

## **TMC Grants and Donations Funding Policy**

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### **1.0 TERUMO'S MISSION**

It is Terumo's mission to improve public health and welfare. Terumo fulfills its mission by: (i) supporting educational opportunities to advance knowledge and understanding new and existing medical technologies, techniques and procedures; and (ii) Terumo may make monetary or product donations for charitable purposes, such as supporting indigent care, patient education, public education, research or the sponsorship of community programs / events where the proceeds are intended for charitable purposes.

Terumo's efforts are never contingent upon, or related to, the purchase, lease, recommendation, procurement, use, or prescription of Terumo products and services.

### **2.0 SCOPE**

The TMC Grants and Donations Funding Policy ("Policy") Policy applies to Terumo Medical Corporation ("TMC"), Terumo Medical Canada, Inc. ("TMCI"), and all of its Associates, and the companies for which TMC has managerial oversight and control, such as Kalila Medical, Inc. ("KMI") and Terumo Puerto Rico, LLC ("TPR") (all above mentioned entities are collectively, and individually referred to as "Terumo").

This Policy generally covers:

- Educational Program Funding Criteria and Priorities;
- Investigator Initiated Research Studies;
- Grants and Donations Application and Review Process;
- Educational Grants to Organizations and Institutions; and
- Charitable Donations.

This Policy does not apply to:

- Company-sponsored training and education for Healthcare Professionals;
- Discounts, rebates, and pricing concessions;
- Evaluation and demonstration products;
- Clinical grants, studies, and research projects that are managed by TMC;
- Promotional practices;
- Fundraising efforts or capital campaigns;
- Terumo associate's initiatives; or
- Education and Research Funding Provided as a Contract Value (in Canada).

### **3.0 REFERENCE DOCUMENTS**

This Policy operates in conjunction with the:

- Global Anti-Bribery and Anti-Corruption Policy;
- Terumo Medical Corporation Comprehensive Compliance Program;
- Terumo Code of Ethics on the Interaction with Health Care Professionals; and
- AdvaMed Code of Ethics on the Interactions with Health Care Professionals.

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### 4.0 EDUCATIONAL GRANTS, CLINICAL PROGRAMS FUNDING CRITERIA AND PRIORITIES

Terumo may provide educational grants to eligible applicants. Eligible applicants include physicians and other healthcare providers, 501(c)(3) non-profit organizations with IRS tax-exempt status, as well as medical associations, educational organizations, public institutions and organizations, community organizations and schools.

In reviewing proposals that relate to the focus areas of health and education, Terumo will give priority to the following types of initiatives:

- Support of innovative or experimental approaches directed in ways that support Terumo's goals.
- Refinement or improvement of existing approaches.
- Cost-effective and results-oriented products, procedures or techniques, where our contributions can make a long-term measurable difference in the quality of people's lives.

Within these focus areas, Terumo may elect to support, among others:

- **Medical Education Events:** Support for medical education events is generally limited to grants for non-Terumo educational meeting expenses or product support for training events involving Terumo products.
- **Grand Rounds and Lectureships:** Grand rounds and lectureships funding can be used for reasonable speaker fees, travel and lodging for speakers, and only occasionally for modest meals for speakers and attendees. Funding may not be used for lodging if the speaker is a staff member at the requesting organization.
- **Fellowship Funding:** Fellowship funding may be provided to third-party funding entities or, in limited circumstances, directly to accredited fellowship programs.
- **General Medical Research Initiatives:** Third-party organizations may request funding for their research initiatives.
- **Enduring Education Materials:** Grants may be used to develop enduring educational materials (i.e., reusable medical education items that are printed, recorded, or computer-based). Requests to develop the content of a live event (e.g., webinars) must be received prior to the event. Participants may not be charged for the materials if the grant covers the full cost of preparing these items.
- **Other Third-Party Programs:** Grants may be provided to training institutions and other third-party entities to support any other legitimate educational or training program or activity not explicitly described above.

### 5.0 CHARITABLE DONATIONS FUNDING CRITERIA AND PRIORITIES

Terumo will focus its charitable giving primarily on the following:

**Improving through education the health of individuals and communities.** Of particular interest are innovative, technology-based approaches to improving quality of care and health outcomes. Terumo will give priority to initiatives that target a clearly defined community or population, and that have strong potential to produce measurable long-term improvements in healthy behaviors, health outcomes, and quality of life.

- **Improving educational opportunity and skill development for practitioners serving target communities or populations.** Of particular interest are: (i) innovative educational efforts to improve outcomes and skill development; and (ii) creative

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- curriculum projects focusing on development of innovative skills and procedures.
- **Improving the health of individuals and communities** through supporting indigent care, patient education, public education, research or the sponsorship of programs / events where the proceeds are intended for charitable purposes.
- **Civic initiatives** of local concern or interest.

Terumo is most interested in opportunities to serve as a catalyst for positive change, support innovation, and leverage significant and long-term impact. It discourages requests for general support for programs that rely primarily on government funding. In addition, it generally will not support programs or other efforts that will benefit a small number of individuals, have minimal impact, or where recipient has a real or apparent conflict of interest, including where a corresponding financial, commercial or competitive benefit may accrue to recipient as a result of receiving a grant or donation.

Terumo will prioritize requests for support falling within the strategic areas described previously, including, without limitation, sponsorship of educational seminars, scholarships, conferences and symposia, as well as research through Investigator Sponsored Studies.

### 6.0 INVESTIGATOR-INITIATED SPONSORED RESEARCH STUDIES (“IISR”)

For purposes of this Policy, Investigator Initiated Sponsored Research Studies (“IISR”) is defined as unsolicited, independent research where the investigator serves as the sponsor for which Terumo provides grant support in the form of funding or by providing devices or both. As the sponsor, the investigator takes responsibility for writing the protocol, meeting regulatory requirements, conducting the study, monitoring, analyzing the results, or other sponsor activities. The sponsor-investigator should retain independent control over the research. The sponsor-investigator owns the data and is responsible for producing a final document (final report, abstract, poster and / or manuscript, as applicable). IISR research may be regulated pre-market studies or exempt studies of market released products.

Before submitting an IISR application, applicants for IISR funding shall review Terumo’s “Requirements and Obligations” page that can be found at <http://www.terumomedical.com/research.html>, which describes the requirements and obligations that an investigator and/or their institution must fulfill throughout the duration of the study, including all applicable regulatory requirements.

Research related grant and donation requests shall follow the Research Grants and Funding of Investigator Initiated Sponsored Research (CA024) procedure. All other grants and donations shall follow the TMC Grants and Donations Standard Operating Procedure (BC402).

### 7.0 GRANT APPLICATION PROCESS

#### Written Requests

Persons or organizations whose efforts fall within the scope of Terumo’s charitable focus areas are invited to apply in writing for funding by submitting an application to: The Grant Review Committee, as set forth by Terumo’s policy BC402.

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Each written request must include a description of the grant or donation's purpose and a budget that sets forth how the funding will be used.

### **Grant Review Committee**

The Grant Review Committee ("GRC") shall be comprised of one representative from Human Resources, Compliance, and Legal. In the case of requests for IISRs, the Committee shall include members, as described in CA024.

The GRC, as further explained and detailed in Terumo's Grants and Donations Standard Operating Procedure (BC402), is responsible for:

- Verifying grants and donations are consistent with this policy and relevant procedures, the Advamed Code of Ethics on the Interactions with Health Care Professionals, the Terumo Code of Ethics on the Interactions with Healthcare Professionals (CC006), and all applicable laws, regulations, and industry codes, as further detailed under the 'Compliance' section below;
- Confirming that grants and donations are properly budgeted and/or approved by Finance;
- Reviewing and evaluating grant and donation requests and potential recipients.

GRC's evaluation of grant and donation requests shall be based on written, objective, selective criteria. In particular, the GRC shall consider:

- The reputation and qualifications of the potential recipient;
- Previous support provided to the potential recipient and associated grant usage reports, if any;
- The educational or charitable objectives of the grant;
- The appropriateness of the grant or donation in light of other programs that receive funding;
- Whether Terumo will be the sole or majority sponsor;
- The location of the event;
- The involvement of any HCPs in the program, activity, or organization and/or conflict of interest;
- For educational grants, if the agenda, faculty, attendees, and educational materials for a third-party conference reflect an objective, legitimate educational, medical, scientific, or policymaking purpose of the meeting;
- For educational grants, whether the request for funding is reasonable and reflective of the educational purpose of the program;
- For educational grants, whether any of the meals or refreshments provided detract from the primary purpose of the program;
- For educational grants, whether the program appears to primarily promote the medical services of a specific provider; and
- The nature of the educational course, CME, non-CME.

Associates in commercial sales and marketing roles may provide input, at GRC request, regarding potential grant and donation recipients, but may not vote to select recipients or act as decision makers. Additionally, the GRC may designate advisors to the Committee as needed.

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### **Grant Liaison Manager**

An Associate from Medical Affairs serves as Grant Liaison Manager (“GLM”) and coordinates all activities relevant to the grants and donations submission, application and review process for the GRC. In particular, the GLM manages: (i) the GRC email account for receiving grants and donation applications; (ii) interfaces externally with applicants and internally with GRC and Associates in Finance, Marketing, Sales, Medical Affairs and other corporate business functions as needed; (iii) coordinates payment by submitting requests for payment through the Terumo CAS system; (iv) provides additional information, if so requested; and (v) maintains copies of all relevant documentation.

### **Review Scope**

The GRC is solely responsible for considering and recommending grant and donation requests. Terumo Associates may not make any oral or written promises that a grant or donation will be approved prior to GRC review and recommendation.

The recommendations from the GRC shall be forwarded to TMC senior management for final funding approval in accordance with Terumo’s Grants and Donations Standard Operating Procedure (BC402). Funding decisions are based on available resources and the degree to which proposals meet the charitable mission and charitable focus and priorities as set forth above.

The Grants and Donations application and review process is further detailed in procedure BC402.

## **8.0 EDUCATIONAL GRANTS TO ORGANIZATION AND INSTITUTIONS**

Terumo may provide grants to organizations and institutions that have a genuine educational or scientific purpose or function to support educational programs and events on scientific, clinical, or healthcare topics. Terumo may place restrictions on a grant, but it may not seek to control or influence the content, faculty, educational materials, or methods of the educational program funded by the grant. Similarly, Terumo may not select, or instruct the organizational or institutional grant recipient to select, specific HCPs or other individuals or organizations to benefit from Terumo’s grant funding.

Permissible Grantees: Organizations and institutions that may receive educational grants include:

- Educational, scientific, and charitable entities and organizations;
- Training hospitals and academic medical institutions;
- International, national, regional, and specialty medical associations and societies;
- Accredited continuing medical education providers and agents;
- Public institutions and organizations; and
- Accrediting bodies.

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Educational grants may be used to:

- Support non-Terumo medical education events, including Third-Party Educational Conferences (“TPECs”), by:
  - Defraying or reducing the costs of conducting the educational components of the TPEC;
  - Reducing the overall attendance costs for all participants;
  - Supporting the provision of meals and refreshments for all participants;
  - Allowing attendance by HCPs in training (i.e., medical students, residents, and fellows), provided Terumo does not select or control the selection of the specific HCPs in training who will benefit;
  - Providing reasonable honoraria, travel, accommodations, and modest meals for bona fide faculty members;
- Support third-party fellowships or medical research initiatives;
- Support grand rounds presentations and lectureships at universities and hospitals;
- Develop, produce, distribute, or purchase enduring educational materials (i.e., print, electronic, or online educational materials);
- Support patient education or public education about important healthcare topics; and
- Support other third-party programs focusing on education or public awareness on therapies and products.

### **Payment**

Payments made in connection with educational grants must be paid directly to the approved individual, organizational or institutional grant recipient. All requests by the grant recipient for Terumo to pay an organizing vendor or third party must be carefully reviewed by the Compliance Officer. Payment may not exceed the approved amount for the specific event or activity. Subject to certain exceptions, such as grants for enduring educational materials, Terumo should not be the sole sponsor or majority sponsor of such programs or events without approval from the Compliance Officer.

### **Charitable Donations**

Terumo may provide charitable donations to programs or non-profit organizations, schools, institutions, and other eligible organizations, so long as the purpose of the program and organization is charitable and/or philanthropic. Terumo does not make charitable donations to for-profit organizations, individual HCPs, or practice groups. When considering a charitable donation, the GRC evaluates the bona fide nature of the charitable organization and its charitable mission using the following non-exhaustive, but relevant factors:

- The entity’s tax status;
- The entity’s corporate status under state law; and
- Whether the organization has a charitable mission or purpose.

Terumo may not pay for, or provide tickets to, HCPs or their spouses or guests to attend charitable events, such as galas or golf outings.

Corporate donations (non-medical donations) and local community donations are subject to a separate review and approval process.

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### 9.0 COMPLIANCE

Grants and donations funding shall not be for the purpose of influencing purchase decisions and applicant shall not be required to purchase any Terumo product as a condition to funding under this policy. This policy and the conduct of the Grant Review Committee is intended to, and shall, (i) comply with all applicable federal, state and local laws, regulations and guidelines, including, without limitation, the Federal Anti-Kickback Statute and the regulations promulgated thereunder; (ii) be guided by the substance of the Final Guidance on Industry-Supported Scientific and Educational Activities (62 Fed. Reg. 64,074 (Dec. 3, 1997)) issued by the FDA; (iii) comply with the AMA's Ethical Guidelines, including but not limited to Opinion 8.061, Gifts to Physicians from Industry; and (iv) comply with the AdvaMed Code of Ethics on Interactions with Health Care Professionals (2020).

### 10.0 AUDITING AND MONITORING

This Policy, together with the supporting documents and records required by it, is subject to periodic auditing and monitoring.

### 11.0 RECORDKEEPING

Terumo requires all documentation and records related to grants and donations be maintained and kept in a central filing location, in addition to being saved on the [grantsanddonations@terumomedical.com](mailto:grantsanddonations@terumomedical.com) account.

### 12.0 REVISION HISTORY

Rev #	Summary of Changes
6	Update version of Word from .doc to .docx
7	Update to align with updates made to the AdvaMed Code
8	Updates to refer associates to CA024 for IISR requests