

**MEDICAL DEVICE INNOVATION CONSORTIUM (“MDIC”)
CONFLICT OF INTEREST AND ETHICS POLICY**

**ARTICLE I
INTRODUCTION AND PURPOSE**

Medical Device Innovation Consortium (the “MDIC”)^{1/} requires all its directors, officers, employees, committee^{2/} members and volunteers to observe high standards of business and personal ethics in the conduct of their duties and responsibilities to MDIC. The Board of Directors (the “Board”) of MDIC, recognizing that it is entrusted with resources devoted to charitable purposes, has adopted this Conflict of Interest and Ethics Policy (the “Policy”). The purpose of this Policy is to protect MDIC’s interest as a tax-exempt organization, when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an Interested Person or might result in a possible excess benefit transaction. MDIC strives to hold itself and its directors, officers, employees, committee members and volunteers to the highest ethical standards and to avoid conflicts of interest to ensure that MDIC continues to operate in accordance with its tax-exempt purpose. This Policy is intended to supplement but not replace any state and federal laws governing conflicts of interest applicable to nonprofit and charitable organizations.

**ARTICLE II
DEFINITIONS**

1. **Interested Person.** Any director, officer, employee, volunteer or member of a committee, subcommittee, task force, and/or advisory committee, who has a direct or indirect personal or financial interest, as defined below, is an Interested Person.

2. **Duty of Loyalty of Interested Persons.** Conflicts of interest can place personal interests at odds with the fiduciary “duty of loyalty” owed to MDIC. The duty of loyalty requires that an Interested Person refrain from using her or his position for personal gain, and avoid acting on issues in which his or her personal or financial interests could conflict with the interests of MDIC.

3. **Direct and Indirect Conflicts of Interest.** Conflicts of interest arise from personal relationships or from a financial interest. Conflicts may arise either directly or indirectly. A direct conflict may arise where an Interested Person herself or himself has a personal or financial interest in any matter involving MDIC or has a financial or agency relationship (*i.e.*, is a director, officer, manager, partner, associate, trustee or has a similar agency relationship) with an entity currently or potentially involved in a transaction or other business with MDIC. An indirect conflict may arise where someone related to an Interested Person by business affiliation, or a “Family Member” of the Interested Person has dealings with MDIC. For purposes of this Policy, “Family Member”

1/ For the purposes of this Policy the Medical Device Innovation Consortium (“MDIC”) includes all affiliates, subsidiaries, and committees.

2/ For the purposes of this Policy “committee” includes all MDIC subcommittees, task forces, and advisory committees.

means, with respect to an Interested Person, her or his spouse, parent, parent-in-law, brother, sister, child, grandchild, great-grandchild, or the spouse of her or his brother, sister, child, grandchild, or great-grandchild).

By way of example, an Interested Person has a financial interest if such person has, directly or indirectly, through business, investment or a Family Member:

(a) an ownership or investment interest in any entity with which MDIC has a transaction or arrangement;

(b) a compensation arrangement with any entity or individual with which MDIC has a transaction or arrangement;

(c) an ownership or investment interest in, or compensation arrangement with, any entity or individual with which MDIC is negotiating a transaction or arrangement;

(d) an ownership or investment interest in or compensation arrangement with a medical device or medical technology company that involves MDIC; or

(e) an ownership or investment interest in or compensation arrangement with any entity that has a pending application for any grant or any grant funding related to research, development or marketing of medical devices or technology that involves MDIC.

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. Under Article III of this Policy a person who has a direct or indirect personal or financial interest may have a conflict of interest only if the appropriate governing board or committee decides that a conflict of interest exists. For example, a potential conflict is if an Interested Person has an ownership or beneficial interest of 20% or more, or in the case of a partnership or professional corporation, a direct or indirect ownership interest in excess of 5%.

4. **Potential and Actual Conflicts of Interest.** Acts that mix the direct or indirect personal or financial interests of an Interested Person with the interests of MDIC are indicative of a conflict of interest. Not every potential conflict is an actual conflict, however. An Interested Person who has a direct or indirect personal or financial interest in a matter involving MDIC may have a conflict of interest requiring application of the mitigating procedures described in this Policy only if the appropriate party designated in Article III, Section 3 decides that such a potential conflict of interest is actual or material. However, acts that have even the appearance of a conflict of interest may be damaging to MDIC's reputation. Consequently, MDIC seeks to avoid potential and actual conflicts of interest, as well as the appearance of conflicts.

5. **Activities that May Present a Conflict of Interest.** The following is a non-exclusive list of the types of activities that may present a conflict of interest and should be disclosed in accordance with Article III.

6. **Adverse Interest.** Participation by an Interested Person in decisions or negotiations related to a contract, transaction or other matter between MDIC and: (i) the Interested Person; (ii) an entity in which the Interested Person or a Family Member of such Person has a financial interest; or (iii) an entity with which the Interested Person has an agency relationship.

7. **Competing Interests.** Competition by an Interested Person, either directly or indirectly, with MDIC in the purchase or sale of property or property rights, interests, or services, or, in some instances, competition directly for the same donor or external resources.

8. **Use of Resources.** Use of MDIC's resources (for example, staff, contracts, donor lists, or name) for personal purposes of the Interested Person or a Family Member of such Person.

9. **Inside Information.** Disclosure, use or exploitation by an Interested Person of information pertaining to MDIC's business for the personal profit or advantage of such Person or a Family Member of such Person or a person/entity with whom the Interested Person has an agency relationship.

10. **Disclosure.** The primary obligation of any Interested Person subject to this Policy who may be involved in a conflict of interest situation is to bring it to the attention of those designated under the disclosure procedures in Article III so that the potential conflict may be evaluated and addressed. An Interested Person is not to make the decision about whether a conflict of interest exists unilaterally.

ARTICLE III

PROCEDURES TO DISCLOSE AND RESOLVE CONFLICTS OF INTEREST

1. **Duty to Disclose.** An Interested Person shall promptly make an appropriate disclosure of all material facts, including the existence of any direct or indirect personal or financial interest, at any time that any actual or potential conflict of interest or ethical question arises. Such disclosure shall be made to the Board or to the chair of the committee considering the proposed transaction or arrangement. In accordance with Section 3 of this Article III, the Board or such committee shall evaluate whether a material personal or financial interest, self-dealing transaction or other kind of actual conflict exists. In addition, Interested Persons shall, in accordance with Article VI, make an annual disclosure of on-going relationships and interests that may present a conflict of interest.

2. **Disclosure of Conflicts of Others.** If an Interested Person becomes aware of any potential self-dealing or common directorship transaction or other conflict of interest involving another Interested Person, he or she should report it in accordance with the requirements of this Article III.

3. **Evaluation of Potential Conflict.**

(a) After disclosure of all material facts and any follow-up discussion with the Interested Person regarding a potential conflict of interest, the Board or relevant committee, as applicable, (either, a "decision-making body") must make a determination about whether a material personal or financial interest, self-dealing transaction or other kind of actual conflict exists. If the potential conflict is first disclosed during a Board or Committee meeting at which

the Interested Person with the potential conflict is in attendance, the Interested Person shall leave the meeting while the determination of whether a conflict of interest exists is either discussed and voted upon or referred to Committee for further consideration. The remaining board or committee members shall decide if a conflict of interest exists. In either event, the decision-making body will evaluate the disclosures by the Interested Person, and will determine on a case-by-case basis whether the disclosed activities constitute an actual conflict of interest. If the disclosure is made outside of the context of a meeting, then the determination of whether a conflict exists will be referred to the Board of Directors for decision and action. Factors the decision-making body may consider when determining whether an actual conflict exists include (i) the proximity of the Interested Person to the decision-making authority of the other entity involved in the transaction or arrangement, (ii) whether the amount of the financial interest or investment is *de minimis* relative to the transaction or arrangement or the overall financial situation of MDIC, and (iii) the degree to which the Interested Person might benefit personally if the particular transaction or arrangement were approved.

(b) In all other circumstances where it is determined that an actual conflict of interest exists, the decision-making body will recommend an appropriate course of action to protect the interests of MDIC. All disclosures and the outcome of the deliberation about whether a conflict of interest exists will be recorded in the minutes of the appropriate deliberative meeting.

4. **Procedures for Addressing a Conflict of Interest.**

(a) An Interested Person may make a presentation at the meeting of the decision-making body at which the conflict is addressed, but after the presentation, she or he she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement involving the possible conflict of interest.

(b) The Chair of the Board or chair committee, whichever is the decision-making body for the matter, shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.

(c) After exercising due diligence, the decision-making body 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.

(d) If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a conflict of interest, the decision-making body shall determine by a majority vote of the disinterested members whether the transaction or arrangement is in MDIC's best interest, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination the decision-making body shall make its decision as to whether MDIC should enter into the transaction or arrangement.

5. **Violations of the Conflicts of Interest Policy.**

(a) If the decision-making body has reasonable cause to believe that an Interested Person has failed to disclose actual or possible conflicts of interest, it shall inform the Interested Person of the basis for such belief and afford such Person an opportunity to explain the alleged failure to disclose.

(b) If, after hearing the Interested Person's response and after making further investigation as warranted by the circumstances, the decision-making body determines the Interested Person has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action.

ARTICLE IV RECORDS OF PROCEEDINGS

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

(a) The names of the Interested Persons who disclosed or otherwise were found to have a financial interest or other interest in connection with an actual or possible conflict of interest, the nature of the 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.

(b) 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.

ARTICLE V COMPENSATION

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

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

3. No voting member of the Board or any committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from MDIC, either individually or collectively, is prohibited from providing information to any committee regarding compensation. Notwithstanding the foregoing, the President and/or CEO may provide information regarding their compensation to the Board or any committee.

ARTICLE VI ANNUAL STATEMENTS AND DISCLOSURE

Each person subject to this Policy shall annually sign a statement on the conflict of interest disclosure form ("Conflict of Interest Disclosure Form") attached as **Schedule 1**, or such other form as the Board adopts from time to time, which at a minimum affirms that such person:

- (a) Has received a copy of the conflicts of interest policy;
- (b) Has read and understands the Policy;

(c) Has agreed to comply with the Policy;

(d) Understands that MDIC is a charitable organization and in order to maintain its qualifications as being exempt from federal income taxation as an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, MDIC must engage primarily in activities that accomplish one or more of its tax-exempt purposes.

In addition, Interested Persons shall make an annual disclosure of on-going relationships and interests that may present a conflict of interest. Disclosures should address current affiliations, as well as past affiliations for the prior two years. Conflict of Interest Disclosure Forms will be submitted to the respective Chairperson of the Board, Committee, Sub-Committee, Task Force or Advisory Committee annually, and when appropriate, at or prior to action on entering into relevant transactions or arrangements. To the extent permitted by law, all disclosure forms and related information will be confidential

ARTICLE VII PERIODIC REVIEWS

To ensure 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:

(a) Whether compensation arrangements and benefits are reasonable, based on competent survey information of comparable compensation arrangement, and are the result of arm's length bargaining.

(b) Whether partnerships, joint ventures, and arrangements with other organizations conform to 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.

ARTICLE VIII USE OF OUTSIDE EXPERTS

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

ARTICLE IX CODE OF ETHICS

In order to ensure robust and fair scientific debate and the highest ethical conduct, MDIC requires that all directors, officers, employees, committee members, volunteers, consultants, contractors and vendors ("MDIC Person") agree to and comply with this Code of Ethics. When an MDIC Person acts as a speaker, presenter, moderator, commentator, or panelists he or she has an obligation to promote ethically responsible business practices, refrain from certain activities that are harmful to the mission of MDIC and/or create actual or potential ethical conflicts. MDIC Persons should undertake their best efforts to ensure that they, and the institutions with which

they have affiliations, act to promote improved patient care and patient safety, and that they act with honor, integrity, responsibility, and transparency at all times.

Code of Ethics. In conducting business and activities that are connected with MDIC, an MDIC Person shall follow these guidelines:

1. **Ethical Conduct.** Be honest and ethical in his or her conduct, including ethical handling of actual or apparent conflicts of interest between personal and professional relationships. An MDIC Person should not engage in activities that have or may have the appearance of impropriety or conflict of interest, or that may call into question the actions or integrity of MDIC, or of the MDIC Person as he or she relates to MDIC.

2. **Legal Compliance.** Comply with applicable laws and regulations and report his or her concerns to the General Counsel of MDIC if it appears that any other director, officer, employee, committee member, volunteer or contractor of MDIC is not complying with applicable laws or regulations with respect to MDIC's business.

3. **Confidentiality.** Maintain the confidentiality of all internal information about MDIC, including its research, grants, donors, clients and beneficiaries, except when such disclosure is authorized, or the information is publicly available, or the person is legally obligated to disclose such information.

4. **Research.** Conduct all research in accordance with generally accepted good research practices. Apply scientifically accepted standards, analysis, methods, and procedures to research.

5. **Fair Dealing.** Deal fairly with MDIC's directors, officers, employees, committee members, volunteers, researchers, donors, institutions, beneficiaries and suppliers.

6. **Protect Assets.** Protect and ensure the proper use of MDIC's assets, including, its name, goodwill, donor community and reputation.

7. **Personal Influence.** Be mindful of the interaction between his or her relationships inside and outside of MDIC, and not allow inappropriate personal influence over the affairs of MDIC.

8. **Commitments.** Do not "speak for" MDIC or make or imply commitments by MDIC without proper internal authorization and communication.

Adopted: As of September 13, 2021

CONFLICT OF INTEREST AND ETHICS POLICY

SCHEDULE 1: CONFLICT OF INTEREST DISCLOSURE FORM

The undersigned, as a director, manager, principal, officer, volunteer or member of a committee of **Medical Device Innovation Consortium** (“MDIC”), acknowledges that:

1. he or she has received a copy of MDIC’s Conflict of Interest Policy (the “Policy”);
2. he or she has read and understands the Policy;
3. he or she has agreed to comply with the Policy;
4. he or she understands MDIC is a charitable organization and in order to maintain its qualifications as an organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, MDIC must engage primarily in activities which accomplish one or more of its tax-exempt purposes; and
5. the following on-going relationships and interests may present a conflict of interest: *(disclosures should address current affiliations, as well as past affiliations for the prior two years, and should include all of the following: the undersigned’s employer, all corporations (nonprofit and for-profit) of which the undersigned is a board member or officer, and the names of such of the undersigned’s Family Members or business affiliates or any other relationships the undersigned has which the undersigned believes may present a potential conflict)*

Name: _____

Title: _____

Signature: _____

Date: _____