日本医学会利益相反委員会 e-Mail 通信　第 2 号 2021.03.15

日本医学会利益相反委員会は,2020 年 4 月に日本医学会 COI 管理ガイドライン一部改定版を公表し,その後に本ガイドライン Digest 版を日本医学会ウエブサイトに掲載しましたのでご活用いただければ幸いです．医学，医療の進歩には産学連携が欠かせないことは言うまでもないが，その健全化にはバイアスリスクの主因となる医学系研究者の COI 状態の透明化と説明責任が大前提となります．医学雑誌編集者国際委員会（ICMJE）は，論文公表にかかる著者 COI の自己申告と開示だけでは不適切な COI 申告漏れや恣意的な申告違反が発生し，研究不正の一因となりうることから，2019 年 12 月に ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals 2019 の一部改定を行い，COI DISCLSOURE にかかる内容について「Financial and Non-Financial Relationships and Activities, and Conflicts of Interest」という下線 2 語を追加しました．すわなち，著者及び所属機関と第三者の企業／団体との関わり並びに諸活動状況の詳細な開示を求めております．今年の 2 月には従来の開示様式を変更した ICMJE DISCLOSURE FORM (Updated February 2021)が website に公表されましたのでそれらの改定ポイントを紹介します．また，Institutional COI 管理に関する理解をより一層深めていただくための情報も提供いたします．

お知らせ

●日本医学会は，医学・医療の発展による国民の健康増進・維持に役立てるために企業・団体との連携と協働が欠かせないと考えており,それらの推進には医学・医療にかかわる研究者や関係する研究機関・組織・団体を守るためにも両者の利害関係を経済面だけでなく，人的関係と協働活動も含めて開示を求めて適正に管理することが必須と考えております．特に，研究成果の公表や診療ガイドライン策定に際しては研究者個人や所属研究機関・組織団体にかかる COI 状態の開示・公開が社会からの信頼性および integrity を確保していく上で前提となります．

2017 年に日本医学会診療ガイドライン策定参加資格基準ガイダンスを公表し，策定参加者の COI 開示様式を提示しました.それ以後,各分科会における診療ガイドラインの新規策定および改定に際して,同様式を用いたCOI開示・公開が着実に増えております.今後とも,各分科会の integrity と reliability を確保するためにも透明性を担保に COI 管理に向けてご尽力の程よろしくお願いいたします.

トピックス ICMJE COI disclosure の改定に関する最新情報

●ICMJE Recommendations Updated December 2019 の改定ポイントは？

2019 年 12 月改定版では，Disclosure of COI の部分に「Financial and Non-Financial Relationships and activities」が追加され，本文の赤線部分が加筆修正されております（資料 1:1-4 ページ）．特に，本文では，Conflicts of Interest の用語はことごとく Relationships and activities に置き換えられており，潜在的な bias リスク情報の開示をより詳細に求めています．公表論文にかかるバイアスリスクの判断者は著者でなく，第三者の読者であるとの視点から，その判断を全面的に委ねるために著者と利害関係にある組織／団体(entities)との関わり合い（Relationships）と諸活動内容(activities)を具体的にかつ詳細に開示させ，透明性を担保に信頼性の確保をより一層図ることを求めています．

【コメント：”Relation”と”Relationship”を直訳すると”関係“となりますが，本文にあ

る”Relationship”は，単なる”関係“でなく，”Friend“と”Friendship“との違いを推察して，”Relationship”をより深い関わり合いのある状態と理解して”関わり“と和訳しました.】

日本医学会COI管理ガイドライン2020は，ICMJE Recommendationsとの整合性を重点課題として改定を随時行っており，利害関係にある組織・団体等とのRelationships and activitiesに関する開示はRole of funding sources, Contributors, Acknowledgementsの項目で具体例を挙げて詳細な記載（資料２）を著者に既に求めており，整合性という視点から十分に対応しております.

●ICMJE Disclosure of Interest (Updated February 2021)の改定内容は？

今回，2021年2月にICMJE DISCLOSURE FORM（として，１３の申告事項が一つの表にまとめられており，それぞれの項目ごとに関わりのある組織・団体等の名称を書き，それぞれに個人(personal)或いは所属の機関／組織（institutional）にかかるRelationships and Activities, and COI状況を記載する新しい様式(form)（資料３）が提示されております．第三者視点で利害関係者とのCOI状況がより詳細に理解されやすくなっており，Old formの使用は2021年6月30日まで有効としています．新しいICMJE DISCLOSURE FORMの日本語訳（日本医学会利益相反委員会）を資料４として添付しますので参考にしていただきたい．重要なポイントは，公表論文内容に関するバイアス有無の判断者を第三者（読者等）と位置付けており，今回のDisclosure Form中にある「If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.」は，研究者が常に心に留めて申告開示しなければならない一文です．ICMJE DISCLOSURE FROMは申告基準額を設けずにすべての関わりを開示させており，日本医学会各分科会発行の学術雑誌も同じ方向での検討と取り組みが必要な時期にあると考えております.

Q/A コーナー

Q：研究機関自体の組織COI開示について日本と米国での違いはあるのでしょうか？

A:米国では，Sunshine 法にて企業等からの医師個人を対象とした資金提供額情報が Open payment programとして政府機関ウエブサイトで公開されていますが，研究機関や学術団体等を対象とした情報は公開されていません．しかし，日本では製薬協公表の透明性ガイドラインに従い，研究者等の個人だけでなく研究機関等，学術団体への資金提供額の詳細が会員企業により詳細に公開されている点が異なります．従って，日本医学会は各分科会が産学連携にかかる疑義や誤解を社会から招かないためにも，医学系研究機関および関係学会自体にかかるCOI状況の開示，公開を求め，利害関係の透明化によりバイアスリスクの回避に努めています.

国際動向：総説論文“学術研究にかかる組織COIとは”

論文タイトル：Institutional Conflicts of Interest in Academic Research

著者：David B. Resnik

雑誌：Sci Eng Ethics. 2019 December; 25(6): 1661-1669

学術研究に財政的な利害関係が存在する場合，組織（研究機関，学術団体等）や組織幹部の財政的利害関係が意思決定に不適切な影響を及ぼしかねないため，組織自体の利益相反(Institutional COI)を生む可能性がある.

【Institutional COI（組織COI)の定義】

組織COIとは，学術研究にかかる組織または組織役職者が，最も重要である専門的・道徳的・法的義務や学問上の目的についての判断や意思決定を行う際に障害となりうる利害関係を有する状況，と定義す

ることができる.

組織 COI は，研究の客観的妥当性や整合性，及び組織・研究者・研究計画への社会的信頼を損なうことにより，道義的問題を引き起こしかねない．さらに，精査や取り締りに不名誉な譲歩を行いかねないため，個人的 COI よりも多くの人々に影響を及ぼす可能性がある.

【組織 COI の一例】

ある大学が，15 年前に設立した受託研究機関の最高経営責任者である富裕な卒業生から 3 億ドルの贈与を受けた．贈与に際しては，その大学の公衆衛生学部を寄贈者の名前に因んで改名すること，公衆衛生学部のカリキュラムに臨床試験計画・管理・規則などを含むいくつかのコースを含めること，さらに臨床試験計画・管理・規則分野の教授ポストを与えること，という条件が明記されていた．公衆衛生学の教授陣は，その寄贈者がカリキュラムに不適切に影響を及ぼしていると感じ，懸念している.

【組織 COI への対処方針】

個人的 COI に対処するための方針は広く認識されているものの，組織 COI に対する最良の対処法についてのコンセンサスはないのが実態である．組織 COI への対処方針には，COI の精査や管理を行う評議員会を含む COI 委員会を設置すること，組織が下す決定を不適切な影響から守る方針を策定すること，株式や知的財産の所有，新設企業へ資本金の提供を行うための私的財団の設置などがある.

【組織 COI の対処が困難な理由】

最近の研究（Resnik et al. 2015）によれば，アメリカで研究資金の合計獲得金額が 1 位から 100 位までの学術研究機関のうち，組織 COI ポリシーを制定しているのはわずか 28%であった．組織 COI ポリシーが策定されていない最大の理由は，連邦の補助金授与機関や学術雑誌が，学術研究を実施する際の組織 COI に対処するための規則やガイドラインの遵守を求めていないことにある.

また，組織 COI への効果的な対処が困難である主な理由として，１）大学組織には多くの異なる利害関係が存在し，それら利害に関係する学部，学科，委員会が複数絡んでおり，組織 COI についての認識が困難であること．また，２）効果的な COI 管理には相反する利害関係もなく権限を持って対処できる独立した第三者グループを活用することが必須であるが，そのような第三者グループを組織内設置することは困難であること （Institute of Medicine 2009)の２つが挙げられる.

【教育的活動の必要性】

COI 管理にかかる認識の欠如は組織 COI 委員会を立ち上げる上で重大な障害となりうる．この問題は，大学組織の幹部が評議員などに対し，組織 COI がいかに大学に不利な影響を与える可能性があるかを教育することにより克服できる．さらに，組織 COI マネージメントに関するセミナーや講演，オンライン学習モジュールなどの教育的な啓発活動を支援することができる.

【最後に】

資金提供する企業・団体は，現在のところ大学組織向け補助金や受託契約先に対し，各々が COI に対処することを求めてはいないが，大学などの組織は，学術研究の客観的な妥当性と整合性を守り，社会的な信頼性を高めるため，そのような要請がなくても，研究機関としての組織 COI の方針を自主的に策定しなければならない.

日本医学会 The Japanese Association of Medical Sciences

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お願い：COI 管理に関する質問，コメント，要望，提案などがありましたら事務局へお寄せください.

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated December 2019

I. About the Recommendations

A. Purpose of the Recommendations

ICMJE developed these recommendations to review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals, and to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, reproducible, unbiased medical journal articles. The recommendations may also provide useful insights into the medical editing and publishing process for the media, patients and their families, and general readers.

B. Who Should Use the Recommendations?

These recommendations are intended primarily for use by authors who might submit their work for publication to ICMJE member journals. Many non-ICMJE journals voluntarily use these recommendations (see www.icmje.org/journals-following-the-icmje-recommendations/). The ICMJE encourages that use but has no authority to monitor or enforce it. In all cases, authors should use these recommendations along with individual journals' instructions to authors. Authors should also consult guidelines for the re-

porting of specific study types (e.g., the CONSORT guidelines for the reporting of randomized trials); see www.equator-network.org.

Journals that follow these recommendations are encouraged to incorporate them into their instructions to authors and to make explicit in those instructions that they follow ICMJE recommendations. Journals that wish to be identified on the ICMJE website as following these recommendations should notify the ICMJE secretariat at www.icmje.org/journals-following-the-icmje-recommendations/journal-listing-request-form/. Journals that in the past have requested such identification but who no longer follow ICMJE recommendations should use the same means to request removal from this list.

The ICMJE encourages wide dissemination of these recommendations and reproduction of this document in its entirety for educational, not-for-profit purposes without regard for copyright, but all uses of the recommendations and document should direct readers to www.icmje.org for the official, most recent version, as the ICMJE updates the recommendations periodically when new issues arise.

C. History of the Recommendations

The ICMJE has produced multiple editions of this document, previously known as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs). The URM was first published in 1978 as a way of standardizing manuscript format and preparation across journals. Over the years, issues in publishing that went well beyond manuscript preparation arose, resulting in the development of separate statements, up-dates to the document, and its renaming as "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" to reflect its broader scope. Previous versions of the document may be found in the "Archives" section of www.icmje.org.

II. Roles and Responsibilities of Authors, Contributors, Reviewers, Editors, Publishers, and Owners

A. Defining the Role of Authors and Contributors

1. Why Authorship Matters

Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The following recommendations are intended to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.

Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship. The ICMJE has thus developed criteria for authorship that can be used by all journals, including those that distinguish authors from other contributors.

2. Who Is an Author?

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged—see Section II.A.3 below. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses. We encourage collaboration and co-authorship with colleagues in the locations where the research is conducted. It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria; it is not the role of journal editors to determine who qualifies or does not qualify for authorship or to arbitrate authorship conflicts. If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not the journal editor, should be asked to investigate. The criteria used to determine the order in which authors are listed on the byline may vary, and are to be decided collectively by the

author group and not by editors. If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.

The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process. The corresponding author typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and disclosures of relationships and activities, are properly completed and reported, although these duties may be delegated to one or more coauthors. The corresponding author should be available throughout the submission and peer-review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication. Although the corresponding author has primary responsibility for correspondence with the journal, the ICMJE recommends that editors send copies of all correspondence to all listed authors.

When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete disclosure forms.

Some large multi-author groups designate authorship by a group name, with or without the names of individuals. When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.

3. Non-Author Contributors

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g., "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

B. Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest

Public trust in the scientific process and the credibility of published articles depend in part on how transparently an author's relationships and activities, directly or topically related to a work, are handled during the planning, implementation, writing, peer review, editing, and publication of scientific work.

The potential for conflict of interest and bias exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest.

Individuals may disagree on whether an author's relationships or activities represent conflicts. Although the presence of a relationship or activity does not always indicate a problematic influence on a paper's content, perceptions of conflict may erode trust in science as much as actual conflicts of interest. Ultimately, readers must be able to make their own judgments regarding whether an author's relationships and activities are pertinent to a paper's content. These judgments require transparent disclosures. An author's complete disclosure demonstrates a commitment to transparency and helps to maintain trust in the scientific process.

Financial relationships (such as employment, consultancies, stock ownership or options, honoraria, patents, and paid expert testimony) are the most easily identifiable, the ones most often judged to represent potential conflicts of interest and thus the most likely to undermine the credibility of the journal, the authors, and science itself. Other interests may also represent or be perceived as conflicts, such as personal relationships or rivalries, academic competition, and intellectual beliefs.

Authors should avoid entering in to agreements with study sponsors, both for-profit and nonprofit, that interfere

with authors' access to all of the study's data or that interfere with their ability to analyze and interpret the data and to prepare and publish manuscripts independently when and where they choose. Policies that dictate where authors may publish their work violate this principle of academic freedom. Authors may be required to provide the journal with the agreements in confidence.

Purposeful failure report those relationships or activities specified on the journal's disclosure form is a form of misconduct, as is discussed in Section III.B.

1. Participants

All participants in the peer-review and publication process—not only authors but also peer reviewers, editors, and editorial board members of journals—must consider and disclose their relationships and activities when fulfilling their roles in the process of article review and publication.

a. Authors

When authors submit a manuscript of any type or format they are responsible for disclosing all relationships and activities that might bias or be seen to bias their work. The ICMJE has developed a Disclosure Form to facilitate and standardize authors' disclosures. ICMJE member journals require that authors use this form, and ICMJE encourages other journals to adopt it.

b. Peer Reviewers

Reviewers should be asked at the time they are asked to critique a manuscript if they have relationships or activities that could complicate their review. Reviewers must disclose to editors any relationships or activities that could bias their opinions of the manuscript, and should recuse themselves from reviewing specific manuscripts if the potential for bias exists. Reviewers must not use knowledge of the work they're reviewing before its publication to further their own interests.

c. Editors and Journal Staff

Editors who make final decisions about manuscripts should recuse themselves from editorial decisions if they have relationships or activities that pose potential conflicts related to articles under consideration. Other editorial staff members who participate in editorial decisions must provide editors with a current description of their relationships and activities (as they might relate to editorial judgments) and recuse themselves from any decisions in which an interest that poses a potential conflict exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should regularly publish their own disclosure statements and those of their journal staff. Guest editors should follow these same procedures.

Journals should take extra precautions and have a stated policy for evaluation of manuscripts submitted by individuals involved in editorial decisions. Further guidance is available from COPE (https://publicationethics.org/files/A_Short_Guide_to_Ethical_Editing.pdf) and WAME (http://wame.org/conflict-of-interest-in-peer-reviewed-medical-journals).

2. Reporting Relationships and Activities

Articles should be published with statements or supporting documents, such as the ICMJE Disclosure Form, declaring:

– Authors' relationships and activities; and

– Sources of support for the work, including sponsor names along with explanations of the role of those sources if any in study design; collection, analysis, and interpretation of data; writing of the report; any restrictions regarding the submission of the report for publication; or a statement declaring that the supporting source had no such involvement or restrictions regarding publication; and

– Whether the authors had access to the study data, with an explanation of the nature and extent of access, including whether access is ongoing.

To support the above statements, editors may request that authors of a study sponsored by a funder with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis."

C. Responsibilities in the Submission and Peer-Review Process

1. Authors

Authors should abide by all principles of authorship and declaration of relationships and activities detailed in section IIA and B of this document.

a. Predatory or Pseudo-Journals

A growing number of entities are advertising themselves as "scholarly medical journals" yet do not function as such. These journals ("predatory"or "pseudo-journals") accept and publish almost all submissions and charge article processing (or publication) fees, often informing authors about this after a paper's acceptance for publication. They often claim to perform peer review but do not and may purposefully use names similar to well established journals. They may state that they are members of ICMJE but are not (see www.icmje.org for current members of the ICMJE) and that they follow the recommendations of organizations such as the ICMJE, COPE and WAME. Researchers must be aware of the existence of such entities and avoid submitting research to them for publication. Authors have a responsibility to evaluate the integrity, history, practices and reputation of the journals to which they submit manuscripts. Guidance from various organizations is available to help identify the characteristics of rep-

日本医学会　COI管理ガイドライン

The Japanese Association of Medical Sciences COI management guideline（2020年）

図５－Ａ　研究成果論文公表時における企業等の関与の詳細な記載法

１．Role of funding sources（資金提供者の役割）

１）何ら関与しなかった場合，「The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.」と記載

２）資金提供者がある場合：
①誰が提供者（funder）か？
②資金提供者が研究データ等の解釈，論文レビューを行ったか？
③関係企業の付属施設等が研究資金提供者か？
④資金管理団体／研究支援財団等を経由した特定企業の資金提供か？

２．Contributors（寄与者）

著者の役割透明化，特に個々の著者がどのような役割を果たし寄与したかを明確に開示
臨床研究の場合
① 研究企画(trial design)，実施計画書(protocol)作成を誰が？
② データ集計(data collection)，管理(management)，解析(analysis)を誰が？
③ データ解釈(interpretation)，論文準備(preparation)，レビュー(review)，
最終承認(approval)を誰が？
留意点：関係企業からの転職研究者が著者の場合は前職の企業名も記載

３．Acknowledgements　（謝辞）

対象：著者資格の４項目すべてに該当しない研究貢献者
１）スポンサー，資金提供者は誰かを記載
２）Authorshipに該当しない研究貢献者，協力者は誰か（名前と所属）を明記
① データ集計(data collection)，保管と管理(management)，
解析(analysis)，データの解釈(interpretation)
② 論文の執筆(writing assistance)，英語訳，レビュー(review)
③一般的な管理業務[general supervision]
④参加研究者[participating investigators]
⑤「被験者の提供 およびケア[provided and cared for study patients]

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Date:_____
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In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: Since the initial planning of the work			
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10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	____None	
11	Stock or stock options	____None	
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13	Other financial or non-financial interests	____None	

Please place an "X" next to the following statement to indicate your agreement:

___ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

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原稿タイトル:_
原稿番号 (既知であれば):_

投稿著者の **conflicts of interests (COI)**にかかる透明性を確保するために、投稿論文の内容に関連し、以下に列記したすべての関わり合い/諸活動/COI について項目ごとに開示を求めます。
「関連する」とは、投稿著者の論文内容によって営利または非営利を目的とした第 3 者組織（企業／団体）が得る利益に影響を与えうる、あらゆる関わり（利害関係）を意味します。
COI 開示は、透明性に対する論文投稿著者の義務責任を表すためにあり、必ずしもバイアスの有無を指し示すための開示ではない。もし、申告者が企業／団体との関わり合い/諸活動/**COI** の項目について開示すべきかどうか迷う状況があれば、申告開示しないよりも開示しておくことがより望ましい。
以下に掲げる質問事項は現在の投稿論文だけを対象として、第三者組織・団体との関わり合い/諸活動/**COI** 状況の申告開示に適用されます。投稿論文著者の第三者組織・団体との関わり合い/活動/**COI** という用語は広い視点から定義されるべきである。例えば、もし投稿しようとした論文内容が高血圧症の疫学に関する研究成果報告であれば、たとえ降圧薬名が論文内に記載されていなかったとしても、降圧薬を製造販売する企業との関わりがあればすべて公表するべきである。
以下の**#1** 項目だけは、投稿論文にかかる研究支援期限を３６ヶ月間と設定せずにすべて申告してください。それ以外の項目については、申告対象期間を論文受理時点から過去 **36** ヶ月間として開示を求めています。

		関わりを持つすべての **entities** 名称の記載、無ければ **None** と記載 **(**必要に応じ行を追加**)**	受け入れ先の詳細/コメント **(**例えば、受け入れが投稿論文著者の誰 **(personal)**か、あるいは所属研究機関 **(institutional)**かどうか**)**
			申告対象期間:研究の初期計画以後
1	論文投稿に至る迄の全てのサポート(例えば、資金提供、研究材料の提供、執筆代行、論文作成経費等) *このアイテムでは申告適用期間を設定しない！*	___None	
			申告対象期間:過去 **36** ヶ月間
2	企業／団体から所属機関への助成金や契約による資金提供 (上記アイテム#1 に適用できない場合)	___None	
3	ロイヤリティまたはライセンス	___None	
4	コンサルティング料	___None	

5	講演、プレゼンテーション、講演者の局、原稿執筆、教育イベントの支払いまたは謝金	___None	
6	専門家助言への支払い	___None	
7	会議や旅行への参加費支援	___None	
8	特許計画、発行、または出願中	___None	
9	データ安全監視委員会 または 諮問委員会への参加	___None	
10	他の理事会、学会、委員会または擁護団体におけるリーダーシップまたは受託者の役割、有給または無給かの明記	___None	
11	ストックまたはストックオプション	___None	
12	機器、材料、薬剤、医学論文執筆、贈答品または他のサービスの受け入れ	___None	
13	その他の経済的または非経済的利益 の受け入れ	___None	

以下の声明の横に、同意を示すために“X”を入れてください。

__私はこの申告書のすべての質問に答え、どの質問の文言も変えていないことを証明します

【用語の定義】

Entity（組織／団体）：行政機関、財団、企業スポンサー、学術研究機関等
Grand（研究奨励金（助成金））：一般的に（必ずしもすべてでないが）、entity から著者の所属機関に支払われる
Personal Fees（特定個人への支払金）:謝金、ロイヤルティ、顧問、講演、speakers bureau、専門的証言、雇用、他の 所属先
Non-financial Support：例えば、特定 entity から提供される医薬品／医療機器、旅費、執筆補助、管理面での支援等
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（日本医学会利益相反委員会訳 2021 年）