

**CHARTER:**  
**THE MEDICAL DEVICE INNOVATION CONSORTIUM**

**ARTICLE I: BACKGROUND**

Regulatory science in the context of medical devices is the scientific discipline and methods, tools, approaches, and standards for assessing the safety, effectiveness, quality, and performance of medical devices. Advances in regulatory science can reduce the time and cost of medical device development, assessment and regulatory review by providing more robust, timely or lower cost evaluations of technologies. However, at present, the U.S. invests little in regulatory science as compared to the basic and applied sciences. Most advances in regulatory science are produced by individual companies, institutions or agencies, which leads to great inefficiencies due to duplicative efforts and the inability to leverage expertise, data and resources. Moreover, the U.S. Food and Drug Administration’s Center for Devices and Radiological Health (“CDRH” or “Center”) does not have the resources to validate and qualify all competing proprietary methods and tools created by medical device companies. In addition, medical device stakeholders, groups interested in medical devices, including but not limited to industry, government agencies, non-profit organizations and professional societies (“Medical Device Stakeholders”) currently lack a mechanism to share pre-competitive proprietary data in order to develop new methods, tools, approaches, and standards.

To provide the needed advancements in medical device regulatory science, the Medical Device Stakeholders decided to work together in a Public-Private Partnership (“PPP”). The Medical Device Stakeholders envisioned that the PPP would support pre-competitive research projects.

The PPP has now been formally incorporated as the Medical Device Innovation Consortium (“MDIC”). It has Minnesota nonprofit and federal 501(c)(3) status. By bringing Medical Device Stakeholders together and leveraging their expertise, resources and data, the MDIC will strive to facilitate the creation of methods, tools, approaches, and standards that will assist in developing safe and effective medical device products that can be brought to market at a faster rate and lower cost.

**ARTICLE II: MISSION AND VISION**

The MDIC will bring together the expertise and resources of Medical Device Stakeholders to address strategic, technical issues that affect the medical device industry and the public.

The MDIC will promote the public health by advancing medical device regulatory science to reduce the time and cost of device development, assessment, and review and advance the safety and effectiveness of medical devices throughout their total product life cycle.

**ARTICLE III: OBJECTIVES**

- Advance the field of medical device regulatory science and its acceptance and use by the device industry.
- Promote collaboration and innovation among the Medical Device Stakeholders.

- Create scientific tools that will assist Medical Device Stakeholders in developing new medical device products and in assessing the safety and effectiveness, quality, and performance of these products.
- Provide education about the medical device regulatory process.
- Provide education about the needs of the medical device community that will increase the throughput of innovation.
- Facilitate improvements in the expeditiousness and transparency of the medical device review process.
- Work to make state-of-the-art health care technology available to those who need it with a goal of making U.S. patients “first in the world” with access.
- Validate and qualify new methods, tools, approaches, and standards that CDRH may adopt as part of the regulatory process.

#### ARTICLE IV: INTELLECTUAL PROPERTY

Acquisition of intellectual property is not a primary goal of the MDIC, although the MDIC may acquire rights in intellectual property, including rights relating to patents associated with regulatory science or the medical device innovation process. Intellectual property generally is expected to be placed into the public domain, but may be licensed by MDIC to interested persons on nonexclusive and nondiscriminatory terms to support MDIC’s activities. Exceptions to this policy must be consistent with the other requirements of this Article IV and must be approved by the Board.

The MDIC’s mission (“promoting the public health by advancing medical device regulatory science to reduce the time and cost of device development, assessment and review” and advancing “the safety and effectiveness of medical devices throughout their total product life cycle”) and the requirements for qualification for tax exempt status under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder, will direct the MDIC’s activities relative to intellectual property rights.

As each project plan is developed, the steering committee for the project will consider the potential for the development of intellectual property and, as appropriate, will adopt policies and procedures that are consistent with the principles set forth above unless otherwise approved by the Board.

Applicable intellectual property and antitrust laws will be complied with in MDIC’s use and dissemination of intellectual property.

#### ARTICLE V: CONFLICT OF INTEREST POLICY

##### Purpose

The purpose of the conflict of interest policy is to protect the interests of the MDIC, as a tax-exempt organization, when it is contemplating entering into a transaction or arrangement or

taking other action that might benefit the personal or private interest of an officer, director or committee member of the MDIC or might result in a possible excess benefit transaction. This policy is intended to supplement but not replace any applicable state and federal laws governing conflict of interest applicable to nonprofit and charitable organizations.

### Definitions

Committee. A Committee means any committee established by the Bylaws of the MDIC or by the board of directors and project steering committees that serve under the leadership of a director.

Conflict of Interest. A Conflict of Interest means any personal or private interest of an officer, director or Committee member or such individual's Relative, employer or other party, which could cause an officer, director or Committee member to not act in the best interests of the MDIC and the public.

Interested Person. Any director, officer or Committee member of the MDIC who has a direct or indirect Financial Interest or a Conflict of Interest is an Interested Person.

Financial Interest. A person has a Financial Interest if the person has, directly or indirectly, through business, investment, employment or a Relative:

- An ownership or investment interest in any entity with which the MDIC has a transaction or arrangement,
- A compensation arrangement with the MDIC or with any entity or individual with which the MDIC has a transaction or arrangement, or
- A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which the MDIC is negotiating a transaction or arrangement.

Compensation includes direct and indirect remuneration as well as gifts or favors that are not insubstantial.

A Financial Interest is not necessarily a Conflict of Interest. A person who has a Financial Interest may have a Conflict of Interest only if the appropriate governing board or committee decides that a Conflict of Interest exists.

Relative. Relative means the spouse, parent(s), sibling(s), child(ren), and domestic partner(s) or any others sharing a financial or household relationship to the potentially Interested Person.

### Procedures

Duty to Disclose. In connection with any actual or possible Conflict of Interest, upon learning that the MDIC is involved in a matter in which an Interested Person believes a real or potential Conflict of Interest may exist, an Interested Person must disclose the existence of the Financial Interest or other Conflict of Interest and be given the opportunity to disclose all material facts to the directors or members of a Committee considering the proposed transaction or arrangement.

*Determining Whether a Conflict of Interest Exists.* After disclosure of the Financial Interest or other Conflict of Interest and all material facts, and after any discussion with the Interested Person, he/she shall leave the governing board or Committee meeting while the determination of a Conflict of Interest is discussed and voted upon. The remaining board or Committee members shall decide if a Conflict of Interest exists.

*Procedures for Addressing the Conflict of Interest*

- An Interested Person may make a presentation at the governing board or Committee meeting, but after the presentation, he/she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement involving the possible Conflict of Interest.
- The chairperson of the governing board or Committee shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.
- After exercising due diligence, the governing board or Committee shall determine whether the MDIC can obtain with reasonable efforts a more advantageous transaction or arrangement from a person or entity that would not give rise to a Conflict of Interest.
- If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a Conflict of Interest, the governing board or Committee shall determine by a majority vote of the disinterested directors or Committee members whether the transaction or arrangement is in the MDIC's best interest, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination it shall make its decision as to whether to enter into the transaction or arrangement or to take other action.

*Violations of the Conflicts of Interest Policy*

- If the governing board or Committee has reasonable cause to believe a potentially Interested Person has failed to disclose actual or possible Conflicts of Interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.
- If, after hearing the member's response and after making further investigation as warranted by the circumstances, the governing board or Committee determines the member has failed to disclose an actual or possible Conflict of Interest, it shall take appropriate action.

*Federal Agencies and Employees*

Each federal agency participating in the activities of the MDIC will implement and enforce all federal rules governing Conflicts of Interest in relation to employee involvement in the MDIC, including in addition to any agency-specific regulations, the applicable criminal provisions of Title 18 of the U.S. Code (e.g., sections 208, 203, 205, 209) and Parts 2634 and 2635 of the Code of Federal Regulations.

Federal employees known by their employing agency to have any apparent or actual Conflict of Interest will not be assigned to participate or will not be permitted to continue participation in the MDIC unless or until any apparent or actual Conflict of Interest has been waived or resolved under federal law and regulation.

In the event a Conflict of Interest is waived for a federal employee to permit that employee's participation in activities of the MDIC, the federal agency will promptly notify the MDIC's President that a waiver is in place with respect to that employee.

#### Records of Proceedings

The minutes of the governing board and all Committees shall contain:

- The names of the persons who disclosed or otherwise were found to have a Financial Interest or other potential Conflict of Interest, the nature of the Financial Interest or other potential Conflict of Interest, any action taken to determine whether a Conflict of Interest was present, and the governing Board's or Committee's decision as to whether a Conflict of Interest in fact existed.
- The names of the persons who were present for discussions and votes relating to the transaction or arrangement, the content of the discussion, including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection with the proceedings.

#### Compensation

A voting member of the governing board who receives compensation, directly or *indirectly*, from the MDIC for services is precluded from voting on matters pertaining to that member's compensation.

A voting member of any Committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from the MDIC for services is precluded from voting on matters pertaining to that member's compensation.

No *voting* member of the governing board or any Committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from the MDIC, either individually or collectively, is prohibited from providing information to any Committee regarding compensation.

#### Annual Statements

Each director, officer and Committee member shall annually sign a statement which affirms such person:

- Has received a copy of the Conflicts of Interest policy,
- Has read and understands the policy,
- Has agreed to comply with the policy, and

- Understands the MDIC is charitable and in order to maintain its federal tax exemption it must engage primarily in activities which accomplish one or more of its tax-exempt purposes.

#### Periodic Reviews

To ensure the MDIC operates in a manner consistent with charitable purposes and does not engage in activities that could jeopardize its tax-exempt status, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

- Whether compensation arrangements and benefits are reasonable, based on competent survey information, and the result of arm's length bargaining.
- Whether partnerships, joint ventures, and arrangements with management organizations conform to the MDIC's written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further charitable purposes and do not result in inurement, impermissible private benefit or in an excess benefit transaction.

#### Use of Outside Experts

When conducting the periodic reviews as provided for in this Article, the MDIC may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the governing board of its responsibility for ensuring periodic reviews are conducted.

### ARTICLE VI: CONFIDENTIALITY

The MDIC Board will adopt appropriate policies to protect information that should be maintained as confidential to protect any individual subjects of research sponsored by the MDIC or as otherwise necessary to further the purposes, or protect the legitimate interests, of the MDIC. As each project plan is developed, the steering committee for the project will consider the need for additional confidentiality policies and procedures that are consistent with MDIC purposes and applicable law.

### ARTICLE VII: FUNDING

#### Membership Fees

The MDIC Board will determine the membership fee structures, keeping in mind that the MDIC is meant to be inclusive of the broad spectrum of Medical Device Stakeholders interested in the MDIC's projects and overall mission.

#### Project Plan Fees

Resources will need to be secured by monetary and in-kind contributions in order to support the MDIC's research projects. The MDIC Board and MDIC project leaders will work together to secure funding for projects that have been approved by the Board.

Directors Employed by the Federal Government

Directors employed by the federal government will not participate in the structuring of membership dues or other financial decisions and will not be involved in soliciting funds for the MDIC.

ARTICLE VIII: ANTITRUST GUIDELINES

The MDIC will comply with applicable antitrust laws. The MDIC Board will adopt appropriate antitrust policies and guidelines to promote compliance with antitrust laws by members and individuals working to fulfill MDIC's mission.

ARTICLE IX: ANNUAL REPORT

The MDIC Board shall issue an annual report to be furnished no later than one hundred and twenty (120) days after the end of each calendar year to all directors and members. The report shall contain the following information in appropriate detail:

- all assets and liabilities;
- the expenses and disbursements of the MDIC;
- the status of all projects funded by the MDIC; and
- relevant potential projects.

ARTICLE X: CHARTER AMENDMENTS AND POTENTIAL CONFLICTS

This charter can be modified by the affirmative vote of a majority of directors in attendance at a meeting at which there is a quorum present. . In the event that this Charter conflicts with the Articles of Incorporation or Bylaws of the MDIC, the relevant provisions of the Articles of Incorporation or Bylaws shall prevail.