

## **ICSI Conflict of Interest Policy**

Revised June 2013

### **Policy**

The Institute for Clinical Systems Improvement (ICSI) requires the disclosure of all real or potential conflicts of interest by everyone who serves on Work Groups and Review Committees charged with developing, maintaining and approving ICSI Scientific Documents. The disclosure shall be made periodically or if a change in personal circumstances causes the previously submitted disclosure to no longer be accurate. Even if a person is uncertain whether a conflict of interest exists, such potential conflicts should routinely be disclosed.

Disclosure statements will be submitted prior to the participation of an interested person on any work group or committee.

Disclosure shall be shared with everyone who prepares, reviews and approves these documents. The development of ICSI Scientific Documents relies on the diverse expertise of ICSI members who volunteer their services. ICSI seeks to appoint Work Group and Review Committee members who have no real or potential conflicts and competing interests to declare. However, the participation of individuals with particular topic expertise is often desirable, and it may be the case that these individuals have a relationship with an organization that has a financial or policy interest in the topic.

ICSI is committed to disclosing all potential conflicts and competing interests and taking action when necessary to assure that ICSI Scientific Documents are free from any real or perceived control and influence of commercial, proprietary, or political interests. Each disclosure is evaluated on a case-by-case basis to determine what action, if any, is necessary.

### **Oversight and Structure**

The ICSI board of directors will appoint a COI Review Committee to review the conflicts of interest declarations submitted to ICSI. ICSI works in conjunction with Minnesota Community Measurement (MNCM) in the review of declared conflicts of interest. The ICSI/MNCM COI Review Committee is a combined committee with representatives from ICSI and MNCM Board, staff and key stakeholders. This committee will review and make recommendations for declared conflicts of interest for ICSI guideline work groups and committees and MNCM measurement work groups and committees.

The ICSI Board has delegated authority of all ICSI COI determinations to the COI sub-committee of the Board unless it is a new declaration that has not been previously discussed, when there is a complex decision needing Board input or in the case of an appeal of a COI determination by a member. The COI Review Committee will submit a summary of all recommendations to the ICSI board. The ICSI Board maintains ultimate responsibility of determining what limitations or actions should be taken related to all ICSI declarations.

## **Definitions**

**Conflict of Interest (COI):** A set of circumstances that creates a risk that professional judgment or actions regarding an individual's professional obligation to patients and/or society will be unduly influenced by a secondary interest such as the potential for financial gain, professional advancement, or recognition for personal achievement, causing a reasonable person to question the recommendations contained in an ICSI scientific document as not being free of control or influence of a commercial, proprietary, or political interest.

**Consultant:** Anyone who provides professional or expert advice.

**Dependent:** Anyone for whom an exemption can be taken on Participant's federal or state income tax return (spouse, qualifying child, or qualifying relative).

**Participant:** Any person who is a member or a consultant to a Work Group or a Committee.

**Review Committee:** Any committee that approves Scientific Documents or standards for grading scientific evidence.

**Scientific Documents:** Any guideline, order set, protocol, or other document developed by an ICSI Work Group that recommends practices that are based on a systematic review of the available scientific evidence and best practices.

**Work Group:** Any group that develops or revises Scientific Documents or develops standards for grading the scientific evidence that is cited in Scientific Documents.

## **Actions to Manage or Mitigate Declarations**

The declaration of any potential conflicts and competing interests does not necessarily imply an individual is incapable of participating in an unbiased manner, nor does it necessarily exclude a Participant from participating on ICSI Work Groups and Review Committees. Each disclosure will be evaluated on a case-by-case basis.

All declared potential conflicts and competing interests will be followed up with the Participant to gather all relevant details in order to determine the level of possible influence present. The ICSI/MNCM COI Review Committee will review declarations and determine which actions are appropriate to manage and mitigate the risk associated with them. Management actions that may be taken include but are not limited to the following:

- Add members to the Work Group or Review Committee so that no more than one third of the Work Group or Review Committee is made up of members with declared potential and competing interests.
- Submit the Scientific Document to ICSI member organizations for critical review before seeking Committee approval.
- Remove Participant as the leader of the Work Group.
- Remove Participant as a member of the Work Group.

- Have Participant recuse him or herself from specific Work Group or Review Committee discussions.

Work Group Participants' disclosures will be shared with the Work Group before the group begins its work. Such disclosures will be shared with all individuals who prepare, review, and approve these documents and will be listed in the document itself.

Participants of Review Committees will verbally declare any potential conflicts and competing interests immediately before Scientific Documents are presented for review. Such disclosures will be recorded in the meeting minutes. Participants may recuse themselves from the approval process; otherwise, the Review Committee chairperson will determine whether or not the declared potential conflicts and competing interests are significant enough to disqualify a Participant from participation in the approval process.

### **Declaration Descriptions**

1. Speaking, Consulting Fees, and/or Honoraria: The Participant and/or a Dependent has received speaking, consulting fees, and/or honoraria from any company (other than an ICSI sponsor or member organization) that sells products or services that are relevant to the topic within the past twelve months, has an agreement to receive such fees in the future, and/or is participating in discussions that could result in such an agreement. The Participant will declare the names of all companies for which a potential conflict exists.
2. Patents (issued or pending), royalties or other compensation for intellectual property: The Participant and/or a Dependent has accepted license fees, royalties or has contractual rights for future royalties from any company that sells medical products or services within the past twelve months, has such an application or contract under consideration, and/or intends to pursue a new application or contract during the next twelve months. The Participant will declare the names of all companies for which a potential conflict exists.
3. Employment, Contracting: The Participant and/or a Dependent is a director, officer, partner, employee, or independent contractor of any company (other than an ICSI sponsor or member organization) that sells medical products or services or represents such companies, has had such a relationship within the past twelve months, and/or is participating in discussions that could result in such a relationship. The Participant will declare the names of all companies for which a potential conflict exists.
4. Advisory Councils, Committees, or other Professional or Political Organizations: The Participant and/or a Dependent serves on a board, council, or committee or holds a position in a political organization that takes policy positions or advocates for changes in statutes and regulations that are relevant to the topic. The Participant will declare the names of all companies, organizations, committees or boards for which a potential conflict exists.

5. Paid expert testimony: The Participant and/or a Dependent has been paid to give expert testimony. The Participant will declare the names of all organizations for which a potential conflict exists.
6. Stock, Stock Options or Other Corporate Ownership Interest: The Participant and/or a Dependent has stock, stock options, investments, partnership, or ownership interest, other than publicly traded mutual funds, in any company that sells medical products or services, has had such investments or ownership interest within the past twelve months, and/or is in the process of obtaining such investments or ownership interest. The Participant will declare the names of all companies for which a potential conflict exists.
7. Research Grants / Pending Grants / Industry or Government Support: The Participant and/or a Dependent has received in the last three years or has pending research grant support from the government, a non-profit company or foundation, or any company (other than an ICSI sponsor or member organization) that sells medical products or services, has an application for such support under consideration, and/or intends to apply for such support within the next six months. The Participant will declare the names of all sources of support for which a potential conflict exists.
8. Loans: The Participant and/or a Dependent has accepted loans from any company that sells medical products or services within the past 12 months, has an outstanding balance from such a loan regardless of when issued, has an application for such a loan under consideration, and/or intends to seek such a loan within the next twelve months. The Participant will declare the names of all companies for which a potential conflict exists.
9. Outside payment for participation in this Work Group: The Participant has been paid to participate in the Work Group or Review Committee by an entity other than the ICSI organization he/she represents. The Participant will declare the names of all companies for which a potential conflict exists.
10. Other Direct or Indirect Benefits: The Participant and/or a Dependent has accepted within the past 12 months lodging, travel or any good or service of sufficient value that the Internal Revenue Service requires that its value be reported on Form 1099-MISC from any company (other than an ICSI sponsor or member organization) that sells medical products or services. The Participant will declare the names of all companies for which a potential conflict exists.
11. Publishing: The Participant has published (in print or on-line) one or more scientific articles, commentaries or opinion pieces relevant to the topic or has had such articles accepted for publication. The Participant will provide citations for all such articles.
12. Non-ICSI scientific document: The Participant has been a member of a work group evaluating evidence or writing recommendations on the same or a related topic for an organization other than ICSI in the last five years. The Participant will declare such participation and indicate whether he/she is willing to endorse the analysis and recommendations that will be included in the Scientific Document produced by the Work

Group, even if different from those contained in documents produced by the non-ICSI work group.

13. Other: The Participant and/or a Dependent has a financial or personal relationship or circumstance not otherwise covered above that could be perceived as a potential conflict of interest. The Participant will state the nature of the potential conflict and explain why it may be relevant.