International Neuromodulation Society Conflict of Interest Policy and
The Council of Medical Specialty Societies' Code for Interactions with Companies Integrated

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Council of Medical Specialty Societies (CMSS) Policy:

I. Preamble

Medical Specialty Societies play an important role in reaching out to health professionals, patients, and other groups. Our members guide biomedical research, discover new therapies, and engage in high quality medical practice. Societies offer educational opportunities that help translate scientific and medical progress into the efficient delivery of effective medical care. Societies develop resources that guide our members in advancing medical care. Societies provide a forum for presenting new skills and scientific developments. For-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions,[1] referred to in this Code as "Companies," also strive to help patients live longer and healthier lives. Companies invest resources to bring new drugs, devices and therapies out of the laboratory and to the patient while maximizing value for shareholders. Members and patients count on Societies to be authoritative, independent voices in the world of science and medicine. Public confidence in our objectivity is critical to carrying out our mission. We know the public relies on us to minimize actual and perceived conflicts of interest. The Council of Medical Specialty Societies (CMSS) believes every Society must be sure its interactions with Companies meet high ethical standards.[2] Societies' interactions with Companies may include receiving charitable contributions, applying for grants in support of programmatic activities, and conducting a range of business transactions.[3] In all of these interactions, Societies are committed to acting with integrity and transparency. We adopt this Code to reinforce the core principles that help us maintain actual and perceived independence. Adopting this Code helps to ensure that a Society's interactions with Companies will be for the benefit of patients and members and for the improvement of care in our respective specialty fields.

INS Specific Policy:

I. Preamble

As a result of a series of informational meetings with our various stakeholders, including scientists, clinicians and academics within our membership, and representatives of industry, it has become apparent that there is growing concern about conflict of interest issues in general and with the real or perceived conflict of interest issues as they apply to the International Neuromodulation Society and its leadership. Based upon this feedback provided to members of the INS Executive leadership and the members of the INS Conflict of Interest Committee, we have been working over the past several months to develop a further revision of our COI policy revisions passed by the Board of Directors in September 2018. Despite the fact that these revisions were recently adopted, there was consensus that additional issues needed to be addressed to meet the ever-changing demands of our stakeholders and external parties including regulators and governmental bodies with respect to the rapidly evolving COI environment.

To initiate these deliberations, it is important to make clear certain predicate history and positions held by the INS and its leadership:

(1) Over the past 20 years, the INS has grown from a small international interest group with enthusiastic practitioners taking on leadership roles to a large, international organization. We have witnessed an expansion of neuromodulation in modern healthcare and a significant increase in the number of our members and our neuromodulation device industry partners. The INS is the only professional society focused solely on neuromodulation. Historically the leadership of the society, journal and annual scientific meeting have had individual relationships with the developing neuromodulation industry. The landscape surrounding professional organizations and its officers relative to industry and direct financial relationships has evolved and it is now important to update COI policy and implementation.

(2) There is a strong will on the part of the current INS leadership to address these issues and conform to more contemporary COI standards.

(3) We do not assume that past and/or future INS leaders are dishonest, participate in criminal activities, intentionally violate INS policies or misrepresent their activities to avoid compliance with INS policies.

(4) We have great respect for and, in fact, fundamentally require the voluntary, unpaid activities of the INS leadership including its Executive Board of Directors (consisting of

the President, President-Elect, Secretary, Treasurer, Immediate Past President and our journal's Editor-in-Chief) and members of the Board of Directors (consisting of all of the Chapter Presidents, Directors-at-Large, Regional Directors, and Liaison Members). Only the Editor-in-Chief will receive a stipend which will be linked to the annual National Institutes of Health (NIH) salary cap. The INS is best served by having the most expert, energetic and knowledgeable people devoted to service to the organization.

(5) We acknowledge that many of the same people above, due to their expertise, energy and knowledge base, are attracted to and invited by industry to contribute to their scientific efforts, product development, clinical trial design, study execution, marketing and sales. The potential for conflict of interest is apparent and the perception of conflict of interest, whether real or not, is even more probable.

II. About the Code

CMSS Policy:

… The Code is divided into Principles and Annotations. The Principles state what is expected of Societies that sign on to the Code.[4] The Principles are expected to remain relatively constant, and may be changed only by the CMSS Board of Directors. The Annotations, on the other hand, reflect CMSS' current interpretation of a given Principle. An Annotation may explain the purpose of a Principle, or give examples of Society policies and safeguards that are consistent with the Code. Annotations may be clarified periodically by CMSS in response to questions or to changes in the landscape of Society-Company interactions.

INS Specific Policy:

The International Neuromodulation Society (INS) is a 501(c)3 non-profit group of clinicians, scientists and engineers dedicated to the scientific development and awareness of neuromodulation – the modification of neural activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body. The INS maintains a unique relationship with those clinicians and industry representatives, who develop, support and promote cost-effective treatment options in the neuromodulation field. The INS is therefore vigilant regarding conflicts of interest involving those responsible for the decision making processes that directly affect the INS, its programs, and the initiatives that the INS supports.

The integrity of the INS is dependent on the avoidance of potential, assumed, or actual conflicts of interest in these relationships.

When direct financial relationships exist between affected parties and a company in the neuromodulation space, there is a potential for creating bias. The INS requires that these relationships are transparent and this transparency is essential when participating in INS activities.

The INS understands that the relationship between industry and physicians is important, and its value in furthering clinical research, scientific discovery and the advancement of the field of neuromodulation cannot be understated.

The INS shall recommend to its chapters that they adopt their own COI policy modeled after this new INS policy. It is further recommended that the chapter president, officers, and scientific program chair avoid speaking or presenting at Industry sponsored programs during their annual scientific meetings.

The purpose of the Code is to establish policies and procedures that safeguard the independence of the Society's programs, policies and publications, and to serve as a guide for the INS leadership, membership and stakeholders. One of the difficulties of our prior proposals was the establishment of a fully individualized set of COI policies de novo. As a result of our informational discussions, it became apparent that consideration and adoption of an umbrella policy statement currently used by several similar medical societies, with revisions based upon our individual needs, was a much more robust and generally acceptable process. Furthermore, adoption of specific modifications of the INS COI policies as requested by industry violates the spirit and intent of such a robust COI policy. Industry modification of the INS COI policy puts the INS, a professional society, under the control and may well reflect the biases of the medical device industry. As in the case with pain societies and their crippling collusion with the opioid industry, we view this to be self-destructive and places us at risk of governmental criticism and/or liability. As such, we have chosen to adopt the umbrella COI policy of the Council of Medical Specialty Societies identified as its Code for Interactions with Companies.

III. Definitions

CMSS Policy:
The following terms are defined for purposes of this Code. CMSS recognizes that some of these terms may be used or defined differently by individual Societies or outside groups. Some of these terms refer to types of interactions in which Societies may engage with non-profit organizations and individuals as well as with Companies. They are defined here in terms of for-profit Companies in order to create a common vocabulary for the Principles under this Code.

Advertising: Advertising is a Business Transaction in which a Company pays a fee to a Society in exchange for the Society's publication of a promotional announcement that highlights the Company or the Company's products or services. For purposes of this Code, Advertiser refers to a Company that purchases Advertising.

Business Transaction: A Business Transaction is an interaction between a Society and a Company in which a Company pays a fee to the Society in exchange for the Society's item, service, or product. Examples of Business Transactions include Company payment of fees associated with subscriptions to Society publications, Advertising in Society publications, registrations for Society meetings, and exhibit space rental.

Charitable Contribution: A Charitable Contribution is a gift, including an in-kind gift, given by a Company to a qualified tax-exempt organization (e.g., a Society or its affiliated Foundation) for use in furthering the organization's charitable purposes and in accordance with applicable tax rules and legal standards.

Clinical Practice Guideline: A Clinical Practice Guideline (or Guideline) is a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.[5] As used in this Code, the term Clinical Practice Guideline also refers to medical technology assessments, clinical opinions, and other evidence-based clinical practice tools, as well as updates to existing Clinical Practice Guidelines ("Guideline Updates"). Societies will determine whether the term Clinical Practice Guidelines applies to clinical performance measures and safety standards developed by the Society.

Company: A Company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.[6] This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients. However, a Society may choose to adopt a broader definition of "Company" if doing so

would better address the Society's interactions.

Continuing Medical Education (CME): CME consists of educational activities for which the learner may receive CME credit (e.g. American Medical Association (AMA) Physician's Recognition Award Credit, American Academy of Family Physicians (AAFP) Prescribed or Elective Credit, American Osteopathic Association (AOA) Credit – various categories) based on accreditation awarded to the continuing education provider by a recognized accrediting body (e.g., Accreditation Council for Continuing Medical Education (ACCME), AOA, AAFP). CME activities "serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession."[7] For purposes of this Code, educational activities for physicians and other health care providers that are not CME-accredited are considered Non-CME Educational/Informational Programs.

Corporate Sponsorship: A Corporate Sponsorship is an arrangement in which a Company, typically through its marketing department, provides monetary or in-kind support for a particular Society product, service, or event, and is then acknowledged in connection with the product, service or event. Corporate Sponsorships are distinct from Educational Grants, and do not constitute Commercial Support of CME. For purposes of this Code, Corporate Sponsor refers to a Company that provides a Corporate Sponsorship.

Direct Financial Relationship: A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual's services or expertise. As used in this Code, the term Direct Financial Relationship does not mean stock ownership or intellectual property licensing arrangements. See Principle 1.4 for additional clarification of the meaning of Direct Financial Relationship.

Educational Grant: An Educational Grant is a sum awarded by a Company, typically through its grants office, for the specific purpose of supporting an educational or scientific activity offered by the Society. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as "Commercial Support" of CME.[8] An Educational Grant may also be "in-kind."

Key Society Leaders: At a minimum, and for purposes of this Code, the Key Society Leaders are officers at the Presidential level (e.g., the President-Elect, and the President as applicable) of a Society's membership organization, the chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s).[9]

Medical Specialty Society: A Medical Specialty Society (or Society) is a non-profit organization whose membership includes predominantly physicians who practice in a specific medical specialty or sub-specialty that seeks to further the medical specialty, to advance the interests and education of individuals engaged in the specialty, to improve patient care, and to provide information for patients and the general public. Societies may have different corporate structures and encompass several affiliated legal entities. If a function described in the Code is carried out by an entity other than a Society's membership organization (e.g., by an affiliated Foundation), Code provisions dealing with that function apply to the other entity to the extent the membership organization controls that entity. Each Society should decide independently how best to comply with the Code in light of its corporate structure.

Non-CME Informational/Educational Program: A Non-CME Informational/Educational Program is a program offered by a Society, Company or other third party that provides educational or promotional information and does not offer CME credit.

Research Grant: A Research Grant is an award that is given by a Society to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide Societies with programmatic support (e.g., an Educational Grant or Charitable Contribution) designated for the specific purpose of funding Research Grants.

Satellite CME Symposium: A Satellite CME Symposium is a Company-supported CME program held as an adjunct to a Society meeting where CME credit for the Symposium is provided by a third party CME provider, and for which the Society receives a fee.

Society CME: Society CME refers to CME programs that are planned by a Society and for which the Society, as an accredited CME provider, provides CME credit.

Society Journal: A Society Journal is a peer-reviewed scientific journal published by a Society or by a publisher on a Society's behalf.

INS Specific Policy:

The INS shall employ the terms as defined by the CMSS policy with the addition of the following:

Industry: Industry is used to describe Companies within a single Industry, specifically the neuromodulation device Industry. The CMSS's definition of Company applies to Industry in the INS's policy.

Commercial Support: Commercial Support in the INS's policy is synonymous with Corporate Sponsorship.

Key Society Leaders: The INS defines Key Society Leaders as the President-Elect, the President and the Editor-in-Chief of Society Journal. In contrast to the CMSS Code, the Past President is not a voting member of the INS Board of Directors and, therefore, is not considered a Key Society Leader in the INS.

IV. Principles for Interaction

1. Independence

CMSS Policy:

1.1. Societies will commit that their educational activities, scientific programs, products, services and advocacy positions are independent of Company influence, and will develop and adopt policies and procedures that foster independence.

Annotation: These policies need not be uniform; rather, each Society's policies can be tailored to fit its individual organizational needs. Societies should make these policies available to the public (See Principle 2.1).

If a Society collaborates with a Company on a project or utilizes a Company's product or service, there will be an arms-length business relationship between the Society and the Company. The Society will apply its independent judgment to the arrangement and will not allow the Company to control content or project decisions.

INS Specific Policy:

INS is committed to providing educational activities, scientific programs, publications and, services that are independent of Company influence, and has developed and adopted policies and procedures that foster independence.

CMSS Policy:

1.2. Societies will separate their efforts to seek Educational Grants, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from their programmatic decisions.
Annotation: The initial step in program development is the independent assessment by a Society that a program is needed (e.g., to address gaps in care or knowledge). Once a Society determines that a program is needed, it is permissible to assess the availability of funds.

INS Specific Policy:

The INS Shall conduct an independent assessment to determine if a program is needed to address educational needs, or gaps in knowledge, practice or care. The INS shall separate its efforts to seek educational grants, commercial or corporate sponsorships, charitable contributions and research grant support from programmatic decisions.

CMSS Policy:

1.3. Societies will identify the high-level group responsible for guiding Society interactions with Companies.
Annotation: A Society may assign the responsibility of monitoring and guiding Society- level interactions with companies to an existing group, such as its Board of Directors (or a subcommittee of the Board), Ethics Committee, or Conflict of Interest Committee, or to a new group created for this purpose.

INS Specific Policy:

The INS has formed a Conflict of Interest Committee that will be responsible for providing additional guidance for Society interactions with Companies. The INS will appoint a senior INS member with no potential conflict of interest as its Compliance Officer (CO) and Chair of the Conflict of Interest Committee, tasked with ensuring compliance with the COI policy for members of the Executive Board and the Board of Directors. See section 2.3 for the full, detailed text.

CMSS Policy:

1.4. No Key Society Leader, defined for purposes of this Code as the Presidential-level officers of a Society's membership organization (e.g., the President, and President-Elect, as applicable), the chief executive officer of a Society's membership organization, and the Editor(s)-in-Chief of Society Journal(s), may have Direct Financial Relationships with Companies during his or her term of service.

Annotation: Each Society may set a reasonable period after election or appointment for Key Society Leaders to terminate any Direct Financial Relationships. A Society may permit Key Society Leaders who are elected or appointed prior to the time the Society signs on to the Code to maintain existing Direct Financial Relationships with Companies for the duration of their terms. These relationships should be disclosed and managed in accordance with Principles 2.3 and 2.4.

Under Principle 1.4, a Key Society Leader may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services. A Key Society Leader may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual. A Key Society Leader may receive wages or other compensation from a Company in exchange for providing or overseeing the provision of health services to Company personnel. A Key Society Leader may accept reasonable compensation for serving on an independent data safety monitoring board in a Company study. A Key Society Leader may own stock or stock options in a Company. A Key Society Leader may receive royalties or similar fees relating to patents or other intellectual property. While permitted under Principle 1.4, all such relationships should nevertheless be disclosed and managed in accordance with Principle 2.3.

If a Key Society Leader receives stock or stock options from a Company as wages, consulting fees, honoraria, or other compensation (other than permitted payments as described in the prior paragraph), this is considered a Direct Financial Relationship. If a Key Society Leader directs a Company honorarium or other fee to the Society, a charity, or another entity, this is considered a Direct Financial Relationship.

See the definition of "Direct Financial Relationship" for additional information relating to Principle 1.4. See Principles 5.2.5 and 5.4.4 for additional limitations on the relationships of Key Society Leaders.

INS Specific Policy:

Divestment

From the INS Bylaws:

6.7 Financial Divestment. The President, President-Elect, and Chair(s) of the INS Congress Scientific Committee, may have no direct financial relationships with a company in the neuromodulation space during their terms of service. The Past President, Secretary, and Treasurer may have limited direct financial relationships with a company in the neuromodulation space during their terms of service; the threshold per each individual is a maximum of $50,000 US per company, per year, though the Board of Directors reserves the right to re-evaluate the exact value on an annual basis. For the incumbent President, President Elect, Past President, Secretary, Treasurer, and Congress Scientific Chair on September 19, 2018, divestment shall occur September 19, 2020. New Officers' and Congress Scientific Chair's divestment shall occur either prior to, or within twelve (12) months of election. The Editor-in-Chief of *Neuromodulation: Technology at the Neural Interface*, journal of the International Neuromodulation Society, may receive zero income from a company in the neuromodulation space during his or her term as Editor-in-Chief. The Editor must terminate any direct financial relationships prior to his or her appointment. The Chair(s) of INS Congress Scientific Committee must terminate any direct financial relationships 12 months prior to the Congress and may receive zero (0) income from a company in the neuromodulation space during their term as Congress Scientific Chair. The Officers, the Editor and Chair(s) of the INS Congress Scientific Committee may accept research support if grant money is paid to the institution (e.g., academic medical center) where the research is conducted, not to the individual. Research support, uncompensated services and other permitted relationships should nevertheless be disclosed to the Society.

INS Specific Policy:

Consulting income

Consulting income of Board and Executive Board members will be limited as follows:

Past-President, Secretary, Treasurer and Board Member:

The maximum combined income, including honoraria, speaking or educational fees, travel expenses and other grants or stipends from any individual company is $50,000 USD per year. In the case of research grants, the Board member must demonstrate which portion of the grant

provides for patient care services (not-chargeable) and which portion that benefits the member by means of salary or through-payments to the individual (chargeable).

No consulting income will be allowed for the following positions:

- Editor-in-Chief (for duration of appointment)
- President (for duration of appointment)
- President Elect (for duration of appointment)
- Chair(s) of INS Congress Scientific Committee (for 12 months before and during the Congress for which they serve)

Equity in Neuromodulation Companies: No Board member may receive "equity in lieu of services provided" during their tenure without disclosing the value of this equity as part of their annual earnings. Stock Options received in lieu of payment for consulting must be included in the COI disclosure along with the number of options held and the value of the options at the time of their granting.

The Key Society Leaders and Congress Scientific Chair(s) who have existing equity holdings, must place neuromodulation-related holdings into an escrow trust structure such that the leader may not direct the buying or selling of stock during their tenure. Equity must be included in the to COI disclosure.

Disclosure of Excess Compensation: In addition to their regular annual disclosure, Board Members must disclose any compensation that exceeds the annual compensation limit of $50,000 USD per company. If a board member's income exceeds the annual limit due to delayed compensation for work completed in the previous year or years, then he or she must disclose the amount of excess and provide an explanation to demonstrate compliance with the INS divestment policy.

Monetary limits may be expected to change over time in line with the cost of living / inflation. For all INS Executive Board meetings and Board meetings the President and the COI Compliance Officer (or their appointed proxy) will have available a list of all current COIs for each attendee. Members with a COI related to the agenda item under discussion will be prohibited from the discussion of or voting on that agenda item and this will be communicated by the President at the beginning of the agenda item discussion. Board members will be required

to provide such disclosure regardless of whether the President has recognized such potential COI.

Despite not being paid directly by a company in the neuromodulation space, medico-legal or legal consulting on behalf of one of these companies is discouraged. Any income earned from such activities should be disclosed and is reportable as annual income from a company in the neuromodulation space as noted previously.

Board Members and Executive Board Members must disclose ownership, partial ownership or an office-holder position for any neuromodulation company or company whose current or future product(s) may compete in the neuromodulation sector. This applies even if there is no reportable salary and/or if there is no current value to the company and/or if the company is pre-revenue.

CMSS Policy:

1.5. Societies will use written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of Research Grants.
Annotation: Good business practices require that funds accepted from Companies be associated with written agreements that specify what the funds are for, the amount given, and the separate roles of the Company and the Society. Such agreements show that a transaction is "arms length," establish clear parameters for the use of funds, and affirm the independence of the Society.
To help Societies comply with this Principle, CMSS will develop customizable agreement templates or standard clauses to serve as a model for Societies' written agreements. Societies may choose to use these templates or create their own agreements independently.

INS Specific Policy:

Ethical Considerations

When entering into contracts with a company in the neuromodulation space, the following guidelines should be considered to address questions of conflict:

a. Proper documentation of the services provided, including time spent and actual services performed.
b. Documentation supporting the fair market value of the service performed.

c. Disclosure of future compensation for services provided.
d. Requirements of the task including marketing, promotion and other duties that may be construed as payment for the financial success of the product or service.
e. Third party strategies to avoid disclosure requirements including payments to family members, corporations, or other entities in which the affected party may have a direct interest.

Some direct financial relationships are not consistent with retaining a role as an INS board member or committee member including employment with device manufactures and pharmaceutical companies.

CMSS Policy:

2. Transparency

2.1. Societies will make their conflict of interest policies and/or forms available to their members and the public.

Annotation: Transparency is a key element in fostering confidence in Societies' independence. Societies should make disclosure forms and policies adopted under Principle 1.1 of this Code available to the public. Societies may choose to make internal conflict of interest management procedures publicly available as well.

INS Specific Policy: The INS makes its conflict of interest policy available to its members and the public. The INS website lists details of any and all industry consultancy agreements with any company in the neuromodulation space for all Board and Executive Board members for the previous three years. The policy is published on the INS website here: https://www.neuromodulation.com/assets/ins-coi-policy6-2011.pdf

A consensus document on conflict of Interest will be produced through the INS Therapy Consensus Committee and the Conflict of Interest Committee with non-conflicted lead authors, and published in the society's Journal and INS website; it will be accessible from the home page as a key navigational element.

INS Specific Policy:

Transparency and Disclosure

A conflict of interest exists when a set of circumstances creates a risk that may lead to a lapse in professional judgment or actions by an affected party through a remunerated relationship with a third party. Any direct financial relationship valued at more than $500.00 must be disclosed at least once per year, and when a new relationship or one of higher monetary value takes effect. The INS contends that:

a. Disclosure of direct financial relationships does not imply impropriety.
b. The conflict of interest disclosure form (COI) must be completed by any affected party at least once per year. Affected parties must also include those whose immediate family members, spouses, and partners have a potential conflict.
c. It is the obligation of the affected party to disclose all interests which may be construed as a conflict of interest, real or implied.
d. A Financial interest is defined as anything of actual or potential monetary value. This may include, but is not limited to, salary, consulting fees, honoraria, stock, stock options, patents, copyrights and royalties.
e. Financial disclosures should be itemised and reported based on the following ranges of the total annual US dollar value of the financial interest for the previous three years as follows: Any income greater than $50,000 per year per company could only be acceptable if it were received prior to the officer taking office.
    1. 500 – 5,000
    2. 5,001 – 20,000
    3. 20,001 – 50,000
    4. 50,001 – 100,000
    5. 100,001 – 500,000
    6. 500,001 – 1,000,000
    7. >1,000,000
    8. Where the value is potential the percentage of the total stock options should be declared
f. Disclosure is required of all INS activity participants and those who serve as representatives of, and leaders within, the INS.

CMSS Policy

2.2. Societies will disclose Company support (at a minimum Educational Grants, Corporate Sponsorships, Charitable Contributions, and support of Research Grants), making this information available to their members and the public.

Annotation: With the support of CMSS, Societies will work together, along with other appropriate stakeholders, to develop a consistent template for disclosure of Company support received by a Society. Generally, disclosure fields should include the name of the Company, the category of support (e.g., Educational Grant, Corporate Sponsorship, Charitable Contribution), the time period of the support, and the dollar amount or range. Some Societies may also decide to disclose information related to Business Transactions, support from donors outside of the for-profit healthcare sector, support from non-profit organizations, and support from individual donors.

INS Specific Policy

The INS currently discloses Company support through its website (www.neuromodulation.com/ins-congress), its congress website (https://2019.ins-congress.com/2019/exhibitors/confirmed-sponsors-and-exhibitors.html) and its annual IRS tax returns, which are available to the public (https://www.guidestar.org/profile/23-2819070).

CMSS Policy:

2.3. Societies will adopt written disclosure policies for Key Society Leaders, Board members, committee members and others who serve on behalf of the Society, and will use the disclosed information to manage conflicts of interest in decision-making. Societies will require volunteers to update disclosure information at least annually and when material changes occur.

Annotation: CMSS will support and participate in efforts to arrive at a consistent scope and format for individual disclosure across multiple organizations and activities.

Societies can manage conflicts of interest in a variety of ways. In some cases, disclosure is sufficient. Additional conflict of interest management mechanisms such as recusal, peer review, and CME session audits may be appropriate. Societies should select conflict of interest management mechanisms that are appropriate for the activity and type of relationship under consideration. Societies will disclose all financial and uncompensated relationships that Key Society Leaders and members of the Board of Directors of the Society's membership

organization have with Companies, making this information available to their members and the public.

With the support of CMSS, Societies will work together, along with other appropriate stakeholders, to develop a consistent template for disclosure of these relationships. Generally, disclosure fields should include employment, consulting or advisory arrangements, stock ownership, honoraria, research funding paid to an individual's institution or practice, expert testimony, and gifts.

A Society is not required to disclose the relationships of Board members elected prior to the time the Society signs on to the Code.

INS Specific Policy:

Disclosure Policy: See section 2.1 above.

Recusal

The Directors shall recuse themselves from any deliberations and votes involving any company with which they have a direct financial relationship. If a conflict pertains to the Journal's Editor in relation to a manuscript submitted to the journal due to bias, the Editor will recuse himself / herself from making a decision on said manuscript and ask one of the associate editors to oversee that specific work. If the conflict applies to an associate editor, then another associate editor without conflicts will oversee the manuscript. The Editor will submit editorials with potential bias to the INS Executive Committee members for review prior to publication.

Review and Resolution of Potential Conflicts of Interests

The INS has established a formal review process for resolving any real or perceived conflicts of interest. If a complaint is communicated to the INS, the person(s) with the concern should submit it in writing for the Executive Officers and Conflict of Interest Committee to determine if it is a reasonable complaint and work to resolve it. All complaints will be resolved internally within the INS Board and Conflict of Interest Committee. When the complaint concerns an individual on the Executive Board or Conflict of Interest Committee, that individual will not take part in the investigation and resolution of the complaint, apart from giving evidence. The Executive Board can co-opt an Emeritus Director at Large to serve on the investigating committee if required.

If a complaint pertains to *Neuromodulation's* Editor-in-Chief in relation to a manuscript submitted to the journal, due to a real or perceived bias, the Editor will recuse themselves from making a decision on said manuscript and ask one of the Section Editors to oversee that specific

paper. If the complaint applies to a Section Editor, then another Section Editor or the Editor-in-Chief will oversee the manuscript.

Improper Disclosure and Non-Compliance

Negligence on the part of an affected party to properly disclose a relevant direct financial relationship or their failure to comply with the COI policy may lead to sanctions or other actions by governing body of the INS including:

a. Reprimand and supervision.
b. Replacement of the individual in the INS activity.
c. Revocation of duties and impeachment or removal of an INS officer.
d. Barring of the individual from future INS activities with the duration to be determined.
e. Suspension of all membership benefits in the INS and removal from all boards, committees, and other membership bodies.

The INS is committed to providing education, review and response to questions or comments regarding disclosure. It is not the intent of the INS to unduly punish or reprimand an affected party. Questions regarding improper disclosure will be addressed by due process. A 30 day period to review and resolve the conflict will be afforded the affected party, and if corrected, may result in no further action on behalf of the INS. Future disclosures by the member will be audited by the COI Compliance Officer annually for a three year period after the failure to disclose is resolved.

Indemnification Statement

This statement is for INS board members to use at non-INS speaking engagements to indemnify the INS from its board members' personal opinions:

> "The opinions of individual members of the International Neuromodulation Society's (INS) board of directors do not necessarily reflect the opinions of the INS." Responsibility for the information and views expressed in the INS's educational events and journal, Neuromodulation: Technology at the Neural Interface, including editorials and guest editorials, lies entirely with the board member, unless the majority of the board of directors has ratified the statement or opinion, and/or has appointed the board member to represent the INS to convey the ratified statement.

The INS board members have independent thought and opinion in their role as therapy leaders in the international neuromodulation market. They are entitled to their opinions and those opinions are independent of the official INS actions unless documented and ratified as an endorsed statement."

INS Specific Policy:

The INS will appoint a senior INS member with no history of potential conflict of interest as its Compliance Officer (CO) and, as head of the Conflict of Interest Committee, tasked with ensuring compliance with the COI policy for members of the Executive Board and the Board of Directors. Following any formal specific complaint, and in addition to the investigation noted above by the Executive Board of Directors, the CO shall perform an independent investigation and issue an evaluation report and correct action program. If intentional COI policy non-compliance is demonstrated, the statement "Found to be Noncompliant" will be made available to the complainant and the INS membership at large.

The Chair of the COI Committee shall be responsible for ensuring that such investigational reports are completed within 45 days of receipt of a complaint and shall ensure that corrective actions are implemented if a violation of the COI policy has been demonstrated and followed up on every quarter thereafter for a period of three years. The CO reports to the Executive Board of Directors and the COI Committee.

All Board members and the Executive Board of Directors shall complete a mandatory compliance training program. A candidate for an appointment to the board must complete and pass the compliance training certification in order to be eligible for a board position. Training must be repeated every two (2) years.

Going forward, an annual meeting between the members of the INS Executive Board, the INS Compliance Officer, and COI Committee will occur, allowing for additional input on COI policy and its implementation.

An annual review of INS COI/Compliance policy will be performed by the INS Conflict of Interest Committee to ensure maintenance of professional society best practice and conflicting opinion.

CMSS Policy:

3. Accepting Charitable Contributions

3.1. Societies will control the use of Charitable Contributions in a manner that is aligned with the Society's strategic plan and mission.[10]

3.2. Societies will decline Charitable Contributions where the Company expects to influence Society programs or advocacy positions, or where Company restrictions would influence Society programs or advocacy positions in a manner that is not aligned with the Society's mission.

3.3. Societies will adhere to applicable tax rules and legal standards for acceptance of Charitable Contributions and management of institutional funds.

3.4. Reasonable restrictions on the purposes for which Charitable Contributions will be used are acceptable, as are reasonable requirements for reporting on the uses of the donated funds.

Annotation: For example, it is appropriate for Charitable Contributions to be designated to support a broad section of a Society's mission (e.g., general research, research in a particular disease area, or patient information). It is also appropriate for Charitable Contributions to be designated to support a specific Society program (e.g., a research award or fellowship), as long as the donor is not permitted to influence or control the program (e.g., selecting award recipients or determining research topics).

3.5. Societies will adopt policies for consistent and appropriate recognition of donors.

Annotation: Donor recognition is a universal part of fundraising and should be conducted with appropriate limitations. For example, donors can be recognized in print materials, in private or public ceremonies, and with banners or other visible displays. Recognition should not be provided in a manner that implies donor influence over Society programs or advocacy positions (See Principle 1.1).

INS Specific Policy:

3.1 The INS shall control the use of Charitable Contributions in a manner that is aligned with the Society's strategic plan and mission. The Mission of the INS is to promote and disseminate the science, education, practice and accessibility of all aspects of neuromodulation. This multidisciplinary society believes that all scientists, doctors, bioengineers, professions allied to medicine and industry partners who have a specialist interest in neuromodulation can work with this society to share science and encourage best practice for the good of humanity. The INS will

only accept commercial support of an item or program if the item or program is aligned with the INS's educational mission.

3.2. The INS will decline Charitable Contributions where the Company expects to influence Society programs or advocacy positions, or where Company restrictions would influence Society programs or advocacy positions in a manner that is not aligned with the Society's mission.

3.3. The INS will adhere to applicable tax rules and legal standards for acceptance of Charitable Contributions and management of institutional funds.

3.4. The INS may apply Charitable Contributions toward supporting a broad section of the INS's mission (e.g., general research or patient information). Charitable Contributions may also be designated to support a specific Society program (e.g., a research award); however, the donor is not permitted to influence or control the program.

3.5. The INS will recognize donors on its website.

4. Accepting Corporate Sponsorships

4.1. Societies will only accept Corporate Sponsorship of an item or program if the item or program is aligned with the Society's strategic plan and mission.

INS Specific Policy:

The Mission of the INS is to promote and disseminate the science, education, practice and accessibility of all aspects of neuromodulation. This multidisciplinary society believes that all scientists, doctors, bioengineers, professions allied to medicine and industry partners who have a specialist interest in neuromodulation can work with this society to share science and encourage best practice for the good of humanity. The INS will only accept commercial support or Corporate Sponsorship of an item or program if the item or program is aligned with the INS's educational mission.

CMSS Policy:

4.2. Societies will make reasonable efforts to seek multiple Corporate Sponsors for sponsored items or programs.

Annotation: In addition to or instead of seeking multiple Corporate Sponsors for sponsored items or products, Societies may seek support from sources outside of the for-profit healthcare sector.

INS Specific Policy:

The INS shall seek support from and provide an equal opportunity to all potential sponsors and exhibitors to support its CME programs.

CMSS Policy:

4.3. Societies will not place the names or logos of Companies or products on Society-distributed, non-educational "reminder" items (e.g., tote bags, lanyards, highlighters, notebooks, and luggage tags) that Companies are not permitted to give directly to healthcare professionals under generally accepted standards for ethical interactions (i.e., PhRMA Code, AdvaMed Code).
Annotation: The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals[11] and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals do not permit Companies to give promotional, non-educational "reminder" items directly to healthcare professionals. 11 In support of these standards, Societies should not permit the placement of Company names or logos on Society- distributed reminder items.

INS Specific Policy:

Commercial Interests' names, logos or products cannot be printed on Society-distributed enduring materials or non-educational items. (e.g. congress bags, lanyards, USB drives, keycards etc.)

CMSS Policy:

4.4. If accepting Corporate Sponsorship of data registries, Societies will prohibit Corporate Sponsors from participating in the direct management of the registry unless the data registry is in part operating as a public/private medical society, device/drug manufacturer and government partnership or for the purpose of meeting regulatory FDA objectives of device/drug surveillance and patient safety.
Annotation: With documented governance structures overseeing registry operations, including representation by multiple stakeholders, Corporate Supporters may be permitted to serve on registry steering groups and committees and be involved in operations decisions including decisions to sell or otherwise disclose or publish registry data relating to post-marketing surveillance and patient safety. Governance structures will not allow device/drug manufacturers to have a collective majority representation on any operating or data committee. Governance

structures and representatives will be disclosed on medical society websites that describe the project. If the registry is being used to meet regulatory requirements for post-marketing surveillance, Corporate Supporters may also receive special access to their specific data device/drug data.

5. Society Meetings

5.1.Society Educational and Informational Programs

5.1.1. When providing Society CME, Societies will comply with ACCME Standards for Commercial Support, including by adopting policies and procedures designed to identify and manage conflicts of interest in Company-supported Society CME programs.

Annotation: Societies should adopt policies and procedures for managing the relationships of individuals who plan, carry out, or contribute to the content of Society CME activities. Adopting and rigorously enforcing these policies precludes Company influence over Society CME content.

INS Specific Policy:

The purpose of the INS Continuing Medical Education Conference Guide is to facilitate the development and implementation of accredited Category 1 CME activities by the International Neuromodulation Society (INS) and to ensure that these activities comply with the guidelines set forth by the Accreditation Council for Continuing Medical Education (ACCME) and European Accreditation Council for Continuing Medical Education (EACCME). It contains guidelines, reference materials and some examples of necessary forms required to implement educational activities.

CMSS Policy:

5.1.2. In providing Society CME, Societies will not seek support for product-specific topics.

Annotation: Where the purpose of a Society CME session is to demonstrate or train attendees in the safe and effective use of a particular drug, device, service or therapy, Societies may accept in-kind support from Companies that develop, produce, market, or distribute that drug, device, service or therapy. In accordance with ACCME Standards, a Society may accept in-kind support from a single Company when other equal but competing products or services are not available for inclusion.

INS Specific Policy:

Commercial Support

Commercial interests may provide support to CME activities in the form of educational grants or "in-kind" (i.e. equipment, instruments, etc). The EACCME's standards for commercial support must be followed to ensure independence of CME activities from commercial interest influence in all aspects of planning, design and implementation. All commercial contributions must be received and managed by either the INS Executive Office staff or the staff of a third-party congress organizing company.

CMSS Policy:

5.1.3. Societies will make reasonable efforts to achieve a balanced portfolio of support for each Society CME program.

Annotation: Societies will make reasonable efforts to seek multiple sources of support for Society CME programs, including support from Companies, support from organizations outside the for-profit healthcare sector, and tuition from attendees.

INS Specific Policy:

The INS shall seek support from and provide an equal opportunity to all potential sponsors and exhibitors to support its CME programs.

CMSS Policy:

5.1.4. Societies will retain control over the use of Educational Grants and implement safeguards designed to ensure that educational programs are non-promotional and free from commercial influence and bias.

5.1.5. Societies will appoint their own planning committees to select the objectives, content, faculty, and format of educational activities in a manner that is consistent with their organizational missions.

5.1.6. Societies will not solicit Companies' suggestions about program topics, speakers, or content.

Annotation: This restriction would not prevent Societies from assessing the availability of funds for a program in accordance with Principle 1.2.

INS Specific Policy:

Commercial Support

Commercial interests may provide support to CME activities in the form of educational grants or "in-kind" (i.e. equipment, instruments, etc). The EACCME's standards for commercial support must be followed to ensure independence of CME activities from commercial interest influence in all aspects of planning, design and implementation. All commercial contributions must be received and managed by either the INS Executive Office staff or a third-party congress organizing company.

Policies and Procedures Governing Grant Requests for Honoraria and/or Expenses

A. The INS Scientific Committee is in sole control of any: faculty, planning, coordination and funding generated by any CME accredited product or activity; and

B. Unrestricted medical education grants requested and/or received by the INS or a third-party congress organizing company may be utilized to pay for reasonable expenses associated with the production of a product or event and may be utilized at the sole direction and discretion of INS's Scientific Committee. Unrestricted medical education grants may NEVER be directed or utilized:

    1. For payment of a specific lecture, session, portion of a lecture or product, topic, chapter or subject matter;

    2. As a provision of offering a specific topic, lecture or instruction;

    3. For payment of honoraria or expenses for a specific faculty member(s) or author(s);

    4. As quid pro quo for a specific topic, invitation of a faculty member, advertisement or special consideration, or for the promise of later work or favors outside of the project, product or event.

CMSS Policy:

5.1.7. Societies will prohibit presenters from using Company-controlled presentation materials, and from using slides with Company logos.

5.1.8. Societies will require presenters to give a balanced view of therapeutic options, and will encourage presenters to use generic names in place of product trade names.

INS Specific Policy

Presentation Instructions

Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

Policy on Commercial Support*

Presentations that constitute promotion and advertising will not be accepted. If the cost of a presentation has been underwritten to any extent, a clear acknowledgement stating the support and identifying the source should be included in the abstract (e.g., "The support of [corporation or institution] for this project is gratefully acknowledged."). Statements made in presentations are the sole responsibility of the author or presenter. Statements should not be viewed as or considered representative of any formal stance or position taken on any subject, issue, or product by the International Neuromodulation Society.

*From ACCME Standards for Commercial Support SM (http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/cme-content-definition-and-examples)

All presentations should meet the following criteria:

1. All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
3. The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

4. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available, trade names from several companies should be used, not just trade names from a single company.
5. Abstracts, posters and presentations must not contain any company logos nor commercial messaging. Institution or hospital logos are allowed.
6. Industry employees' participation as presenters in the scientific program is only allowed if they agree to speak only on completely non-commercial topics, unrelated to any of their company's products, such as:
   - basic science research (e.g. pre-clinical research, or therapy discovery)
   - process or methodologies of research unrelated to a specific disease or device
   - mechanisms of action unrelated to a specific product

CMSS Policy:

5.1.9. Societies will clearly distinguish their Non-CME Informational/Educational Programs from Society CME.

INS Specific Policy:

The INS will clearly distinguish any non-CME information or educational programs from Society CME.

A COI session shall be a mandatory part of each INS Scientific Congress so that INS general members have continued exposure to COI guidance.

CMSS Policy:

5.2.CME-Accredited Satellite Symposia

5.2.1. Societies will require Satellite CME Symposia[12] undergo an application and selection process.

5.2.2. Societies will require Satellite CME Symposia to comply with ACCME Standards.

Annotation: Societies can best implement Principle 5.2.2. by requiring written agreements with third party CME providers. Written agreements should also include consequences for non-compliance.

To minimize the potential for bias in Satellite CME Symposia, Societies may also consider the following best practices:

1. Requiring presentations to be evidence-based;
2. Requiring peer review of slide presentations in advance;
3. Prohibiting presenters who disclose unmanageable conflicts from making practice recommendations. These presenters may present on general topics only (e.g., pathophysiology, research data). An additional speaker without unmanageable conflicts may be added to the program to make practice recommendations instead.
4. Requiring presentations to be monitored by reviewers trained to recognize bias.

5.2.3. Societies will ensure that Satellite CME Symposia are clearly distinguished from Society CME in Society meeting programs and promotional materials.

5.2.4. Societies will require third party organizers of Satellite CME Symposia to use appropriate disclaimers to distinguish the Symposia from Society CME programs in Symposia advertising and program materials.

5.2.5. Societies will not permit Key Society Leaders to participate in Satellite CME Symposia as faculty members, presenters, chairs, consultants, or in any other role besides that of an attendee who receives no honoraria or reimbursement.

Annotation: See Principle 1.4 for additional limitations on the relationships of Key Society Leaders.

5.3.Company Informational/Educational Programs

5.3.1. Societies will require Company Informational/Educational Programs to be clearly distinguished from CME.

Annotation: Through the Company's use of appropriate disclaimers in advertising and informational materials, attendees of Non-CME Informational/Educational Programs should be able to easily ascertain that the Programs are not CME accredited.

5.4.Exhibits

5.4.1. Societies will adopt written policies that govern the nature of exhibits and the conduct of exhibitors, including by requiring exhibitors to comply with applicable laws, regulations, and guidance.

Annotation: Society policies can place limits on exhibits and exhibitor conduct (e.g., booth décor, size, and activities) to ensure that the tone of the exhibit hall is professional in nature. Policies should be provided to exhibitors and made available to others upon request.

5.4.2. Societies will only permit exhibitor giveaways that are educational and modest in value.

Annotation: The requirement that Company giveaways be educational (for physicians or patients) and modest in value originates in the standards for ethical interactions set out by AMA, PhRMA, and AdvaMed. The educational giveaway requirement stated in Principle 5.4.2 applies equally to Companies that have signed on to the PhRMA or AdvaMed Codes and those that have not. This approach allows Societies to place all Company exhibitors on an even playing field. Principle 5.4.2 does not apply to non-profit exhibitors or to exhibitors outside of the healthcare sector. However, Societies may apply these requirements more broadly at their individual discretion.

5.4.3. Societies will make reasonable efforts to place exhibit booths out of attendees' obligate path to Society CME sessions.

5.4.4. Key Society Leaders may not participate as leaders or presenters in Company promotional/marketing events held in exhibit space.

Annotation: Participation of Key Society Leaders in Company promotional or marketing events has the potential to create the perception that the Society endorses a particular Company or product. In order to avoid this perception, Societies should prohibit Key Society Leaders from participating as leaders or presenters, and may consider extending this restriction to the entire Board of Directors.

INS Specific Policy:

5.2.CME-Accredited Satellite Symposia

5.2.1. The INS will require Satellite CME Symposia[12] undergo an application and selection process.

5.2.2. The INS will require Satellite CME Symposia to comply with ACCME and/or EACCME Standards. The INS will implement Principle 5.2.2. by requiring written agreements with third party CME providers. Written agreements will include consequences for non-compliance.

To minimize the potential for bias in Satellite CME Symposia, INS will employ the following best practices:

1. Requiring presentations to be evidence-based;
2. Requiring peer review of slide presentations in advance;
3. Prohibiting presenters who disclose unmanageable conflicts from making practice recommendations. These presenters may present on general topics only (e.g., pathophysiology, research data). An additional speaker without unmanageable conflicts may be added to the program to make practice recommendations instead.
4. Requiring presentations to be monitored by reviewers trained to recognize bias.

5.2.3. The INS will ensure that Satellite CME Symposia are clearly distinguished from Society CME in Society meeting programs and promotional materials.

5.2.4. The INS will require third party organizers of Satellite CME Symposia to use appropriate disclaimers to distinguish the Symposia from Society CME programs in Symposia advertising and program materials.

5.2.5. The INS will not permit Key Society Leaders to participate in Satellite CME Symposia as faculty members, presenters, chairs, consultants, or in any other role besides that of an attendee who receives no honoraria or reimbursement.

5.3.Company Informational/Educational Programs

5.3.1. The INS will require Company Informational/Educational Programs to be clearly distinguished from CME. Through the Company's use of appropriate disclaimers in advertising and informational materials, attendees of Non-CME Informational/Educational Programs should be able to easily ascertain that the Programs are not CME accredited.

5.4.Exhibits

5.4.1. The INS employs an exhibitor agreement that governs the nature of exhibits and the conduct of exhibitors, including by requiring exhibitors to comply with applicable laws, regulations, and guidance.

5.4.2. The INS only permits exhibitor giveaways that are educational and modest in value.

5.4.3. The INS makes reasonable efforts to place exhibit booths out of attendees' obligate path to Society CME sessions.

5.4.4. Key Society Leaders may not participate as leaders or presenters in Company promotional/marketing events held in exhibit space.

5.4.5. Speaking at Industry or Company Supported Events During the INS Events

INS Board Members must refrain from speaking at public Industry- or Company-supported events that occur during the INS Congresses and Interim Meetings. This includes non-CME luncheon and dinner symposia, or round tables that Industry supports and promotes during the congress. (e.g. Promotion from their exhibit) As leaders in this non-profit organization, the Directors should not put themselves in situations that can be perceived as an endorsement of a particular company or product during INS-hosted events.

Board members may participate in private events during the congress; however, the companies cannot market these private events. For example, the companies cannot display a poster or video in their exhibit that advertises that private dinner, event, or panel, etc. The INS Executive Officers will issue a cease and desist letter to any company that ignores this policy.

CMSS Policy:

6. Awarding of Research Grants

6.1. Societies will not permit Companies to select (or influence the selection of) recipients of Research Grants.

6.2. Societies will appoint independent committees to select recipients of Research Grants based on peer review of grant applications.

6.3. Societies will not require recipients of Research Grants to meet with Company supporters.

Annotation: An individual, institution or practice that receives a Research Grant may publicly acknowledge the Company that supported his or her Research Grant, if known. Research Grant

recipients may be required to disclose known Company support in connection with the presentation or publication of grant-funded research.

6.4. Societies will not permit Companies that support Research Grants to receive intellectual property rights or royalties arising out of the grant-funded research.

6.5. Societies will not permit Companies that support Research Grants to control or influence manuscripts that arise from the grant-funded research.

6.6. If a Society receives programmatic support (e.g., an Educational Grant or Charitable Contribution) from a Company to support the Society's own research, the Society will disclose the Company support. The Society will act independently in the selection of research topics and the conduct of the research itself.

INS Specific Policy:

At the time that this document was ratified, the INS was not awarding research grants. If the INS begins to award research grants, the Society shall implement the relevant CMSS policy.

7. Clinical Practice Guidelines

7.1. Societies will base Clinical Practice Guidelines on scientific evidence.

Annotation: Many Societies develop and publish Clinical Practice Guidelines, medical technology assessments, and other clinical practice opinions in order to meet their members' needs for tools that help improve the quality and effectiveness of patient care. The credibility and authority of Society Guidelines depends on a common understanding that Guidelines are developed through a rigorous independent process, based on the best available scientific evidence. Societies may refer to published criteria for rating studies and other evidence, or may use another recognized means of characterizing the strength of medical evidence.

The definition of Clinical Practice Guidelines in this Code includes "other clinical practice tools." Some Societies develop and publish measures or standards for quality, safety, or other types of performance. Performance measures may apply to clinical care, research or other professional activities. To underscore the credibility of its performance measures, a Society may choose to treat them as Clinical Practice Guidelines for purposes of this Code, applying the standards for independence and transparency set out in this Principle 7.

7.2. Societies will follow a transparent Guideline development process that is not subject to Company influence. For Guidelines and Guideline Updates published after adoption of the Code, Societies will publish a description of their Guideline development process, including their

process for identifying and managing conflicts of interest, in Society Journals or on Society websites.

Annotation: Healthcare providers, payors, and patients regard Society Clinical Practice Guidelines as an important source of information from experts in the field. Societies must therefore take steps to ensure that Guidelines are free from commercial bias and Company influence.

7.3. Societies will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates.

Annotation: Societies will not accept Corporate Sponsorship, Educational Grants, Charitable Contributions, support of Research Grants, or any other direct Company support of Guideline development activities. Company support of the overall mission- based activities of a Society is not considered direct support of Guideline development.

7.4. Societies will not permit direct Company support for the initial printing, publication, and distribution of Clinical Practice Guidelines or Guideline Updates. After initial development, printing, publication and distribution is complete, it is permissible for Societies to accept Company support for the Society's further distribution of the Guideline or Guideline Update, translation of the Guideline or Guideline Update, or repurposing of the Guideline content.

Annotation: After initial development, printing, publication, and distribution of a Guideline or Guideline Update is complete, it is permissible for a Society to engage in Business Transactions where Companies purchase Guideline reprints or license Guideline content for translation or repurposing. A Society may choose to require a written statement with the purchased or licensed material, acknowledging the Company's role and describing the independent nature of the Society's Guideline development process.

7.5. Societies will require all Guideline development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Guideline development process.

7.6. Societies will develop procedures for determining whether financial or other relationships between Guideline development panel members and Companies constitute conflicts of interest relevant to the subject matter of the guideline, as well as management strategies that minimize the risk of actual and perceived bias if panel members do have conflicts.

Annotation: For example, Societies may decide not to permit panel members with conflicts of interest to draft text or vote on panel recommendations.

7.7. Societies will require that a majority of Guideline development panel members are free of conflicts of interest relevant to the subject matter of the Guideline.

Annotation: If Guideline development panel members and chairs (see Principle 7.8) have conflicts of interest at the time of adoption of the Code, a Society may permit these individuals to remain actively involved in drafting the Guideline. However, each panel for which this exception is made must meet the requirements of Principle 7.7 by the time of the next Guideline Update. For the minority of panel members who are not free of conflicts, Societies will apply procedures for disclosure and conflict of interest management developed in accordance with Principles 7.5 and 7.6.

7.8. Societies will require the panel chair (or at least one chair if there are co-chairs) to be free of conflicts of interest relevant to the subject matter of the Guideline, and to remain free of such conflicts of interest for at least one year after Guideline publication.

Annotation: In addition to minimizing potential conflicts, remaining free of conflicts of interest helps to ensure that a panel chair remains eligible to participate in subsequent Guideline Updates.

7.9. Societies will require that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts. Societies will not select as reviewers individuals employed by or engaged to represent a Company.

Annotation: As part of their published Guideline development processes, Societies will seek critical feedback on draft Guidelines from independent reviewers. These may include subject matter experts, healthcare practitioners, biostatisticians, and patient representatives, among others.[13] Societies may permit public or member comment on draft Guidelines as a part of the Society's published Guideline development process

7.10. Societies' Guideline recommendations will be reviewed and approved before submission for publication by at least one Society body beyond the Guideline development panel, such as a committee or the Board of Directors.

7.11. Guideline manuscripts will be subject to independent editorial review by a journal or other publication where they are first published.

Annotation: Editorial review provides an additional safeguard independent of a Society's Guideline development and approval process.

7.12. Societies will publish Guideline development panel members' disclosure information in connection with each Guideline and may choose to identify abstentions from voting.

7.13. Societies will require all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline development panel, to disclose financial or other substantive relationships that may constitute conflicts of interest.

Annotation: To identify and manage conflicts of interest among contributors, advisors, and reviewers, Societies should follow similar procedures as those applied to the Guideline development panel. Societies collaborating with or seeking input from outside organizations on guideline development should investigate the conflict of interest standards of those organizations.

7.14. Societies will recommend that Guideline development panel members decline offers from affected Companies to speak about the Guideline on behalf of the Company for a reasonable period after publication.

Annotation: A period of at least one year is recommended. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the Guideline.

7.15. Societies will not permit Guideline development panel members or staff to discuss a Guideline's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Guidelines in draft form, except if a Society permits public or member comment on draft Guidelines as a part of the Society's published Guideline development process.

INS Specific Policy:

7.1. The INS will base Clinical Practice Guidelines on scientific evidence.

Guidelines shall be developed through a rigorous independent process, based on the best available scientific evidence. The INS shall refer to published criteria for rating studies and other evidence.

7.2. The INS will follow a transparent Guideline development process that is not subject to Company influence. For Guidelines and Guideline Updates published after adoption of the Code, the INS will publish a description of the Guideline development process, including the process for identifying and managing conflicts of interest. The INS shall appoint at least one panel member who has no conflicts of interest to each Guidelines document to ensure that Guidelines are free from commercial bias and Company influence.

7.3. The INS will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates. Company support of the overall mission- based activities of the INS is not considered direct support of Guideline development.

7.4. The INS will not permit direct Company support for the initial printing, publication, and distribution of Clinical Practice Guidelines or Guideline Updates. After initial development, printing, publication and distribution is complete, it is permissible for the INS to accept Company support for the Society's further distribution of the Guideline or Guideline Update, translation of the Guideline or Guideline Update, or repurposing of the Guideline content. (e.g. The purchase of Guideline reprints or license Guideline content for translation or repurposing through the INS journal's publisher.)

7.5. The INS requires all Guideline development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Guideline development process.

7.6. The INS Conflict of Interest Committee's Compliance Officer shall review the disclosures to determine whether financial or other relationships between Guideline development panel members and Companies constitute conflicts of interest relevant to the subject matter of the guideline. The Compliance Officer will work with the panel members to resolve any actual or perceived bias if panel members do have conflicts. e.g. Panel members with conflicts of interest may not vote on panel recommendations related to their conflicts.

7.7. The INS will require that a majority of Guideline development panel members are free of conflicts of interest relevant to the subject matter of the Guideline.

Annotation: If Guideline development panel members and chairs (see Principle 7.8) have conflicts of interest at the time of adoption of the Code, a Society may permit these individuals to remain actively involved in drafting the Guideline. However, each panel for which this exception is made must meet the requirements of Principle 7.7 by the time of the next Guideline Update. For the minority of panel members who are not free of conflicts, Societies will apply procedures for disclosure and conflict of interest management developed in accordance with Principles 7.5 and 7.6.

7.8. The INS requires the panel chair (or at least one chair if there are co-chairs) to be free of conflicts of interest relevant to the subject matter of the Guideline, and to remain free of such conflicts of interest for at least one year after Guideline publication.

7.9. The INS requires that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts. The INS and the INS's journal will not select as reviewers individuals employed by or engaged to represent a Company.

7.10. The INS's Guideline recommendations will be reviewed and approved before submission for publication by the INS Board of Directors and the INS Conflict of Interest Committee.

7.11. Guideline manuscripts will be subject to independent editorial review by a journal or other publication where they are first published.

7.12. The INS will publish Guideline development panel members' disclosure information in connection with each Guideline and may choose to identify abstentions from voting.

7.13. The INS will require all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline development panel, to disclose financial or other substantive relationships that may constitute conflicts of interest.

7.14. The INS will recommend that Guideline development panel members decline offers from affected Companies to speak about the Guideline on behalf of the Company for a period of one year. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the Guideline.

7.15. The INS will not permit Guideline development panel members or staff to discuss a Guideline's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Guidelines in draft form, except if the INS permits public or member comment on draft Guidelines as a part of the INS's published Guideline development process.

8. Society Journals

8.1. A Society Journal will maintain editorial independence from the Society and from Advertisers.

Annotation: In general, a firewall separates the editorial decisions of a Society Journal from Society governance and operations. Editorial independence should be consistent with accepted standards for medical publishing, such as those established by the International Committee of Medical Journal Editors (ICMJE) and the World Association of Medical Editors (WAME). [14]

INS Specific Policy

From the INS Bylaws:

Editor-in-Chief of *Neuromodulation*, Journal of the International Neuromodulation Society, shall act as a representative of the Society for all the Journal's publishing and business-related matters. The Editor shall maintain editorial independence over the journal content.

From the Journal Conflicts of Interest Policy:

The International Neuromodulation Society (INS) is vigilant regarding conflicts of interest involving those responsible for the decision making processes that directly affect the INS, its programs and its peer-reviewed journal, *Neuromodulation: Technology at the Neural Interface*. The integrity of the INS is dependent on the avoidance of potential, assumed, or actual conflicts of interest in these relationships and, therefore, the journal strives to publish content that is fair, balanced, free from commercial influence, and supported by the best available evidence.

The Editor-in-Chief of *Neuromodulation: Technology at the Neural Interface*, Journal of the International Neuromodulation Society, shall act as a representative of the Society for all of the Journal's publishing and business-related matters. The Editor shall maintain editorial independence over the journal content.

CMSS Policy:

8.2. Society Journals will require all authors to disclose financial and other relationships with Companies.

Annotation: Authors' disclosure information will be considered by Society Journal editors in evaluating an article for publication. If the article is published, Society Journals will publish the authors' disclosure information with the article or issue. The "look-back" period for disclosure should be at least one year. Society Journals will adopt policies governing the scope and format of disclosure, including consistent disclosure categories.

8.3. Society Journals will require editors and reviewers to disclose financial and other relationships with Companies.

Annotation: Each Society Journal will publish its editors' disclosure information on its website.

INS Specific Policy:

From the Journal Conflicts of Interest Policy:

In alignment with the INS's Conflict of Interest Policy the INS and the Journal have established a formal disclosure and review process for resolving any real or perceived conflicts of interest. All Journal editors, editorial board members and editorial staff must disclose their financial interests through the Journal's disclosure process. Each reviewer who agrees to review a manuscript must disclose any conflicts related to said manuscript in the reviewer disclosure section of the review form. Journal editors, editorial board members, and peer reviewers are asked to withdraw from the review or decisions about manuscripts in which any circumstances might prevent them from offering unbiased editorial decisions.

Journal Editors, Editorial Board Members, and Reviewers must not use their position with the Journal for the promotion of any company or commercial product; nor should they use knowledge of the work they are reviewing before its publication to further their own interests. Guest editors should follow these same procedures.

Improper Disclosure and Non-Compliance

Negligence on the part of an affected party to properly disclose a relevant direct financial relationship or their failure to comply with the COI policy may lead to sanctions or other actions by the governing body of the INS and Journal including but not limited to:

a. Replacement of the individual in the Journal activity.

b. Revocation of duties or removal of an Editor, Editorial Board Member or reviewer.

c. Barring of the individual from any future Journal activities.

d. Suspension of all membership benefits in the INS and removal from all boards, committees, and other membership bodies.

e. Reprimand of the individual in the Journal activity and supervision.

The INS is committed to providing education, review and response to questions or comments regarding disclosure. It is not the intent of the INS to unduly punish or reprimand an affected party. Questions regarding improper disclosure must be submitted in writing to the INS Executive Board and COI Compliance Officer and will be addressed by due process. A 45-day period to review and resolve the conflict will be afforded the affected party and, if corrected, will result in no further action on behalf of the INS. Future disclosures by the member will be

reviewed by a minimum of two board members annually for a three year period after the failure to disclose is resolved.

CMSS Policy:

8.4. The Editor-in-Chief of each Society Journal will have the ultimate responsibility for determining when a conflict of interest should disqualify an editor or reviewer from reviewing a manuscript, according to established policies.

Annotation: When establishing these policies, Society Journals may find it helpful to consult accepted standards for medical publishing, such as those established by ICMJE and WAME. [15]

INS Specific Policy:

From the Journal Conflicts of Interest Policy:

If a conflict pertains to the Journal's Editor-in-Chief in relation to a manuscript submitted to the journal due to bias, the Editor will recuse himself / herself from making a decision on said manuscript and ask one of the associate editors to oversee that specific work. If the conflict applies to an associate editor, then another associate editor without conflicts will oversee the manuscript.

For information regarding the responsibilities and rights of editors and reviewers, please refer to The Council of Science Editors' "Editorial Policy Statements" to which *Neuromodulation* subscribes: http://www.councilscienceeditors.org.

Review and Resolution of Potential Conflicts of Interests

The INS has established a formal review process for resolving any real or perceived conflicts of interest. If a complaint is communicated to the INS, the person(s) with the concern should submit it in writing for the Executive Officers and Conflict of Interest Committee to determine if it is a reasonable complaint and work to resolve it. All complaints will be resolved internally within the INS Board and Conflict of Interest Committee. When the complaint concerns the Editor, an individual on the Executive Board or Conflict of Interest Committee, that individual will not take part in the investigation and resolution of the complaint, apart from giving evidence. The Executive Board can co-opt an Emeritus Director at Large to serve on the investigating committee if required.

If a complaint pertains to *Neuromodulation's* Editor-in-Chief in relation to a manuscript submitted to the journal, due to a real or perceived bias, the Editor will recuse themselves from making a decision on said manuscript and ask one of the Section Editors to oversee that specific paper. If the complaint applies to a Section Editor, then another Section Editor or the Editor-in-Chief will oversee the manuscript.

A 45-day period to review and resolve any identified conflicts will be afforded the affected party and, if corrected, will result in no further action on behalf of the INS.

To communicate a complaint or inquiry to the INS, the person(s) with the concern should submit it in writing to the **INS Executive Office** at tsofatzis@neuromodulation.com.

Neuromodulation invites comment and dissenting opinion on any and all Editorials and manuscripts that it publishes. All opinions and comments regarding published material in *Neuromodulation* will be published as "Letters to the Editor." All "Letters to the Editor" regarding a published article or Editorial will be sent to the original author of the article or Editorial for rebuttal and published with the letter. Please email Editorial letters to the editor to **mprice@neuromodulation.com**. All letters to the editor are not to exceed 1,500 words, 2 authors and 5 references. The submitting author will be asked to complete an Author Contributorship Form and a Conflict of Interest Disclosure form.

CMSS Policy:

8.5. Society Journals will adopt policies prohibiting the submission of "ghost-written" manuscripts prepared by or on behalf of Companies.

INS Specific Policy:

Authorship and Contributorship

Neuromodulation: Technology at the Neural Interface bases its authorship criteria on those outlined by the International Committee of Medical Journal Editors' (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Publications. (http://www.icmje.org/recommendations/) The corresponding author must submit the manuscript, related files, and all required data and information. From the point of submission until publication, all communication related to the manuscript will be directed to and received from the designated corresponding author only.

Authorship credit should be based on:

1) Substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data;

2) Drafting the article or reviewing it critically for important intellectual content; and

3) Final approval of the version to be published.

Corresponding authors are required to complete an Authorship and Contributorship Form upon submission of their manuscripts. Authorship statements will be published with each article. The Authorship Form is available here: http://mc.manuscriptcentral.com/ner

CMSS Policy:

9. Standards for Advertising

9.1. Societies will adopt written policies that set standards for Advertising.

Annotation: Advertising in all Society publications should be easily distinguishable from editorial content (e.g., through labels and color-coding). Advertising should not be designed to look like scientific articles. In Society Journals, the placement of Advertising adjacent to articles or editorial content discussing the Company or product that is the subject of the ad should be prohibited. Advertising in Society Journals should subject to review by the Editor-in-Chief and overseen by the Society. Society Journals and other Society publications that publish Advertising for CME activities or provide activities through which readers can earn CME credits should also comply with ACCME requirements for Advertising set out in the Standards for Commercial Support.

INS Specific Policy:

Advertising

Neuromodulation requires that all advertisements are completely separate from the editorial content of the journal.

CMSS Policy:

10. Standards for Licensing

10.1. Societies will adopt written standards for licensing that are intended to prevent misuse, unintended use, and modification of licensed materials, prohibit modification of licensed materials in a way that would change their meaning, and prohibit use of Society trademarks to imply Society endorsement of Company products or services.

INS Specific Policy:

The International Neuromodulation Society owns the copyright to the journal, *Neuromodulation: Technology at the Neural Interface.*

Copyright and Liscensing

If a paper is accepted, the author identified as the formal corresponding author for the paper will receive an email prompting them to login into Author Services; where via the Wiley Author Licensing Service (WALS) they will be able to complete the license agreement on behalf of all authors on the paper.

Copyright Transfer Agreement:

Neuromodulation requires Authors to complete Wiley's Copyright Transfer Agreement in which authors must confirm that they are submitting their own work and will adhere to ethical practices. https://authorservices.wiley.com/author-resources/Journal-Authors/licensing/licensing-info-faqs.html

Copying

Authorization to photocopy material for the Journal for any purpose must be granted by Wiley Periodicals, Inc. and the International Neuromodulation Society.

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manufacturer of said product or service. Please make every effort to comply with the previously stated requirements. Failure to do so may delay review and subsequent publication in the Journal.

Policy Ratified 28 July 2020

CMSS References:

1. See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. http://www.advamed.org/MemberPortal/About/code/. Accessed May 4, 2009; Accreditation Council for Continuing Medical Education. Definition of commercial interest. http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm. Accessed December 17, 2009.

2. Lo B. Field MJ (eds): Conflict of interest in medical research, education and practice. Washington, DC, National Academies Press, 2009.

3. This Code does not address a Society's interactions with non-profit entities or entities outside of the healthcare sector.

5. Lohr KN, Field MJ: A provisional instrument for assessing clinical practice guidelines, in Field MJ, Lohr KN (eds): Guidelines for clinical practice: From development to use. Washington, D.C., National Academy Press, 1992, p 346.

6. See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. http://www.advamed.org/MemberPortal/About/code/. Accessed May 4, 2009; Accreditation Council for Continuing Medical Education (ACCME): Definition of commercial interest. http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm. Accessed December 17, 2009.

7. Accreditation Council for Continuing Medical Education (ACCME): CME content. http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm. Accessed October 25, 2009; American Medical Association (AMA): The Physician Recognition Award and credit system. http://www.ama-assn.org/ama1/pub/upload/mm/455/pra2006.pdf. Accessed December 18, 2009.

8. Accreditation Council for Continuing Medical Education (ACCME): Standards for commercial support. http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf. Accessed December 17, 2009.

9. See definition of Society Journal.

10. See Definition of Society for discussion of the role of affiliated foundations.

11. See Pharmaceutical Research and Manufacturers of America (PhRMA): Code on interactions with healthcare professionals. http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf. Accessed March 9, 2010; Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. http://www.advamed.org/MemberPortal/About/code/. Accessed May 4, 2009.

12. See Definition of Satellite CME Symposium. Based on the definition of Satellite CME Symposium, Section 5.2 of the Code does not apply to programs that are held adjunct to Society meetings but (1) are not Company-supported; (2) are not CME accredited; or (3) for which Societies do not receive a fee.

13. The AGREE Collaboration: Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. Quality and Safety in Health Care 2003; 12(1): 18-23.

14. International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals: Ethical considerations in the conduct and reporting of research: Editorship. http://www.icmje.org/ethical_2editor.html. Accessed October 20, 2009; World Association of Medical Editors: The responsibilities of medical editors. http://www.wame.org/resources/policies#responsibilities. Accessed October 20, 2009.

15. International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals: Ethical considerations in the conduct and reporting of research: Conflict of interest. http://www.icmje.org/ethical_4conflicts.html. Accessed March 8, 2010; World Association of Medical Editors: Conflict of interest in peer-reviewed medical journals. http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals. Accessed March 9, 2010.

V. INS Specific Policy Appendices

Appendix 1: INS and Board of Director Agreement

The INS holds its members who are responsible for the decision making processes that directly affect the INS, its programs, and the initiatives that the INS supports to certain standards. The integrity of the INS is dependent on the avoidance of potential, assumed, or actual conflicts of interest in these relationships.

When an INS Board Member or Director has a conflict, s/he will not:

1) Take any action on behalf of INS 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 INS when discussing the relevant subject with third parties, including;
5) Fail to clarify with third parties, including device manufacturers and pharmaceutical companies with whom he/she deals on the relevant subject that he/she is not acting on behalf of INS; or
6) Use his/her position in the INS for the promotion of any company or commercial product;
7) Share confidential information, including disclosure of embargoed journal article and abstract data which would break laws relating to insider trading.

- ❑ I have received a copy of the INS Conflict of Interest Policy and I have read and understand the policy.
- ❑ I agree to comply with the Policy.

Full Name:
Position with the INS:

Signature:
Date:

Appendix 2: INS Direct Financial Relationship and Conflict of Interest Disclosure

The current disclosure form is available here: https://www.surveymonkey.com/r/22FPC8L

Appendix 3: Industry-INS Director Consulting Agreement

This Agreement is made this _____ day of _____, 20__, by and between _____ _____ (the "Company"), a corporation organized and existing under the laws of the _____, and _____ (the "Consultant"), a Director of the International Neuromodulation Society (INS), a 501(c)3 nonprofit organization located in San Francisco, California, USA.
WHEREAS, the Company desires that the Consultant provide advice and assistance to the Company in his or her area of expertise; and
WHEREAS, the Consultant, as a member of the INS Board of Directors, desires to provide such advice and assistance to the Company under the terms and conditions of this Agreement;
NOW, THEREFORE, the Company and the Consultant hereby agree as follows:

1. The Consultant is participating in this consultancy as an individual and not as a representative of the International Neuromodulation Society.

2. The opinions of this the Consultant do not reflect the opinions of the International Neuromodulation Society. Responsibility for the information and views expressed lie entirely with the Consultant.

3. Company shall not use the Consultant's name or depiction in his/her role as a Director of the INS, or the INS name, logos, trademarks, or depictions of INS, or any officer, director, employee, or any adaptation thereof, in any promotional, advertising or marketing literature, or in any other way without the prior written consent of the INS Executive Office, as appropriate, provided however that in neutral circumstances that do not imply endorsement or advocacy, or otherwise misrepresent the terms of this Agreement or Consultant's role, Company may accurately state that Consultant is a consultant to Company, and list his/her office in the INS with his/her employment titles.

IN WITNESS WHEREOF, the parties have executed this Agreement on the dates indicated below.

_____ _____
[Consultant's Signature] [Date]

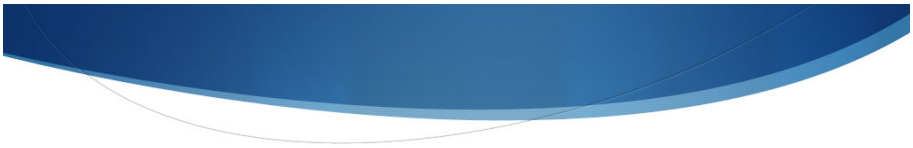
[COMPANY]
By: _____ [Company Representative Signature]

Title: _____ Date: _____

Appendix 4: Disclaimer Slide for Non-CME Events

This disclaimer slide is for INS board members to use in non-CME presentations for which they are compensated, to clearly state that the views expressed in this presentation are their personal views and are not meant to reflect opinions or ideas of the INS or its Directors. If no slides accompany the presentation, then the board members should read this disclaimer aloud.

Example of the Disclaimer Slide



Disclaimer:

This presentation was prepared by [insert author's name] in his/her personal capacity. The opinions expressed in this presentation are the author's own and do not reflect the views or opinions of the International Neuromodulation Society or its Board of Directors.