Industry Conflict of Interest Policy

The International Neuromodulation Society (INS) is a non-profit group of clinicians, scientists and engineers dedicated to the scientific development and awareness of neuromodulation – the alteration of nerve 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 financial relationships exist between affected parties and industry, 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.

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 financial relationship valued at more the $500.00 must be disclosed. The INS contends that:
a. Disclosure of 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 may also include those whose family members 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 per item and reported based on the following ranges of the total annual US dollar value of the financial interest in the year until the date of financial disclosure:
   1. 500 – 5,000
   2. 5,001 – 20,000
   3. > 20,000
   4. 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.

**Ethical Considerations**

When entering into contracts with industry, 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 financial relationships are not consistent with retaining a role as an INS board member or committee member including full time employment with device manufactures and pharmaceutical companies.

**Improper Disclosure**

Negligence on the part of an affected party to properly disclose a relevant financial relationship may lead to sanctions or other actions by governing body of the INS including:

a. Replacement of the individual in the INS activity.
b. Revocation of duties and impeachment or removal of an INS officer.
c. Barring of the individual from any future INS activities.
d. 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, 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. Members, who feel an improper disclosure has been reported by an individual, may discuss the perceived concern with members of the INS board.

**Review and Resolution of 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 in a diplomatic manner. 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 the Emeritus Director at Large to serve on the investigating committee if required.
If a complaint pertains to *Neuromodulation*’s Editor in relation to a manuscript submitted to the journal, due to a real or perceived 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 paper. If the complaint applies to a Section Editor, then another Editor will oversee the manuscript.

**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.”

**Speaking at Industry Supported Events During the INS Events**

INS Board Members are asked to refrain from speaking in public Industry-supported events that occur during the INS Congresses and events. 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.
Industry Conflict of Interest Policy Addenda

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: ____________________________
Industry–INS Director Consulting Agreement Addendum

This Agreement is made this _____ day of _________, 200__, 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 the Consultant do not reflect the opinions of the International Neuromodulation Society. Responsibility for the information and views expressed lies 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.

____________________________________  [Date]
[Consultant’s Signature]  [Date]

[COMPANY]

By: ____________________________________  [Company Representative Signature]

Title: ___________________________  Date: _______________
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.

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.
Conflict of Interest Resolution Section from the INS Congress Faculty Disclosure form

Do you feel that you have a conflict of interest as a speaker at sponsored events based on the disclosure information provided? If yes, please complete the Resolution of Conflict of Interest Form.

☐ NO

☐ YES

Resolution of Conflict of Interest Form

If you have a conflict to resolve, please check one or more of the following options:

☐ I will support my presentation and clinical recommendations with the “best available evidence” from the medical literature.

☐ I will refrain from making recommendations, regarding products or services, e.g., limit presentation to pathophysiology, diagnosis, and/or research findings.

☐ I will recommend an alternative presenter for this topic for the Scientific Program Committee’s consideration.

☐ I will submit my abstract(s) and slides in advance to allow for adequate peer review.

☐ I will or have divested myself of this financial relationship.

Certification:

I certify that the information I have provided is true and complete to the best of my knowledge. I understand that relevant financial relationships (last 12 months) with any commercial company whose product(s) I may discuss in my educational presentation or enduring material must be disclosed prior to and will be listed in the materials for the ACCME certified activities.

Name: ________________________________

Signature: ________________________________

Date: ________________________________