Guidance for Management of Institutional Conflict of Interest in Medical and Science Research Institutions

Table of Contents

Introduction

The management of institutional COI (institutional COI, hereinafter abbreviated as iCOI) in research institutions has become a pressing issue internationally from the viewpoint of potential risk of bias. If the research institution or its affiliated senior officials (e.g. chairman of the board of directors, president, vice-president, executive board members, dean, heads of departments, etc.) have a serious COI situation, the scientific, ethical, or legal judgements and decision making of academia (education, research, medical practice etc.) may be influenced inappropriately thereby creating bias. In particular, in clinical research or medical practice, situations may occur that threaten the rights of research subjects and patients, and the reliability and integrity of research institutions may occur. Such situation is what is referred to as iCOI of research institutions, and its management should be handled as a top priority matter. In the United States, the American Association of Medical Colleges (AAMC) and the American Association of Universities (AAU) publicized iCOI guidelines in 2002, and in 2008 a model policy for iCOI management in human subjects research was proposed. Since then, discussions on how to manage iCOI have been actively conducted, however, there has been little concern raised in Japan.

The Gelsinger case at the University of Pennsylvania in 1999, is an example of a case that became a social problem, not only as a case of COI of the individual researcher but also of iCOI management. In this case, the subject of the research, a young boy, died as a result of an inappropriate research intervention because the COI and iCOI of the principal investigator, who founded the venture company, was undisclosed and not managed properly. Furthermore, iCOI management became an issue because the university was an equity and patent holder of the venture company.

In response to this concern, the National Institutes of Health (NIH) (2013) and the National Science Foundation (NSF) (2005) each requested researchers to disclose iCOI, however, since most medical journals only ask individual authors who submit manuscripts to disclose personal COI and not iCOI, this has not become the norm. In 2013, the International Committee for Medical Journal Editors (ICMJE) created its COI disclosure form, which not only asks for the individual author to disclose COI at the time of submission, but also asks for iCOI disclosure. Since many international journals have adopted the ICMJE COI disclosure form, the issue of iCOI disclosure is becoming more significant.

Due to its complex nature, iCOI management is much more difficult to manage compared with COI management of individual researchers. The reason is that the COI possessed by research institutions is so diverse and complex that it is sometimes difficult to recognize an iCOI. However, from the perspective of appropriately managing industry-academia collaboration in clinical research, it is important to ensure the ①objectivity of human subjects research, ② transparency of information in industry-academia collaboration activities, and ③ maintaining public trust. It is therefore necessary to clearly express and specify cases where iCOI management is required. Furthermore, in principle, the committee that reviews iCOI, should be free and independent of the head or executive of the department of the research institution that may be receiving any financial gain from a specific company or organization.

This Guidance on research iCOI management was established for the purpose of COI management of officials who have authority to make decisions and have rights to auditing (hereinafter referred to as senior officials) regarding activities (research, medical practice, education), and who are affiliated with research institutions of life sciences (universities, research institutions, hospitals etc.) to promote appropriate industry-academia collaboration. In the process of conducting medical research that contributes greatly to the development of disease prevention, diagnosis, and treatment, financial COI, or substantial, potential or evident COI situations associated with industry-academia collaboration with specific companies or for-profit organizations etc. may occur. This may occur not only to the principal investigator (mainly the clinician) but also to senior officials of the research institution, which may affect judgment or decisions regarding research results, thereby compromising its objectivity, integrity, and reliability. In order to ensure the clarity and reliability of research institutions, this Guidance recognizes how and in what way research institutions and senior officials may have influence on the clinical research to be conducted, and how to prevent or minimize the risk of bias. Furthermore, how the research institution itself should prevent research misconduct by transparentizing any potential financial and non-financial relationships that may occur from industry-academia collaboration, and how to manage such situations so as not to arouse suspicion in society. However, in order to promote appropriate industry-academia collaboration, making flexible judgments and handling individual cases accordingly will become necessary.
We, as the Committee of Clinical Research/Conflicts of Interest Review Committee of the Association of Japanese Medical Colleges, have published this Guidance with the hopes of raising the awareness of the significance of iCOI to our member organizations.

1. Basic Thinking

Pharmaceutical drugs and medical devices are subject to basic research, non-clinical testing, medical science research (clinical research) and clinical trials involving clinical subjects and patient participation, to confirm clinical efficacy and safety, and undergo national approval before they are marketed. With such developments in medical innovations as we face intensifying international competition, it is essential for Japanese industrial and medical communities, in addition to academic organizations, to share their respective roles and cooperate under good partnership to promote industry-academia collaboration activities. In addition, research institutions contribute to the development of prevention, diagnosis and treatment methods for diseases, and the results of such research are presented to companies for obtaining licenses, and to strengthen efforts to promote the start-up of venture companies under the auspices of the university to contribute to society for the public benefit.

On the other hand, research institutions are officially public organizations, and therefore should strive to protect human dignity and human rights of clinical research subjects and improve the social reliability of the research institution. However, if a publicly-funded research institution owns patents or stocks of a company that develops or manufactures pharmaceutical drugs and medical devices, a potential COI will occur. As a result, if senior officials of headquarters and divisions who have the authority to make decisions and have rights to audit in research institutional activities, make decisions in a way that prioritizes the interests of the research institutions, or if the decision-making is based on such, the integrity and reliability of the research will become distorted and the risk for study subjects and patients will increase. Furthermore, if research institutions prioritize promoting sales of pharmaceutical drugs and medical devices, it will undoubtedly raise concern that they are trying to pursue profits, or that they are trying to pursue more profit by publishing papers. However, such iCOI situations are inevitable in industry-academia collaboration and cannot be avoided. For this reason, when research institutions conduct clinical research closely related to the life and health of people, in order to ensure objectivity and integrity of the organization, COI management of individual senior officials in conjunction with iCOI management of the research institution must be properly handled. On the other hand, it should also be noted that management should be conducted flexibly and accordingly to specific cases of iCOI so that collaboration activities between the medical and industrial community are not intimidated or decelerated.

2. Objectives

This Guidance states the items needed to be abided by the research institution and its affiliated senior officials, based on the significance of human subjects research whereby the dignity and human rights of study subjects and patients are ensured, in addition to other ethical and scientific viewpoints so that understanding and cooperation for the research institution from society can be obtained. The objective is to ensure integrity and reliability of clinical research, and to promote transparency by appropriately managing iCOI and individual COI.

3. Those Subject to iCOI Management

Since research institutions and its affiliated senior officials have an interest in a specific company or group etc., we have determined the judgement criteria on whether they may affect or appear to affect the planning, conducting, reporting, reviewing or auditing of human subjects research. In addition, judgments should be made from the same viewpoint regarding activities in medical practice and procurement of pharmaceutical drugs and medical devices. Special attention must be given to the potential risks of research participants and patients receiving care in order to protect human rights. The management of iCOI should be mainly based on financial iCOI, but management of non-financial iCOI is also required.

1) Research Institutions (iCOI)

If the research institution itself has a financial relationship with a specific company, it may affect medical science research in human beings. COI disclosure is necessary if the COI situation pertaining to the organization in Table 1 exceeds the base amount for each item. However, in practicality, because the chairman of the board of directors or the president will act as the representative of the institution (or the director of the research institution), and has the authority to make final decisions on its behalf, it is necessary to disclose both COI of the research institution or director of the institution. In particular, the following items, which involve the heads of affiliated organizations and departments (research institutions, hospitals, departments or centers, etc.) in relation to the research content of senior officials, are subject to disclosure.

Items for Disclosure (Table 1)

(1) Stock ownership and profit

(2) Remuneration from patent royalties or licensing fees

(3) Research funding for commissioned research, joint research

(4) Substantial donations (e.g. scholarships, endowed departments, facilities, research etc.)

(5) Investment in a commercial entity (e.g. venture companies)

(6) Payments resulting from transfer of technology to companies

(7) Procurement of equipment etc. (e.g. devices, materials for research and medical practice)

2) Senior Officials

Due to the fact that higher ranking officials have official duties and obligations, COI will exist with specific companies and for-profit organizations. Therefore, iCOI should be managed if the headquarters or departments of the research institution are involved in the decision-making process. The following officials are subject to review. Officials whose positions give authority in decision-making in the activities of medical science research of institutions, or those who play a role in special audits, such as, the president, vice-president, executive board members, or those who have special prominent roles such as the dean, director of research (head of department), chairman of a large department, medical research review committee member, auditor, director, management director, pharmaceutical division director etc. In addition, those who have the authority to decide on procurement and purchase of pharmaceutical drugs, medical instruments, and medical devices, should also be subject to iCOI management, as necessary.

Senior officials who may be expected to influence activities of research institutions or departments should submit an official COI disclosure form to the head of the research institution. COI disclosure for senior officials and spouses, or persons who share income or financial assets, must include items for the previous 3 years starting from the year before taking office (from January 1-December 31), and submit using the form in Table 2.

3) iCOI Committee, Ethics Review Committee etc.

Those involved in iCOI review should also disclose COI using the official form in the same manner as senior officials. At the same time, external committee members must declare if there is any non-financial COI with the head or senior officer of the research institution and if a COI exists, the option to recuse oneself from the review process must be given.

4. Items for Disclosing iCOI

When planning, conducting, reporting, reviewing, or auditing clinical research in a research institution or in a way related to a research institution, the decision to determine whether or not the benefits obtained by the research institution or affiliated senior officials may have inappropriate influence or appear to have inappropriate influence (bias) must be made from a third-party perspective. In particular, regarding the potential risks of research subjects participating in medical science research, special consideration to protect research subjects is required. ICOI will become an issue if research institutions have COI with companies and for-profit organizations involved in clinical research, such as technology transfer ownership, possession of patent rights and equity holdings, or the involvement of a venture company in research development. Furthermore, if significant donations (hundreds of millions of yen) or expensive facilities are donated by a specific company, senior officials involved may be affected unintentionally to give consideration to the corresponding company. For this reason, the contents of the iCOI disclosure form must take into account the complexity of financial COI involved in industry-academia collaboration. Specifically, there is an obligation to disclose COI of 1) the research institution, and 2) individual COI of senior officials who have discretionary power. Regarding individual COI disclosure, the official form and Items 1 to 9 of the Japan Medical Association and the Association of Japanese Medical Colleges should be used for disclosure. However, if there is any medical science research being conducted with a specific company, individuals must also disclose any social activities and COI with other companies, in addition to any working experience in a company within the past 5 years using Items 10-12.

Not only financial interests that trigger the risk of bias (financial COI), but also non-monetary interests (intellectual COI) should be considered when determining judgment criteria. The base amount for disclosure for each item for individual financial COI is based on the Guidelines of the Japan Medical Association and the Association of Japanese

Medical Colleges, and if it exceeds the amount, the individual is required to disclose the total annual amount. In addition, it should be noted that regarding iCOI management, it should be conducted cooperatively with the IRB and the Clinical Research Ethics Committee, together with the COI review of the clinical research conducted, and should be conducted appropriately, in a setting that is not under the influence of senior officials.

1) Financial COI

For use by senior officials for individual COI disclosure (Table 2)

(1) Position as an officer or advisor of a company or for-profit organization, and amount of remuneration
(2) Stock ownership and profit from stock (profit from stock for the previous year)
(3) Remuneration received for patent royalties or licensing fees from companies or for-profit organizations.
(4) Honoraria such as lecture fees, attending conferences (presentations, providing advice etc.) received from a company or for-profit organization for the time and labor given per day.
(5) Manuscript fees received for writing articles for pamphlets, roundtable discussion articles, etc., from a single company or for-profit organization.
(6) Research funding provided by a company or for-profit organization (joint research, commissioned research, clinical trials etc.)
(7) Scholarship (incentive) donations provided by a company or for-profit organization.
(8) Endowed departments established through donations by a company.
(9) Other remuneration (not directly related to research such as travel, gifts, etc.)
(10) Position as an officer of a venture company or incorporated foundation
(11) Involvement in clinical research conducted by a company or organization that is subject to COI
(12) Transfer from a specific company or organization

Note that (6) and (7) refers to the actual amount distributed from the head of the affiliated research institution (direct expenses) and should be research funds and donations that are actually used or determined to be used by the individual disclosing COI.

COI Disclosure for spouses, first degree relatives or any persons who share income or property assets with the individual subject to COI disclosure.

(1) Position as an officer or advisor of a company or for-profit organization, and amount of remuneration
(2) Stock ownership and profit from stock (profit from stock for the previous year)
(3) Remuneration received for patent royalties or licensing fees from companies or for-profit organizations.

2) Management of Non-financial iCOI

The management of non-financial iCOI is extremely difficult, as we must rely on individual disclosure. For example, if a senior officer has a personal relationship with an individual of specific company (teacher-student, history of joint research, classmate etc.) i.e., a non-financial COI situation, if it is likely to affect the decision-making of activities, there should be the option of recusing oneself in the decision-making process. As a result, the research institution would have fulfilled its accountability.

5. Period for Disclosure

Those subject to iCOI disclosure will submit a COI disclosure form to the iCOI Committee using the official form, once a year, in March. However, in projects where a contract is involved and if there is possible iCOI, the iCOI Committee should immediately review and manage the validity of the contract contents in order to ensure the credibility and integrity of the research institution, before agreeing to the contract.

6. Circumstances that may present potential iCOI

1) Circumstances where senior officials may have influence

① If a large amount of donation is provided by a pharmaceutical company A, priority may be given to clinical trials using pharmaceutical drugs of pharmaceutical company A, and it may affect the ethical review process.

② If a large amount of donation is received from Company A, a contract including terms advantageous to Company A may be drawn up. On the other hand, even if the director of the research institution handles all situations appropriately, there may be

circumstances where it may be impossible to prevent public perception that a bias exists.

2) Circumstances involving medical science research involving human subjects

In medical science research involving human subjects (clinical trials, clinical tests), we will illustrate circumstances that may become problematic in terms of iCOI management.

① K University has established an EBM center using the donation from T Pharmaceuticals (¥ 700 million). T Pharmaceuticals planned a large-scale comparative clinical trial of a new antihypertensive drug X, and conducted the trial at the EBM center. (Company T, which is the vendor company expects positive test results from K university)

② AB is the clinical developer of antihypertensive drug X. AB retires from T pharmaceuticals but participates in a research as a researcher in the EBM center (paid employee using donations from T pharmaceuticals) and publishes a paper on the research (T pharmaceuticals has expectations that the publication of this paper will promote drug sales)

③ University T has invested heavily in Company A for asset management. T university hospital is engaged in, and prioritizes, a large-scale clinical trial of a joint research using new pharmaceutical drugs from Company A (T University and Company A both expect positive data)

④ Company A, which manufactures heart catheters, after providing 3% of its own shares to S medical institution, requested post-marketing clinical trials and publication of the results of their new heart catheters. (Company A and S medical institution both expect favorable results that will promote sales)

⑤ Prof. B of University A, is conducting research as a principal research clinician on a candidate drug T, developed by a university-based venture company, using national funds from the "Pharmaceutical industry strengthening comprehensive strategy" project. (if successful, Prof. B is expecting good evaluation of his achievement in research and financial profit after the drugs are approved)

3) Circumstances related to the purchase of pharmaceutical drugs/medical devices

There are cases where research institutions that have received large amounts of money (donations, grants etc.) from companies, or own patents or royalties for specific pharmaceutical drugs and medical devices, to preferentially purchase them without evaluating its efficacy or validity.

① University X has built a new research center for joint disease using the donation given by former university president A, who spent the past 10 years working for the university. Artificial hip joint B, for which former president A is receiving royalties, has been used although the evaluations of this is poor among orthopedic surgeons. (The company selling B is expecting University X to use and purchase B)

② Emergency physician A at University Hospital X received a research grant of 50 million yen from contractor B, as funds to use a new model artificial respirator, when he agreed to signing a contract. (Company B expects advertising effects that will promote sales)

4) Circumstances involving daily clinical activities

① University X has received royalties of 60 million yen per year for the past 10 years for Company B's FDA-approved artificial hip joint. Over 90% of orthopedic surgeons at University X have been using this for treatment and continue to do so.

② Orthopedic surgeon A presents a sample of an artificial hip joint that he was personally involved in the making of, to show its function so that he can prescribe it to is patients. Orthopedic surgeon A obtains consent from the patients before surgery.

7. iCOI Committee

1) Status of the iCOI Committee

A committee that reviews financial COI of individuals affiliated with a research institution is, per se, established under the director of the research institution. However, since senior officials of the affiliated research institution are subject to review by the iCOI Committee, it should be positioned as an independent committee without being influenced by the director

and senior officials of the research institution. For this reason, it becomes significantly important to ensure the integrity and credibility of the research institution by granting the authority to make appropriate judgements and decisions from a third-party perspective. In order to do so, the iCOI Committee should be chaired by an external member or expert (for example, an audit committee member), and should review situations based on objectivity and transparency, with the advice of the director of the research institutions.

2) Composition of the iCOI Committee

In principle, the iCOI Committee should act as a committee that is able to objectively maintain neutrality and independence, mainly by external experts and specialists who are capable of giving evaluation and review from a medical, scientific, ethical and legal perspective. It should consist of at least seven members, including "external experts and specialists familiar with laws regarding patent, intellectual property, research ethics, COI management, clinical trials, etc." in addition to having a public member. At least two members should be either external experts, or specialists, or public members with no active transactional relationship with the research institution. Also, at least two members should be appointed from the standing COI Committee who will review individual financial COI. The iCOI Committee quorum for voting shall be more than half of the fixed number of members (including 2 or more external members), and all members and related staff must have received training in iCOI management (includes online training).

3) Role of the iCOI Committee

The iCOI Committee must fulfil its role to evaluate and review the impact on activities related to the research institution, based on COI disclosed by the research institution and its senior officials, etc., while ensuring objectivity and neutrality in accordance with the terms of this Guidance. In particular, regarding clinical research conducted by the research institution, this information should be shared among the IRB, the Ethics Review Committee, and the COI Committee, and should be properly managed so as not to cause any social misperception. For example, if the secretariat in charge of handling COI predicts that after COI review, a senior officer's specific COI may clearly influence the clinical research to be conducted, then it should be reviewed by the iCOI Committee, and the situation should be reported to the IRB, the Ethics Review Committee, and the COI

Committee, in addition to the corresponding principal investigator (in the case of multi-institutional joint research, the research representative), and should be used in the review of the clinical research implementation plan. Furthermore, if a principal research has already began conducting the clinical research, and if new iCOI should occur, the iCOI should be disclosed and undergo additional review.

4) Role of the Secretariat

In order to enable sharing of information and efficiently manage the running of the Research Ethics Review Committee, the secretariat (e.g., the Research Compliance Office or the COI Management Office), which is responsible for handling medical science research applications, manage the running of the IRB and the Research Ethics Review Committee, in addition to the management of COI of individual researchers, should also handle iCOI administrative duties (management of industrial-academia collaboration activities and handling of information of related companies, preparation of management plans, etc.). It should be noted that the settlement of contracts and transactions with a company subject to COI will be reassessed at the iCOI Committee after it is clearly indicated that it is subject to iCOI review.

5) Audit of iCOI Committee Activities

Assessment and auditing of whether the iCOI Committee's role is being properly and objectively fulfilled will be handled by the iCOI Audit Committee (or iCOI Advisory Board) consisting of external members (including iCOI Committee members of other research institutions) which will be set up appropriately every few years.

8. Procedures for iCOI Management

The secretariat will respond appropriately, under the iCOI Committee, in accordance with the Guidance under the following procedure.

1) If research institutions and senior officials have a potential COI situation in relation to the activities taking place, full COI disclosure using the official form is required. In particular, if there is a COI that may affect a specific clinical research, either scheduled or conducted by the organization, senior officials will be required to disclose the name of the clinical research and the name of the company involved, to the iCOI Committee.

2) The COI situation mentioned in 1) will be reviewed objectively as it is related to activities of the research institution and concerns its clinical research, practice, education, and procurance. In addition, it is essential for the COI Committee, which reviews the COI of the individual researcher in addition to clinical research implementation plans, to collaborate with the Research Ethics Review Committee by sharing and exchanging information.

3) It is necessary to determine the possibility of bias or reputational risk associated with activities of the research institution. In particular, if it is determined that there is an iCOI that affects the conduct of clinical research, the principal investigator (research representative) should be notified, and iCOI should be disclosed at the time of publication and research plan implementation, including submission of informed consent (IC) documents.

4) If research institutions of senior officials have a serious iCOI situation, ways to ameliorate or avoid risk of bias to a tolerable level should be considered, and a management plan should be drawn up. Each research institution is required to appropriately manage the judgment criteria by setting a tolerable amount for each item of the iCOI disclosure form.

5) The researcher of the activity being conducted should be notified, and the progress status of the plan should be monitored. If a large amount of scholarship donations are provided to a particular researcher by a company that has a serious COI situation with the affiliated research institution, it must be carefully reviewed as an individual case, and regular review and monitoring may be conducted.

6) If the iCOI situation is deemed to be serious and apparent but the clinical research cannot be terminated or iCOI cannot be mitigated, and the clinical research must inevitably be carried out, the iCOI Committee will prepare a COI management plan on the 1) status of the COI situation, 2) risks that may occur concerning research subjects, 3) risks that may affect the integrity of the research, and 4) risks that may damage the reputation of the research institution, and report to the head of the corresponding department in addition to recommended corrective measures. The decision to allow the clinical research should be made after obtaining approval. In general, analyzing each individual situation accordingly and responding flexibly is necessary. As a means to handle this, e.g., 1) disclose iCOI within the informed consent document, 2) disclose iCOI on the website, 3) replace senior officials who have iCOI who are involved in the

decision-making process of activities, with those who do not, 4) request review by an iCOI Committee from another research institution, 5) request external monitoring of the research study, or review by an external review board, 6) in the case of a multi-institutional joint research, request iCOI disclosure of participating facilities involved.

9. Statement of Objections to Sanctions

If senior officials disregard or violate this iCOI Guidance and are subject to sanctions, a request for appeal can be made by sending a written request of reconsideration using the complaint form, briefly stating specific objections and disagreements, and submitting it to the iCOI Committee within a short period (e.g. within 7 days) from the date of notification. If a request to reconsider a reprimand or punishment is received, the director of the research institution must promptly set up an Appeals Review Committee and designate members whereby, external members must account for the majority. A review by the committee must be conducted promptly after the request has been made, and the director of the research institution should be notified.

10. Disclosure of iCOI

The foundation for which the integrity and reliability of the research institution lies as well as the quality of medical science research, education and medical practice, is based on disclosure and transparency of iCOI of the research institutions, in addition to its senior officials and specific companies. The iCOI status of research institutions and senior officials should be disclosed on the Website, in reference to items for disclosure according to the Japan Pharmaceutical Industries Association's Transparency Guidelines and the Guidelines for Publishing Guidelines on Public Funds from Companies etc. of the National University Hospital Council of Japan, using the official form (Form 3). In addition, if there is any misperception from society, the director of the research institution must promptly fulfill its accountability.

11. Training in iCOI

The director of the research institution should provide training opportunities for iCOI management to its senior officials, administrative staff involved with iCOI management, researchers, iCOI committee members, etc., and require them to attend.

12. Miscellaneous

(1) This Guidance was approved by the Board Meeting of the Association of Japanese Medical Colleges held on April 27, 2018, and its General Assembly held on May 25, 2018.

(2) The Guidance will be modified accordingly in order to adapt to social factors, amendment and establishment of laws related to industrial-academia collaboration, and conditions associated with medicine and clinical research.

References

1） 世界医師会．日本医師会・訳．ヘルシンキ宣言． 2013 年.
http://www.med.or.jp/wma/helsinki.html

2） 厚生労働省　高血圧症治療薬の臨床研究事案に関する検討委員会。高血圧症治療薬の臨床研究事案を踏まえた対応及び再発防止策について。平成 26 年 4 月 11 日
http://www.mhlw.go.jp/stf/shingi/0000043367.html

3） 製薬工業協会「企業活動と医療機関等の関係の透明性ガイドライン」
2011 年 3 月公表、2016 年 6 月改訂
http://www.jpma.or.jp/tomeisei/aboutguide/pdf/150402_02.pdf

4） 国立大学附属病院長会議「企業等からの資金提供状況の公表に関するガイドライン」
平成 26 年 6 月公表
http://www.univ-hosp.net/guide_funding.pdf

5） 文部科学省・厚生労働省「人を対象とする医学系 研究に関する倫理指針」
平成 26 年 12 月 22 日
http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/0000153339.pdf

6） 日本医学会「COI 管理ガイドライン」平成 29 年 3 月改訂
http://jams.med.or.jp/guideline/coi_guidelines.pdf

7） the International Committee of Medical Journal Editors； Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals、Updated December 2015、http://www.icmje.org/icmje-recommendations.pdf

8） 全国医学部長病院長会議「医系大学・研究機関・病院の COI(利益相反)マネージメントガイドライン」平成 26 年 2 月改訂
https://www.ajmc.jp/pdf/coi26-2-24.pdf

９） 全国医学部長病院長会議「研究者主導臨床試験の実施にかかるガイドライン」
平成 27 年 2 月　https://www.ajmc.jp/pdf/guideline_02.pdf

１０） Resnik DB, Ariansen JL, Jamal J, Kissling GE. Institutional Conflict of Interest Policies at U.S. Academic Research Institutions. Acad Med. 2016 Feb;91(2):242-6.

１１） AAMC/AAU(2008): Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI policies in Human Subjects Research、page 36-42 APPENDIX A Model Policy on Institutional Conflict of Interest in Human Subjects Research

１２） Ehringhaus SH[1], Weissman JS, Sears JL, Goold SD, Feibelmann S, Campbell EG Responses of medical schools to institutional conflicts of interest. JAMA. 2008 Feb 13;299(6):665-71..

１３） Kaur S, Balan S. Towards a balanced approach to identifying conflicts of interest faced by institutional review boards. Theor Med Bioeth. 2015 Oct;36(5):341-61.