

The Guidelines Concerning Conflict of Interest of the Japanese Society of Balneology, Climatology and Physical Medicine

I. Introduction

The Japanese Society of Balneology, Climatology and Physical Medicine (hereinafter abbreviated to “this Society”) is a scientific body aimed at undertaking researches regarding diagnoses, treatments, and preventions in the field of medical balneo-climatology and physical medicine and making the results available to the public. It is also proactively pursuing contribution to society including enlightenment to the general citizens and collaborations with industries and universities.

With consideration for existing circumstances where medical researchers are making progress while increasingly deepening relationships with society, the Japanese Association of Medical Sciences to which this Society belongs issued “COI Management Guideline (Revised March 2022) : jams.med.or.jp/guidelines/coi_guidelines_2022.pdf” in order to promote medical researches of the affiliated societies properly from the aspect of Conflict of Interest (COI) and requested each society to develop its activities in accordance with the guidelines.

In response, this Society decided to prescribe “The Guidelines Concerning Conflict of Interest” (hereinafter referred to as “these Rules”) in conformity with the “The Guidelines Concerning Conflict of Interest” of the Japanese Association of Medical Sciences and to promote further academic activities in this Society in an appropriate manner.

II. Those subjects to COI Management Guidelines

Those subject to COI management are as follows.

1. Authors and co-authors presenting their study results in scientific journals or at scientific meetings
2. Board members of this Society (regents, auditor-secretaries), presidents of scientific meetings or those responsible, all committee chairpersons, committee members of ethical and COI committees, committee members of temporary groups (investigation committees, working groups, etc.), officers of the Balneotherapy medicine society (president, vice president, district secretaries), employees the Society, and other people deemed necessary by the president.
3. Spouses, immediate family or those who share income or property with those listed above if they have an indirect effect or a non-financial effect on the implementation or the understanding of medical research.

III. Items that should be avoided in medical research

The following items should be avoided by those specified in II. of these Guidelines from the point of view of COI policy.

1. In case of implementing relevant medical research
 - (1) Receiving financial incentives for implementation of research
 - (2) Receiving remuneration for a specific study result
 - (3) Conclusion of a contract which allows financial supporters or commercial organizations to exert influence over the presentation of the results in scientific journals or at scientific meetings
2. Those responsible for the planning and carrying out of medical study must have the appropriate financial relationship with financial sponsors and commercial organizations and pay special attention to avoid the following items.
 - (1) Having stocks or responsibilities as an executive member of a financial sponsor or

- commercial organization involved with clinical study
- (2) Having obtained any right to patent or patent fees regarding clinical study
 - (3) Receiving payment for travel or accommodation from a financial sponsor or commercial organization in order to take part in medical meetings unrelated to the research
 - (4) Receiving financial remuneration that considerably exceeds the actual costs required by the research
 - (5) Receiving extra money or gifts other than adequate compensation for the time or labor expended on the research

IV. Items that must be disclosed

Those specified in II. of these Guidelines shall make a declaration of the precise circumstances to this Society's Chairman of the Board of Directors in accordance with V. of this Guidelines if any situation listed below has arisen in the past three years regarding the clinical study subject to this Guidelines.

1. Having responsibility as an executive member or an advisor at a corporate or commercial organization (hereinafter referred to as "for-profit organization")
2. Receiving profit of over one million yen per year from the shares of a for-profit organization holding five percent or more of its total shares
3. Receiving patent income of over one million yen per year from a for-profit organization
4. Receiving per-diem allowances of over five hundred thousand yen per year from a for-profit organization
5. Receiving lecture fees of over five hundred thousand yen per year from a for-profit organization
6. Receiving medical research fees of over five million yen per year from a for-profit organization
7. Receiving donations of over one million yen per year from a for-profit organization
8. Receiving travel expenses or gifts from a for-profit organization, which are equivalent to over fifty thousand yen per year but not directly related to clinical study
9. Taking part in an endowed lecture sponsored by a for-profit organization
10. Receiving human resources for planning study design, or collecting, management or statistical analysis of clinical data of the research.
11. Any other item determined to be subject to COI management by a person involved with the clinical study.

V. Method of self-disclosure

Those subjects to self-disclosure shall follow the prescriptions below and submit a self-disclosure form in accordance with IV. of these Guidelines.

1. Authors and speakers who present their study results in scientific journals or at scientific meetings shall make a declaration of the COI circumstances regarding the implementation of the research for all co-presenters, using the format attached as Reference 1 at the end of this Guidelines. However, presentations from overseas shall be handled by the COI committee separately. Authors and speakers who will present study results in scientific journals or at scientific meetings must disclose their COI status at the end of their presentation paper or in the presentation slides, regardless of whether or not they have the declaration items stipulated in the section. If there are any changes in COI status not only in the past three years from the year prior to the time of submission or presentation of the paper, but also in the time of acceptance of the paper for publication or presentation, it should be submitted including an additional COI self-report.

2. Board members of this Society (regents, auditor-secretaries), presidents of scientific meetings or those responsible, all committee chairpersons, committee members of special committees (scientific organizing committee, editorial board committee, nomination and commendation committee, ethical committee, COI committee etc.), committee members of temporary groups (investigation committees, working groups, etc.) shall make a declaration of the COI circumstances to this Society's Chairman of the Board of Directors on assuming a post, using the format attached as Reference 2A at the end of this Guidelines. Those applicable to the above shall immediately make amendment if a new state of COI arises after taking office.
3. Spouses, immediate family or those who share income or property with those listed above, if they have an indirect effect or a non-financial effect on the implementation or the understanding of the medical research, shall make a declaration of the COI circumstances to this Society's Chairman of the Board of Directors, using the format attached as Reference 2B or Additional Form at the end of this Guidelines.

VI. Structure, duty and term of the COI management committee

COI management committee of this Society shall consist of four members; three of them are the members of this Society who are named by the Chairman of the Board of Directors and approved by the Board, and one external member. Their roles include raising awareness of COI declaration, screening submitted forms, and handling inquiries regarding COI. The terms of each member of the COI committee shall be the same period as of the Board of Directors.

VII. Handling COI self-disclosure forms submitted

COI self-disclosure forms submitted in accordance with V. of this Guidelines shall be screened by the COI management committee and the forms accepted by the committee shall be handled very carefully with a highly secure management in this Society under the supervision of the president from a viewpoint of confidentiality. If there is a request for COI disclosure, the Board of Directors shall judge the validity.

However, the Chairman of the Board of Directors can disclose forms to those approved by the members of COI management committee and the Board of Directors after imposing confidentiality requirement regarding the contents of the forms. The forms submitted by those listed in V.1 . of this Guidelines shall be filed in this Society for three years after the end of one's term and the forms submitted in accordance with V.2 . of this Guidelines shall be filed in this Society for three years after declaration, and then both shall be disposed. However, if the Board of Directors decides that information should not be deleted, the COI management committee shall place a hold on disposing of the form concerned for a certain period of time.

VIII. Handling problems in COI Management Guideline

If a problem regarding COI management or any question arises concerning a member of this Society, the COI committee shall conduct a thorough investigation and hearing. If the committee determines that the Society should take action against the problem, it has to ask for deliberations within the Board of Directors based on the consultation of the ethical committee. The Board of Directors shall have the authority to take measures on the following.

1. Calling for retraction of a presentation concerned if it is before a member of this society present his/her study results in scientific journals or at scientific meetings, as well as prohibiting the lead author from presenting study results in scientific journals or at scientific meetings for up to one year, in addition to suspending activity in this society for up to one year if the lead author is the board member.
2. Publishing an apology letter or statement if a presentation concerned has already been presented in scientific journals or at scientific meetings by a member of this society.

3. Suspending activity in this Society for up to one year if the Board of Directors judges that a problem arises concerning the Board members of this Society (regents, auditor-secretaries), presidents of scientific meetings or those responsible, all committee chairpersons, committee members of special committees (scientific organizing committee, editorial board committee, nomination and recommendation committee, ethical committee, COI committee etc.), committee members of temporary groups (investigation committees, working groups, etc.).

In case any other measure should be taken, the committee shall decide based on the consultation of the Board of Directors.

IX. Statements of Disagreement

A member of this Society against whom measures are taken in accordance with VIII. of this Guidelines may submit a statement of disagreement to this Society if he/she has any objection to the measures. The request for review must be made in writing and it has to be received by this Society within three months after the member has received notification regarding measures that shall be taken. If this Society receives a statement of disagreement based on this paragraph, the president must promptly set up a screening committee and conduct examination on this matter. The screening committee shall consist of four members: a member of the Board of Directors nominated by the president, a member of ethical committee (shall be appointed from the editorial committee for the time being), a member of the COI management committee, and one external member.

X. Enforcing awareness and compliance of COI management

If a question arises with regard to interpretation of this Guidelines and handling of specific cases, the COI committee shall cope with each question respectively and enforce raising awareness and compliance of COI management among the members of this Society and people concerned through academic journals and websites. The COI committee shall also disclose information on a regular basis regarding this Society's status of receiving funds and donations from for-profit organizations.

XI. Changes to COI Management Guidelines

This Guidelines shall be reviewed appropriately and revised in order to accord with changes in conditions surrounding medical research and social factors, and amendments or improvements to the COI Guidelines of the Japanese Association of Medical Sciences to which this Society belongs.

ICMJE DISCLOSURE FORM

Date:

Your Name:

Manuscript Title:

Manuscript Number (if known):

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.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

	Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
Time frame: Since the initial planning of the work								
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 60%; height: 20px;"></td><td style="width: 40%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td style="text-align: right; font-size: small;">Click the tab key to add additional rows.</td></tr> </table>						Click the tab key to add additional rows.
	Click the tab key to add additional rows.							
Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 60%; height: 20px;"></td><td style="width: 40%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>						
3	Royalties or licenses	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 60%; height: 20px;"></td><td style="width: 40%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>						

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> 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.

(Form Reference 2)

COI Disclosure Form for Committee Members

(**20** **01.01~12.31** ; Disclosure period is for the past 3 years for each year from a year prior to the time of office)

Name of Individual Disclosing COI: (Member Number) : _____ (- _____)

Affiliation (Institution, Department, Hospital Department), Title: _____

Official Title in Society:

- President Board member Supervisor Congress President
 Next Congress President Academic Conference President

Name of Designated Committee:

- Committee, Section Head Academic Meeting Steering Committee
 Committee for Lifelong Education Journal Editorial Board Committee
 Committees Related to Clinical Practice Guideline Formulation
 Ethics/Medical Safety Committee COI Committee Working Group Staff Other

A. Items for COI self-disclosure

1. Position as an officer or advisor of a company or for-profit organization, and amount of remuneration

(Applicable · Not Applicable)

(Give amount if remuneration exceeds 1,000,000 yen or more from a single company or for-profit organization)

	Name of company/organization	Title (Officer, Consultant etc.)	Amount
1			
2			
3			

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

2. Stock ownership and profit from stock (profit from stock for the previous year)

(Applicable · Not Applicable)

(Give amount if annual profit from stock from a single company exceeds 1,000,000 yen, or if ownership is 5% or more of total shares.)

	Name of Company	Number of Shares	Share Price (per share)	Amount
1				
2				

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

3. Remuneration received for patent royalties or licensing fees from companies or for-profit organizations.

(Applicable · Not Applicable)

(Give amount if royalties or licensing fees exceeds 1,000,000 yen per year for a single patent.)

	Name of company/organization	Patent Name	Amount
1			
2			

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

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 by the researcher
 (Applicable · Not Applicable)

(Give amount if annual honoraria from a single company or organization exceeds 500,000 yen)

	Name of company/organization	Amount
1		
2		
3		
4		
5		
6		
7		
8		
9		

Amount: ① 500,000 yen or more ② 1,000,000 yen or more ③ 2,000,000 yen or more

5. Manuscript fees received for writing articles for pamphlets, roundtable discussion articles, etc. from a single company or for-profit organization(Applicable Not Applicable)

(Give amount if annual manuscript fees from a single company or organization exceeds 500,000 yen)

	Name of company/organization	Amount
1		
2		

Amount: ① 500,000 yen or more ② 1,000,000 yen or more ③ 2,000,000 yen or more

6. Research funding provided by a company or for-profit organization (Applicable · Not Applicable)

(Give amount if research funding from a single company or organization allocated for medical science research (joint research, commissioned research, clinical trials etc.) exceeds 1,000,000 yen)

	Name of company/organization	Research classification	Amount
1			
2			
3			

Research classification: ① Industrial-academic cooperative research, ② commissioned research, ③ clinical trials, ④ other

Amount: ① 1,000,000 yen or more ② 10,000,000 yen or more ③ 20,000,000 yen or more

7. Scholarship (incentive) donations provided by a company or for-profit organization

(Applicable · Not Applicable)

(Give amount if scholarship (incentive) donations provided by a single company or organization to the affiliated department or division allocated for use exceeds 1,000,000 yen)

	Name of company/organization	Amount
1		
2		
3		
4		
5		
6		
7		

8		
9		
10		

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

8. Endowed departments established through donations by a company (Applicable • Not Applicable)

(Give amount if affiliation is with an endowed department)

	Name of company/organization	Name of Endowed Department	Installation Period
1			
2			

*Give amount if funding allocated for research is 1,000,000 yen or more.

9. Other remuneration (not directly related to research such as gifts etc.) (Applicable • Not Applicable)

(Give amount if annual remuneration received from a single company or organization exceeds 50,000 yen)

	Name of company/organization	Details of Remuneration	Amount
1			
2			
3			

Amount: ① 50,000 yen or more ② 200,000 yen or more

B. COI disclosure for spouse, first degree relatives or any persons who share income or property assets with the declarant.

Please check the box applicable.

No items to disclose: There is no need to fill out the rest of this form

Items to disclose: Please check the following items. If not applicable, check 'Not Applicable'.

1. Position as an officer or advisor of a company or for-profit organization, and amount of remuneration

(Applicable • Not Applicable)

(Give amount if remuneration exceeds 1,000,000 yen from a single company or organization)

	Name of Corresponding Person		Relationship with Declarator	
	Name of company/organization		Title (Officer, Consultant, etc.)	Amount
1				
2				
3				

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

2. Stock ownership and profit from stock (profit from stock for the previous year)

(Applicable • Not Applicable)

(Give amount if annual profit from stock from a single company exceeds 1,000,000 yen, or if ownership is 5% or more of total shares.)

	Name of Corresponding Person		Relationship with Declarator	
	Name of Company	Number of Shares	Declared share price (per share)	Amount
1				
2				

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

3. Remuneration received for patent royalties or licensing fees from companies or for-profit organizations.

(Applicable • Not Applicable)

(Give amount if annual royalties or licensing fees exceeds 1,000,000 yen for a single patent.)

	Name of Corresponding Person		Relationship with Declarator	
	Name of company/organization		Patent Name	Amount
1				
2				

Amount: ① 1,000,000 yen or more ② 5,000,000 yen or more ③ 10,000,000 yen or more

Pledge: I hereby declare that there is no discrepancy in my conflict of interest status described above. I have no other COI that may impede my work for the ©© Society other than those I have stated. I agree that the contents of this disclosure form may be made public if subject to social or legal requests.

Date: //(month /date /year)

Signature:

Receipt Number:

(This form will be archived for 3 years after expiration or retraction from office)

Use this form if you require more space to disclose items. (Additional Form)

Name of Individual Disclosing COI: _____

< Items to Declare >

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 single company or for-profit organization
5. Manuscript fees received for writing articles for pamphlets, roundtable discussion articles, etc. from a single company or for-profit organization
6. Research funding (joint research, commissioned research, clinical trials etc.) provided by a single company or for-profit organization
7. Scholarship (incentive) donations provided by a single company or for-profit organization
8. Endowed departments established through donations by a company
9. Other remuneration (travel expenses, gifts etc. not directly related to research)

Name (A • B)	Disclosure Number	Name of company/organization	Applicable (Title, Patent name, Type of research etc.) *If #2, give the total number of shares and share price	Amount (refer to each item)

*Please make copies if more space is require