Global Business Conduct Standards

The Office of Ethics and Compliance (OEC) has revised the Global Business Conduct Standards Policy (BCS) to reflect global changes in industry codes of ethics. In 2020, the OEC will continue to review and update requirements related to the BCS. If you discover existing policy or guidance that is in conflict with the updated BCS Policy, please contact your Business Group or Regional Compliance Officer. A list of Compliance Officers can be found here.

Purpose

Medtronic is committed to interacting with all healthcare providers, healthcare organizations, and anyone with a material influence over the use or purchase of Medtronic Technologies with integrity and in compliance with all applicable laws, regulations, and industry codes of conduct. This policy outlines the requirements employees must follow to conduct business in an ethical and compliant manner.

Scope

The Global Business Conduct Standards and related policies and procedures (“BCS”) regulate interactions between employees and any individuals or entities who prescribe, purchase, lease, recommend, use, or arrange the purchase and lease of Medtronic Technologies (“Healthcare Professional” or “HCP”).

For purposes of this policy, HCP includes:

- Healthcare providers, including non-physician practitioners, medical fellows, medical students, or healthcare providers who are government officials (collectively, “Healthcare Providers”);
- Healthcare organizations, including but not limited to hospitals, universities, medical practices, companies formed/owned by Healthcare Providers to perform personal consulting services (e.g. LLC), or patient advocacy groups led or directed by Healthcare Providers (collectively, “HCOs”);
• Any HCP or HCO staff member, Relative, or affiliated organization, if in a position to influence the decision to buy or use Medtronic Technologies; or
• Any other individuals or entities in a capacity to directly recommend or materially influence the purchase or use of Medtronic Technologies.

For the purposes of this policy, Medtronic Technology(ies) means any Medtronic medical devices and products, technologies, digital and software platforms, related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities.

The BCS applies to all Medtronic employees regardless of citizenship, the country in which they work, their level in the company, or the legal entity that employs them (collectively, “Employees”).

Although the scope of the BCS does not include Medtronic’s board members or third parties acting on behalf of Medtronic (such as distributors, sales agents, or consultants), many of the same principles apply. Medtronic may not engage third parties to do what the BCS prohibits Employees from doing themselves. In many cases, Medtronic has adopted specific compliance policies or other guidance to ensure appropriate interactions with HCPs by these third parties. (See Related Policies.)

Similarly, although the scope of the BCS does not include interactions with others with whom we do business such as non-HCP government officials or patients, many of the same principles apply. Medtronic will not attempt to inappropriately influence these parties to advance its business. In many cases, Medtronic has adopted specific policies to address these interactions (See Related Policies).

**Policy Statement**

Medtronic has a responsibility to ensure that interactions with HCPs are conducted in an ethical and compliant manner. Medtronic will not attempt to inappropriately influence an HCP through an improper inducement. This means that Employees will not offer or provide (directly or indirectly) an improper payment or anything of value to an HCP as a reward for prior business or to encourage the future use or purchase of Medtronic Technologies.
The General Provisions section and 12 Standards outline how Medtronic ensures Employee interactions with HCPs are ethical, compliant, and aligned with legal and industry standards or requirements.

- General Provisions: Requirements for every HCP interaction
- Standard 1: HCP Consulting Arrangements, product development agreements, and clinical research arrangements
- Standard 2A: Medtronic-sponsored training and education
- Standard 2B: Business meetings
- Standard 3: Grants, donations, and sponsorships
- Standard 4: Jointly conducted education and marketing programs
- Standard 5: Travel and lodging
- Standard 6: Meals and refreshments
- Standard 7: Educational items and gifts
- Standard 8: Entertainment and recreational activities
- Standard 9: Communicating about approved and unapproved uses of Medtronic Technologies
- Standard 10: Reimbursement activities
- Standard 11: Provision of products or equipment at reduced prices or no charge.
- Standard 12: Technical support in Clinical Setting

Employees must comply with this policy unless a more restrictive law, regulation, rule, industry code, or Medtronic policy applies. If a more restrictive requirement exists, then Employees must comply with the more restrictive provision.

For many Standards additional global, regional, or group policies, procedures, or guidance apply. Employees are responsible for knowing and understanding the rules that apply to their interactions with HCPs. Additionally, managers must supervise their direct reports’ compliance with these requirements. Employees should consult with their manager or Compliance/Legal partner for questions about this policy or a proposed interaction with an HCP.

Exceptions. Medtronic strongly discourages exceptions to the BCS. While the following Standards govern most situations, there might be occasions
where a proposed interaction is appropriate even though it appears to conflict with the BCS. In these rare cases, a regional or group Compliance/Legal partner may grant an exception if the proposed interaction is lawful and ethical. Employees seeking an exception must follow the applicable exception process and receive approval prior to engaging in the activity. Please contact the applicable Compliance/Legal partner for additional guidance.

**Investigations and Misconduct.** Employees must be candid and cooperative during any investigation, BCS-related or otherwise, including being truthful and forthcoming during any review of a potential policy violation. This is consistent with the Global Code of Conduct. Medtronic may discipline an Employee, up to and including termination, if the Employee violates this policy or directs or encourages another to do so. Each Employee is responsible for promptly bringing violations and suspected violations of this policy to the attention of Medtronic through management, their regional or group Compliance/Legal team, the Human Resources team, or by using the Voice Your Concern confidential reporting mechanism.

**General Provisions**

This section outlines requirements that apply to all interactions with HCPs.

**Part A. Legitimate Need.** Legitimate Need is a justifiable clinical, business, charitable, or educational reason for an interaction or activity. Anything of value provided directly or indirectly to reward past purchases or to influence an HCP to purchase or use Medtronic Technologies in the future is not a “Legitimate Need” and is prohibited.

**Part B. Payments or other benefits to HCPs.** All payments or the provision of any benefit to an HCP must be reported in a timely and traceable manner. Payments, services, or grants to HCPs or contracts to supply Medtronic Technologies must also be documented in writing, based on Fair Market Value, and approved in advance. The following requirements apply:

1) **Timely Reporting.** Employees must report payments and all other benefits provided to or on behalf of HCPs to Medtronic in a timely manner (as defined by local regulations) using the applicable Finance reporting system and attributing them to individual HCPs accurately and completely.
2) **Traceable.** When an HCP provides goods or services directly to Medtronic, Medtronic must pay the HCP with traceable company funds (i.e. by Medtronic check, Medtronic credit card, or wire transfer from a Medtronic account). Employees must not pay an HCP in cash, by personal check, or by personal credit card.

3) **Fair Market Value.** When Medtronic transfers value to an HCP, it must represent Fair Market Value (“FMV”) for the goods or services provided. FMV is the market or objective value of the goods or services. How FMV is determined depends on what is being provided and to whom. Please review the additional requirements outlined in the Standards below.

4) **Approval.** Employees must not make commitments to HCPs until they obtain all required approvals according to the applicable policy/system. Employees must follow the appropriate approval process regarding each interaction and expense. Certain roles at Medtronic are subject to additional restrictions or specific rules (e.g. limits on how sales personnel may be involved in decisions on Clinical Research).

**Part C. Engaging a Healthcare Provider from Another Country (Cross Border Engagements).** Medtronic must comply with the laws and regulations of the country where a Healthcare Provider is licensed to practice or where they work, regardless of where they interact with Medtronic. When an Employee plans an interaction with a Healthcare Provider, the Employee must consult with the local Compliance/Legal partner responsible for the country where the Healthcare Provider works for guidance on the requirements applicable to that Healthcare Provider. The Employee then must obtain necessary approvals from that local Compliance/Legal department prior to committing to the Healthcare Provider.

**Part D. Undue Influence by Sales Personnel.** Sales personnel may not unduly influence decisions related to the selection of HCPs under Standard 1 or the award (both in terms of recipient and amount) of research, grants, or donations under Standard 3. Follow regional or group policies for how sales personnel may be involved.
Standard 1. HCP Consulting Arrangements

Medtronic engages HCPs to provide a wide range of valuable, bona fide services to support Medtronic’s business needs.

Part A. HCP Consulting Arrangements. Medtronic relies on HCPs for various consulting services (e.g., training and education, proctoring and preceptorships, reference center or center of excellence services, and participation on advisory boards or in focus groups) (collectively “Consulting Arrangements”). Before engaging an HCP for a Consulting Arrangement, the Employee accountable for the Consulting Arrangement must document (1) an appropriate purpose for the type of Consulting Arrangement; (2) the need for use of the HCP; and (3) the scope of work conducted by the HCP. Designing or creating a Consulting Arrangement to generate business from that HCP is not a Legitimate Need and is a clear BCS violation. Employees must not engage more HCPs than necessary to conduct a specific Consulting Arrangement. Employees should assess the frequency of using an HCP for repeat Consulting Arrangements to confirm there is still a Legitimate Need to use the HCP and to ensure the aggregate payment will not unduly influence the HCP. All HCP Consulting Arrangements further require:

1) A Written Agreement. There must be a written agreement (“Consulting Agreement”) that:
   a. Identifies the Legitimate Need for the consulting services;
   b. Specifies all services that the HCP will provide, the term of the agreement, the payment rate or amount, and any Medtronic obligation to reimburse for travel, lodging, meals, and other expenses relating to the consulting activity; and
   c. Is executed by both Medtronic and the HCP before the start of the services.

2) Qualified HCPs. Employees must select HCPs based on their qualifications, expertise, and capacity to provide the services needed for the Consulting Arrangement. While the qualifications may include experience with, usage of, or familiarity with a Medtronic Technology, Employees must not select HCPs to reward their past usage or to unlawfully induce them to provide future business to Medtronic.
3) **Fair Market Value Compensation.** Medtronic determines appropriate compensation rates based on Fair Market Value (FMV) for the services sought under the Consulting Agreement in the country where the Healthcare Provider resides or practices or the Healthcare Organization is located (“FMV Rates”). The FMV Rate is set using objective criteria such as the HCP’s specialty, years and type of experience, geographic location, practice setting, industry standards, and an evaluation of the types of services performed (taking into consideration effort, length of time, and the unique expertise needed for the service or activity.)

When Employees hire an HCP as a consultant, Medtronic may pay for reasonable and actual expenses incurred by the HCP that are necessary to carry out the consulting services, such as costs for travel, lodging, and modest meals. Employees must not hire HCPs for general services or services on an as-needed basis with payment prior to the receipt of services (e.g. retainer agreements). Employees must confirm that the services subject to the Consulting Agreement have been provided before paying the HCP. Finally, Employees must not perform any duties for which an HCP has been contracted and paid to carry out.

**Part B. Product Development Services.** The following additional requirements apply to Consulting Arrangements for services provided by a Healthcare Provider or group of Healthcare Providers to support the joint development of a new/enhanced Medtronic product or therapy where the Healthcare Provider contributes intellectual property important to the design of the Medtronic Technology. (“Product Development Arrangements.”)

Product Development Arrangements may be initiated when the following requirements are met:

1) **Design Healthcare Provider Qualifications.** Healthcare Providers participating in a Product Development Arrangement should have previous design experience, familiarity with similar systems (both Medtronic and competitive), significant experience with the disease state or condition for which the product is being developed, and an understanding of the capabilities and experience of the average Healthcare Provider in treating the condition. Diversity
across the development team is also useful in creating a robust design and broad applicability of the solution.

2) Novel, Significant, or Innovative Contribution. Payments may be triggered when Healthcare Providers (either individually or part of a team) make a novel, significant, or innovative contribution to the development of a product, technology, process, or method. Such contributions may be in the form of trade secrets, know how, patents, or patent applications. The contributions from the Healthcare Providers must exist in the final commercial Medtronic Technology where Medtronic can demonstrate that the contribution provides a benefit to the design over existing products or technologies.

3) No Excessive or Duplicate Payments. Product Development Arrangements may involve alternative payment arrangements such as royalties (e.g. a percentage of product sales) or milestones (e.g. payment upon the achievement of certain development milestones). Employees must document these payment arrangements in a written agreement (“Product Development Agreement.”) These payment models must consider the total benefit to Medtronic over the course of the product sales model and fairly compensate Healthcare Providers for their contributions of intellectual property. The key principle is that Medtronic must not pay for this intellectual property twice. Therefore:

a. Royalty Payments. Product Development Agreements with royalties should (1) include a cap on the total amount of royalties that Medtronic may pay to the HCP over the life of agreement; and (2) ensure that payments a Healthcare Provider receives for Product Development Arrangements provided during the development of the product or therapy are deducted from any subsequent royalty payments owed for the same product or therapy.

b. Milestone Payments. Milestone payments should be risk-adjusted to account for the risks associated with bringing Medtronic Technologies to market.

4) Avoid Undue Influence. Employees must calculate payments for Product Development Arrangements based on factors that preserve the objectivity of medical decision-making and avoid the potential for
improper influence. This includes limiting the ability of the Healthcare Providers to earn royalties from sales of the products in any HCO where the Healthcare Provider practices or has influence over purchasing or decisions about the use of Medtronic Technologies. Medtronic also limits the ability of Healthcare Providers with Product Development Agreements to participate in clinical trials (see Section 1, Part C.4).

5) **No Promotional Requirement.** Product Development Agreements must not condition payments on either (1) a requirement that the Healthcare Provider purchase, order, or recommend any Medtronic Technology or any product or technology products as a result of the Product Development Arrangement; or (2) a requirement to market the product or technology upon commercialization.

**Part C. Arrangements for Clinical and Pre-Clinical Research.** Clinical (human subject) and Pre-Clinical (bench, animal, or cadaver) research arrangements should (1) be driven and managed by the appropriate scientific function; (2) fulfill a clear and documented legitimate research purpose related to Medtronic strategy; and (3) not be inappropriately influenced by sales personnel. In addition to the requirements listed in Part A, the following requirements apply to Consulting Arrangements involving clinical studies and research.

1) **Clinical and Pre-Clinical Research Arrangements with an HCO.** Medtronic generally enters research arrangements directly with an HCO for Medtronic Sponsored or Collaborative Research involving Clinical and Pre-Clinical Research. A written agreement with the HCO is required to document the payment to the HCO (a “Clinical Research Agreement”). Compensation for the research arrangements are based on the costs associated with the funding of the research (e.g. for study execution activities based on local FMV Rates and/or infrastructure costs, equipment, or material costs based on local FMV Rates). A written protocol is required for Clinical Research. Pre-Clinical Research needs a protocol, research plan or written procedures. No Clinical or Pre-Clinical Research may occur without being approved by the responsible ethical review board at the HCO if required (for example, for Clinical Research review by an institutional review board and for Pre-Clinical Research review by an institutional animal care and use committee). If permitted by regional
policy, limited consulting services (e.g. research design or protocol development) may be included in an agreement for Pre-Clinical Research. Employees should consult regional or group Compliance/Legal teams on the requirements for consulting services for Pre-Clinical Research. All Medtronic-sponsored research must adhere to the executed research agreement and to any applicable local laws.

2) **Consulting Arrangements with a Healthcare Provider.** Clinical Consulting Arrangements may include activities related to the conduct of Clinical Research or Pre-Clinical Research such as developing or advising on the protocol or design of the research but does not include the conduct of any activities covered under the Clinical Research or Pre-Clinical Research Arrangements with an HCO. In these situations, Employees must create a separate written agreement with the Healthcare Provider meeting the requirements under Standard 1, Part A. The agreement must differentiate the work done under any agreement with the HCO for the same research. There must be no overlap in the scope of services between the two sets of agreements and no duplication of compensation.

3) **Scientific Publications.** Healthcare Providers and Employees who serve as authors, contributors, editors, or reviewers for peer-reviewed publications must follow internationally-accepted standards for authorship, contribution, and disclosure of financial interests such as the International Committee of Medical Journal Editors. Medtronic prohibits compensation for publication writing or editing activities to Healthcare Providers.

4) **HCPs with Product Development Agreements.** HCPs with Product Development Agreements:
   a. May participate as investigators for clinical feasibility or post-market surveillance studies required by regulatory authorities only with approval from their institutional review board regarding research subject protections;
   b. Must not participate as investigators in any Medtronic-sponsored clinical study activities regardless of whether the HCP’s invention is involved in the study; and
c. Must not participate on any data safety monitoring board or adverse events adjudication committee for products that incorporate their inventive contributions.

Standard 2. Medtronic-Conducted Programs and Meetings

Part A. Medtronic Training and Education Programs (“Medical Education”). Medtronic may organize instruction, education, or training sessions on the safe and effective use of Medtronic Technologies and role of Medtronic Technologies in the continuum of care. Medical Education programs may include experiential product training and didactic education on the approved use of Medtronic Technologies and related services and support programs. Educational content must be consistent with the regulatory approval for the product and should not include discussion of uses of Medtronic Technologies that are inconsistent with approved labeling. Only Medtronic Employees and/or faculty who have relevant experience or qualifications may provide training on Medtronic Technology.

All Medical Education events must meet the travel and lodging (Standard 5) and meals (Standard 6) requirements. To conduct a Medical Education event, Employees must meet the following requirements:

1) Agenda. Training and education must constitute a substantial majority of the program on each day of the program. The agenda must not include activities that would constitute entertainment or recreation under Standard 8.

2) Setting. Conduct live and virtual training and education programs in settings that are conducive to the exchange of scientific or educational information and appropriate under any local laws or regulations. Appropriate settings may include the Healthcare Provider’s own facility, clinical, educational, or other settings such as hotels, conference centers, or other suitable meeting facilities. Hold programs involving experiential technical training and instruction on Medtronic Technologies (e.g. a cadaver lab) at Medtronic facilities, surgical training facilities, medical institutions, laboratories, or other appropriate facilities.

3) Attendees. All HCP attendees must have a Legitimate Need to learn the information presented at the Medical Education program. HCPs
or guests who do not individually have a Legitimate Need to learn the content must not attend Medical Education programs. Employees must not pay honoraria or service fees to HCPs for attending Medical Education events as participants or attendees.

**Part B. Business Meetings.** Business Meetings are meetings between an Employee and an HCP to discuss product features, instructions for use of Medtronic Technologies, sales terms, contracts, coding and reimbursement, patient access to therapies, and other scientific, educational, or business topics relevant to Medtronic. Employees may conduct Business Meetings with HCPs to have bona fide scientific, educational or business discussions. Employees must not conduct Business Meetings in conjunction with entertainment or for the primary purpose of socializing or building relationships.

1) **Setting.** Employees must hold Business Meetings at locations, settings, and times conducive to genuine scientific, educational, or business discussions. Plan interactions in the location where most or all HCP attendees live or work, unless there is a Legitimate Need to hold the meeting elsewhere.

2) **Attendees.** Each HCP in attendance must have a Legitimate Need to attend a Medtronic Business Meeting. Guests who do not themselves have a Legitimate Need to participate in a Business Meeting should not attend.

3) **Medtronic Facilities.** Employees may hold Business Meetings at Medtronic facilities (e.g. manufacturing, research and development, or learning labs) when there is a Legitimate Need to bring the HCP to the specific location. Plant tours and other such product or manufacturing-oriented Business Meetings with HCPs must follow applicable local procedures approved by the regional or group Compliance/Legal team.

**Standard 3. Grants, Donations, and Sponsorships**

Medtronic may donate money or Medtronic Technology for appropriate educational, scientific, or other charitable purposes. Medtronic must not make monetary or product donations:

- To individual HCPs;
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- To influence the judgment of an individual HCP;
- As a reward for past purchases or to induce the future purchase of Medtronic Technologies; or
- During a period restricted by local tendering or other laws and regulations (if applicable and known).

Employees must follow regional procedures to obtain required preapprovals and document in writing the support for giving grants, donations, and sponsorships. The type of documentation required is based on the program and type of support provided. Medtronic must not pass along any benefits to an HCP that Medtronic receives in exchange for its support, including for educational or charitable purposes (e.g., receipt of a badge for access to the conference or tickets to charitable events, such as galas or golf outings).

Part A. Third-Party Medical Conferences and Other Programs (“Third-Party Programs”). Medtronic has an interest in building awareness and understanding of its products and related disease states through support for third-party scientific forums. Medtronic may support such medical conferences, professional meetings, and other similar events through educational grants and Commercial Sponsorship. Any permitted HCP travel, lodging, or meals that is sponsored by Medtronic must meet the requirements of this Standard, Standard 5, and Standard 6.

Part A1. Educational Grants. Medtronic may support independent educational, scientific, and policy-making conferences and professional meetings if they:

- Promote scientific knowledge, advance the practice of medicine, or enhance the delivery of effective healthcare;
- Are generally recognized and respected within the relevant professional or medical community;
- Relate to Medtronic’s business, Medtronic Technologies, or a disease state in which Medtronic has an interest; and
- Have faculty and content selected at the sole discretion of the conference organizer.

1) Grant Recipient. Medtronic may provide grants to (a) conference organizers to reduce overall conference costs, sponsor attendance by HCPs-in-training or those in need of support, defray faculty costs and expenses, or support modest meals or receptions; or (b) to a healthcare institution, professional association, foundation, training
institutions, or other third party permitted by local policy to enable HCPs to attend a third-party conference or professional meeting.

2) **Adherence to Program Standards.** Medtronic must adhere to all standards established by the Third-Party Program organizer or the third-party accrediting the program. In the absence of such requirements, Employees must appropriately disclose when and how Medtronic provided support and must follow the Third-Party Program organizer’s requirements regarding selection of faculty. If expressly requested by the Third-Party Program organizer, Medtronic may recommend faculty, categories of attendees, or comment on the program content. However, Medtronic must not inappropriately influence the organizer about the choice of individual speakers, attendees, or content.

3) **Programs Happening in Other Countries (Cross Border Events).** Grants originating in one country provided to Third-Party Programs held in a different country require review and approval by the regional or group Compliance/Legal team both (a) in the country in which the Third-Party Program will take place and (b) where the recipient of the funding is located, if different.

4) **Support of HCP Attendees.** Except in accordance with regional policy, Medtronic must not directly sponsor an HCP attendee to a Third-Party Program by paying admission fees, honoraria, travel, or lodging expenses. Employees must consult with the regional or group Compliance/Legal teams to ensure the Employees are following the most recent guidance on such sponsorships.

**Part A2. Satellite Symposium.** A congress or organization may offer Medtronic the opportunity to host a Satellite Symposium in conjunction with a Third-Party Program. Unlike a Medtronic-organized Medication Education program where Medtronic controls the faculty, content, and selection of attendees, Medtronic may only control the faculty and content in a Satellite Symposium (i.e., the event is open to conference attendees based on the criteria set by the Third-Party Program organizer). The Satellite Symposium is subject to the Third-Party Program organizer’s application and approval process. Even though such an event may be listed on the Third-Party Program’s agenda and promotional materials, these are considered Medtronic-sponsored events and Medtronic must appropriately disclose its sponsorship when promoting the events.
1) **Faculty.** Medtronic may engage a Healthcare Provider to serve as a bona fide faculty member on its behalf with an appropriate Consulting Arrangement under Standard 1, Part A. If payment is required by the Third-Party Program organizers, the Consulting Arrangement may include covering the Healthcare Provider’s relevant registration fees. Under this situation, the registration fees must be limited to the time necessary to speak at the Satellite Symposium. Related travel expenses may be paid only if solely incurred to participate in the Satellite Symposium. Medtronic must not structure this Consulting Arrangement to circumvent the rules prohibiting direct sponsorship to Third-Party Programs.

2) **Attendees.** Medtronic must not pay for travel, lodging or registration fees for non-faculty attendees.

**Part B. Supporting Other Third-Party Activities through Educational Grants.** Medtronic may provide educational grants to HCOs, teaching institutions, and other third parties for the purpose of training and education. These donations include:

- Supporting an endowed chair at an academic institution;
- Educating fellows in recognized medical training programs;
- Educating the public on healthcare topics;
- Facilitating the travel of HCPs selected by the grant recipient to attend training and educational events; and
- Supporting educational and policy-making conferences and meetings.

**Part C. Support for Third Party Research.** Medtronic provides monetary or in-kind support to third parties conducting research in three different ways.

**Part C.1. Support for General Research.** General Research is research conducted by an independent third party aimed at increasing scientific knowledge and to improve scientific theory. Unlike other categories of research, General Research may not follow a structured scientific process and does not need to be related to a Medtronic Technology, but should have defined goals and objectives. Medtronic may request study reports or other deliverables that are commiserate with the type of research support provided (e.g. heavily dependent on independent third-party discretion). Requests for support of General Research must follow Medtronic’s grants process.
Part C. 2. Support for External Research Programs. An External Research Program (ERP) is defined by Medtronic as an independent investigator-initiated study in which Medtronic is a potential supporter but is not the study sponsor. Therefore, Medtronic does not direct the design, conduct the study, or determine the outcomes of these studies. This means that the investigator is responsible for conducting the study and assuring the validity of the study data. The investigator, or investigator’s institution, also assumes the roles and responsibilities of the study sponsor, including compliance with all regulatory requirements. ERPs involve research related to a Medtronic Technology or a new therapeutic use tied to Medtronic’s business strategy, and Medtronic often requests rights to use the data following the completion of the study. ERPs must not be confused with General Research and must follow Medtronic’s ERP Policy and approval process.

1) ERP Requests. Requests must include documented goals, objectives, and milestones (e.g. clinical protocol, nature and scope of study, and budget), and, where applicable, the requirements for independent authorizations or approvals. ERP requests must also include documented deliverables to be verified before payment is made. Requests may include in-kind or monetary support for legitimate, study-related documented expenses, services, and/or reasonable quantities of no-charge product for the limited duration of the research.

2) ERP Agreement. ERP agreements will define, at a minimum: deliverables associated payments tied to milestones; if product support will be provided; Medtronic’s right to review publications; and any rights that Medtronic has for use of the study data (consistent with local regulations.)

3) Involvement by Medtronic. The investigator must retain independent control over the research. Employees may not take on activities that would fall within the responsibility for a clinical sponsor such as writing a protocol, developing a patient informed consent, medical writing or data management and analysis. Employees may provide limited technical support activities if Medtronic has unique capabilities and expertise required for the study conduct. Document any technical support in the ERP agreement.
Part C.3. Support for Collaborative Research. Collaborative Research is research conducted jointly by Medtronic and an HCP where both parties contribute to the design, implementation and scope of the research. It is important to note that Collaborative Research is neither General Research under Part C.1 nor an ERP under Part C.2. Employees should consult regional or group Compliance/Legal teams on the requirements for conducting Collaborative Research.

Part D. Charitable Donations. Medtronic may make donations to Charitable Organizations or fundraising activities supporting Charitable Organizations in accordance with regional or local policies. Additional requirements may apply to requested product donations.

1) **Charitable Organizations.** Donations must be made for genuine charitable purposes and only to organizations with bona fide charitable and/or philanthropic purposes (“Charitable Organizations”). Any donation must be used for the stated charitable or philanthropic purposes of the Charitable Organization.

2) **Fundraising Events.** Medtronic may donate to support an HCP’s fundraising event (such as a golf fundraising event or formal gala) if the recipient is a Charitable Organization and at least a portion of the donation qualifies for a charitable tax deduction.

3) **Indigent Care Donations.** Donations of Medtronic Technologies for indigent patients must exclusively benefit patients and must be permitted under applicable local laws. Product donations for indigent cases should be contingent upon confirmation or agreement that no third parties or patients will be billed for the donated product. Product donations must be provided with an invoice or other notice which appropriately discloses that the product was provided without a charge to the HCP.

Part E. Commercial Sponsorships. Medtronic may provide a payment or in-kind support to a third party in exchange for advertising or promotional opportunities (“Commercial Sponsorships”).

1) **Commerically Reasonable Fee.** Medtronic may provide Commercial Sponsorships if the level of Commercial Sponsorship reflects a commercially reasonable fee in exchange for the marketing and promotional benefits received by Medtronic. Examples of the...
marketing or promotional benefits may include advertising, signage, or display and exhibit space.

2) **Appropriate Marketing Activities.** Any Commercial Sponsorship must comply with applicable laws governing the marketing and promotion of Medtronic Technologies. Employees must follow the appropriate approval process for Commercial Sponsorships for each region or group.

**Standard 4. Joint Education and Marketing Programs**

Medtronic may partner with HCPs to conduct joint-education and marketing programs to educate patients and other HCPs on: medical conditions; the range of testing or treatment options available; the availability of Medtronic Technology; and the HCP’s ability to diagnose or treat related medical conditions. These programs include therapy awareness programs or patient awareness programs. In addition to the requirements in the General Provisions section, Employees must ensure that:

- Medtronic and the HCP share contributions (in-kind and/or financial) and costs of the program;
- The event/activity must highlight both the Medtronic Technology and the HCP’s role relating to diagnosis or treatment of related medical conditions;
- The arrangement is documented in a written agreement describing the purpose of the arrangement and the roles, responsibilities, and contributions of each party, including payment of costs;
- The HCP discusses only approved uses of Medtronic Technologies;
- Medtronic either controls or reviews and approves the agenda of any jointly conducted education and marketing programs; and
- Any invitations, promotional material, and/or presentations appropriately disclose Medtronic as a co-sponsor.

It is important to work with the regional or group Compliance/Legal team when conducting these types of events to ensure compliance with applicable local laws.

**Standard 5. Travel and Lodging**

In addition to the General Provisions requirements, Medtronic may pay
reasonable travel and lodging costs for HCPs when there is a Legitimate Need that supports the HCP’s in-person participation, namely in conjunction with:

- Meetings related to HCP Consulting Arrangements (e.g. consulting, clinical, product development, or advisory services) (Standard 1);
- Medical Education (Standard 2, Part A);
- Business Meetings (Standard 2, Part B); and/or
- Satellite Symposium under limited circumstances (Standard 3, Part A2).

Travel expenses must be modest and reasonable.

1) **Air.** Medtronic only allows economy class travel. Please consult regional or group procedures for any permitted exceptions.

2) **Lodging.** When Medtronic is responsible for selecting the location and lodging for an HCP interaction, Employees must select a location and lodging based on program requirements, convenience of attendees, and cost savings to Medtronic. Employees should not select a facility based on the amenities provided, but on the facility’s capabilities to serve the needs of the program. Employees should consult regional or group procedures for specific guidance on appropriate lodging for events conducted in the region.

3) **Payment.** HCP expenses must be paid directly to a third-party vendor (hotel, airline, travel agent, etc.) or other third party (if the organization is not affiliated with the HCP) as required under local policies.

4) **Guests or Other Personal HCP Expenses.** Medtronic will not pay for or contribute to any expenses for an HCP’s partner or guest. Similarly, Medtronic will not pay for or contribute to an HCP’s personal travel or lodging.

**Standard 6. Meals and Refreshments**

Employees may provide modest meals to HCPs if:

- The occurrence is an occasional business courtesy (i.e. infrequent and not routine);
- The cost of the meal is within Medtronic spending limits;
• The HCP attends and has a Legitimate Need for attending the activity associated with the meal; and
• The meals and refreshments are provided in a manner conducive to the discussion or presentation of scientific, educational, or business information.

A Medtronic representative must attend throughout a Business Meeting meal.

Employees must not pay for or contribute to:
• Excessive amount of or unreasonably expensive alcohol;
• Meals or refreshments for a partner or other guest of an HCP, even if the guest is also an HCP (unless the guest as their own Legitimate Need of attending the activity);
• A casual get-together with an HCP for the development of general goodwill;
• A celebratory event (e.g. holiday, retirement, birthday, promotion, or year-end department celebration); or
• Meals, refreshments, or events hosted by an HCP that do not qualify as a Joint Education or Marketing Program under Standard 4.

Standard 7. Educational Items and Gifts

Medtronic adheres to industry codes of ethics regarding nominal gifts to an HCP or an HCP’s close family member where there is a strong cultural custom. Such items are not permitted by most industry codes. Employees must consult with local Compliance/Legal for those few countries with strong cultural customs for modest cultural-courtesy gifts. In all other countries, Employees are prohibited from giving personal items and non-monetary gifts to HCPs.

Employees may provide items, modest in value, that have a genuine educational function or benefit patients (e.g. textbooks or anatomical models) to HCPs. Such items must be reported if required under local transparency regulations.

Standard 8. Entertainment and Recreation Prohibition

Employees must not pay for entertainment or recreation given to HCPs in any form. Such activities include theater, golf, skiing, hunting, sporting events, and leisure or vacation trips. This prohibition applies regardless of:
• The value of the activity;
• Whether Medtronic engages the HCP as a consultant; or
• Whether the entertainment or recreation is part of an activity with an educational purpose.
Standard 9. Communications About Uses of Medtronic Technologies

Medtronic may promote uses of its products that are consistent with the product labeling developed and approved (if applicable) in accordance with the regulatory requirements of the geography or country where the promotional activities occur. This could be different from how HCPs may use Medtronic Technologies. Generally, HCPs may use a Medtronic Technology for any purpose that they determine is in the medical interests of their patients, according to their medical judgment. That is, clinical practice includes uses that are contained in the approved Medtronic labeling or are otherwise consistent with such labeling but could also include uses that are neither specifically included in, nor consistent with, the regulatory approved or cleared label (e.g. “off-label” uses).

In general, Employees should not prompt discussions, or otherwise communicate, about how Medtronic Technology can be used off-label. Medtronic personnel are prohibited from promoting Medtronic Technologies for off-label uses.

There are a limited number of circumstances in which Employees may communicate about off-label information with HCPs, including:

- Presentations at medical or scientific conferences regarding clinical trial results or research and development data for an investigational use (if no claims are made regarding safety and effectiveness of any unapproved use);
- Discussions with HCPs to obtain advice or feedback relating to topics such as unmet patient needs or product research and development; or
- Proper dissemination of peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines that have been approved through the appropriate process (for example, materials sent by the Office of Medical Affairs [OMA]).

Consult local policy and procedure for country-specific standards on who may engage in these types of conversations and any applicable requirements that apply to how the information is communicated (see, e.g., Medtronic’s Interactions Regarding Off-Label Use Policy (U.S.)).
Information related to unapproved or uncleared uses should be identified or labeled as “off-label” or other applicable regional term and Employees should ensure that no claims are made in relation to the off-label uses.

All HCPs retained by Medtronic to speak, write, or present training and education programs on Medtronic Technologies must be trained by Employees regarding local labeling restrictions and advised to train only on uses that are consistent with the approved (if applicable) product labeling.

**Standard 10. Provision of Health Economics and Reimbursement Information**

Medtronic may support patient access to Medtronic Technologies by providing HCPs (and sometimes non-HCPs) with accurate and objective coverage, reimbursement, and health economic data related to Medtronic Technology (collectively “Reimbursement Activities”) Due to the unique nature of these activities, Reimbursement Activities may be conducted only by Employees designated by the business unit or geography who have appropriate knowledge and expertise. More specifically:

**Part A. Information Support.** Medtronic may provide HCPs with information related to Reimbursement Activities to enhance an HCP’s understanding of:

1) The clinical value of Medtronic Technologies and the services and procedures in which they are used;
2) The most economically efficient use of Medtronic Technologies, including how the technology fits within the continuum of care, available coverage, reimbursement, and associated costs; and
3) How to appropriately bill payors or government entities for services and procedures using Medtronic Technology and any proposed regulatory changes that might impact the HCP’s decision of whether to buy or use Medtronic Technology.

**Part B. Advocacy.** Medtronic may collaborate with HCPs, their professional organizations, and patient groups to conduct joint advocacy on Reimbursement Activities. This may include providing HCPs and their professional organizations support in developing materials and otherwise providing direct or indirect input into payer coverage and reimbursement policies.
Part C. Coverage Support. Medtronic may assist HCPs to obtain patient coverage decisions from payers by providing:

1) Information on payer policies;
2) Training on procedures for obtaining prior authorizations; and
3) Sample letters and information on medical necessity and appeals of denied claims.

Part D. Direct Patient Support Activities. At the request of an HCP or patient, Medtronic may implement programs to assist patients in obtaining coverage determinations, prior authorizations, pre-certifications, and appeals of denied claims relating to Medtronic Technology to facilitate patient access to Medtronic Technology. Such assistance is subject to appropriate privacy safeguards and local law and must not be provided as an inappropriate incentive to purchase or use Medtronic Technology.

Part E. Prohibited Activities. Employees must not:

1) Interfere with an HCP’s independent clinical decision making or provide coverage, reimbursement, and health economics support as an unlawful inducement;
2) Provide coverage, reimbursement, or health economics support to patients or HCPs that eliminates an overhead or other expense that the HCP would otherwise incur;
3) Provide support services that have not been approved according to local requirements; or
4) Suggest ways for an HCP to:
   a. Bill for services that are not medically necessary;
   b. Get inappropriate reimbursement or reimbursement not in accordance with payor or government rules; or
   c. Engage in fraudulent practices to achieve inappropriate payment.

Standard 11. Provision of Products or Equipment at Reduced Prices or No Charge

Medtronic may provide HCPs with product or equipment at reduced prices or at no charge under certain circumstances.

Part A. Commercial Arrangements for Products or Equipment. Medtronic may offer products or equipment to HCPs at a reduced price through a commercial arrangement (such as a rebate, discount, loan, or
product bundle) that adheres to local pricing policies and procedures. Employees must give written notice to an appropriate HCP account representative when selling a Medtronic Technology at a reduced price or no charge. Employees may fulfill the notice requirement by giving the HCP a purchase agreement, invoice, or other notice that reflects the actual or potential discounted price, rebate amount, loan arrangement, or zero charge, or provides notice that the listed amount may be subject to an additional discount, credit, or other price reduction.

There are certain types of arrangements that may result in a prohibited inducement if done incorrectly. Therefore, the following additional requirements apply:

1) **Consignment.** Consignments are generally products (a) that Medtronic provides to an HCP for use in and storage at the HCP’s patient care setting; and (b) to which Medtronic retains title until the product is used. Once the product is used, the HCP must be charged for the product according to the local policies and the commercial contract with the HCP. In addition, Employees must follow local policies regarding how consignment inventory will be tracked (i.e. periodic inventory, reconciliation reports, and return/removal of expired products).

2) **Support Equipment.** “Support Equipment” is an instrument or equipment issued to HCPs that aids the use of a related Medtronic Technology. Employees may provide Support Equipment to HCPs if local policy determines that the equipment has no independent value (i.e. is not of use by itself) without the related Medtronic Technology. Medtronic retains title to Medtronic Support Equipment.

3) **Capital Placement.** Capital Placement is an arrangement with an HCP where equipment is provided without a separate charge under a written agreement to purchase a defined amount of product over a certain period of time. In addition:
   a. Medtronic typically retains title to the equipment;
   b. The written agreement must address what will happen if the HCP fails to purchase enough of the contracted-for products during the specified time period and whether Medtronic will remove or charge for the equipment;
   c. The contract price for a capital placement must be based on a financial model that considers the Fair Market Value of the
equipment and products and is approved by Finance, Compliance or Legal;
d. Transparently and separately disclose the prices of products and the equipment to the HCP; and
e. The written agreement must specify what happens to the equipment once the HCP fulfills the purchase commitment (e.g., whether Medtronic will collect the equipment or if the HCP will return the equipment).

Part B. Products or Equipment Provided for Evaluation.
There are three ways that Employees may provide Medtronic Technologies to HCPs for evaluation. In these situations, the Medtronic Technology is provided to the HCP at no charge and, where applicable, must be tracked for the purposes of reporting for transparency.

1) Demonstration Products or Equipment (“Demos”). Demos are non-sterile products or equipment Employees use to demonstrate a product’s capabilities and/or promote the sale of the product. Demos are not intended to be used in patient care and must be identified as not intended for patient use through designations like “Not for Human Use” on the product, the packaging, or documentation that accompanies the product. Demos are only intended for use by Medtronic Employees and generally should not be left with an HCP. In certain circumstances, Employees may provide Demos to HCPs for patient awareness or education.

2) Samples. Samples are generally products provided free of charge to an HCP for the HCP to clinically evaluate the Medtronic Technology for future purchase. Samples are intended for use by the HCP on patients and are typically provided as finished goods in sterile packaging. Employees may only provide a reasonable number of single-use or disposable products to an HCP for the purpose of evaluation. If an HCP already purchased a product, Employees should not continue to provide samples of the previously purchased product without a legitimate clinical reason (e.g. the product has a new clinical indication or is being used in conjunction with a new product.)

3) Equipment Loans for Evaluations. Loans for evaluations are generally equipment provided at no charge to an HCP for the HCP to familiarize him or herself with the equipment in a clinical setting. In addition:
a. During the evaluation, Medtronic retains title to the equipment;
b. Equipment may be furnished only for a period that is (1) reasonable under the circumstances to allow an adequate evaluation as to whether the HCP wants to buy or otherwise acquire the equipment; and (2) consistent with applicable transparency reporting requirements;
c. Equipment must be promptly removed at the conclusion of the evaluation period unless the HCP enters into a commercial agreement for purchase of the equipment; and
d. There must be a written agreement set in advance that addresses the term of use and return or purchase of the equipment at the end of the term.

Part C. Products or Equipment Provided for Grants, Research, or Donations. Employees must follow the requirements outlined in Standard 1, Part C.1 and Standard 3 for products or equipment requested through a grant, research, or donation.

Standard 12. Technical Support in a Clinical Setting

Employees in the field organization or who otherwise provide technical support directly to HCPs (“Field Personnel”) are highly trained on the operation and safe and effective use of Medtronic Technologies. Field Personnel play an important role by providing technical support to HCPs on the safe and effective use of Medtronic Technologies. Technical support activities may include but are not limited to:

- Providing labeling information including product warnings, precautions, indications, and contraindications;
- Sharing device performance specifications, physical attributes and parameters, operational details, and detailed instructions for use;
- Providing support and education to HCPs and patients for the device (e.g., programming at the HCP’s direction); and/or
- Identifying surgical hardware, access devices, and instruments desired by the HCP during the surgery or procedure as it relates to Medtronic Technologies.

To provide technical support, Field Personnel must be trained on the specific Medtronic Technology for which they are providing support and comply with applicable HCP’s policies and requirements, including patient privacy and
credentialing requirements. Field Personnel must comply with all group or regional policies governing these activities. In addition, Field Personnel must comply with the following requirements:

1) **Practice of Medicine.** In the course of providing technical support, Field Personnel must not engage in activities that might constitute the practice of medicine (e.g. diagnosing or treating illnesses or taking patient vitals or health histories, even if otherwise licensed to do so).

2) **Interaction with Patients.** Technical support must occur at the request and direction of an HCP and, whenever practicable, be provided in the presence of medical personnel. When interacting with patients and their families, Field Personnel must identify themselves as Medtronic Employees. The HCP must complete any required consent forms prior to Field Personnel providing any technical support.

3) **Do Not Perform HCP Duties.** In the course of providing technical support, Field Personnel must not perform duties typically expected to be performed by an HCP, such as scheduling patient appointments or accessing patient records. Similarly, Field Personnel must not fill out paperwork for HCPs that contains reimbursement, coding, or billing information.

4) **Clinical Decision-Making.** Field Personnel may not interfere with an HCP’s independent clinical decision-making. If an HCP plans to use Medtronic Technology in a manner that poses a risk to patient safety, Field Personnel should raise that concern to the HCP.

5) **Unapproved Uses of Medtronic Therapies.** Field Personnel may provide technical support in situations involving a Medtronic Technology that an HCP has decided to use in a manner that is inconsistent with approved labelling if the support is limited to providing information consistent with the approved product labeling.

**Procedures**

N/A
Roles and Responsibilities

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<td>Employees</td>
<td>• Know and understand the rules that apply to interactions with HCPs</td>
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<td></td>
<td>• Consult with appropriate regional or group Compliance/Legal individuals with questions regarding interacting with HCPs</td>
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<tr>
<td>Corporate Office of Ethics &amp; Compliance,</td>
<td>• Provide guidance on BCS Policy questions</td>
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<td>Regional or Group Compliance/Legal</td>
<td>• Provide guidance on the BCS Exceptions process</td>
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<td>• Develop and implement policies and procedures to ensure compliance with the Global Business Conduct Standards</td>
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<td>• Consult with Employees on appropriate sponsorships, agreements, offers, research, and information provided to HCPs</td>
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Abbreviations, Acronyms and Definitions

**Business Meetings** – Meetings between an Employee and an HCP to discuss product features, instructions for the use of Medtronic Technologies, sales terms, contracts, coding and reimbursement, patient access to therapies, and other scientific, educational, or business topics relevant to Medtronic.

**Charitable Organizations** – Organizations with bona fide charitable and/or philanthropic purposes.

**Clinical Research** – Research that involves human subjects.

**Clinical Research Agreement** – A written agreement documenting payment to an HCO for Clinical or Pre-Clinical Research arrangements.

**Collaborative Research** – Research conducted jointly by Medtronic and an HCP where both parties contribute to the design, implementation and scope of the research.
**Commercial Sponsorship** – A payment or in-kind support provided to a third-party in exchange for advertising or promotional opportunities for Medtronic.

**Consulting Arrangements** – An arrangement with an HCP where Medtronic pays an HCP to provide a wide range of valuable, bona fide services to support Medtronic’s business needs. These services may include training and education, proctoring and preceptorships, reference center or center of excellence services, and participation on advisory boards or in focus groups.

**Consulting Agreement** – A written agreement documenting the consulting services provided by an HCP to Medtronic and the payment due to the HCP for rendering those services. Examples may include the provision of clinical, research, advisory, education, training, honoraria, or product development services.

**Demonstration Products or Equipment (”Demos”)** – non-sterile products or equipment Employees use to demonstrate a product’s capabilities and/or promote the sale of the product.

**Employees** – All Medtronic employees regardless of citizenship, the country in which they work, their level in the company, or the legal entity that employs them.

**External Research Program (ERPs)** – An independent investigator-initiated study in which Medtronic is a potential support but is not the study sponsor. External Research Program (ERP) are also referred to in the medical device industry as “Investigator Initiated Sponsored Research,” “Investigator Initiated Studies,” or “Physician Sponsored Studies.”

**Fair Market Value (FMV)** – The market or objective value of a good or service.

**FMV Rates** – An objective market rate for compensation based on the Fair Market Value for the services sought under the Consulting Agreement in the country where the Healthcare Provider resides or practices or where a Healthcare Organization is located.

**Field Personnel** – Employees in the field organization or who otherwise provide technical support directly to HCPs.
**General Research** – Research conducted by an independent third party aimed at increasing scientific knowledge and to improve scientific theory.

**Healthcare Organization (HCO)** – Entities engaged in the provision of healthcare, including, but not limited to, a hospital, university, medical practice, company formed/owned by a Healthcare Provider to perform personal consulting services (e.g. LLC), or patient advocacy group led or directed by Healthcare Providers. These entities are typically in a position to purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe Medtronic Technologies.

**Healthcare Professional (HCP)** – Any individuals or entities who prescribe, purchase, lease, recommend, use, arrange the purchase and lease of or have a material influence over purchasing decisions for Medtronic Technologies. This includes Healthcare Providers, Healthcare Organizations, any person affiliated with a Healthcare Provider or Healthcare Organization in a position to influence decisions to buy or use Medtronic Technologies, and any individual or entity in a capacity to directly recommend or material influence the purchase or use of Medtronic Technologies.

**Healthcare Providers** – Physicians, non-physician practitioners, medical fellows, and medical students, even when such individuals are interacting with Medtronic in their capacity as a government official.

**Legitimate Need** – A justifiable clinical, business, charitable, or educational reason for an interaction or activity.

**Medical Education** – Medtronic-organized instruction, education, or training sessions regarding the safe and effective use of Medtronic Technologies.

**Medtronic Technology(ies)** – Any Medtronic medical devices and products, technologies, digital and software platforms and related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities.

**Pre-Clinical Research** – Research involving animal, cadaver, or bench research.

**Product Development Arrangements** – Consulting services provided by a Healthcare Provider or group of Healthcare Providers to support the joint
development of a new/enhanced Medtronic product or therapy where the Healthcare Providers contributes intellectual property important to the design of the Medtronic Technologies.

**Product Development Agreements** – Written agreements with Healthcare Providers that document Product Development Arrangements involving the payment of royalties or milestones.

**Relative(s)** – Immediate family members (spouse, domestic partner, child, parent, sister, or brother), and other family members (uncle, aunt, niece, nephew, first cousin, grandchild, grandparent, and parent-, brother, sister-, son-, or daughter-in-law). These definitions also include all "step" and "half" relations of the listed relatives (e.g., stepbrother, half-brother).

**Reimbursement Activities** – Medtronic-provided coverage, reimbursement, and health economic information support given to HCPs related to Medtronic Technology.

**Satellite Symposium** – A Third-Party Program for which Medtronic only controls the faculty and content of the event and does not control the selection of attendees.

**Support Equipment** – An instrument or equipment issued to HCPs that aids the use of a related Medtronic Technology.

**Third-Party Program** – A genuine independent healthcare-related educational, scientific, business, and/or policymaking conference, meeting or event put on by a third party other than Medtronic. This term includes accredited and non-accredited continuing education programs.

### References & Related Policies

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**FAQs**

[Forthcoming link to separate FAQ document]

**Policy Contacts**

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<tr>
<td>Policy Sponsor</td>
<td><strong>Thomas Schumacher</strong>, Vice President and Global Chief Ethics and Compliance Officer</td>
</tr>
<tr>
<td>Policy Owner</td>
<td><strong>Mona Peterson Rosow</strong>, Sr. Director, Global Ethics and Compliance</td>
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**Appendices**

N/A

**Document History**