

ESC Declaration and Management of Conflict of Interest Policy

The European Society of Cardiology (ESC) is dedicated to reducing the burden of cardiovascular disease and improving the standards of care offered to patients with cardiovascular disease. To accomplish this mission, the ESC provides support for a variety of activities in the areas of research, education, training, and advocacy. The integrity of the ESC and the activities it undertakes depend on the avoidance of conflicts of interest, or even the perception of conflicts, by the individuals involved in these activities. Such conflicts may arise directly from the declaring person but may also arise from partners or other members of a household. With this policy, the ESC continues to provide leadership for robust and unbiased science, as attested by the paper published by its Board in the European Heart Journal of March 2012, on the “[Relations between professional medical Associations and the Health Care Industry, concerning scientific communication and continuing medical education](#)” (1). As a member of the Biomed Alliance, the ESC led the task force that prepared and published the [Biomed Alliance Code of Conduct](#), that was formally adopted by the ESC in December 2015 (2). More recently, in February 2018 the ESC issued a policy statement entitled “[The future of continuing medical education: the roles of medical professional societies and the health care industry](#)” that focuses on the need for continuing medical education in cardiovascular medicine in Europe, interaction between the medical profession and medical industry, and proposes measures to safeguard the provision of high quality, balanced medical education (3).

This “Declaration and Management of Conflict of Interest” policy is well in line with the existing paper: “Governing Policy for the writing of Clinical Practice Guidelines”. These 2 documents together with the Biomed Alliance Code of Conduct, mentioned above, represent the trilogy of policies which inspire and regulate the ESC objective of providing unbiased Clinical Practice Guidelines, and/or in general scientific and educational programmes, daily practice and advocacy, with the highest ethical standards.

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Summary of Contents

[Chapter I. Principles:](#) that underline the commitment to managing real or perceived conflicts of interest.

[Chapter II. Policies:](#) that lay out how the ESC safeguards the integrity of the programs and activities in which its membership is engaged.

[Chapter III. Declaration of Interest Form, Rules for review and Thresholds:](#) that describe the ESC DOI form and define rules for review of various categories of conflicts of interest, using financial yardsticks.

Chapter IV. Processes: that formalize the various steps to deal with the administration, management, and enforcement of this policy.

Principles

Principle 1: The integrity of the ESC and its scientific, educational, and advocacy activities depend on the avoidance of bias arising from conflicts of interest, or from the perception of such conflicts, by the individuals involved in these activities. Personal financial considerations must never be allowed to influence physicians' and scientists' decisions on care of patients, evaluation and development of drugs or devices, or proper conduct of biomedical research. This includes continuing postgraduate medical education (CME) activities provided to physicians by the ESC and the development of clinical practice guidelines which must be free of bias, or perceived bias, evolving from financial arrangements or considerations.

Principle 2: A direct conflict of interest exists when an individual has material interests that could influence or could be perceived as influencing his/her decisions, actions or presentations in an inappropriate manner. These interests include employment, consultancy, equity, research funding, honoraria, patents and royalties, speakers' bureau involvement, advisory committee or board of directors' membership, expert testimony and financial support from a commercial entity. Conflicts of commercial interest may involve either an agent or device concerning the subject in question or an agent or device that might be in competition with the subject in question. In addition, indirect conflicts of interest may arise from institutional interests (e.g., research grants) or from interests of partners or other members in a household which may include, among others, employment in a health-care related industry or holding major shares in such companies.

The ESC recognizes that there are varying degrees of conflict. All potential conflicts must be disclosed so that the audience or a relevant committee can evaluate the relevance of the conflict to the relevant ESC activity.

Principle 3: The ESC desires a professional environment in which its officers and contributors are comfortable asking questions relating to conflict of interest and where excluding oneself from participation in discussions that might be perceived as constituting a conflict is the norm rather than the exception.

Principle 4: A member of the ESC with a conflict of interest for one specific ESC activity or task is not necessarily precluded from participation in all other ESC activities. In fact, such external relationships may enhance the value of that member to the Society. The ESC does not wish to imply that *any* involvement with a commercial entity prohibits a role within the

ESC, but rather that the review of such relationships is appropriate and correct thereby encouraging transparency and ethical integrity.

Principle 5: The ESC subscribes to the view that research and development sponsored by the biomedical industry play an important role in biomedical research and development of better health care and that academic-industrial relationships have developed useful and life-saving products.

Principle 6: The mission of ESC does not include marketing of pharmaceutical or biomedical products. While the ESC offers opportunities for renting of space for commercial exhibitions at the ESC annual meeting and various sub-specialty meetings and while the Society's publications sell advertising pages, the revenues generated are devoted to the support of the Society's mission.

Principle 7: The ESC policies are congruent with the general positions of European standards of accreditation of CME activities which include: (a) support from a commercial entity for CME must be acknowledged, (b) no employees or consultants in the supporting company can be involved in the development of the CME activities and (c) attendees should be encouraged to report on their perceptions of any possible bias.

Principle 8: The considerations of conflict of interest are relevant not only to clinical research but may extend to all phases of biomedical research, including pre-clinical research.

Policies

The requirements of the ESC to declare conflicts of interest apply to all:

1. Volunteers, officers or scientific contributors of the ESC;
2. Directors of the ESC;
3. Presenters at any ESC meeting or to authors of material submitted for any ESC publication.

Policy 1: Some individuals serve as expert witnesses, officers, directors or members of scientific advisory boards of companies, participate in company-sponsored speakers' bureaus, or accept subsidies from a commercial entity for the costs of travel and/or hospitality to an ESC activity. All of these activities must be declared and will be reviewed to identify potential conflicts of interest in a particular ESC activity.

Policy 2: The ESC holds its volunteers serving in governance positions (the ESC Management Group, ESC Board Members, ESC Association Presidents and Boards, ESC

Council Chairmen and Board members and ESC Working Group Chairmen and Nucleus members) to certain standards with regard to conflict of interest.

Specifically, when an ESC volunteer has been identified as having a conflict of interest in a particular activity, he/she will not:

1. Take any action on behalf of ESC concerning the subject in conflict or any issue relevant to the subject in conflict;
2. Participate in discussions on the subject without full disclosure;
3. Participate in decision-making discussions or cast a vote;
4. Imply that he/she is acting on behalf of ESC when discussing the relevant subject with third parties;
5. Fail to clarify with third parties with whom he/she deals on the relevant subject that he/she is not acting on behalf of ESC; or
6. Share confidential information, including disclosure of embargoed data which would break laws relating to insider trading.

The ESC strongly recommends that its Officers (i.e. President, President-Elect, immediate Past-President, Vice Presidents, Secretary/Treasurer, Editor in Chief) refrain from simultaneously serving the Society and holding an officer position with another international medical organization, without prior approval from the ESC. The ESC also strongly discourages the Officers from simultaneous service in any position on the board of organizations with significant overlap with the ESC without prior approval from the ESC. As of August 2022, newly appointed ESC Journal Editors in Chief cannot simultaneously serve as Editors in Chief of another publication.

Policy 3: The ESC has the right to take action regarding ESC members and contributors to ESC activities who have exhibited biased behaviour or action. These actions may include:

1. Requiring an individual to choose between the competing activities.
2. Prohibiting an individual from playing a decision-making role in the ESC relevant to the conflict.
3. Prohibiting an individual from presenting at ESC events.
4. Exclusion from publishing in ESC publications.
5. Exclusion from participating in ESC committees.
6. Revocation of membership in the ESC.

7. Revocation of the ESC title of Fellow of the ESC

Policy 4: No donor, commercial or otherwise, can select speakers or awardees or be involved in the production of ESC educational and/or scientific content, with the exception of satellite or industry organised symposia or session clearly denoted as such.

Policy 5: Commercial support for post-graduate education (or post-graduate CME) must be acknowledged and no employees or consultants of the interested company can be involved in the development of the content of CME of the ESC. Meeting attendees are provided with a formal opportunity to report on their perceptions of any possible bias in their review of the sessions for CME credit.

Policy 6: Special precautions are taken to safeguard against an undue influence with regard to the ESC Research and Training Grants which are targeted at helping trainees.

Policy 7: The ESC sponsors the development of evidence-based clinical practice guidelines. Special policies intended to prevent bias from conflicts of interest apply to participants in the ESC guideline development. These policies are described in the published document “Relations between professional medical associations and the health-care industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology,” published in European Heart Journal (2012) 33, 666–674.(1)

Declaration of Interest Form, Rules for review and Thresholds

1. The Declaration of Interest (DOI) Form (see Annex 1)

This Form includes two main Chapters, i.e.

a. Financial Declaration that requires the disclosure of:

- Direct personal payments, received from industry-related activities,
- Payments received by an Institution or any other body like Associations for services rendered by the volunteer personally
- Travel and meeting support from the Healthcare Industry
- Receipt of royalties
- Research funding

b. Other Position of Influence, that requires the disclosure of:

- Direct ownership of shares in Healthcare, Media, Education Companies, etc.
- Employment in the Healthcare Industry,
- Appointment to a political or government position, or similar
- Any other interest that should be declared in view of holding an ESC position

2. The DOI review (see Annex 2 and 3)

The review of a volunteer's DOI is triggered in the following cases:

- a. when a volunteer is appointed to a key executive leadership position (Board, Chairs of Audit and Ethics Committees),
- b. when a volunteer is involved in expert writing committees or scientific task forces,
- c. when chosen during the annual random spot-check.

To manage eventual conflicts of interest, the ESC is adopting a system of checks and balances that, for example, give relevance to topics and categories of conflicts. In this way, when confronted with potentially conflictual situations, the unbiased behavior is protected and enhanced.

The in-depth review could eventually establish the existence of conflict(s) of interest. If so, this could result in a proposal of exclusion which necessitates the validation of the Senior Compliance Council.

1. The Thresholds

The ESC realizes that even small amounts received, e.g., from the Health Care Industry may cause bias and, thus, may constitute a conflict of interest. It is for practical reasons that each Declaration of Interest being reviewed will need to fit one of the following categories:

- a. **No Interest:** Zero financial income from industry-related activities
- b. **Modest Interest:** The total financial income per annum from industry-related activities is less than Euro 10,000.
- c. **Substantial Interest:** The total financial income per annum from industry-related activities exceeds Euro 10,000.

These two categories (b, c) apply to payments received for activities based on a personal contract between the declaring person and a given company, whether received in person or administered by an institution. Payments received by an institution based on a contract between said institution and a health care-related industry is considered as indirect and will be evaluated independently of these categories on a case-by-case basis.

Process

1. Education/Awareness

The ESC takes its commitment to preserving the scientific integrity of its programmes through transparency and proper management of conflicts of interest seriously. Over the past several years, the Society has taken a number of steps to educate its leadership and volunteers about the importance of adhering to the ESC Declaration and Management of Conflict of Interest Policy. In an effort to ensure that sensitivity to potential conflicts is intrinsic to the Society's culture, the following measures have been implemented.

- a. The Nominating Committee reviews the declarations of interest of potential candidates for leadership election to determine any conflicts of interest; agreement to resolve such conflicts and comply with all aspects of the ESC Declaration and Management of Conflict of Interest Policy relevant to individuals in governance positions is a prerequisite for inclusion on the election slate.
- b. A meeting to introduce new members is held every second year for incoming Management Group and Board members (officers, standing committee chairs and editors-in-chief) which includes a detailed presentation on the ESC Declaration and Management of Conflict of Interest Policy.
- c. All ESC committee members must be aware of and have discussed the ESC Declaration and Management of Conflict of Interest Policy and processes for managing conflicts. This should occur at the time of their appointment and members should be reminded of this at the beginning of each meeting.
- d. Any meeting speaker is provided with a reminder about the ESC Declaration and Management of Conflict of Interest Policy prior to his/her presentation and will be asked to present a declaration at the beginning of the presentation.

2. Design of Meeting Programme

The ESC fully complies with the guidelines regarding educational programme design

and evaluation, ensuring that the programme design, implementation, and evaluation processes are free from commercial influence.

- a. Each individual in a position to determine the content of an educational activity must disclose all relevant relationships of a direct or indirect financial nature.
- b. The terms, conditions and purposes of any commercial support of the CME programme are documented in a written letter of agreement between ESC and the commercial supporter. The agreement states that the ESC, not the commercial supporter, makes all decisions regarding the educational content of the programme, selection of speakers, and disbursement of commercial support.
- c. Under no circumstances may honoraria be paid directly to speakers/faculty by commercial supporters for these ESC educational events.
- d. Acknowledgment of corporate support is provided on the ESC website, in the printed meeting materials, and on signage on-site.
- e. Product promotion and product-specific advertisement of any type are prohibited in or during CME activities.

3. Clinical Practice Guidelines

The document: “Governing Policies and Procedures for the Writing of Clinical Practice Guidelines” that describes all the activities associated with selecting the topics, writing and reviewing, updating, maintaining and approving the ESC’s Guidelines.

4. Administration

To facilitate the collection of information about potential conflicts, the ESC utilizes an online system, the DOI platform, in which participants in ESC committees, Guidelines Task Forces, publications and programmes enter or update information about their relevant disclosures in a central database.

- a. To deal with the review and evaluation process, the ESC has established an Office of Compliance that is responsible for assuring the appropriate handling of DOI, via the online system.
- b. To resolve complex and unclear situations, the ESC has set up a Senior Compliance Council that is responsible for reviewing and making decisions in such situations. It is made up of 4 members, the ESC CEO plus the

respective Chairmen of the Audit, Ethics & Oversight, and Practice Guidelines (CPG) Committees.

5. Disclosure of Declarations of Interest

- a. For publications and CME activities, relevant disclosure information is provided to the audience in conjunction with each activity.
- b. For all ESC CME meetings (including the ESC congresses), speaker disclosure information is provided at the beginning of the presentation. For poster presentations, disclosure is provided on the poster itself during the presentation at a congress.
- c. In ESC publications, author disclosures are provided in a prominent location, as are Editor in Chief disclosures on www.escardio.org.
- d. For committee meetings and study sections, it is critical for participants to be aware of conflicts, so decisions can be made without bias. When a subject comes up that presents a potential conflict, the member must state the conflict and refrain from participating in decision-making or voting on that particular issue by leaving the room.

6. Enforcement

A number of action points are put in place to ensure compliance with the ESC Declaration and Management of Conflict of Interest Policy and address any violations.

- a. Staff members ensure there is a disclosure slide for each presentation made at an ESC congress.
- b. Session chairs are provided with disclosure information for each of the speakers in their sessions.
- c. The centralized disclosure system allows staff to track and follow-up with any individual who neglects to disclose; no one is allowed to participate in an ESC meeting until this is addressed.
- d. If an ESC volunteer does not comply with the ESC Declaration and Management of Conflict of Interest Policy or does not complete their declaration of interest form annually, they will be suspended from their duties and cannot contribute to any ESC activity. Such a decision is made by the ESC Management Group of the ESC Board and confirmed by the ESC Board, upon the proposal of the Senior Compliance Council. If an ESC

volunteer who is suspended for non-submission of their DOI form subsequently correctly and comprehensively submits the form within a reasonable period from the date of suspension, the ESC secretary/treasurer can approve the lifting of the volunteer's suspension.

- e. Any person concerned about discrepancies between any published information on interests and other known facts may confidentially contact the chairmen of either the Audit or the Ethics and Oversight Committees directly. Confidentiality is guaranteed.
- f. In the event that the ESC identifies “speaker bias” or “failure to disclose”, a report is presented to the Senior Compliance Council, which determines consequent action on a case-by-case basis. Such action may range from a written warning to the speaker about adherence to the ESC Declaration and Management of Conflict of Interest Policy to prohibition from participation in future ESC events.

7. Oversight

An annual **report** on the overall data of DOIs submitted and the process followed will be published annually / be presented to the General Assembly of the ESC at its annual meeting.

To help ensure that the policy is followed, the Audit Committee, by virtue of the ESC Statutes, will oversee the ESC's compliance with this policy. The Audit Committee will review the annual report submitted by the Office of Compliance on the key happenings related to this policy.

ANNEXES:

[Annex 1 - Declaration of Interest Form](#)

[Annex 2 - Rules for the review of DOI](#)

[Annex 3 - Rules for assessment of conflicts](#)

Questions

Questions and comments regarding the ESC conflict of interest principles and policies can be directed to

- a. the Chairman of the ESC Audit Committee at escboard@escardio.org or
- b. the ESC through the “[contact us](#)” form on the ESC website.

References

1. [Relations between professional medical associations and the health-care industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology](#). European Heart Journal (2012) 33, 666–674.
2. [Biomed Alliance Code of Conduct](#)
3. [The future of continuing medical education](#): the roles of medical professional societies and the health care industry. Position paper prepared with contributions from the European Society of Cardiology Committees for Advocacy, Education and Industry Relations, Endorsed by the Board of the European Society of Cardiology.

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- ESC DOI Policy - 6 October 2022
- Annex 1 - 12 February 2024
- Annex 2 - 6 October 2022
- Annex 3 - 23 February 2023