



**CODE OF ETHICS AND
PROFESSIONAL STANDARDS FOR MEMBERS**

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**HEART RHYTHM SOCIETY
CODE OF ETHICS AND
PROFESSIONAL STANDARDS**

OVERVIEW

The Heart Rhythm Society (HRS) recognizes that its members have ethical obligations to their patients, the profession, and each other, as well as to the community and world at large. In their efforts to fulfill the mission of the Society, members must adhere to ethical standards and comply with applicable laws.

This document, referred to collectively as the “Heart Rhythm Society’s Ethics Policy,” consists of two parts: i) the Code of Ethics sets standards and provides guidance for Members acting on behalf of the Society, and ii) the Code of Professional Standards sets standards and provides guidance to members in their clinical or laboratory practice, or other institutional environment. Adherence to the Society’s Ethics Policy is a condition of HRS membership. To adapt to today’s rapidly changing environment, the Ethics Committee will review this document annually.

CODE OF ETHICS

1 CONDUCT OF MEMBERS ACTING ON BEHALF OF THE SOCIETY

It is the policy of the Heart Rhythm Society to uphold the highest ethical values and to encourage professional and principled behavior by its members. It is the role of the Society to educate all Members acting on behalf of the Society on these issues, actively recognize potential problems, and develop proactive policies for individuals and the organization. All Members acting on behalf of the Society shall receive a copy of the Society’s ethics policy, which they shall be required to read and acknowledge. Conflict of interest disclosure statements shall be filed at the beginning of all Society assignments and updated as circumstances change, and at least annually.

In general, all Members acting on behalf of the Society shall:

- Work to ensure the attainment of the Society’s mission and objectives.
- Act only within the scope of authority as specified in the Bylaws and written policies of the Society.
- Make only commitments they are authorized to make or that the Society can keep without violating established practices and policies.
- Always act in accordance with policies.
- Diligently carry out agreed-upon assignments and tasks.
- Protect the confidentiality of the Society’s information, including intellectual property, business plans, personnel information, member lists, and identity of individual donors.

- Honor the confidentiality of all Board, committee, subcommittee, writing group and/or task force deliberations, privileged discussions and information and not reproduce or communicate any material without the prior consent of the chair of the applicable committee, group, or other body, or until the Society has issued a public statement, posted information on the HRS website, or submitted a comment letter to a federal agency.
- Make statements on organizational positions only if the Society has taken an official position and they are authorized to speak for the organization.
- Exercise care in lobbying and political activities to avoid jeopardizing the Society's tax exempt status or otherwise harming the reputation of the Society.
- Report misconduct to appropriate individuals.

2 ORGANIZATIONAL POLICIES

The Society shall articulate its core values in a written code of conduct, and maintain policies and procedures that protect the organization's reputation and integrity, ensure regulatory and legal compliance, and promote the proper use of authority and decision making. These policies include but are not limited to the following areas:

2.1 Legal/Regulatory

- Compliance with federal and state laws and regulations governing financial reporting, employment and compensation, privacy, and the fiduciary duties of trustees and officers.
- Compliance with obligations and restrictions governing nonprofit organizations, including lobbying, political activities, taxes, solicitations and compensation.
- Protecting the integrity of the Society's name, logo, assets, and reputation for authorized uses and not for personal gain.

2.2 Governance

- Board operating procedures that support Board policy and ensure professional conduct at Board and other leadership meetings.
- Decision-making authority that defines roles, responsibilities, and fiduciary duties.
- Nominations and election processes to ensure qualified candidates.
- Internal audit to identify and address noncompliance with policies and procedures.
- Process to identify violations which assures anonymity and no retaliation against volunteers or staff.

2.3 Finances

- Expenditures/use of resources.
- Purchasing and vendor selection.

- Internal and external controls and audits.
- Compliance with key provisions of the Sarbanes-Oxley Act, specifically:
 - Establishment of an audit committee with the independence and authority to oversee financial reporting and the audit process.
 - Independent and financially literate audit committee members.
 - Written statements from the Chief Executive Officer and Chief Operating Officer certifying the fair presentation of financial information.

2.4 Educational Activities

- Policies safeguarding the integrity of educational materials, both CME (Continuing Medical Education) and non-CME, ensuring they are free of bias in content or selection, offer a balanced view, and promote health care, not a specific proprietary business interest.

2.5 Journal

- Editor-in-Chief responsibilities and financial restrictions.

2.6 Research Grant Awards

- Policies to ensure the design, conduct, and reporting of research grants are unbiased and industry's contributions to research advance science and human health.

2.7 Health Policy

- Development of performance measures.
- Legislative initiatives.
- Reimbursement.
- Health care quality improvement initiatives.
- Safety advisories and recalls.
- Increasing public awareness of arrhythmia-related disorders and therapies.
- Access to safe medical device and medication therapies.

2.8 Scientific and Clinical Documents

- Financial policies; selection of authors; topics and basis for recommendations; review process and approval for publication.
- Guidelines.

2.9 International Meetings

- In order to obtain HRS support or endorsement, international meetings have standards on:
 - Program independence, travel support, disclosure, and endorsement of documents.

3 SPOKESPERSON CONDUCT

The Society shall designate an official spokesperson to give public testimony and/or provide information to the media with regard to specific issues, programs or policy statements. Spokespersons shall have expertise in areas being addressed and, whenever possible, no actual or perceived conflict of interest that could influence their opinions or the integrity of the Society's positions. If a person without conflict of interest cannot be identified, such conflicts of interest must be clearly and fully disclosed as a preamble to any oral or written public statement.

3.1 Media Representatives

When working with the media, members shall clearly state whether they are acting as a spokesperson for the organization. If so, they should be certain they are accurately expressing the position of the Society; and if not, they should clearly state that their opinion is personal or professional, not organizational.

3.2 Public Testimony

The Society shall select members to give public testimony. It is the responsibility of the members acting in this capacity to be familiar with the Society's position on which they are being asked to testify.

Members giving public testimony who have not been designated as official spokespersons by the Society shall clearly state that they are expressing their individual personal or professional opinion. A formal statement may be required by the individual to prevent personal opinion from being construed as the Society's opinion or position. For officers, trustees, or committee chairs, where information about their leadership role in the Society is used to demonstrate their professional qualifications, a formal statement is especially important.

4 DISCLOSURE OF RELATIONSHIPS POLICY

As part of the Society's commitment to transparency and accountability, and to attain the highest standards of excellence, HRS maintains independence, objectivity, and scientific rigor in all of its activities. HRS requires Volunteers, Session Participants, and Authors, all as defined in Section 4.1 below, to disclose and manage relationships between personal, professional, financial, or business interests when engaged in Society activities. Interests include relationships with for-profit companies, nonprofit organizations, and governmental agencies with interests or activities related to those of the Society and apply as well to the immediate family or household members with such relationships. While not all relationships are prohibited or harmful, full disclosure of such relationships is required and mechanisms are in place to identify and resolve potential or perceived conflicts of interest. Any relationship from the previous 12-month period that could influence objectivity related to Society activities needs to be disclosed and should be updated as circumstances change, and at least annually.

The Society shall proactively educate and promote compliance with standards guiding interactions with industry, including but not limited to the following:

- *AMA Gifts to Physicians from Industry.*¹

- ACCME *Standards for Commercial Support*.²
- ACGME *Principles to Guide the Relationship between Graduate Medical Education, Industry, and Other Funding Sources for Programs and Sponsoring Institutions Accredited by the ACGME*.³
- ACCME *National Faculty Education Initiative* - <http://www.nfeinitiative.org/>
- CMS' Open Payments program (i.e. Physician Payments Sunshine Act)

4.1 Affected Individuals

Affected individuals include members of the Society's Board of Trustees, committees, subcommittees, writing groups, task forces, and the journal's Associate Editors and Editor-in-Chief (hereafter referred to as 'Volunteers'); activity and abstract directors, faculty, planners, managers, applicable joint sponsors/educational partners, course directors, reviewers, moderators, speakers, presenters, any others involved in the planning and dissemination of CME and non-CME programs/educational activities (hereafter referred to as 'Session Participants'); and authors of original articles, policy statements, editorials, textbooks and textbook chapters, and guidelines (hereafter referred to as 'Authors').

4.1.1. Volunteers

Volunteers must complete a disclosure form upon initiation of their volunteer role and update this form as circumstances change, and at least annually while serving as a Volunteer. All meetings of HRS's Board, committees, subcommittees, writing groups*, and task forces shall commence with the chair's reading of a disclosure statement reminding members of their obligation to disclose relevant relationships and recuse themselves from voting on any issue with which they have a conflict of interest. In some circumstances, this may require leaving the meeting for the duration of that discussion. Associate Editors must also disclose all relevant relationships and recuse themselves from participation as necessary if conflict of interest issues arise.

The Ethics Committee will review all volunteer disclosures if the total disclosure amount is greater than \$100,000, excluding research and fellowship support.

*See sections 5.9 and 6 for additional requirements for writing groups and others in high-level and influential positions

4.1.2. Session Participants

All Session Participants must complete a disclosure form for each educational activity of the Heart Rhythm Society (e.g., Scientific Sessions, Board Review Course) and shall disclose their relevant relationships to the audience. The relationship may be communicated in written materials, by the participants themselves, by the session chairs during their introduction, or as determined by the Society. Faculty members also are required to disclose off-label or investigational uses of a commercial product to be included, discussed, or referenced during their presentations.

This requirement includes satellite symposia not sponsored or endorsed by the Society and live case demonstrations.

4.1.3. *Authors*

Authors of Society publications shall disclose information when manuscripts are submitted and prior to editorial submissions, as well as when additional information regarding potential conflicts of interest is requested.

See section 6 for additional requirements for writing groups.

4.2 **Types of Support Requiring Disclosure**

Affected individuals shall disclose the source(s) of their relationships from commercial, personal, professional, financial, or business interests, which are defined as entities with a financial interest in heart rhythm management. Interests include relationships with for-profit companies, nonprofit organizations, and governmental agencies with activities related to those of the Society and apply as well to the immediate family or household members of such affected individuals. Sources of support include: a) personal income and investments, and b) programmatic support, as follows:

Personal income/investments

- Consulting fees, honoraria, gifts, in-kind compensation for consulting, lecturing/speaking engagements, advisory board membership, legal testimony or consultation, or other such activities.
- Disclosure of travel, entertainment, food, beverage, and education expenses for industry-sponsored meetings.
- Speakers Bureau.
- Equity interests, including stock options but excluding mutual funds.
- Royalty income derived from patents or publications sponsored by a commercial interest.
- Non-royalty payments or entitlements that are not directly related, such as travel expenses to a meeting for a spouse.
- Service as an officer, director, or in another fiduciary role for a “financially interested company,” whether remunerated or not.
- Sole ownership, partnership, or principal of an enterprise.
- Intellectual Property Rights.

Programmatic Support

- Research grants.
- Fellowship support.
- Funding of a salary or position (full or part time).
- Reimbursement for clinical studies, registries, or post-market databases.

- In-kind support.
- Other programmatic financial support not falling into any other category.

Individuals shall calculate the annual cumulative amount of support received from each commercial source, and disclose the results for each source, as follows:

- None
- \$1-\$10,000;
- \$10,001-\$25,000;
- \$25,001-\$50,000;
- \$50,001-\$100,000;
- Greater than \$100,000.

4.3.1. Additional Volunteer Disclosure Requirements

Volunteers shall also disclose whether and to what extent they are involved in the leadership of another organization, including other medical professional societies. While the Society recognizes that the type of person it wants to serve in leadership positions is likely to be interested in and similarly sought after by other organizations, potential for conflicts in both subject matter and time will be evaluated.

Board members shall additionally disclose any business or family relationships with another member of the Board.

4.3 Transparency

All volunteer and session participant disclosure forms are publicly available on HRS's website. Disclosure information is included in every educational presentation and Society-initiated document.

4.4 Noncompliance

Refusal to adequately disclose may prohibit an individual's participation in all Society activities and may lead to suspension or revocation of membership. Violations may also be reported to an individual's academic institution or organization.

4.5 Collection and Maintenance of Disclosures

Disclosure information is collected and stored in a secure, uniform database and updated as required.

4.6 Auditing of Disclosures

The Ethics Committee will review all Volunteer disclosures if the total disclosure amount is greater than \$100,000, excluding research and fellowship support.

5 CONFLICT OF INTEREST POLICY

All Volunteers, Session Participants, and Authors are required to identify, disclose, and resolve potential and actual conflicts of interests promptly as they may arise in their professional practice and service to the Society. Upon acceptance of his or her position, each shall complete and submit to the Society a disclosure form listing all interests that such person has which do, or potentially could, represent a conflict of interest with the Society, as dictated by the policy below, and update this information as circumstances change. At a minimum, the disclosure form shall be updated annually by each such Volunteer, Session Participant, or Author who continues to participate in activities on behalf of the Society. The Ethics Committee will review all HRS Volunteer disclosures if the total disclosure amount is \geq \$100,000, excluding research and fellowship support.

Individuals can appeal to the Ethics Committee if they have an inadvertent and minimal amount of RWI and wish to be considered RWI-free.

5.1 Conflict of Interest Definition

A conflict of interest may occur if an individual has relationships that could compromise his or her ability to carry out Heart Rhythm Society activities. The Society recognizes that having relationships with industry (RWI) does not necessarily imply a conflict of interest.

5.2 Purpose

The purpose of the conflict of interest policy is to ensure that decisions are made in the best interest of the Society and free from individual bias.

5.3 Oversight

The Ethics Committee is responsible for: a) obtaining and auditing disclosures, and, on an annual basis, reviewing those submitted by the Board and committee chairs and other Volunteers as deemed necessary; b) providing and communicating a process for reporting potential violations; c) evaluating complaints; d) assisting to determine appropriate measures to resolve or mitigate any actual or perceived conflicts of interest; e) levying and enforcing sanctions; and f) providing a mechanism for the appeal of decisions.

While the Ethics Committee has responsibilities for ensuring the overall compliance with the Society's Code of Ethics, committees have a role in the oversight of these procedures, and, as necessary, will forward issues to the Ethics Committee for resolution.

Each volunteer chair and staff liaison shall review his or her members' disclosure statements prior to each meeting for any potential conflicts related to the meeting agenda. In addition:

5.3.1. Education

The Education Committee is responsible for developing, implementing, and overseeing disclosure and conflict of interest processes for all educational activities which are aligned with ACGME and ACCME accreditation requirements.

5.3.2. *Scientific Sessions*

The Program Committee is responsible for developing, implementing, and overseeing disclosure and conflict of interest processes for Scientific Sessions faculty to ensure alignment with ACCME requirements.

5.3.3. *Clinical Documents*

The Scientific and Clinical Documents Committee (SCDC) is responsible for overseeing the collection, review, and publication of disclosed financial relationships with industry for all authors on clinical documents. (See Section 6.4).

5.3.4. *Publications*

The Editor-in-Chief and Managing Editors are responsible for overseeing the collection, review, and publication of disclosed relationships with industry for all authors of journal articles.

The Editor-in-Chief and Managing Editor have primary oversight of the conduct of reviewers and contributors and may refer potential conflicts to the Ethics Committee at their discretion.

5.4 Resolution of Conflicts

The Ethics Committee shall review all circumstances which come to its attention. The Committee shall determine whether there is an actual, potential, or perceived conflict of interest and which actions, policies, or processes can be implemented to resolve, mitigate, or manage the conflict. The Committee has the authority to set and enforce all sanctions. An appeals process is provided via an independent appeals panel, appointed by the Ethics Committee, whose decision on sanctions is final.

If a conflict cannot be adequately resolved, mitigated, or managed, then the Ethics Committee or the Board of Trustees (upon recommendation from the Ethics Committee) may require the person to limit or curtail certain activities, either within the Society or outside of it, in order to eliminate or remedy the conflict.

5.5 Complaints

Any member of the Society, including Volunteers, Session Participants, and staff, may report a potential violation of the Society's disclosure and conflict of interest policies to the Ethics Committee. However, in all allegations of bias, real or perceived, Volunteers are encouraged to first raise their concerns at the committee level.

5.6 Violations

Violations are reported to the Ethics Committee for review and sanctions if appropriate. Violations also may be reported to an individual's academic institution or organization. The Society maintains a process for disqualifying individuals who have a conflict that cannot be adequately resolved by other measures.

5.7 Relationships That Carry the Potential for Conflict of Interest

The Society recognizes that there may be circumstances in which there is benefit to the Society for entering into a relationship with a trustee, committee chair, or other related party, but only

after the relationship and benefit to the related party have been disclosed can the benefits to the Society be evaluated and other options considered.

The disclosed relationships described below carry the potential for conflict of interest depending on the matter under discussion. All of these relationships should be disclosed according to Section 4.

- Industry (e.g., grants, donations, sponsorships, promotions, research funding, consulting, advisory boards).
- Leadership positions in other professional societies could represent either a conflict of interest or a conflict of commitment.
- Institutional obligations.
- Family relationships with businesses, organizations, or individuals with competing or overlapping interests.
- Ownership of business interests or intellectual property that could represent a conflict of interest.
- Investment authority or decision-making responsibility for competing organizations or entities.

5.8 Activities That Carry the Potential for Conflict of Interest

- Prospect of personal or family financial/commercial gain in situations where the Society is involved or has an interest.
- Authority for decisions (e.g., fiscal responsibilities, purchasing decisions, co-ventures, policy statements, guidelines).
- Unfair advantage for self, family, and colleagues, such as non-merit based judgment of performance or skills.
- Accepting gifts from vendors.
- Use of the Society's confidential or proprietary information for personal gain or purposes that are not in the organization's best interests.
- Remunerative relationships (such as publishers, exhibitors, and high-level supporters).
- Ownership of, or control over, intellectual property or products in which the Society has an interest.
- Opportunity for personal gain or activities in conflict with the Society's best interests.
- Offers of research or charitable funding with actual, apparent, or potential restrictions on the use of funds that either benefit the donor inappropriately or are not in the best interest of the Society.

5.9 Special Requirements for High-Level and Influential Volunteer Positions

Certain high-level and influential volunteer positions in the Society, including trustees (particularly Executive Committee members), committee and subcommittee chairs, Reimbursement and Regulatory Affairs Subcommittee members, officers (particularly the President, President-Elect, and other 'presidential track' officers), and the Editor-in-Chief, carry an extraordinary fiduciary obligation to protect the integrity and credibility of the organization. Individuals who serve in such positions are special stewards of the Society's reputation and assets. They are expected to demonstrate the highest standard of professional conduct, both in their service to the Society and their personal and professional activities, which can reflect on the Society's credibility either positively or negatively, and as such their disclosures will be reviewed on an annual basis.

Persons who hold such high level positions must avoid both actual and perceived conflicts that could harm the Society's image or undermine the scientific credibility of its statements, guidelines, public testimony, or general reputation as an ethical organization.

To minimize the potential for bias, all meetings of HRS's Board, committees, subcommittees, and task forces (whether in-person or via conference call) shall commence with the chair's reading of a disclosure statement reminding members of their obligation to disclose relevant relationships and recuse themselves from voting on any issue in which they have a conflict of interest. When votes are cast outside of meetings, such as by email and/or online surveys, members should be reminded of their need to recuse themselves if they have a conflict of interest.

Additional restrictions apply to the following:

Board Members

- Must have disclosure totals less than \$100,000, excluding research and fellowship support. Prospective Board members must agree in writing to divest of amounts totaling more than \$100,000, excluding research and fellowship support, before their term as a Board member begins.

Ethics Committee

- Ethics Committee members' relationships must total less than \$100,000, excluding research and fellowship support.

Reimbursement and Regulatory Affairs (RRA) Subcommittee

- The RRA Subcommittee Chair must have no financial relationships with industry, excluding research and fellowship support.
- The RRA Subcommittee members' relationships must total less than \$100,000, excluding research and fellowship support.

Writing Groups (*see section 6*)

5.9.1 Additionally, Board members are ineligible to serve as Editor-in-Chief of another heart-rhythm-related journal.

5.10 Restrictions on Members in the Presidential Track

The Society's President and President-Elect shall be prohibited from receiving income from commercial entities which have the potential for conflict of interest, during the year(s) in which they hold the position.

All consulting relationships, with remuneration from companies with financial interest in heart rhythm management, are disallowed, except for cases of expert witness testimony that were established prior to assuming the Presidential Track.

Industry funds to support travel, food and beverage are permitted only for meetings pertaining to multi-center clinical trials or other pre-existing research commitments where attendance is deemed critical by the Ethics Committee.

Requests for any other industry-funded travel expenses should be submitted to the Ethics Committee which will determine if it is allowable for industry to pay for food, beverage, and travel costs to the meeting.

5.10.1. Active Income

Sources of active income from financially interested companies are prohibited and include the following:

- Fees for consulting, lecturing, or serving on advisory boards.
- Fees for giving legal testimony or consulting on legal cases
- Honoraria. (*See additional provisions regarding honoraria below.*)
- Gifts.
- Entertainment.
- In-kind compensation for consulting.
- Non-royalty payments or entitlements such as travel, food, and beverage reimbursement to a meeting for a spouse.
- Remunerated service as an officer, director, or other fiduciary role in a financially interested enterprise.
- Compensation for travel, food, and beverage as a consultant to industry advisory boards or other industry-sponsored events, with the exception of meetings pertaining to multi-center clinical trials or other pre-existing research commitments where attendance is deemed critical by the Ethics Committee

The President and President-Elect may not defer active income for the purpose of avoiding this requirement.

Active income cannot be directed to any institution or organization.

5.10.2. Passive Income

Sources of passive income from financially interested enterprises, as determined by the Society, are prohibited and include the following:

- Stock options and equity interests, including stock in a financially interested enterprise, but excluding mutual funds that may hold such stock in its portfolio.
- Sole ownership, partnership, or principal of a financially interested enterprise.

5.10.3. Industry Boards

The President and President-Elect shall not serve on business-related industry Boards, regardless of compensation, including: Boards of Directors, Governance Committees, Finance Committees, or Medical Advisory Boards.

5.10.4. Programmatic and Other Support

The Society recognizes that other forms of programmatic and non-income support may be provided by financially interested enterprises for the purposes of training, research, and other academic activities that promote excellence in patient care and the well-being of the community and world at large. Such support recognizes the professional expertise of recipients and may ante- or post-date the years in which an affected individual holds the office of President or President-Elect.

Affected individuals shall not be required to divest themselves of such support but shall disclose the sources and levels of all programmatic support from financially interested enterprises, including the following:

- Research grants.
- Fellowship support.
- Funding of a program salary or position (full or part time).
- Reimbursement for clinical studies, registries or post-market databases.
- In-kind support.
- Non-remunerated service as an officer, director, or other fiduciary role in a financially interested enterprise.
- Industry funds to support travel, food, and beverage for meetings pertaining to multi-center clinical trials or other pre-existing research commitments where attendance is deemed critical by the Ethics Committee

5.10.5. Honoraria and Participation in Industry Sponsored Symposia

The President and President-Elect may chair, speak, or otherwise participate in industry-sponsored events or symposia, provided that all material information is disclosed regarding his or her participation as an individual and not as a Society representative.

The President or President-Elect may not accept honoraria for chairing, speaking at, or participating in a symposia or other event sponsored by industry. For these purposes, directing

the sponsoring entity to pay the honoraria amounts to the Society or other not-for-profit organizations shall likewise be prohibited. Industry funds to support travel, food, and beverage are prohibited, except for meetings that pertain to multi-center clinical trials or other pre-existing research commitments where attendance is deemed critical by the Ethics Committee.

The President and President-Elect may receive honoraria for their participation in non-industry supported symposia, programs, and other events. Such permitted symposia, programs, and other events would include those sponsored by academic institutions, hospitals, health care organizations, and other tax-exempt entities.

With full disclosure, the President and President-Elect may participate as speakers at a symposium held in conjunction with the HRS Scientific Sessions, but may not serve as chairs of these programs. This restriction should be made clear to the sponsors of these programs.

5.11 Restrictions on Editor-in-Chief and Editors of HeartRhythm Affiliated Journals

The Editor-in-Chief of **HeartRhythm** and Editors of **HeartRhythm**-affiliated journals shall be bound by the Society's Disclosure and Conflict of Interest policies, and must disclose all relationships with financially interested companies. In addition, these Editors shall not receive remuneration from competing print publications or products. He or she may serve on the editorial board (but not in a more senior role) for other publications, and shall not serve on advisory boards for competing organizations. The policies regarding income and consulting relationships as applied to the President and President-Elect of the Society as described above, shall apply equally to these Editors. (see sections 5.10.1 – 5.10.5).

6 GUIDANCE FOR WRITING COMMITTEES/GROUPS

Members of the Society's organizational statements and clinical document writing committee/groups (i.e., writing groups) have a special obligation for full disclosure due to the impact on organizational integrity of actual or perceived conflicts of interest. All disclosures will be reviewed prior to appointment to a writing group.

6.1 Disclosure of Relationships with Industry and other Entities

Consistent with the Disclosure of Relationships Policy defined in Section 4, all writing group members are required to fully disclose all relationships with industry and other entities, including intellectual property¹ royalty and royalty income.

6.2 Reporting Timeframe

- Individuals shall complete a full disclosure at the onset of document development prior to the initial meeting of the writing group.
- Authors are discouraged from adding new relationships with industry during the writing effort and prior to publication. If new relationships are added, or being

¹ whether or not such rights are currently commercialized via a license agreement or other means (e.g., patent, trademark, or copyright)

considered, this information must be verbally disclosed during any conference calls or meetings.

- Disclosures should be updated by the conclusion of the document.

6.3 Relevance to Document/Topic

At the onset of document development, the Scientific and Clinical Documents Committee (the “SCDC”) Chair and Staff Liaison will determine *relevant* relationships with industry.

- A relevant relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; or
- The company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document, or makes a competing drug or device addressed in the document; or
- The person or a member of the person’s immediate family or household has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the document.

6.4 Oversight

- The SCDC is responsible for reviewing all writing group member disclosure statements for relevance to the assigned document topic; the SCDC may seek additional review by the Ethics Committee as needed.
- The SCDC will ensure disclosures are reported for each clinical document and provide oversight to ensure conflict of interest policies are enforced.
- The role and responsibilities of the Ethics Committee are set forth generally in Section 5.3 above.

6.5 Restrictions on Chair or Vice Chairs

- The Chair, and one of the Vice Chairs, of any HRS-led document, is prohibited from having relevant relationships with industry as determined by the Society. (See Section 6.3 for the definition of relevant relationships.)
- For HRS-led documents, the Chair and Vice-Chairs (and their immediate family members) should not own equity interests, stocks, or stock options or have ownership, partnership, or principal interests in a financially interested enterprise, excluding mutual funds that may hold such stock in its portfolio, nor have the potential to profit financially from the recommendations of the document.
- At the discretion of the SCDC, as guided by the HRS Ethics Committee, certain disclosed relationships of the Chairs and Vice-Chairs on HRS-led documents, such as and participation in government-sponsored or university-managed Data Safety Monitoring Boards, as well as certain institutional/ organizational and government/nonprofit relationships, may be considered not relevant to the document.

6.6 Group Members:

The inclusion of experts on writing committees strengthens the writing effort and the final published document. Many experts may have relationships with industry and other relevant entities on writing groups, but these relationships must be transparent and properly managed. No authors should own equity interests, stocks, or stock options or have ownership, partnership, or principal interests in a financially interested enterprise, excluding mutual funds that may hold such stock in its portfolio, nor have the potential to profit financially from the recommendations of the document. Authors are permitted to have such financial interests if these interests are not relevant to the document (See Section 6.3). Any member who has divested relevant equity interests, stocks, or stock options within one year of the initial meeting of the writing group is eligible to participate.

All potential writing group disclosures will be reviewed if the total disclosure amount is greater than \$100,000, excluding research and fellowship support. A member will be disqualified if over \$100,000 of the relationships is determined to be relevant by the SCDC in consultation with the Ethics Committee.

- The SCDC monitors writing group composition for relationships with industry, as well as other potential areas of bias or conflicts of interest. The SCDC strives to maintain balance among potential biases that may stem from academic versus nonacademic physicians, race, gender, geographic location, intellectual bias/perspectives, and organizational relationships potentially competitive with the Society. The SCDC and the Executive Committee must approve each writing group before the group begins its work. Once selected, authors are asked to avoid forming any new relevant relationships with industry during the writing effort, and prior to publication, to maintain balance of the writing committee.

This requirement pertains to all guidelines, consensus statements, and clinical documents.

6.7 Relationships with Industry Impact on Consensus Development

- HRS values the expertise of all writing committee members and allows open discussion to inform the writing committee's final deliberation on document content.
- The document chairs are expected to manage discussions during meetings or conference calls to avoid one or more individuals from unduly influencing the outcome of the discussion, whether they have a relevant relationship with industry related to the topic under discussion, a relevant relationship with another (non-industry) entity related to the topic, or other bias related to the discussion.

6.8 Managing Conflict of Interest

The potential for a conflict of interest exists with any writing group member independent of his/her financial compensation.

- The SCDC, with oversight of the Ethics Committee, shall determine whether there is an actual, potential, or perceived conflict of interest and which actions, policies, or

processes can be implemented to resolve, mitigate, or manage the conflict on a case-by-case basis. The writing group chair must review all official recommendation votes to ensure accurate recusal by all writing group members.

- Any member of the writing group may report a potential violation of the Society's Code of Ethics, confidentiality, or Conflict of Interest policies to the writing group chair, the SCDC writing group liaison, the SCDC chair, or staff liaison. All potential violations are reviewed by the SCDC and, if necessary, presented to the Ethics Committee for further action.
 - If a member of the writing group is dissatisfied with the response by the Chair or staff liaison, he or she may submit this concern directly to the Ethics Committee. In such cases, the conclusions and recommendations of the Ethics Committee will be reported directly to the Executive Committee for further action if needed.
- All disclosed Intellectual Property (IP) will be reviewed by SCDC and if necessary the Ethics Committee. An individual's IP will be reviewed to determine whether it creates or presents a potential conflict of interest or perceived conflict of interest relative to the proposed writing project. If there is a potential for a conflict of interest, actual or perceived, the Ethics Committee will determine if the conflict can be resolved in a satisfactory manner.

6.9 External Peer Review

There are no restrictions on participation for peer reviewers; however, all reviewers must disclose all relationships with industry, nonprofit organizations, and government agencies. This promotes the opportunity for comment on the document from a variety of constituencies/viewpoints to inform final document content.

6.10 HRS Endorsement

Endorsement decisions for all clinical documents are made by the HRS Board of Trustees. A 2/3 majority vote by the Board is required for HRS Endorsement. In order to be considered for endorsement there must be a written policy to collect and publish RWI for all document authors. Exceptions to this rule will be considered on a case-by-case basis and approved by the HRS President.

6.11 Public Disclosure of Relationship with Industry

The HRS disclosure policy is cited in the published document and *all authors'* relationships with industry and other entities of authors and peer reviewers are published in a document appendix.

CODE OF PROFESSIONAL STANDARDS

7 CLINICAL CARE

Patient welfare must be paramount in the practice of medicine and under no circumstances shall a member of the Society place his or her self-interest above the welfare of the patient.

- Members shall not practice medicine beyond the scope of their training, experience, and license. Members shall uphold standards of professionalism and be honest in all professional interactions with patients and other health care providers.
- Members shall support access to medical care for all people and shall not discriminate on the basis of gender, race, color, national origin, sexual orientation, or any other basis that would constitute illegal discrimination.
- Members who are experiencing substance abuse or physical or emotional/psychological impairment should seek the appropriate assistance and limit their activities to ensure that the impairment does not affect the quality of care provided.
- Members are obligated to report patient abuse, neglect, or harassment to the relevant authorities. Members shall report colleagues who demonstrate illegal or unethical conduct or deficient competence to the appropriate legal, regulatory, or peer-based entity. Members shall cooperate in the legal, regulatory, or peer-review process in connection with alleged unethical or illegal conduct of any Member, including himself or herself, and accept the profession's discipline.

7.1 Safeguards

The Society's mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. The Society champions the highest standards of care and supports the use of safeguard mechanisms, including:

- Use of evidence-based guidelines, such as practice guidelines and clinical competence statements developed by the Society, ACC, AHA, and cardiology subspecialty societies, as well as systems-based approaches, such as ACC's *Guidelines Applied in Practice (GAP)* program and AHA's *Get With the GuidelinesSM*.
- Procedural training and credentialing of physicians, technicians, and other health care providers by ACC, AHA, ABIM, and subspecialty societies.
- Procedural oversight of laboratories by physician laboratory directors to monitor self-referral, patient referral indicators, procedural quality, and outcomes.
- Accreditation and credentialing of diagnostic laboratories.
- Clinical case conferences to broaden input into patient management decisions, and which may include invasive and non-invasive cardiologists, primary care physicians, independent cardiovascular surgeons, and cardiac care associates).
- Participation in databases, such as the ACC/HRS ICD Registry⁴.
- Review of medical care by experts outside the geographic region when review is deemed necessary and local review is impractical.

7.2 Advertising

The Society recognizes that direct-to-consumer advertising is professionally accepted and legal, and encourages advertising that: a) uses content that is appropriate and not misleading, and b) clearly discloses any commercial relationships. The Society also recognizes that diagnostic tests

are not currently regulated, and that additional oversight by the appropriate regulatory agencies is needed. The Society supports efforts by professional societies, including ACC, AHA, and the subspecialty societies, to develop guidelines for advertising and diagnostic tests.

8 SCIENTIFIC RESEARCH

The Society promotes the responsible conduct of research and encourages compliance with ethical standards and government regulations governing research. Members of the Society who are involved in research activities are expected to protect the integrity of their scientific data and meet accepted ethical standards for conducting research and publishing scientific data. The Society's policy applies to all Members, including physicians, scientists, students, and postdoctoral fellows, whether performing research funded by the Heart Rhythm Society or by other organizations.

8.1 Scientific Misconduct

Members involved in research activities shall comply with guidelines dealing with scientific misconduct established by the government's Office of Research Integrity.⁵ *Scientific misconduct or misconduct in science* is defined as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."⁶

8.2 Vertebrate Animal Research

The Society supports research involving vertebrate animals and encourages the humane treatment of laboratory animals. Members of the Society are expected to adhere to accepted standards and governmental regulations on the humane care and use of laboratory animals,^{7,8,9} and to comply with the requirements of their institutions concerning animals used in research. In cases where research by a Member or HRS postdoctoral fellow is supported by the Society, failure to adhere to this policy may mean the suspension of HRS funding.

8.3 Human Subject Research

The Society encourages members to develop new knowledge and participate in clinical research. Members conducting clinical research are expected to be transparent in all dealings with clinical trial subjects, and to work to enroll patients of underrepresented groups.

The Society recognizes that, as investigators, members have two primary obligations: a) to conduct the study according to protocol, and b) to comply with legal and ethical responsibilities toward a subject who has given consent. Therefore, members must be familiar with both the experimental therapy to be tested and the guiding principles of human subject research.

It is the position of the Society that an investigator's obligation to a sponsor is superseded by his or her obligation to act on behalf of the subject independently from the sponsor, and that rules of engagement are needed to maintain appropriate independence while participating in a partnership with industry.

In cases where research by a member or HRS postdoctoral fellow is supported by the Society, failure to adhere to this policy may lead to suspension of HRS funding.

8.3.1. *Informed Consent*

Members conducting research with human subjects are expected to obtain informed consent and comply with the detailed disclosure requirements of their Institutional Review Board.

8.3.2. *Data Analysis and Publication*

Heart Rhythm Society supports publication of results regardless of outcome, including having a contractual arrangement for publication in place at outset of the trial to avoid the potential for undue delay or obstruction by the sponsor.

While the preferred mechanism is publication in a peer-reviewed journal, posting on public website or other public access is allowed. In multicenter trials, the study's steering/executive committee should have a formal mechanism to oversee publication established by contract prior to start of study to prevent control of the process by the sponsor, investigator, or "renegade" publication.

9 EXPERT WITNESS TESTIMONY

Expert witness testimony is considered the practice of medicine and should be provided in an objective manner using medical knowledge to form expert medical opinions. The Society believes it is appropriate for members to act as expert witnesses in their area of expertise, including litigation in class action or patent cases involving pharmaceutical and medical device industries. Members acting as expert witnesses do not represent the Society.

9.1 Malpractice Litigation

Before agreeing to serve as an expert witness, members should assess the merits of the case and give an honest opinion to the requesting attorney. Members should understand that their role is to assist the judge and jury to understand the medical facts of the case. Members should testify impartially.

Members should give medical testimony that is clearly stated, concise, and understandable. They should be fair, thorough, and objective, and not exclude any relevant information with a bearing on the case. Members should be willing to submit transcripts of prior and current depositions and courtroom testimony for peer review.

Members may receive reasonable compensation that is commensurate with the time and effort expended.

9.2 Qualifications of Expert Witnesses

- Witnesses should have expertise in the relevant area, such as:
 - For technical details of an electrophysiological or device implantation nature, the witness should be a board certified practicing specialist in the relevant area.

- For aspects of diagnosis and general management of patients with cardiovascular disease, the witness should be a cardiologist with expertise in the relevant area.
- The member should have a current, valid, and unrestricted license in his or her area of professional practice, and be Board certified by ABIM or ABOIM in cardiovascular disease, or equivalent certification in pediatric cardiology or cardiovascular surgery.
- The member should be actively and primarily engaged in the practice of the specialty or subspecialty under consideration, including electrophysiology and interventional cardiology. The member should also be knowledgeable of, and qualified in, the area of testimony, and familiar with commonly accepted clinical practice standards.
- Compensation for expert testimony should be reasonable and commensurate with the time and effort expended.
- An expert witness shall not accept compensation that is contingent upon the outcome of litigation, and an expert witness shall not testify solely for financial gain because of the potential for such motivation to influence the expert's testimony.

REFERENCES

¹American Medical Association. "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501 and Food and Drug Law Journal. 2001; 56: 27-40); Updated June 1996 and June 1998. See also <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.page?>

²Accreditation Council for Continuing Medical Education (ACCME), "2004 Updated ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities." Adopted April 2004, approved September 2004. 2 pp.
<http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

³Accreditation Council for Graduate Medical Education (ACGME). "Principles to Guide the Relationship Between Graduate Medical Education Industry, and Other Funding Sources for Programs and Sponsoring Institutions Accredited by the ACGME."
<http://www.acgme.org/acgmeweb/Portals/0/PFAssets/PublicationsPapers/GME-Funding-Industry-Other-Sources.pdf>. Sept. 10, 2002. 7 pp.

⁴ American College of Cardiology/Heart Rhythm Society ICD Registry. The registry is one of three national registries contained in the National Cardiovascular Data Registry®, which is a confidential quality measurement program for cardiac and vascular facilities. For more information, see <http://www.hrsonline.org/Practice-Guidance/Quality-Outcomes-Reporting/ICD-Registry#axzz2bIwGMBQQ>.

⁵U.S. Department of Health and Human Services. Office of Research Integrity. "Model Policy and Procedures for Responding to Allegations of Scientific Misconduct."
http://ori.hhs.gov/images/ddblock/model_policy_responding_allegations.pdf).

⁶U.S. Code of Federal Regulations, 42 C.F.R. Part 50.102.
http://ori.dhhs.gov/misconduct/reg_subpart_a.shtml).

⁷U.S. Department of Health and Human Services. Public Health Service. "Policy on Humane Care and Use of Laboratory Animals."
<http://grants.nih.gov/grants/olaw/references/phspol.htm>).

⁸Institutional Animal Care and Use Committee (IACUC) procedure for approving research applications. (<http://www.iacuc.org>).

⁹Association for Assessment and Accreditation of Laboratory Animal Care International. (AAALAC) accreditation guidelines, which are based on the National Research Council's "Guide for the Care and Use of Laboratory Animals," Institute of Laboratory Animal Research, Commission on Life Sciences, National Research Council, Eight Edition, 2011.
<http://www.aaalac.org/resources/theguide.cfm>).

Appendix A: Relationship Category Descriptions
All relationships with industry, non-industry, and other professional societies
over the last 12 months should be disclosed.

Category	Description
Compensation for Services	Honoraria from a third party, gifts or in-kind compensation for consulting, lecturing, speaking engagements, advisory board, or membership, legal testimony or consultation (e.g., expert witness), or other purpose. Disclosure of travel, entertainment, food, beverage, and education expenses for industry-sponsored meetings is required.
Speaker’s Bureau*	When a company has the right to dictate or control the content of the presentation or talk, and/or the company creates the presentation material and has final approval of the content and edits, and/or you are expected to act as a company’s agent or spokesperson for the purpose of disseminating company or product information.
Equity Interests/Stock Options - Non-Public	Includes equity interests and any stock or stock options for a non-publicly traded company.
Equity Interests/Stock Options - Public	Includes any equity interests and any stock or stock options for a publicly traded and financially relevant company.
Royalty Income	The right to receive current or future royalties under a license or copyright.
Non-Royalty Payments	Non-Royalty Payments or entitlements to payments in connection with the activity that are not directly related to the reasonable costs of that activity.
Officer, Trustee, Director, Committee Chair, or Any Other Fiduciary Role	Officer, Trustee, Director, Committee Chair, or Any Other Fiduciary Role of a relevant for-profit or non-profit organization, whether or not remuneration is received for service.
Ownership/Partnership/Principal	Status or position of Ownership/Partnership/Principal in an entity excluding mutual diversified funds.
Research Grants**	Grants received from or submitted to industry, foundation, or government sources if you are a PI or co-PI, or receive salary support.
Fellowship Support	Fellowship Support
Salary	Salary or position funding (partial or full) or “in-kind” support of program.
Intellectual Property Rights	Including patent or other intellectual property in a for-profit corporation ² , manifested in a tangible form that can be legally protected whether or not such rights are currently commercialized via a license agreement or

² intellectual property is defined as property from original thought protected by law: original creative work

	other means (e.g., patent, trademark, or copyright).
Other	Other relevant relationships not described above must be disclosed.

*ACCME-accredited programs do NOT have to be disclosed due to firewall restrictions between industry and program content.

** From a commercial interest whether compensated or uncompensated or government or nonprofit interest. Includes principal investigator, investigator, steering committee member, collaborator, or consultant and pending grants as well as grants already awarded or received. Also includes receipt of drugs, supplies, equipment, or other in-kind support over which you have direct decision-making responsibility.