



Merit Medical Global Compliance Policy

A Message on Compliance from Merit's Chairman and Chief Executive Officer

Merit Medical Systems, Inc., a leading manufacturer and marketer of proprietary disposable medical devices used in interventional and diagnostic procedures, is committed to following the highest ethical standards as well as all legal requirements in conducting its business and in its interactions with the medical community.

Merit was founded on the principles of honesty, integrity, innovation, and the determined pursuit of success. Each day, employees strive to understand physician and patient needs and deliver unmatched service in each discipline of our business.

Merit's policies are designed to ensure that its interactions with medical or health care professionals are intended to benefit patients and to enhance the practice of medicine. Merit also believes in safeguarding medical decision-making from improper influence. By following the attached Compliance Program, we improve patient care and protect our customers, employees, and our company.

Fred Lampropoulos
Chairman and Chief Executive Officer

Table of Contents

1	Introduction	3
2	Interactions with Health Care Professionals	3
2.1	Sales and Promotional Meetings with Health Care Professionals	3
2.2	Prohibition on Entertainment and Recreation	3
2.3	Prohibition on Gifts to Health Care Professionals	4
2.4	Providing Meals to Health Care Professionals	4
2.5	Merit-Sponsored Training and Education of Health Care Professionals	4
2.6	Providing Product Support to Health Care Professionals	5
2.7	Evaluation and Demonstration of Products	6
3	Consultants	7
4	Royalty Agreements	8
5	Grants and Donations	9
5.1	Sponsoring Third-Party Educational Conferences	9
5.2	Charitable Donations	10
5.3	Scholarships and Educational Grants	10
5.4	Research Grants	10
5.5	Public Education	10
6	Promotional Materials and Off-Label Promotion	11
7	Sunshine/Transparency Laws	11
8	Reporting Non-Compliance	12
9	Global Compliance Program Charter and Description	12
9.1	Compliance Committee	13
9.2	Auditing and Monitoring of the Compliance Program	13
9.3	Training	13
9.4	Reports	14
9.5	Response to Suspected Violations of the Compliance Program	14
9.6	Enforcement and Discipline	14
9.7	Duties and Powers	14
10	Definitions	15

1 INTRODUCTION

Merit's operations are subject to numerous international, federal, state and foreign laws, directives and regulations. Merit is committed to conducting all of its business activities in compliance with all applicable directives, laws, rules, codes and regulations. Merit's management and employees are dedicated to the highest ethical standards and recognize Merit's duty to conduct its affairs within the bounds of the law.

All Merit Personnel shall be subject to and comply with the standards set forth in the Merit Code of Conduct ("**Code of Conduct**") and this Merit Global Compliance Policy (collectively the "**Compliance Program Documents**"). Appropriate Merit Personnel shall receive a copy of the Compliance Program Documents. Appropriate Merit Personnel shall execute a statement affirming that they have received, reviewed and understood the Compliance Program Documents. In addition, all executive management personnel, sales representatives, and officers and directors shall execute a statement once a year affirming that they have reviewed the most current version of the Compliance Program Documents.

Merit has adopted the Advanced Medical Technology Association's Code of Ethics on Interactions with Health Care Professionals ("**AdvaMed Code**"), and the Medtech Europe Code of Ethical Business Practice ("**Medtech Europe Code**") as guidance for the Merit Compliance Policy.

Merit Personnel should direct any questions regarding the Compliance Program Documents to the Chief Compliance Officer.

2 INTERACTIONS WITH HEALTH CARE PROFESSIONALS

2.1 SALES AND PROMOTIONAL MEETINGS WITH HEALTH CARE PROFESSIONALS

Merit Personnel may conduct informational presentations and discussions with Health Care Professionals to discuss product features, sales terms, and contracts, provided that such communications occur at or close to the Health Care Professional's place of business.

- 2.1.1 **Meals.** In connection with such presentations or discussions, Merit Personnel may offer occasional, modest meals in a manner conducive to the exchange of information.
- 2.1.2 **Travel Costs.** Merit may pay for reasonable travel costs of Health Care Professional attendees, but only when travel is necessary for the presentation of the information, *e.g.*, where plant tours or demonstrations of non-portable equipment are necessary.
- 2.1.3 **Compensation.** Merit Personnel are prohibited from offering anything of value, either directly or indirectly, to a Health Care Professional for time spent listening to marketing information.
- 2.1.4 **Spouses and Guests.** Merit Personnel may not, directly or indirectly, provide meals or refreshments for any person who does not have a good faith professional interest in the information being shared at the meeting. Because spouses and guests are viewed as not having a good faith professional interest, meals or refreshments cannot be provided to such persons.

2.2 PROHIBITION ON ENTERTAINMENT AND RECREATION

Merit Personnel are prohibited from offering entertainment or recreational activities (*e.g.*, sports events; golf outings) to Health Care Professionals who are not Merit employees, regardless of:

- 1. the activity's value,
- 2. whether the Health Care Professional is a Merit speaker or consultant, or
- 3. whether the entertainment is secondary or incidental to an educational purpose.

2.3 PROHIBITION ON GIFTS TO HEALTH CARE PROFESSIONALS

2.3.1 U.S. Rule(s). Merit Personnel may not offer cash or cash equivalents (such as gift certificates, book or music vouchers, etc.) as gifts to Health Care Professionals either directly or indirectly. Merit Personnel may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts, cash or cash equivalents.

2.3.1.1 Allowed Educational Items. Merit Personnel may occasionally supply Health Care Professionals with modest educational items, but only if: (i) the educational item benefits patients and (ii) has a fair market value of less than \$100.

2.3.1.2 Branded Promotional Items. Merit Personnel may not give Health Care Professionals any type of non-educational branded promotional items, even if the items are of minimal value and related to the Health Care Professional's work or for the benefit of patients. Examples of prohibited non-educational branded promotional items include pens, notepads, mugs, and other items that have Merit's logo or name, or the logo or name of one of Merit's products.

2.3.2 Europe Rule(s). Merit Personnel may provide inexpensive educational items and/or gifts, in accordance with national laws, regulations and professional codes of conduct of the country where the Health Care Professional is licensed to practice. Such educational items and/or gifts may only be provided in accordance with the following principles:

- Educational items and/or gifts may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Health Care Professional's practice nor are they for the benefit of patients.
- No educational items and/or gifts should be provided in response to requests made by Healthcare Professionals.
- Educational items and/or gifts must not be given in the form of cash or cash equivalents.
- Educational items and/or gifts must be modest in value, and can be branded or non-branded items.

2.4 PROVIDING MEALS TO HEALTH CARE PROFESSIONALS

Merit Personnel may provide meals of modest value to Health Care Professionals if such a meal is offered incidental to the good faith presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. Meals should only be provided to Health Care Professionals and office staff who actually attend the meeting. Merit Personnel may not provide a meal where a Merit representative is not present.

2.4.1 Setting. Meals should be in a setting that is conducive to scientific, educational or business discussions. The meal should not be part of an entertainment or recreational event.

2.4.2 Guests. Merit may not pay for guests of Health Care Professionals or for any other person who does not have a good faith professional interest in the information being shared at the meeting.

2.5 MERIT-SPONSORED TRAINING AND EDUCATION OF HEALTH CARE PROFESSIONALS

Merit Personnel may conduct informational presentations and discussions with Health Care Professionals to provide product education and training to facilitate the safe and effective use of Merit's products.

2.5.1 Location. Merit Personnel may offer such programs at centralized locations in clinical, laboratory, educational, conference, or other settings, including Merit's own premises, that are

appropriate and convenient for the training. If the product training or education requires “hands on” training, Merit shall provide the training at a training facility, medical institution, laboratory, or other appropriate facility. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen.

- 2.5.2 Instructors.** Merit Personnel shall ensure that the training staff has the proper qualifications and expertise to conduct the training.
- 2.5.3 Hospitality.** Merit Personnel may only provide modest hospitality to Health Care Professional attendees in connection with training programs. Merit shall only provide meals that are modest in value and subordinate in time to the educational or training purpose of the meeting. Merit may not arrange or provide, directly or indirectly, for the cost of any recreational activity by attending Health Care Professionals.
- 2.5.1 Travel Costs.** Merit may pay for reasonable travel costs incurred by the attending U.S.-licensed Health Care Professionals in compliance with the laws and regulations of the United States and the AdvaMed Code, and for Europe-licensed Health Care Professionals in compliance with the laws and regulations of the country where the Health Care Professional carries on their profession, the Europe Medtech Code, and with due consideration to the requirements in the country where the meeting is being hosted. It may be appropriate to consider economy or business class travel in accordance with Merit’s travel policy. For training or educational programs necessitating overnight stays, Merit may pay lodging costs incurred by the attending Health Care Professionals in compliance with, as applicable, the AdvaMed Code and Europe Medtech Code.
- 2.5.2 Guests.** Merit Personnel may not, directly or indirectly, provide meals or refreshments for any person who does not have a good faith professional interest in the information being shared at a meeting. Because spouses and guests are viewed as not having a good faith professional interest, meals or refreshments cannot be provided to them. Merit Personnel may not facilitate or make travel, lodging or meal arrangements or bookings on behalf of a Health Care Professional’s spouse or guest. If a Health Care Professional wants to bring a spouse or guest with him/her to the educational or training event, he/she must make the necessary arrangements. Merit Personnel will not otherwise encourage the participation at Merit-sponsored education or training events of Health Care Professional’s spouses or guests, even if paid for and arranged by the Health Care Professional.
- 2.5.1 Disclosure.** Merit must, in all cases, document in writing the payment of travel, hospitality or lodging costs to Health Care Professionals in relation to their attendance at Merit-sponsored training or education. All payments or transfers of value to U.S.-licensed Health Care Professionals must be reported in accordance with the Sunshine section of this policy, and to non-US Health Care Professionals in accordance with any local transparency laws and regulations. In European countries where no transparency or “Sunshine” laws apply, Merit Personnel should require Employer Notification by the Health Care Professional. “Employer Notification” means the prior written notification provided to a health care entity (*e.g.* hospital administration), a Health Care Professional’s superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Merit and any Health Care Professional, the purpose and/or scope of which requires notification under the Medtech Europe Code.

2.6 PROVIDING PRODUCT SUPPORT TO HEALTH CARE PROFESSIONALS

Merit supports accurate and responsible billing to reimbursement authorities and other payors by providing coverage, reimbursement and health economic information to Health Care Professionals regarding Merit’s products. Merit may provide such information if it is accurate and objective to facilitate

patient access to Merit's products, or identify the clinical value of Merit's products and the services and procedures in which they are used.

Permissible activities involving the providing of coverage, reimbursement and health economic information may include, but are not limited to:

- a. Identifying the clinical value of Merit's products and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
- b. Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- c. Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding Merit's products, including identifying coverage, codes and billing options that may apply to those products or the services and procedures in which they are used.
- d. Providing accurate and objective information about the economically efficient use of Merit's products, including where and how they can be used within the continuum of care.
- e. Providing information related to Merit's products regarding available reimbursement revenues and associated costs.
- f. Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use Merit's products.
- g. Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of Merit's products.

Merit may support the appropriate and efficient use of Merit's products in connection with the sale of Merit's products. Such support should be provided:

- a. in accordance with Merit's own policies,
- b. in accordance with the product's authorized use,
- c. under the clinical supervision and instructions of the Health Care Professional, and
- d. in a manner consistent with the protocols and guidelines of the Health Care Professional's hospital, clinic, or institution.

Merit prohibits the providing of support services for the purpose of unlawfully inducing a Health Care Professional to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Merit's products.

Merit may not interfere with a Health Care Professional's independent clinical decision making or provide coverage, reimbursement and health economics support as an unlawful inducement.

2.7 EVALUATION AND DEMONSTRATION OF PRODUCTS

In accordance with local laws and the AdvaMed and Medtech Europe Codes, Merit may provide single use (e.g., consumable or disposable) products and multiple use products (sometimes referred to as "capital equipment") that have been authorized for marketing, e.g., are approved or cleared by the FDA or bear the CE mark, to Health Care Professionals at no charge for evaluation or demonstration purposes to allow Health Care Professionals to assess the appropriate use and functionality of Merit's products and to determine whether and when to use, order, purchase or recommend Merit's products in the future.

- 2.7.1 Quantity.** Merit may only provide the quantity of single-use products at no charge that is reasonably necessary for the adequate evaluation of Merit's products.
- 2.7.2 Length of Evaluation.** Merit may provide multiple-use products without transfer of title for evaluation purposes only for a period of time that is reasonable to allow an adequate evaluation. The term of an evaluation of such multiple-use products should be set in advance in writing. Merit Personnel must promptly remove such multiple-use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases Merit's products.
- 2.7.3 Demonstration Products.** Merit may provide demonstration products at no charge (typically unsterilized single-use products or mock-ups of such products) for use by Health Care Professionals for patient awareness, education and training. Demonstration products are not intended to be used in patient care. Demonstration products must be designated as not intended for patient use. Merit must provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

2.8 THIRD-PARTY EDUCATIONAL CONFERENCES.

U.S. Rule. Merit may not pay directly for the registration, seminar fees or travel expenses of a U.S.-licensed Health Care Professional's attendance at a third-party educational conference, nor should Merit provide such benefits indirectly as a charitable contribution to a Health Care Professional's not-for-profit institution for the purpose of defraying the costs of an individual's attendance. This restriction applies equally to all non-European jurisdictions, and shall extend to Europe beginning on January 1, 2018. Such a restriction, however, does not prevent Merit from providing educational grants to the third-party conference organizer pursuant to Section 5 below.

Europe Rule. Until December 31, 2017, Merit may provide financial support directly to individual European Health Care Professionals to cover the costs of attendance at third-party educational conferences, if permitted under national laws, regulations and professional codes of conduct. Such support is conditioned on the following:

- The program for the event directly relates to the specialty and/or medical practice of the Health Care Professional;
- The agenda for the educational event is under the sole control and responsibility of the third-party organizer;
- The third-party conference should have the approval of the Conference Vetting System (CVS); see <http://www.ethicalmedtech.eu/conference-vetting-system/objective>;
- Merit may not organize events that include social, sporting and/or leisure activities or other forms of entertainment, nor support such elements as part of the third-party conference event;
- Merit may not facilitate or pay for meals, travel, lodging or other expenses for the guests of Health Care Professionals, or for any person who does not have a bona fide professional interest in the information presented at the event; and
- Hospitality, travel, and other elements of the event are otherwise in accordance with the Medtech Europe Code.

3 CONSULTANTS

Merit may engage Health Care Professionals to furnish bona fide professional services as consultants or advisers for Merit, including research, participation on advisory boards, presentations at Merit-sponsored training or third-party educational conferences, and product research and development. In addition to the

criteria below, the engagement of Health Care Professionals as consultants must also be consistent with the principles set forth in the AdvaMed and Medtech Europe Codes.

- 3.1.1 Selection of Consultants.** Merit Personnel must select consultants on the basis of their qualifications and expertise to address the identified need and under no circumstances explicitly or implicitly related to the past, current or future use, recommendation, prescription or purchase of Merit's products. The selection of consultants must be on the basis of their qualifications and expertise and not on the basis of volume or value of business generated or expected to be generated. The consultant's CV must be included as an attachment to the consulting agreement.
- 3.1.2 Approval.** Prior to entering into a contract with a Health Care Professional for consulting services, the Chief Compliance Officer must identify (i) a legitimate need for the consulting services, (ii) the skills and expertise required of each consultant, (iii) the number of consultants needed, and (iv) the Merit representatives able to select consultants on the basis of their scientific or medical expertise.
- 3.1.3 Contract Requirements.** Merit requires that each consultant enter a written contract approved by the Legal Department specifying the nature of the services to be provided and the basis for payment of the services. This written contract must specifically describe all services to be provided under the contract, must be permitted under the laws and regulations of the country where the Health Care Professional is licensed to practice, and be consistent with applicable professional codes of conduct in that country. Any contract with a consultant for research and development services must include a written research protocol or written schedule of work as appropriate and all required approvals must be obtained.
- 3.1.4 Compensation of Consultants.** The compensation paid to the Health Care Professional engaged as a consultant must be the fair market value of the services provided. To this end, Merit should periodically conduct an assessment of each consultant's value and make, as needed, adjustments to the duration of the relationship, the amount of compensation and/or the type and frequency of deliverables. All payments must comply with applicable tax and other legal requirements. Each consultant must document the activities the consultant performs at Merit's request in advance of receiving compensation, and Merit must retain such documentation.
- 3.1.5 Consultant Expenses.** Merit may pay for reasonable and actual expenses incurred by the consultant in providing the consultancy services, including reasonable and actual travel, meal, and lodging expenses incurred in attending consultancy meetings. The written agreement must describe all expenses that can be claimed by the consultant in relation to the providing of the consultant's services. Records must be kept of all expenses that are reimbursed by Merit.
- 3.1.6 Training of Consultants.** Merit may provide a consultant with training at venues and under circumstances appropriate to the subject matter of the consultation. Merit shall conduct consultant training meetings in clinical, educational, conference, or other settings that are conducive to the exchange of information. Merit may reimburse the consultant for reasonable, actual and documented travel, lodging and meal expenses that the consultant incurs in connection with training when carrying out the subject of the consulting arrangement. Merit prohibits paying honoraria, travel or lodging expenses for any non-consultant attendee.

4 ROYALTY AGREEMENTS

Merit may enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is, based on his/her research and development services, expected to make or has made a novel, significant or innovative contribution to, for example, the development of a product, technology, process or method. Any such arrangement must be set out in a written agreement.

- 4.1.1 Compensation.** The compensation paid to the Health Care Professional under any royalty agreement must be the fair market value of the services provided. Merit must support compensation under each royalty agreement with a fair market value analysis. Documentation of this analysis must be attached to the royalty agreement and maintained by the Compliance Officer. All payments must comply with applicable tax and other legal requirements. Royalties paid in exchange for intellectual property must not be conditional on any requirement that the Health Care Professional purchase, order, recommend, or market any Merit product or technology produced as a result of the development project. Merit must document any significant contribution by an individual or group if it is the basis for compensation.
- 4.1.2 Royalty Rate.** The calculation of royalties payable to a Health Care Professional in exchange for intellectual property must be based on factors that preserve the objectivity of medical decision making and avoid the potential for improper influence, and should exclude from the calculation of royalties the number of units purchased, prescribed, used or ordered by the Health Care Professional or member of his or her practice or health care organization.

5 GRANTS AND DONATIONS

5.1 SPONSORING THIRD-PARTY EDUCATIONAL CONFERENCES

Merit recognizes that bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective health care.

- 5.1.1 Grants.** Merit may provide financial grants directly to the conference organizer to reduce the overall cost of attendance of participants and to cover reasonable honoraria, travel, meals and accommodation expenses to Health Care Professionals who are good faith conference faculty members, provided that: (i) the grant is requested in writing by the conference organizer, (ii) it is paid directly to the conference organizer or training institution, and (iii) the conference organizer is alone responsible for the program content and the faculty selection. Merit may recommend a speaker or comment on the conference's program only if requested by the conference sponsor.
- 5.1.2 Advertising and Booth Space.** Merit may purchase advertisement and lease booth space for Merit displays at conferences.
- 5.1.3 Meals and Refreshments.** Merit may also provide funding to the conference sponsor to support the providing of meals and refreshments to conference attendees if such meals and refreshments are provided to all Health Care Professional attendees and in a manner that is consistent with the standards established by the conference sponsor and the body accrediting the educational activity. Merit may provide meals and refreshments to fewer than all attending Health Care Professionals if the providing of such meals would be otherwise acceptable under Section 2.4, *Providing Meals to Health Care Professionals* and any other applicable Merit policies. All meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.
- 5.1.4 Recreational Activity.** Merit may not arrange or provide, directly or indirectly, for the cost of any recreational activity by attending Health Care Professionals.
- 5.1.5 Satellite Symposia.** Merit may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous. Merit may determine the content of these events and be responsible for faculty selection. All related arrangements must be documented in written contract and all satellite symposia-related materials must disclose Merit's sponsorship.

5.1.6 Documentation. Merit must, in all cases, document the sponsorship of Health Care Professionals' attendance at conferences or the providing of financial grants to conference organizers. Documentation must be maintained by the Compliance Officer.

5.2 CHARITABLE DONATIONS

Merit may make donations for charitable or other philanthropic purposes which may include supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations may be made to support the general activities of a bona fide organization or may be made to support the general fundraising drives for projects undertaken by such an organization. Merit shall have no control over the final use of funds provided.

5.2.1 Recipient. Merit may make donations only to charitable organizations and may not make donations to Health Care Professionals or other individuals. Charitable donations may not be tied in any way to past, present or potential future purchase or use of Merit's products. Merit may not make charitable donations in response to requests made by Health Care Professionals unless the Health Care Professional is an employee or officer of the charitable organization and submits a written request on behalf of the organization.

5.2.2 Documentation. Merit Personnel must maintain accurate and appropriate documentation of all donations. Documentation must be maintained by the Compliance Officer.

5.3 SCHOLARSHIPS AND EDUCATIONAL GRANTS

If the academic or training institution is responsible for recipient selection or if the grant is paid directly to a third-party conference sponsor, then Merit may provide financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other Health Care Professionals in training to attend bona fide educational conferences.

5.3.1 Recipient. Merit may only provide grants to organizations with a genuine educational purpose or function that will use the funds for legitimate expenses for educational activities consistent with relevant guidelines established by professional societies or organizations.

5.3.2 Documentation. Merit Personnel must maintain accurate and appropriate documentation of all scholarship and educational grants, which documentation must be maintained by the Compliance Officer.

5.4 RESEARCH GRANTS

Merit may provide financial support for good faith, independent general research grants that are intended to provide valuable scientific and clinical information, improve treatment, promote better delivery of health care, or otherwise benefit patients. Merit prohibits the funding of a research grant if it is, expressly or implicitly, provided for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Merit's products.

5.4.1 Restricted Grants. Merit prohibits the awarding of any restricted grants or grants made conditional with respect to content or faculty. This prohibition applies in Europe, even though restricted grants are allowed, subject to certain conditions, under the Medtech Europe Code.

5.4.2 Documentation. Merit Personnel must maintain accurate and appropriate documentation of all grants. Documentation must be maintained by the Compliance Officer.

5.5 PUBLIC EDUCATION

Merit may make grants for the purpose of supporting education of patients or the public about important health care topics. Such grants may only be made to entities such as hospitals, associations, or other

entities with a charitable or public health mission. Merit may not make grants to Health Care Professionals or entities that are owned and operated by Health Care professionals.

- 5.5.1 Documentation.** Merit Personnel must maintain accurate and appropriate documentation of all public education grants, including documents demonstrating how the public education grants were used. Such documentation must be collected from the grant recipient within a reasonable time following the distribution of grant funding or the occurrence of the public education event. Documentation must be maintained by the Compliance Officer.

6 PROMOTIONAL MATERIALS AND OFF-LABEL PROMOTION

All promotional and marketing materials shall be accurate, clear, non-misleading, fully informative and in compliance with applicable laws. All of Merit's marketing, promotional and training materials and messages must be consistent with the product's intended purpose, authorized labeling, and instructions for use.

- 6.1.1 Approval.** All materials used in the promotion and marketing of Merit's products require the prior authorization by Merit's Regulatory, Legal and Compliance departments.
- 6.1.2 Off-Label Promotion.** Merit Personnel, or third-party intermediaries, carrying out sales functions, must under no circumstance discuss with Health Care Professionals unauthorized uses of Merit's products, or the use of Merit's products in a way that is not in conformance with their intended purpose, authorized labeling and instructions for use. Inquiries made by Health Care Professionals about uses of Merit's products outside their authorized use or in a way that it is not in conformance with their intended purpose, authorized labeling or instructions for use, can only be responded to by Merit's Medical Science Liaisons, in accordance with GPS 999.124.
- 6.1.3 Promotion Before Product Approval Prohibited.** Merit Personnel, or third-party intermediaries, carrying out sales functions, must under no circumstance promote any product until its formal regulatory approval. This includes making statements concerning efficacy, safety, superiority, or implying efficacy, safety or superiority of a particular product. Merit Personnel or any person acting on behalf of Merit shall not represent to Health Care Professionals or other third parties that an investigational product is safe or effective for the purpose for which it is currently under investigation.
- 6.1.4 Scientific Information.** This policy is not intended to restrict the full exchange of scientific information, including dissemination of scientific findings.

7 SUNSHINE/TRANSPARENCY LAWS

Merit Personnel must track and report payments or other transfers of value made by Merit to U.S.-licensed Health Care Providers as required by Section 6002 of the Patient Protection and Affordable Care Act, Transparency Reports, and Reporting of Physician Ownership or Investment Interests (the "**Sunshine Act**"), as well as reporting under analogous state laws and the transparency laws of any country, *e.g.*, France. Merit recognizes that Health Care Providers play an essential role in the development, testing and training involved in producing safe and effective medical devices. Merit also recognizes that the interests of the patient are often best served by a collaborative relationship with Health Care Professionals. Tracking and reporting payments and transfers of value made to health care providers in the context of these relationships ensures that Merit's financial arrangements with Health Care Professionals are fully transparent.

- 7.1.1 Reporting.** For U.S.-licensed Health Care Providers, Merit will collect and report data to the Centers for Medicare and Medicaid Services (CMS) and applicable state agencies on an annual basis (or as required by law) regarding direct and indirect payments or other transfers of value provided to Health Care Providers during the preceding calendar year, and direct and indirect

payments or other transfers of value provided to a third party at the request of or designated by Merit on behalf of a Health Care Providers during the preceding calendar year. The Chief Compliance Officer will be responsible for preparing the reports containing the required data according to the due dates and applicable deadlines. The Chief Compliance Officer will certify the reports before they are submitted to CMS, as well as any state reports that require certification by an officer of Merit.

- 7.1.2 Recipients Subject to Tracking.** The Sunshine Act requires Merit to report payments and transfers of value to physicians and teaching hospitals. Because certain state laws may require the reporting of payments and transfers of value to other recipients such as physicians assistants and nurse practitioners, Merit will track and report all payments and transfers of value to Health Care Professionals.
- 7.1.3 Examples.** The following are examples of the types of payments and transfers of value that must be tracked and reported: meals, educational gifts, travel expenses, speaking and consulting fees, journal and text reprints, referral and advertising services, suggestion of speakers with funding for CME events, grants and charitable contributions, payments made in connection with clinical trials, and royalties. However, the specific payments and transfers of value that must be reported varies by jurisdiction.
- 7.1.4 Tracking System.** Merit Metro Expense Tracker and the Sunshine Check Request Form are the systems employees must utilize for tracking and requires employees to document the following:
- a. Date of payment or transfer of value
 - b. Amount
 - c. Name and/or national provider identifier (NPI)
 - d. Nature or category of payment or transfer of value
 - e. Related product and therapeutic area
 - f. Name of principal investigator, research institution and research study (as applicable)
- 7.1.5 Disputes by Recipients.** The Sunshine Act provides for a 45-day period in which covered recipients can dispute payments and transfers of value reported by Merit. All disputes should be directed to the Chief Compliance Officer. As needed, the Chief Compliance Officer will oversee the disputes and make timely corrections if necessary.
- 7.1.6 Training.** Merit will train its affected employees on the Sunshine Act and analogous state laws when hired and provide refresher training to such employees at least once every three years.

8 REPORTING NON-COMPLIANCE

Merit has an anonymous Whistleblower Hotline to report all compliance and legal violations, including those in this policy, as well as fraud, theft, organizational conflicts, bribery, kickbacks or other violations. The Whistleblower Hotline is managed by an independent third party outside of Merit. Merit does not permit retaliation of any kind against employees for good faith reports of ethical violations. See <https://merit.alertline.com/gcs/welcome> (in Europe please use <https://meriteu.alertline.com>) or call 1 (877) 874-8416.

Any individual who reports a compliance concern in good faith will not be subject to retaliation or harassment as a result of the report. Merit Personnel are encouraged to self-report any of their own suspected violations, although self-reporting does not necessarily shield Merit Personnel from disciplinary action resulting from his or her own violation of the Compliance Program.

9 CORPORATE COMPLIANCE PROGRAM CHARTER AND DESCRIPTION

Merit has adopted policies and procedures addressing legal requirements and industry standards in connection with interactions with medical or health care professionals, including the policies and

procedures contained in this document, which are designed to ensure compliance with any relevant guidance published by the Office of Inspector General, the Department of Health and Human Services, and the Center for Medicare and Medicaid Services.

9.1 COMPLIANCE COMMITTEE

- 9.1.1 Overview.** Merit has designated the Corporate Compliance Committee (“**Committee**”) and a Compliance Officer to oversee the implementation and operation of the Corporate Compliance Program. The Committee, Compliance Officer, and Chief Legal Officer have the authority to report directly to the Board of Directors and the CEO with respect to compliance issues. The Committee shall assist the Compliance Officer in overseeing Merit’s compliance with laws, regulations and the Compliance policies and procedures.
- 9.1.2 Composition and Qualification.** The Committee shall consist of the Chief Compliance Officer, Chief Regulatory Officer, Chief Legal Officer, and certain members of senior management (“**Management Members**”).
- 9.1.3 Appointment and Removal.** The Management Members of the Committee shall serve until such member’s successor is duly appointed or such member’s earlier resignation or removal. The Management Members of the Committee may be removed, with or without cause, by the Committee at any time.
- 9.1.4 Chairman.** The Chairman of the Committee shall be the Compliance Officer. The Chairman will chair all regular sessions of the Committee and set the agendas for Committee meetings.
- 9.1.5 Meeting Procedures.** The Committee shall meet on a quarterly basis or as otherwise necessary or desirable to carry out its responsibilities, on notice to all by the Chairman. Any meeting of the Committee may be held telephonically. In addition, as the Compliance Officer finds it necessary or desirable, the Committee shall meet with management, internal and external auditors, regulatory affairs personnel, legal department, and other Merit employees to assess the state of regulatory compliance.
- 9.1.6 Quorum and Minutes.** A majority of the Committee shall constitute a quorum for the transaction of business, and the acts of a majority of those present at any meeting at which there is a quorum shall be the act of the Committee. The Committee shall keep regular minutes of its proceedings.

9.2 AUDITING AND MONITORING OF THE COMPLIANCE PROGRAM

Periodic audits of the Compliance Program shall be conducted to measure the effectiveness of the program. These audits shall ensure that the Compliance Program has been disseminated appropriately, that the anonymous reporting system has been implemented and is functioning properly, and that any reported compliance or legal issues have been addressed and no longer occur. All audit results shall be incorporated into training and education programs as appropriate. The Compliance Committee will establish monitoring and auditing priorities based on factors that may include: 1) identified risk factors; 2) industry trends; 3) government enforcement actions; 4) changes in statutes, regulations, or case law; or 5) other relevant factors as determined by the Compliance Officer. The results of all internal and external audits will be communicated to the Compliance Committee.

9.3 TRAINING

The Compliance Officer will provide all Merit Personnel with appropriate training and education on the Compliance Documents.

- 9.3.1 Employees.** The Compliance Officer will identify new employees who should receive compliance training, and will provide training within 90 days of hire. Sales and marketing employees will also be provided with such training every three years. Attendance at training

sessions shall be documented by the Compliance Officer. Following training, all employees must execute a certification demonstrating receipt and understanding of the Compliance Program training. The Compliance Officer will retain these certifications for ten years.

9.3.2 Contractors. The Compliance Officer will also identify Merit contractors with potential compliance responsibilities to ensure that appropriate training and education is provided to those contractors.

9.3.3 Education and Alerts. The Compliance Officer will conduct general compliance seminars on an as-needed basis to discuss pertinent laws and regulatory developments. When appropriate, the Compliance Officer or a member of the Legal Department shall disseminate to appropriate Merit Personnel alerts regarding new rules, regulations, fraud alerts or similar compliance notices issued by relevant government or professional entities. A record of these alerts shall be maintained by the Compliance Officer for ten years. The identity of the Compliance Officer shall be stated in all education materials, alerts, notices, manuals, and presentations.

9.4 REPORTS

The Compliance Officer and Chief Legal Officer shall track all reports and provide a summary to the Compliance Committee and the Merit Board of Directors on a quarterly basis, or more frequently as needed or requested by the Compliance Committee or Merit Board of Directors. Reported compliance issues shall be investigated and analyzed by the Chief Compliance Officer and Chief Legal Officer. The Chief Compliance Officer will track the matter to ensure that all necessary follow-up action has been taken. The Chief Legal Officer will analyze all facts as it applies to the law and policy.

9.5 RESPONSE TO SUSPECTED VIOLATIONS OF THE COMPLIANCE PROGRAM

If a violation of any applicable law, regulation, or standard of conduct relating to Merit's business is detected, Merit shall take all reasonable steps to respond appropriately to the violation and to prevent further similar violations, including any necessary modifications to its Compliance Program. The Chief Legal Officer and Compliance Officer shall have the discretion to determine the scope of any investigation and the response. Appropriate responses to a violation or suspected violation may include, without limitation: 1) investigating all aspects of the alleged violation; 2) preparing recommendations for corrective action; 3) considering the advisability of disclosing the incident to government entities; or 4) formally notifying Merit's Board of Directors of the incident and the planned response.

9.6 ENFORCEMENT AND DISCIPLINE

It is Merit's policy that the Compliance Program Documents shall be consistently enforced through appropriate disciplinary mechanisms. Disciplinary actions may be up to and including dismissal, and may extend, as appropriate, to individuals responsible for the failure to prevent, detect, or report an offense. The annual employment review of applicable Merit Personnel shall include an assessment of adherence to the Compliance Program Documents. A record of any discipline resulting from noncompliance with the Compliance Program Documents shall be maintained, both in the compliance file and in the personnel record.

9.7 DUTIES AND POWERS

The Compliance Officer is responsible for the operation of the Corporate Compliance Program, including: a) assisting the Legal and Regulatory departments to develop policies and procedures to ensure compliance with laws and regulations, and if applicable, Merit's Code of Conduct and Policies and Procedures; b) implementing, maintaining, and administering the Corporate Compliance Program, including written policies and procedures; ensuring that independent contractors and agents, including distributors, are aware of the requirements of the Corporate Compliance Program; c) assisting Merit's

internal auditors in coordinating internal compliance review and monitoring; reviewing audits and reports prepared by auditors or investigators; developing effective lines of communication, including providing contact information for Merit's compliance department and anonymous hotline to facilitate reporting violations; d) reviewing and, where appropriate, promptly taking corrective action in response to reports of noncompliance received through the hotline (or other established reporting mechanism) or otherwise brought to his or her attention; e) with the Chief Legal Officer, investigating matters related to compliance; f) organizing and maintaining all documentation regarding the Corporate Compliance Program; g) interpreting and providing guidance on any issue concerning the Corporate Compliance Program; h) monitoring developments relating to compliance with applicable directives, laws, regulations, and the Compliance Program Documents; i) certifying annually that Merit had adopted and effectively implemented a Corporate Compliance Program; and j) any other duties as may be assigned by the Board of Directors or as required, ensuring that the Corporate Compliance Program meets its objectives.

10 DEFINITIONS

- 10.1.1 **"AdvaMed Code"** means the Advanced Medical Technology Association's Code of Ethics on Interactions with Health Care Professionals (effective July 1, 2009), available at: <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>.
- 10.1.2 **"Medtech Europe Code"** means the Medtech Europe Code of Ethical Business Practice (effective January 1, 2017), available at: http://www.medtecheurope.org/sites/default/files/resource_items/files/Medtech%20Europe%20Code%20of%20Conduct.pdf
- 10.1.3 **"Health Care Professional"** means individuals (clinical or non-clinical, including but not limited to physicians, nurses, technicians and research coordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of or prescribe Merit's products.
- 10.1.4 **"Merit Personnel"** includes Merit officers, directors, executives and employees as well as the officers, directors, executives and employees of its wholly-owned subsidiaries and affiliated entities.