannot serve as commissioners on a Claim Review Committee. The Claim Review Committee shall meet to examine the claim filed within 30 days of its receipt.

2. The Claim Review Committee may consult with the chairman of the Ethics Committee and undertake additional hearings with the person who has filed the claim.

3. The Claim Review Committee shall complete a report regarding the claim filed and submit it to the President within 1 month of the first review meeting unless there are special circumstances justifying a delay of the report.

4. The decision of the Claim Review Committee regarding the filed claim is final.

**Article 9: Amendment of the Detailed Regulations**

9.1 Future changes to the Detailed Regulations are expected in response to future societal factors or changes in the laws concerning collaborations between industry
and academia. The Ethics Committee may conduct a review of the Regulations and, according to resolutions made by the Executive Board, the Regulations may be changed accordingly.

9.2 The Detailed Regulations shall be reviewed every few years to enable consideration of changes in societal factors, revisions to or the establishment of new laws concerning collaborations between industry and academia, and changes in biomedical and/or medical research.

Supplementary Provisions

The Detailed Regulations will come into effect on March 1, 2012.

Partial amendments: Made on October 1, 2013 (“clinical research” was changed to “medical research” with changes in related particulars.)