

## **ESC BYLAWS – ANNEX III: ESC Declaration and Management of Conflict of Interest Policy**

[ESC DOI Policy]

### **1 Introduction**

The European Society of Cardiology (ESC) is a non-profit organisation committed to reducing the burden of cardiovascular disease and improving patient care worldwide. It supports ethical and innovative research, education, training, and advocacy in cardiovascular medicine, while integrating patients as active stakeholders in its initiatives. The ESC's integrity relies on avoiding conflicts of interest, and even the perception of bias, and it promotes open and transparent discussion on these matters to maintain trust in its activities. Personal interests must never influence decisions related to patient care, biomedical research, or the evaluation of drugs, devices, or diagnostic modalities.

Since the early 2010s, the ESC has developed an ethical framework through key initiatives, including a 2012 paper on industry relations (1), the 2015 adoption of the Biomed Alliance Code of Conduct (2), and a 2018 statement on continuing medical education (3). These efforts ensure that ESC Clinical Practice Guidelines (CPG) and delivered postgraduate medical education are of the highest quality, ethical, and unbiased. In line with those principles, the ESC follows the general rules and ethical standards of the European Accreditation Council for Continuing Medical Education (EACCME), operated by the Union of European Medical Specialists (UEMS), for all its UEMS-EACCME-accredited educational activities, along with best practice in the ethics of scholarly publishing as defined by the Committee on Publication Ethics (COPE). The ESC DOI Policy serves as an annex to the ESC Bylaws (4) which also contain the ESC Ethical Conduct Policy.

The ESC recognises that biomedical industry sponsorship according to established standards is important to advancing research and healthcare. Academic-industrial partnerships have contributed to life-saving innovations, and collaborations with external stakeholders can enrich ESC activities. At the member level, the ESC emphasises transparency and requires full disclosure of relationships with the healthcare industry. It recognises that volunteers with a conflict of interest in one area are not necessarily barred from participating in all other activities, provided appropriate safeguards are in place.

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 other session formats, clearly denoted as industry-sponsored, at ESC meetings.

Likewise, no donor, commercial or otherwise, can sponsor or be involved in the development of CPGs and Scientific Documents, which are solely financed by the ESC. A rigorous process, built on a framework of checks and balances to ensure unbiased content, underpins the development of CPGs (5) and Scientific Documents (6).

### **2 Key definitions**

**Competing activity:** Any initiative or activity organised by an entity with which the ESC has no formal partnership or collaborative agreement, that overlaps with the ESC's main activities, including, but not limited to, Clinical Practice Guidelines, congresses, educational programmes, scholarly publishing, and membership engagement.

**Competing position:** Holding leadership positions in an entity with which the ESC has no formal partnership or collaborative agreement, that organises activities considered as competing (see competing activity definition).

**Conflict of interest:** A conflict of interest arises when an individual's—or their partner's—financial, professional, or personal interests could influence, or be reasonably perceived as influencing, their decisions, actions, or presentations in a way that compromises objectivity. This risk applies across every stage of biomedical research, from pre-clinical investigations to clinical applications. *Appendix 3*

addresses how interests shall be assessed to determine the presence of conflicts of interest in the context of specific ESC activities and positions.

**Employment in healthcare industry:** A contract of full or part time employment in healthcare industry as defined in this policy, therefore does not include the main employment in a hospital or university nor ad-hoc contract-based work (e.g., participation in advisory boards, giving presentations), which is to be reported as direct or indirect payment from healthcare industry instead.

**Financial interest:** A direct or material indirect ownership of debt or equity securities or participation in mutual funds or other rights of participation, including shares, puts, calls, options, warrants, bonds, short sales, seed capital and any derivatives related to such interests. A financial interest ‘beneficially owned’ is one where an individual or entity has the right, in a company or sector, to some or all of the benefits of ownership. These include rights to direct the voting, detailed investment decisions within a mutual fund, or to receive the benefits of ownership. In the context of this policy financial interests are only relevant when they relate to companies operating in the healthcare, media, education companies or in companies related to (suppliers), or in competition with the ESC and its mission.

**Healthcare industry:** Any legally incorporated, revenue-driven entity engaged in direct commercial/profit activities within the healthcare sector. Examples: Pharmaceutical companies, medical device manufacturers, imaging companies, biotechnology firms, diagnostic service providers (e.g. core laboratories), digital health companies, profit medical education organisations, and profit contract research organisations (CROs).

In the context of this policy, healthcare industry excludes health service delivery such as private and public hospitals, universities, institutions, and charities focusing on direct patient care and clinical decision-making—and, by extension, professionals employed in these settings: physicians (general practitioners and specialists), nurses and allied professionals (including paramedics, hospital pharmacists, rehabilitation/clinical social workers/mental health counsellors), physician assistants, emergency medical technicians (EMTs) & healthcare administrators (within healthcare institutions).

**Interest:** Any relationship or engagement—financial or not, direct or indirect—that has the potential to affect the impartiality of an individual’s professional activities or be perceived to do so. This requires disclosure of relationships such as employment, consultancy, equity holdings, research funding, honoraria, patents, royalties, speakers’ bureau involvement, advisory or board memberships, proctoring, expert testimony, or commercial financial support, personal, professional, or academic considerations that could reasonably be seen to influence judgment. Additionally, it includes indirect interests like institutional affiliations (e.g., funding through grants from healthcare industry) and interests held by spouse/partners.

**Profit Contract Research Organisation (CRO):** Part of the healthcare industry definition if it is a for-profit, independent entity that is hired by healthcare industry sponsors—typically pharmaceutical, biotechnology, diagnostic or medical device companies—to manage and conduct clinical studies. This includes activities such as designing study protocols, recruiting participants, managing clinical trials, overseeing data collection, ensuring regulatory compliance, and performing statistical analysis. Profit CROs are essentially service providers that allow healthcare industry sponsors to outsource parts of the research process, thereby leveraging specialised expertise.

This definition excludes non-profit CROs, e.g. CRO services provided by academic centres, hospitals and government-funded research institutions.

**Spouse/partner:** A domestic partner or a person who cohabitates and/or shares a stable relationship, generally equivalent to that of a spouse/partner. This is not limited to relationships where there is a formal agreement or registered partnership.

### **3 Methods of disclosure**

Depending on the specific activity or position, various methods of declaration may be used. Individuals designated for disclosures, as stipulated in Section 4.1, shall be informed of the applicable method and reminded of the ESC DOI Policy. In addition to dedicated processes for congresses, educational presentations or journal submissions (e.g., using the International Committee of Medical journal Editors [ICMJE] form), the ESC utilises a standard electronic declaration of interests (DOI) form.

DOI forms are administered through a dedicated online platform accessible via the ESC Website. The current DOI form is provided in *Appendix 1*. It includes a comprehensive set of questions including direct and indirect ties with the healthcare industry for both individuals and their spouse/partner. All data submitted must refer to the calendar year immediately preceding the current year. Declarations are requested annually, for as long as the individual holds a position or participates in ESC activities requiring disclosures, with each request pertaining solely to the preceding year. All relevant affiliations and interactions must be fully disclosed to enable a transparent and thorough assessment of potential or perceived conflicts of interest.

## **4 Responsibilities**

### **4.1 Declaration**

Interests must be disclosed by individuals in a position of influence, including but not limited to:

- Board members, Board Committee members, and Board Task Force members of the ESC and ESC Subspecialty Communities
- Statutory Committee members
- Editors in Chief of any Journal within the ESC Journal Family
- Webinar and Congress faculty (presenters, chairs, panellists/discussants)
- Individuals in a position to determine the content of an educational activity
- Authors and reviewers of ESC CPG and ESC Scientific Documents
- Contributors to UEMS-EACCME-accredited activities
- Staff in an Officer or Director position

### **4.2 Review**

Certain positions or activities necessitate a comprehensive review of digital disclosures to ensure compliance with the ESC DOI policy as a prerequisite for inclusion. *Appendix 2* sets out the applicable review framework while *Appendix 3* identifies interests that are incompatible with specific positions or functions. Declarations are reviewed annually, for as long as the individual holds a position or participates in ESC activities requiring disclosures.

### **4.3 Oversight**

#### **4.3.1 Annual reporting**

An annual report detailing data submitted and the processes undertaken during the year shall be compiled and published annually by the ESC and presented to the General Assembly at its annual meeting.

#### **4.3.2 Policy oversight**

The ESC DOI Committee maintains oversight of the ESC DOI Policy implementation and its developments.

To ensure adherence to this policy, the Audit Committee, as mandated by the ESC's statutes, monitors overall compliance and reviews the annual report.

#### **4.3.3 Resolution of complex or ambiguous cases**

The ESC has established a Senior Compliance Council empowered to assess and resolve complex or ambiguous DOI cases concerning positions in guidelines, scientific documents and journals. The Senior Compliance Council consists of the following four members: ESC CEO, Audit Committee Chairperson, Ethics Committee Chairperson, and CPG Committee Chairperson. DOI cases concerning governance positions are assessed by the Presidential Trio and the CEO (ESC Bylaws article 4).

#### **4.3.4 Reporting concerns and ensuring impartiality**

Any individual who identifies a discrepancy between publicly disclosed information regarding interests and other known facts is encouraged to report their concerns in confidence to the Chairperson of either the Audit Committee or the Ethics Committee. The confidentiality of all communications will be strictly maintained.

Furthermore, in alignment with UEMS-EACCME regulations, all UEMS-EACCME accredited activities shall incorporate a formal mechanism through which participants may report any perceived bias.

### **4.4 Administration**

Staff ensures there is a disclosure slide for each presentation made at congresses or webinars organised by the ESC and ESC Associations, Working Groups and Councils.

To facilitate the collection of information about potential conflicts, the ESC utilises an online system, the DOI platform, through which individuals, as identified in Section 4.1, enter or update information about their relevant disclosures in a central database.

## **5 Managing conflicts**

### **5.1 DOI assessment**

*Appendix 3* sets out guidance for the assessment of potential conflicts of interest. The applicable criteria vary according to the ESC position held.

In accordance with the mechanisms outlined in *Appendix 2* and *Appendix 3*, any instance of non-compliance with the DOI policy will result in the imposition of sanctions or restrictions by the ESC proportional to the level of conflict, the specific role of the volunteer and the activity involved. If a case is not addressed by the mechanisms outlined in *Appendix 2* and *Appendix 3*, or if the assessment process is inconclusive, the matter shall be reported for evaluation to the entities as described in section 4.3.3, with a subsequent recommendation for the appropriate sanction submitted to the oversight body for the relevant activity.

In case of major or systematic non-compliance, a full suspension from all ESC activities may be triggered. Full suspensions are determined by the Management Group and subsequently confirmed by the Board. If such a suspension arises from the non-submission of a DOI, it may be lifted—subject to the individual submitting a complete and correct DOI and obtaining the approval of the ESC Secretary/Treasurer.

The ESC is aware that any financial remuneration received from the healthcare industry may cause bias, thus, may constitute a conflict of interest. For practical purposes, the following thresholds have been defined:

- No Interest: Zero financial income from industry-related activities
- Modest Interest: The total financial income per annum from industry-related activities is less than Euro 10,000.
- Substantial Interest: The total financial income per annum from industry-related activities is equal or above Euro 10,000.

## **5.2 Restrictions and sanctions**

When identified as having a conflict of interest in a particular activity, an ESC volunteer will not:

- Take any action on behalf of ESC concerning the subject in conflict or any issue relevant to the subject in conflict;
- Participate in discussions on the subject without full disclosure;
- Participate in decision-making discussions or cast a vote;
- Imply that he/she is acting on behalf of ESC when discussing the relevant subject with third parties;
- 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
- Share confidential information, including disclosure of embargoed data which would break laws relating to insider trading.

The ESC has the right to take action regarding ESC members and contributors to ESC activities who have exhibited biased behaviour or action. ESC members might be subject to disciplinary proceedings as provided for in the ESC bylaws. These actions may include but are not limited to:

- Require the individual to choose between competing activities.
- Prohibit the individual from assuming a decision-making role within the ESC related to the conflict.
- Prevent the individual from presenting at ESC events.
- Exclude the individual from publishing in ESC publications.
- Exclude the individual from participating in ESC committees.
- Revoke the individual's membership in the ESC.
- Revoke the ESC title of Fellow of the ESC.

## **6 Transparency**

To uphold transparency, the ESC adopts distinct disclosure practices appropriate to the nature of each specific activity.

- Disclosures of ESC Board members and ESC Association Board members are posted on the ESC Website.
- The Audit Committee Chairperson's DOI is published on the ESC Website.
- Congress session and webinar speakers shall present a declaration slide at the beginning of their presentation.
- Poster presenters shall provide their disclosures on their poster during the presentation.
- For educational programmes including UEMS-EACCME-accredited activities, acknowledgment of healthcare industry support is provided on the ESC website, in the printed meeting materials, and on signage on-site.
- All working or operational meetings (e.g. Board, Committee, Task Force) shall start with a reminder of the terms of the ESC DOI Policy and disclosure of interests.
- A meeting to introduce new members is held every second year for incoming Management Group and Board members (officers, standing committee chairpersons and editors-in-chief) which includes a detailed presentation on the DOI Policy.
- For CPGs and documents published under the auspices of the CPG Committee, a summary of DOIs of all contributing experts is made publicly available at the time of publication and remains accessible as an appendix to the CPGs. This includes the DOIs of individuals involved in both the writing and review processes.
- In ESC publications, author disclosures are provided in a prominent location as per standard journal practice.
- Disclosures of Editors in Chief of Journals within the ESC Journal Family are posted on the ESC Website.

## 7 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.* **ESC Board.** 2012, European Heart Journal, pp. 666–674.
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<https://yjsxzhi.files.cmp.optimizely.com/download/a0c33740c14311f0b8baa65fd3420a34>.
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 Relati.* **ESC Board.** 21, 2019, European Heart Journal, Vol. 40, pp. 1720-1727.
4. **ESC Board.** EUROPEAN SOCIETY OF CARDIOLOGY (ESC) BYLAWS. [www.escardio.org](http://www.escardio.org). [Online]  
<https://yjsxzhi.files.cmp.optimizely.com/download/de0c33e4cc7511f0bdd362aee2a0ddab>.
5. **ESC.** ESC Clinical Practice Guidelines: Policies and Procedures. [www.escardio.org](http://www.escardio.org). [Online]  
<https://yjsxzhi.files.cmp.optimizely.com/download/09fb61f6b59111f0ba78e6553fb45ee4>.
6. **ESC.** ESC Scientific Documents Policy. [www.escardio.org](http://www.escardio.org). [Online]  
<https://yjsxzhi.files.cmp.optimizely.com/download/56e8b316c6fc11f0a21c2e30dc0688ad>.

## 8 Appendices:

- Appendix 1: DOI form
- Appendix 2: Framework for the assessment of DOIs
- Appendix 3: Rules for assessment of DOIs