

Global Business Conduct Standards (BCS) Policy

Version 4.0

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Purpose

Medtronic is committed to interacting with all healthcare professionals, healthcare organizations, and anyone with a material influence over the purchase or use of Medtronic Technologies with integrity and in compliance with all applicable laws, regulations, rules, 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 (collectively, “BCS”) regulate interactions between employees and any individuals or entities who prescribe, purchase, lease, recommend, use, or arrange the purchase or lease of Medtronic Technologies (collectively, “Healthcare Professional(s)/Healthcare Organization(s)” or “HCP(s)/HCO(s)”).

For purposes of this policy, “Healthcare Professional” or “HCP” collectively includes:

- Healthcare providers, including but not limited to physicians, non-physician practitioners, medical fellows, medical students, or healthcare providers who are government officials (collectively, “Healthcare Providers”);
- Any HCO staff member or HCP Relative, if in a position to influence the decision to purchase or use Medtronic Technologies;
- Any other individuals in a capacity to directly recommend or materially influence the purchase or use of Medtronic Technologies; and
- Any other individuals within scope of transparency reporting.

For purposes of this policy, “Healthcare Organization” or “HCO” collectively includes:

- Entities engaged in the provision of healthcare, including but not limited to hospitals, universities, medical practices, home healthcare agencies, and government agencies;
- Companies formed or owned by HCPs to perform personal consulting services (e.g., LLC);
- Organizations led or directed by HCPs or in which HCPs are members, including but not limited to patient advocacy groups, medical societies and professional organizations;
- Any HCO or HCP affiliated organizations, if in a position to influence the decision to purchase or use Medtronic Technologies;

- Any other entities in a capacity to directly recommend or materially influence the decision to purchase or use of Medtronic Technologies; and
- Any other entities within scope of transparency reporting.

For purposes of this policy, “Medtronic Technology(ies)” means 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.

All Medtronic employees are required to comply with the BCS regardless of citizenship, the country in which they work, their level in the company, or the Medtronic legal entity that employs them (collectively, “Employee(s)”).

Medtronic may not engage contractors, board members, or third parties (such as but not limited to distributors, sales agents, and consultants) to do what the BCS prohibits Employees from doing themselves. When these contractors, board members, and third parties are acting on behalf of Medtronic, many of the same principles apply. In some cases, a written agreement with the contractor or third party may be entered into that requires compliance with the principles of the BCS. In other cases, Medtronic has adopted specific compliance policies or other guidance to ensure appropriate interactions with HCPs and HCOs by these contractors, board members, and third parties when acting on behalf of Medtronic (see Related Policies).

For ease of reference, the term “Employee(s),” as used throughout this BCS, shall be deemed to include, as applicable, contractors, board members, and third parties, but use of this term shall have no legal force or effect regarding the relationship between Medtronic and the contractors, board members, or third parties.

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 (Details)

Medtronic has a responsibility to ensure that interactions with HCPs/HCOs are conducted in an ethical and compliant manner. Medtronic will not attempt to inappropriately influence HCPs/HCOs through an improper inducement. This means that Employees must not offer or provide (directly or indirectly) an improper payment or anything of value to HCPs/HCOs as a reward for prior business or to encourage the future purchase or use of Medtronic Technologies.

The General Provisions section and 12 Standards outline how Medtronic ensures Employee interactions with HCPs/HCOs are ethical, compliant, and aligned with legal and industry standards or requirements.

- General Provisions: Requirements for every HCP/HCO Interaction
- Standard 1: HCP/HCO Services Arrangements
- Standard 2A: Medtronic Training and Education Programs
- 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 Recreation Prohibition
- Standard 9: Communications about Uses of Medtronic Technologies
- Standard 10: Provision of Health Economics and Reimbursement Information
- Standard 11: Provision of Products or Equipment at Reduced Prices or No Charge
- Standard 12: Technical Support in a 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 or regional policies, procedures, or guidance apply. Employees are responsible for knowing and understanding the rules that apply to their interactions with HCPs/HCOs. Additionally, managers must supervise their direct reports' compliance with these requirements. Employees should consult with their manager or Compliance/Legal team for questions about this policy or a proposed interaction with HCPs/HCOs.

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 global or regional Compliance leader, as applicable, may grant an exception via the Global BCS exception process if the proposed interaction is lawful and ethical. Employees seeking an exception must engage with a regional Compliance partner so Compliance may submit the exception request for review, and the Employee must receive Compliance leader approval prior to engaging in the activity. Please contact the applicable Compliance 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 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/HCOs.

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 HCPs/HCOs 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/HCOs. All payments or the provision of any benefit to HCPs/HCOs must be reported in a timely and traceable manner. Payments, services, or grants to HCPs/HCOs 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 (including expenses) provided to or on behalf of HCPs/HCOs 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 HCPs/HCOs provide goods or services directly to Medtronic, Medtronic must pay the HCPs/HCOs with traceable company funds (i.e., by Medtronic check, Medtronic credit card, or wire transfer from a Medtronic account). Employees must not pay HCPs/HCOs in cash, with gift cards, or through any personal accounts (e.g., check, credit card, or electronic payments).
3. **Fair Market Value.** When Medtronic transfers value to HCPs/HCOs, it must represent Fair Market Value (“FMV”) for the goods or services provided or transferred. FMV is the market or objective value of the goods or services. How FMV is determined depends on what is being provided or transferred and to whom. Please review the additional requirements outlined in the Standards below.
4. **Approval.** Employees must not make commitments to HCPs/HCOs 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 B1. Expenses. When Medtronic transfers value to HCPs/HCOs (e.g., travel, lodging, meals), the expense must be modest and reasonable and may not exceed limits established by Medtronic or those

defined by local laws, regulations, rules, or industry codes, whichever is more restrictive. Please review the additional requirements outlined in Standards 5 and 6 below.

Expenses related to HCPs/HCOs include:

- Expenses incurred by a Medtronic Employee on behalf of or associated with HCPs/HCOs; and
- Expenses submitted by HCPs/HCOs directly to Medtronic for reimbursement.

This includes but is not limited to expenses incurred in conjunction with Medtronic-conducted activities, Business Meetings, and expenses incurred by HCPs/HCOs while engaged in performing services for Medtronic.

1. **Expense Management System and Form of Payment.** Employees must comply with regional policy as to (i) use of the applicable Finance (i.e., expense management) reporting system to accurately and completely attribute expenses to individual HCPs and other expense recipients, and (ii) the required form(s) of payment to be used for expenses related to HCPs/HCOs. Expenses related to HCPs/HCOs under Standards 5 and 6 submitted through Medtronic's Finance reporting system include:
 - a. Expenses incurred by Employees using a corporate card (travel & expense card or meeting card);
 - b. Expenses submitted for reimbursement by an Employee or HCP/HCO;
 - c. Expenses incurred through Medtronic's online booking tool for travel or Medtronic's designated travel agency for domestic and international trips; and
 - d. Expenses covered by this policy and submitted through an alternative system.
2. **HCP Attendees vs HCP Consultants.** There are times when the appropriateness of the expense depends on the role that individual HCP has in relation to Medtronic. In certain places, this policy distinguishes between individual HCPs who are attendees ("HCP Attendee(s)") and individual HCPs who are consultants ("HCP Consultant(s)").
3. **HCP Travel Costs.**
 - a. **Temporary Licensing or Credentialing Costs.** If permitted by regional policy, Medtronic may purchase, or reimburse HCP Consultants for, temporary licensing or temporary credentialing costs if HCP Consultants need to obtain special licensing or credentialing to conduct Medtronic activities under Standard 1.
 - b. **Travel Documents.** Medtronic may purchase, or reimburse HCPs/HCOs for, expenses associated with obtaining a business visa or immunizations required for participating in a Medtronic activity. The business visa must be purchased based on Medtronic's need (i.e., for the duration of the meeting or activity that Medtronic is asking HCPs to attend).
 - c. **Passports.** Medtronic may not pay for, or reimburse HCPs/HCOs for, costs associated with passports.

4. **Other HCO-Related Expenses.** Expenses such as exhibit fees, facility rentals from HCOs, and other HCO expenses should be submitted according to regional policy. However, Employees may not use their corporate card (travel & expense card or meeting card) or personal card to pay for a grant, donation, or Services Arrangements, as those expenses are currently processed outside of Medtronic's expense management system. As permitted by regional policy, charitable event tickets may be purchased on a travel & expense card.
5. **HCP/HCO Expense Reimbursement.** If an expense is allowed under this policy, as permitted by regional policy, HCPs/HCOs may request reimbursement for expenses with appropriate documentation. The reimbursement payment must be made in accordance with Part B1.1 above. The expense documentation must include the HCP recipient name(s), establishment/supplier, date of the transaction, business purpose, and itemization of the expense. If a receipt is misplaced, it is the responsibility of the HCP/HCO to contact the supplier for a replacement receipt.
6. **Employee Receipts.** To ensure adequate documentation of the expense, Employees must follow receipt submission requirements under the Employee [Global Travel and Expense Reimbursement Policy](#). Reporting should occur within the timeframe required by the [Global Travel and Expense Reimbursement Policy](#) after the expense is incurred. Employees must accurately and completely capture attendance of all participants or expense/benefit recipients.
7. **Use of Personal Funds.** Employees must not use personal funds to pay for any expense that is otherwise prohibited. If an expense is submitted by an Employee that is otherwise considered non-reimbursable, the Employee Expense Management team must work with the regional Compliance partner to determine how best to handle the incurred expense.
8. **Non-Reimbursable HCP/HCO Expenses.** The following items are prohibited HCP/HCO expenses (see Standards 5 and 6 for additional prohibited expenses):
 - a. Insurance costs (e.g., life insurance, travel insurance, medical insurance, personal insurance, etc.) (see Standard 5, Part A.6 for limited circumstances under which travel insurance may be purchased with air travel tickets);
 - b. Hospitality or entertainment expenses of any kind (e.g., lift tickets, golf fees, excursion tour fees, sports tickets, etc.);
 - c. Personal grooming expenses (e.g., barber, hairdressers, shoeshine, etc.);
 - d. Loss or theft of cash advance money, airline tickets, personal funds, or property; and
 - e. Cigarettes, cigars, shisha, tetrahydrocannabinol ("THC"), and all other forms of tobacco, vaping, and any similar products.

Part C. Engaging an HCP/HCO from Another Country (Cross Border Engagements). Medtronic must comply with the laws and regulations of the country where an HCP resides, is licensed to practice, or works, or where an HCO is located, regardless of where they interact with Medtronic. When an Employee plans an interaction with an HCP or HCO, the Employee must consult with the local Compliance partner

responsible for the country where the HCP resides, practices, or works, or where the HCO is located, for guidance on the requirements applicable to that HCP or HCO. The Employee then must obtain necessary written approvals from that local Compliance partner prior to committing to the HCP or HCO.

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

Part E. Establishments Owned by an HCP. Conflicts of interest, corruption, or transparency reporting risks may arise when Medtronic resources (i.e., people or dollars) are spent where an HCP has a financial interest (see Related Policies). These risks may arise where considerations of personal gain or benefit to an HCP or an HCP's immediate family member conflicts with (or appears to conflict with) the legitimate business interests of Medtronic. Therefore, Employees are prohibited from organizing a Medtronic-conducted activity or Business Meeting, or paying for meals, lodging, rental fees, or any other costs related to a Medtronic business purpose, at restaurants, hotels, or other venues that the Employee knows is owned by an HCP or an HCP's immediate family member, or in which the HCP has an ownership interest. Ownership interests do not include insubstantial ownership interests in publicly-traded securities.

Part F. Transparency Laws. Medtronic is committed to transparency in its relationships with HCPs/HCOs and must comply with all global transparency laws and regulations (i.e., regional, national, federal, state, provincial, local) applicable to Medtronic. Employees are responsible for being aware of and complying with any transparency reporting requirements related to transfers of value provided to HCPs/HCOs. Employees should consult with the applicable regional Compliance team to ensure accurate and complete tracking of transfers of value in scope for transparency reporting based upon the country where the HCP resides, practices, or works, or where the HCO is located.

Standard 1. HCP/HCO Services Arrangements

Medtronic engages HCPs/HCOs to provide a wide range of valuable, bona fide services to support Medtronic's business needs ("Services Arrangements"). These Services Arrangements include Consulting Arrangements, Product Development Arrangements, Clinical Research Arrangements, and Pre-Clinical Research Arrangements.

Part A. General Principles. The following general principles apply to all Services Arrangements with HCPs/HCOs:

- Designing or creating a Services Arrangement to generate business from that HCP/HCO is not a Legitimate Need and violates the BCS;
- Employees must not engage more HCPs/HCOs than necessary to conduct a specific Services Arrangement;

- Employees must not engage an HCP/HCO for more time or services than necessary to accomplish the Legitimate Need;
- Employees must assess the frequency of using an HCP/HCO for repeat Services Arrangements to confirm there is still a Legitimate Need to use the HCP/HCO and to ensure the aggregate payment will not unduly influence the HCP/HCO;
- Employees must assess whether the Legitimate Need for the HCP/HCO Services Arrangement could be met through a virtual engagement, or if there is an objective, legitimate reason that supports the need for an in-person engagement; and
- Employees must not perform any duties for which an HCP/HCO has been contracted and paid to carry out.

In addition, all HCP/HCO Services Arrangements require:

1. **Written Agreement.** There must be a written agreement that:
 - a. **Legitimate Need.** Identifies the Legitimate Need for the services;
 - b. **Specifications.** Specifies:
 - i. **Services.** All services that the HCP/HCO will provide;
 - ii. **Term.** The term of the agreement;
 - iii. **FMV Rate/Amount.** The FMV payment rate or amount; and
 - iv. **Expenses.** Any Medtronic obligation to pay for or reimburse modest, reasonable and actual travel, lodging, meals, and other expenses that are necessary to carry out the services; and
 - c. **Executed.** Is executed by both Medtronic and the HCP/HCO before the start of the services.
2. **Qualified HCPs/HCOs.** Medtronic must select HCPs/HCOs based on their qualifications, expertise, and capacity to provide the services needed for the Services Arrangement. While the qualifications may include experience with, usage of, or familiarity with Medtronic Technologies, Medtronic must not select HCPs/HCOs to reward their past usage of Medtronic Technologies or to unlawfully induce them to provide future business to Medtronic. Where experience with or usage of Medtronic Technologies is a qualification, such experience or usage must relate to the Legitimate Need and Medtronic should not require experience or usage exceeding what is reasonably needed to accomplish the Legitimate Need.
3. **Fair Market Value Compensation.** Medtronic must determine appropriate compensation rates based on Fair Market Value ("FMV") for the services sought under the Services Arrangement in the country where the HCP resides, practices, or works, or where the HCO is located ("FMV Rates"). The FMV Rate is set using objective criteria, including but not limited to the geographic location, industry standards, evaluation of the types of services to be performed (taking into consideration effort, length of time, and the unique expertise needed for the services), and market value of the services. For individual HCPs, additional objective criteria used to determine the FMV Rate may include the HCP's specialty, years and type of experience, and practice setting.

4. **Payments.** Medtronic is prohibited from hiring HCPs/HCOs 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 Services Arrangement have been provided before paying the HCP/HCO.

Part B. HCP/HCO Consulting Arrangements. Medtronic relies on HCPs/HCOs for various consulting services (collectively, "Consulting Arrangements"), including:

1. **Advisory Services**, such as but not limited to participation on advisory boards or in focus groups, market research, etc.;
2. **Clinical Consulting**, such as but not limited to serving on a clinical study oversight committee like an adverse events adjudication committee ("AEAC") or a data safety monitoring board ("DSMB"), or serving as medical monitor for a clinical study, etc.;
3. **Pre-Clinical Consulting**, such as but not limited to developing or advising on the protocol or design of Pre-Clinical Research, etc.;
4. **Product Development Consulting**, such as but not limited to providing input on the development of a new or enhanced Medtronic Technology, product usability feedback, etc.; and
5. **Training and Education**, such as but not limited to Medtronic Technology training, sales training, proctorships, speaking engagements, content development, etc.

In addition to the requirements listed in Standard 1, Part A, the following additional requirements apply to Consulting Arrangements. Before engaging HCPs/HCOs for a Consulting Arrangement, the Employee accountable for the Consulting Arrangement must document (in accordance with regional process):

- An appropriate purpose for the type of Consulting Arrangement;
- The need for use of the HCP/HCO; and
- The scope of work to be conducted by the HCP/HCO.

Collectively, this Consulting Arrangement documentation process is referred to as "Needs Assessment."

Part C. Product Development Arrangements. In addition to the requirements listed in Standard 1, Part A, the following additional requirements apply to Product Development Arrangements for services provided by HCPs/HCOs to support the joint development of a new/enhanced Medtronic product or therapy where the HCP/HCO 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 HCP/HCO Qualifications.** HCPs/HCOs 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 HCPs/HCOs (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 HCPs/HCOs 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 alternative payment arrangements in a written agreement (“Product Development Agreement”), separate from the Consulting Agreement for the product development consulting services. These payment models must consider the total benefit to Medtronic over the course of the product sales model and fairly compensate HCPs/HCOs 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:
 - i. Include a cap on the total amount of royalties that Medtronic may pay to HCPs/HCOs over the life of an agreement; and
 - ii. Ensure that payments HCPs/HCOs receive for Consulting Arrangements provided during the development of the product or therapy are deducted from any subsequent royalty payments owed for the same product or therapy under the Product Development Agreement.
 - b. **Milestone Payments.** Product Development Agreements with 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 Agreements based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. This includes limiting the ability of an HCO to earn royalties from sales of the product at the HCO, or an HCP to earn royalties from sales of the products in any

HCO where the HCP practices or has influence over purchasing or decisions about the use of Medtronic Technologies. Medtronic also limits the ability of individual HCPs with Product Development Agreements to participate in clinical studies (see Standard 1, Part D.4).

5. **No Promotional Requirement.** Product Development Agreements must not condition payments on either:
 - a. A requirement that HCPs/HCOs purchase, order, or recommend any Medtronic Technology or any product or technology products as a result of the Product Development Agreement; or
 - b. A requirement to market the product or technology upon commercialization.

Part D. Clinical and Pre-Clinical Research Arrangements. Clinical (human subject) and Pre-Clinical (bench, animal, or cadaver) research arrangements should:

- Be driven and managed by the appropriate scientific function;
- Fulfill a clear and documented research purpose reflecting a Legitimate Need related to Medtronic strategy; and
- Not be inappropriately influenced by sales personnel.

In addition to the requirements listed in Standard 1, Part A, the following additional requirements apply to arrangements involving clinical studies and pre-clinical research (“Clinical and Pre-Clinical Research Arrangements”).

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” or “Pre-Clinical Research Agreement”). Compensation for the research arrangements is 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 a Pre-Clinical Research Agreement. Employees should consult regional 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 HCPs/HCOs.** Clinical and Pre-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 Agreements with an HCO. In these situations, Employees must create a separate written Consulting Agreement with the HCP/HCO meeting the requirements under Standard 1, Part B. The Consulting Agreement must differentiate the work done under any Clinical Research Agreement or Pre-Clinical Research 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.** HCPs/HCOs 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 to HCPs/HCOs for publication writing or editing activities (see [Publication & Authorship Policy](#)).
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 adverse events adjudication committee or data safety monitoring board 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.** Live and virtual training and education programs must be conducted 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 HCP's/HCO's own facility, clinical, educational, or other settings such as hotels, conference centers, or other suitable meeting facilities. Programs involving experiential technical training and instruction on Medtronic Technologies (e.g., a cadaver lab) may be held 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, including the requirement that all HCP Attendees must have a practice or specialty that relates to an approved use of the Medtronic Technology (that is the subject of the Medical Education program) in the country where the HCP practices or works. 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 HCPs/HCOs 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/HCOs 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. Employees must 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. **HCP Attendees.** All HCP Attendees must have a Legitimate Need to attend a Medtronic Business Meeting. HCPs or guests who do not individually 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 HCPs 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 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;
- 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).

The provision of products or equipment at reduced prices or no charge for commercial arrangements or evaluation is governed by Standard 11, Parts A and B.

Employees must follow regional procedures to obtain required pre-approvals 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/HCO 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 Sponsorships. Any permitted HCP/HCO travel, lodging, or meals that is sponsored by Medtronic must meet the requirements of this Standard 3, as well as Standards 5 and 6.

Part A1. Educational Grants. Medtronic may support Third-Party Programs (i.e., 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 Third-Party Program organizer.

1. **Grant Recipient.** Medtronic may provide grants to:

- a. Third-Party Program 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 institution, or other third party permitted by local policy to enable individual HCPs to attend a Third-Party Program.
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 via the applicable regional grants and donations process both:
 - a. By the country in which the Third-Party Program will take place; and
 - b. By the country where the recipient of the funding is located, if different.
4. **Support of HCPs.** Except in limited circumstances as permitted in Standard 3, Part A2 below, Medtronic must not directly sponsor or make travel arrangements for individual HCPs to attend or speak at a Third-Party Program by paying for, offering to pay for, or reimbursing admission fees, honoraria, travel, or lodging expenses. Medtronic is also prohibited from selecting, or influencing the selection of, any individual HCP to attend or speak at a Third-Party Program.

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-conducted Medical 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 the Satellite Symposium 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 Satellite Symposium.

1. **HCP Consultants (Faculty).** Medtronic may engage an HCP to serve as a bona fide faculty member on its behalf for the Satellite Symposium with an appropriate Consulting Arrangement under Standard 1, Part B. When practical, faculty members for Satellite Symposiums should be drawn from those HCPs who are attending the Third-Party Program. Medtronic must not structure this Consulting Arrangement to circumvent the rules prohibiting direct sponsorship of HCPs to

attend Third-Party Programs. The following additional rules apply to registration fees, travel, lodging, and meal expenses.

a. **HCP Consultants (Faculty) Attending the Third-Party Program.**

- i. **Registration Fees.** Regardless of the party paying for the faculty member's travel expenses, the Consulting Arrangement may include covering the faculty member's registration fees, limited to the time necessary to speak at the Satellite Symposium.
- ii. **Travel Expenses (Third-Party Paid).** If the faculty member has or is able to have their travel, lodging, and meal costs separately arranged by a third party (i.e., the Third-Party Program organizer, employer, or other entity), then Medtronic must not pay for or reimburse those costs, and may only pay for or reimburse any incremental costs solely incurred to attend the Satellite Symposium.
- iii. **Travel Expenses (Medtronic Paid).** If no other third party has committed to pay for a faculty member's travel, lodging, or meal costs to attend the Third-Party Program, then Medtronic may pay for or reimburse the travel, lodging, and meal costs associated with the faculty member's attendance at the Satellite Symposium, even if the faculty member attends the Third-Party Program. All travel must be booked and expenses solely limited to Medtronic's business needs for the time period necessary for the faculty member's provision of services at the Satellite Symposium.

b. **HCP Consultants (Faculty) Not Attending the Third-Party Program.** Medtronic may pay for or reimburse the faculty member's associated expenses including registration fees (limited to the time necessary to speak at the Satellite Symposium), travel, lodging, and meals, only if the faculty member was not planning to otherwise attend the Third-Party Program. All travel must be booked and expenses solely limited to Medtronic's business needs for the time period necessary for the faculty member's provision of services at the Satellite Symposium.

2. **HCP Attendees.** Medtronic must not pay for registration fees, travel, lodging, or any other costs to attend the Third-Party Program or Satellite Symposium for non-faculty HCP Attendees.

Part A3. HCP Travel & Other Expenses for Medtronic-Conducted Activities Held Adjacent to a Third-Party Program. Medtronic may not structure a Medtronic-conducted activity or arrange to pay for or reimburse HCP Consultant or HCP Attendee costs in such a way that circumvents the prohibition of direct sponsorship to attend a Third-Party Program. The following rules apply to Medtronic-conducted activities that take place during, around, or at the same time and in the same approximate location as a Third-Party Program. Medtronic must not pay for or reimburse the registration fees, travel, lodging, or any other costs associated with HCPs attending the Third-Party Program (such as a flight to the location where the Third-Party Program is being held). However, when allowed, Medtronic may pay for or reimburse incremental expenses solely limited to those expenses directly related to attending the Medtronic-conducted activity, and not to attend the Third-Party Program.

1. **Medtronic-Conducted Training & Education Programs.** Under Standard 2, Part A, Medtronic may organize Medtronic-conducted training & education programs for HCPs attending the Third-

Party Program. Medtronic may engage an HCP to serve as a bona fide faculty member (“HCP Consultant”) on its behalf for the Medtronic-conducted training & education program with an appropriate Consulting Arrangement under Standard 1, Part B. Medtronic may only pay for or reimburse the incremental lodging or other incremental expenses of HCP Consultants or HCP Attendees for expenses solely incurred to attend the Medtronic-conducted training & education program.

2. **Medtronic Manufacturing-Oriented Business Meetings.** If allowed by local law, under Standard 2, Part B, Medtronic may organize manufacturing-oriented Business Meetings for HCPs attending the Third-Party Program. Medtronic may only pay for or reimburse the incremental lodging or other incremental expenses of HCP Attendees for expenses solely incurred to attend the Medtronic manufacturing-oriented Business Meeting.
3. **All Other Medtronic Business Meetings.** If allowed by local law, under Standard 2, Part B, Medtronic may organize Business Meetings for HCPs attending the Third-Party Program. However, with the exception of manufacturing-oriented Business Meetings (see Standard 3, Part A3.2 above), Medtronic may not pay for or reimburse any incremental expenses of HCP Attendees for expenses incurred to attend the Medtronic Business Meeting.
4. **Medtronic HCP/HCO Services Arrangements Meetings.** Under Standard 1, Medtronic may organize Medtronic meetings for HCPs attending the Third-Party Program and who are providing services to Medtronic under an HCP/HCO Services Arrangement, such as advisory boards or clinical investigator meetings, based on the availability of HCPs already attending that Third-Party Program. Medtronic may only pay for or reimburse the incremental lodging or other incremental expenses solely incurred for the provision of the services by the HCPs to participate in the Medtronic HCP/HCO Services Arrangements meetings.

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 educational grants 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 Third-Party Programs; 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 improving 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 commensurate with the type of research support provided (e.g., dependent on independent third-party discretion). Requests for support of General Research require review and approval via the applicable regional grants and donations 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 resulting from 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 Clinical Research or Pre-Clinical 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 [External Research Program \(ERP\) Policy](#) and require review and approval via the applicable regional grants and donations process. The following additional requirements apply:

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:
 - a. Deliverables associated payments tied to milestones;
 - b. If product support will be provided;
 - c. Medtronic’s right to review publications; and
 - d. 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 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 conducting the study. Medtronic must 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/HCO 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

Standard 3, Part C.1 nor an ERP under Standard 3, Part C.2. Employees should consult regional 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, as determined by the standards of the country where the organization is registered (“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 HCO’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 or are otherwise expected to pay for the donated product. Product donations must be provided with an invoice or other notice which appropriately discloses the value of the donated product and the fact that the product was provided without a charge to the HCO.

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. **Commercially Reasonable Fee.** Medtronic may provide Commercial Sponsorships if compensation for 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. All Employees responsible for creating, reviewing, and/or approving materials used to promote Medtronic Technologies must comply with the [Global Promotional Materials Policy](#).

Standard 4. Jointly Conducted Education and Marketing Programs

Medtronic may partner with HCPs/HCOs to jointly conduct 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 an 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/HCO share contributions (in-kind and/or financial) and costs of the program (Medtronic cannot compensate the HCP/HCO for their contributions, such as time spent preparing, planning or presenting);
- The event/activity must highlight both the Medtronic Technology and an 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/HCO discusses only approved uses of Medtronic Technologies consistent with applicable labeling;
- 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.

Employees must work with the regional 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/HCO Services Arrangements (see Standard 1);
- Medical Education (see Standard 2, Part A);
- Business Meetings (see Standard 2, Part B); and
- Satellite Symposia under limited circumstances (see Standard 3, Part A2).

Travel expenses must be modest and reasonable.

If a Medtronic-conducted activity or Business Meeting is being held adjacent to a Third-Party Program, additional restrictions apply (see Standard 3, Part A3).

All reservations (air, hotel, and car) must be made through Medtronic's online booking tool or the designated travel agency for domestic and international trips. Approved and preferred Medtronic

suppliers (e.g., airlines, hotels, and rental car firms) must be used whenever possible. Airlines, hotels, or rental car firms cannot be selected with regard for HCP's frequent traveler memberships.

- **Payment.** Unless permitted by regional policy, HCP travel expenses must be paid directly to a third-party supplier (airline, hotel, travel agent, etc.) or other third party (if the organization is not affiliated with the HCP).
- **Arrival and Departure Dates.** Depending on the agenda and flight availability, HCPs should arrive no earlier than the day beforehand and depart no later than the day after the activity or engagement.
- **Travel Extensions.** Medtronic must book travel for HCPs based on Medtronic's business needs. HCPs are responsible for any change requests to extend travel. This includes any costs for the requested extensions and for making any logistics changes directly with the travel and lodging suppliers.
- **Guests or Other Personal HCP Expenses.** Medtronic will not pay for or contribute to any expenses for an HCP's partner, spouse, or guest. Similarly, Medtronic will not pay for or contribute to an HCP's personal travel or lodging change requests or extensions.

Part A. Travel by Air. The following rules apply when arranging air travel for HCPs:

1. **Booking Air Travel.**

- a. **Booked by Medtronic.** Air travel must be booked by Medtronic using Medtronic's online booking tool or designated travel agency.
- b. **Booked by HCP (Business Travel).** In the rare instance that an HCP separately books his or her own air travel, Medtronic is not obligated to reimburse the HCP for that expense. If Medtronic does reimburse the HCP, Medtronic may only reimburse the HCP up to the amount Medtronic would have paid for the air travel. Medtronic will not provide HCPs cash in lieu of a ticket.
- c. **Booked by HCP (Non-Business Travel).** Air travel changes for additional time beyond Medtronic's business needs must be booked by the HCP, are at the HCP's personal expense, and may not be reimbursed.

2. **Class of Service.**

- a. **Economy Class.** In general, Medtronic only allows economy class travel.
- b. **Business Class or Equivalent.** For travel with flight segments equal to or greater than five hours, business class travel or its equivalent is permitted.
- c. **Limited Circumstances.** In limited circumstances, business class travel or its equivalent may be provided for flights less than five hours, subject to applicable laws and industry codes if:
 - i. There is a genuine medical condition with medical certificate presented; or
 - ii. Other extenuating circumstances apply (such as market conditions or specific business needs) that require consideration for business class travel.

These exceptions must be approved in accordance with the Global BCS exception process.

3. **Class of Service Upgrades.** In limited circumstances and associated with the use of low-cost carriers, Medtronic may pay for early boarding or seat assignment if this will reduce the risk of delay for an HCP. However, in all other circumstances, Medtronic will not pay for upgrades, fees for seat selection, or fees for early boarding based on a request from an HCP. HCPs choosing to incur these fees do so at their own expense, and the fees must not be paid for or reimbursed by Medtronic.
4. **Restrictions on Modes of Air Travel.** All air travel is limited to commercial airlines or MDT-approved commercially chartered aircraft. Medtronic will not pay any costs associated with a private plane. Helicopter travel is not permitted for point-to-point travel. Helicopter transfers between airports for domestic to international connections are permitted only if provided free of charge by the airline from which air transportation is purchased.
5. **Baggage Fees.** When permitted by regional policy, HCPs may be reimbursed for baggage fees if reasonable and in proportion to the duration/business reason for travel.
6. **Travel Insurance.** When permitted by regional policy and allowed by law, Medtronic may purchase travel insurance for HCP Consultants or HCP Attendees in conjunction with the air travel ticket. The following additional requirements apply:
 - a. **Legitimate Need.** Travel insurance may only be purchased when the HCP is traveling because of a Legitimate Need to provide services for Medtronic or to attend a Medtronic-conducted activity.
 - b. **Limited Circumstances.** Medtronic may purchase travel insurance for two limited circumstances:
 - i. Based on established local custom, Medtronic may purchase travel insurance for HCPs who reside, practice or work in the APAC region; or
 - ii. In all other regions, Medtronic may only purchase travel insurance as required for HCPs to gain entry into a country (e.g., when required by a government for travelers to cover medical costs, typically associated with epidemics such as COVID-19).
 - c. **Minimal Coverage.** Travel insurance must not exceed the minimal amount of coverage necessary.
 - d. **Medtronic Business Needs.** Travel insurance must be limited to Medtronic's business needs for the time period necessary for the provision of services or attendance at a Medtronic-conducted activity.For all other circumstances, purchase of travel insurance for HCP Consultants or HCP Attendees is not permitted.

Part B. Travel by Rail. The following rules apply when arranging rail travel for HCPs:

1. **Booked by Medtronic.** In general, rail travel must be booked by Medtronic using Medtronic's online booking tool or designated travel agency.

2. **Booked by HCP.** In the event that Medtronic is unable to book rail for the HCP, Medtronic may reimburse an HCP for the reasonable costs incurred by the HCP.
3. **Guidelines.** Rail travel should be booked consistent and aligned with regional and/or country guidelines.

Part C. Lodging. The following rules apply when arranging lodging for HCPs:

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 HCP 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 procedures for specific guidance on appropriate lodging for events conducted in the region.

1. **Hotel Accommodations.** Employees should arrange HCP hotel accommodations at an intermediate, business-class hotel where Medtronic has negotiated special discount rates and/or at hotel properties where Medtronic's designated travel agency has negotiated discount rates. If the Medtronic activity is in a venue with sleeping rooms, Employees should reserve accommodations at that venue (if the venue is appropriate) or within a reasonably close proximity. When HCPs are from another country, it is important to check with the local Compliance partner from the HCP's country to determine which hotel accommodations are appropriate for the HCP.
2. **Alternate Lodging Requests.** In rare circumstances and if permitted by regional policy, HCPs may be reimbursed up to, but not to exceed, the amount Medtronic would have paid at the preferred hotel property if an HCP elects to stay at an alternate location. The HCP is responsible for arranging and paying for any alternative lodging.
3. **Room Types.** HCPs should stay in a standard room or a room of an equivalent level. Employees will not arrange for or reimburse HCPs for upgrades to lodging accommodations.
4. **Requested Additional Days.** In the event an HCP wants to alter the travel plans for travel outside of Medtronic's business needs, the HCP is responsible for arranging and paying any fees related to hotel or travel modifications (e.g., extending or changing the trip based on personal needs).
5. **Hotel Charges.** Incidental lodging expenses are not reimbursable (e.g., in-room movies, mini-bar, movies or pay TV, telephone, laundry, dry cleaning, spa services, etc.). However, Medtronic may pay for resort fees when the hotel requires payment of the fee from every person who stays at the facility.

6. **Damage.** HCPs are personally responsible for any damage to hotel property due to misconduct or negligent behavior. This includes, but is not limited to, hotel fines, smoking in non-smoking room, pets, theft, etc.

Part D. Other Travel. The following rules apply when arranging or reimbursing other travel for HCPs:

1. **Ground Transportation.** Medtronic may provide ground transportation for HCPs attending Medtronic-conducted activities. Employees arranging for ground transportation should use the most cost-effective means of ground transportation regulated by local authorities. The use of limousines or forms of luxury ground transportation is strongly discouraged unless other safe forms of transportation are not available.
2. **Rental Cars.** In general, HCPs are not permitted to rent cars at Medtronic's expense. When permitted under regional policy, Medtronic may choose to reimburse an HCP for a mid-size rental car, including fuel charges, in situations where it is more convenient for an HCP to drive to the location of the Medtronic-conducted activity or engagement. Medtronic does not reimburse HCPs for car washes, parking tickets, fines for traffic violations, supplemental insurance, damages/repair costs, or towing charges incurred when using a rental car.
3. **Personal Cars.** HCPs may use their personal automobiles at their own risk and liability. With the submission of appropriate documentation:
 - a. **HCP Consultants.**
 - i. **Allowable Expenses.** For Medtronic-related business travel exceeding 30 miles / 48 kilometers per round trip, Medtronic will reimburse for mileage, tolls, and parking charges.
 - ii. **Prohibited Expenses.** Medtronic will not reimburse for fuel, car washes, parking tickets, fines for traffic violations, insurance premiums, damage/repair costs, or towing charges incurred when using a personal car.
 - b. **HCP Attendees.**
 - i. **Allowable Expenses.** When permitted by regional policy or allowed by law, same as above for HCP Consultants.
 - ii. **Prohibited Expenses.** Same as above for HCP Consultants.
 - c. **HCP Mileage Reimbursement.** When permitted, the mileage reimbursement rate is based upon the local Medtronic Employee mileage rate in effect and the distance traveled to and from the Medtronic-conducted activity, provided the round trip exceeds 30 miles / 48 kilometers. The mileage reimbursement is set to cover all expenses related to the operations of the personal car.

Part E. Non-Reimbursable Travel and Lodging Expenses. Medtronic may neither purchase on behalf of, nor reimburse an HCP for, the following items which are prohibited expenses:

1. Use of airline frequent flyer club facilities;
2. Lost baggage charges;
3. Wi-Fi on flights for HCP Attendees;
4. Travel and ground transportation upgrades;
5. Lodging upgrades or the additional cost of an alternate and more expensive hotel;
6. Lodging charges for additional hours beyond check-out time or additional nights;
7. Other travel and lodging change costs not related to a Medtronic schedule change or HCP personal or professional emergency; and
8. Travel and lodging costs related to a partner, spouse, or other guests.

Standard 6. Meals and Refreshments

Employees are responsible for ensuring responsible business interactions, including how the provision of occasional, modest meals and refreshments may be perceived as part of a legitimate business interaction. The term “meal” as used throughout this policy collectively refers to both meals and/or refreshments. In addition to the General Provisions requirements, Medtronic may pay modest costs for meals provided to HCPs, namely in conjunction with:

- Meetings related to HCP/HCO Services Arrangements (see Standard 1);
- Medical Education (see Standard 2, Part A);
- Business Meetings (see Standard 2, Part B);
- Meals provided as part of Jointly Conducted Education and Marketing Programs (see Standard 4); and
- Satellite Symposia (see Standard 3, Part A2).

Meal expenses must be modest and reasonable. Meals should be subordinate in time and in focus to the bona fide discussion and presentation of scientific, educational, or business information.

If a Medtronic-conducted activity or Business Meeting is being held adjacent to a Third-Party Program, additional restrictions apply (see Standard 3, Part A3).

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 modest by local standards (e.g., within Medtronic spending limits);
- The HCP attends and has a Legitimate Need for attending the activity associated with the meal; and
- The meal is provided in a manner conducive to the discussion or presentation of scientific, educational, or business information.

A Medtronic Employee must attend throughout a Medtronic-provided meal with HCPs.

Employees must not pay for or contribute to:

- Excessive amount of or unreasonably expensive alcohol. Employees should consider both the cost of an individual drink and the amount consumed by individuals at the activity or meal when evaluating whether the alcohol consumption is modest;
- Meals for a partner, spouse, or other guest of an HCP, even if the partner, spouse, or guest is also an HCP (unless the partner, spouse, or guest has their own independent Legitimate Need for attending the activity);
- A casual get-together with an HCP for the development of general goodwill;
- A celebratory event with an HCP (e.g., holiday, retirement, birthday, promotion, or year-end department celebration); or
- Meals or events hosted by an HCO/HCP that do not qualify as a Jointly Conducted Education and Marketing Program under Standard 4.

Part A. Spending Limits. Employees should calculate spending limits as follows:

1. **Medtronic HCP Meal Limits.** To determine the appropriate spending limit for meals with HCPs, Employees must consult the Medtronic HCP Meal Limits (see [Global HCP Meal Limits](#)).
2. **Location.** In general, the per person spending limit is determined based on the location of the meal (country and/or city where the meal is taking place).
3. **Per Person Limit.** When determining whether a meal falls within the applicable spending limit, take the total cost of the meal divided by the number of attendees (e.g., average cost per meal per attendee) and compare to the applicable spending limit based on the location of the meal unless a country-specific spending limit applies (see exception below).
4. **Taxes, Tips and Service Charges.** Unless otherwise prohibited by law, the per person spending limit is calculated inclusive of taxes, tips, and service charges.
5. **Exception.** There are some countries that apply specific meal limits to HCPs from that country regardless of where in the world the meal occurs. Therefore, it is important to check in the [Global HCP Meal Limits](#) to see if any specific country requirements apply when an HCP attending the meal is from another country.

Part B. Approvals. To ensure an objective, one-over approval when one or more Employees are present at a meal, the most senior-level Employee from the function hosting must pay and expense the itemized bill on their travel & expense card. Employees must not instruct nor allow suppliers to split a single expenditure into multiple transactions in order to avoid the meal limit. Employees also are not permitted to split checks with another Employee. The Employee who submits the expense is responsible for accurately and completely attributing the expense to all individual attendees. In the event a meeting

planner is arranging the meal, the meeting planner may pay for the meal on their meeting card, even if a more senior-level Employee is present at the meal.

Part C. External Attendees.

1. **HCP Partners, Spouses or Guests.** Meals must never be offered or provided to the partner, spouse or other guest of an HCP unless the partner, spouse or guest has their own independent justifiable clinical, business, or educational reason for attending the meal.
2. **Employee Partners, Spouses or Guests.** Expenses associated with a partner, spouse or guest of an Employee who attends a meal with an HCP are not reimbursable, without pre-approval from the Employee's manager.
3. **No-Shows.** If a Medtronic-conducted activity involves a meal with a fixed cost (either a required minimum amount or a fixed price menu) and an HCP or other attendee fails to attend the activity, then an Employee may indicate that there was a "No-show." However, "No-show" may never be used in an attempt to circumvent meal limits by decreasing the cost per attendee.

Part D. Meals Associated with In-Service/Product Training. The following requirements apply to any meals provided to HCPs and/or HCO office staff members as part of an in-service or product training held at an appropriate venue:

1. **Provision of Meals.** Employees may only provide meals:
 - a. In connection with the informational presentation/scientific discussion;
 - b. Provided only to HCPs and/or HCO office staff member(s) who are attending the presentation/participating in the discussion; and
 - c. When the HCPs and/or HCO office staff member(s) are expected to consume it during the informational presentation/discussion.
2. **Form of Food and Beverages; No Gifts.** Unless otherwise permitted by regional policy, Employees must not provide food and/or beverages in a form that is, or could be, perceived as a gift. This includes, for example:
 - a. Food arrangements that could be taken home by the HCPs and/or HCO office staff member(s);
 - b. Wrapped or boxed cakes, pies, pastries, unless consumed during the informational presentation/discussion; or
 - c. Boxes, packages, or tins of candy that could easily be taken home, or boxes or tins of coffee or teas.
3. **Use of Medtronic-Issued Corporate Card.** Employees are responsible for ordering and paying for all meals with their corporate card (travel & expense card or meeting card). Employees must

not provide their corporate card information to an HCP or HCO office staff member to order food or beverages on behalf of Medtronic.

4. **Attendance Sheets.** Regional policies will identify when attendance sheets are required. Employees must accurately and completely reflect in the applicable Finance reporting system who is consuming the food or beverage during the in-office presentation.
5. **Drop-Off Food and Beverages.** Drop-off meals, snacks, or beverages are prohibited.

Part E. Meal Expenses Submitted by an HCP for Reimbursement.

1. **HCP Consultants.** Medtronic may reimburse HCP Consultants for individual meal expenses according to actual and reasonable out-of-pocket costs incurred while the HCP is traveling in a professional capacity related to, or on behalf of, Medtronic and consistent with the meal limits for HCP individual meals, as determined by regional policy.
2. **HCP Attendees.** When permitted by regional policy, Medtronic may reimburse HCP Attendees for individual meal expenses according to actual and reasonable out-of-pocket costs incurred during the course of the HCP traveling to or from a Medtronic-conducted activity, and consistent with the meal limits for HCP individual meals, as determined by regional policy.

Part F. Non-Reimbursable Meal Expenses. The following items are prohibited expenses:

1. **HCP Partners, Spouses or Guests.** Costs related to a partner, spouse or other guest of an HCP (unless the partner, spouse or other guest has their own independent Legitimate Need to attend the activity); and
2. **Duplicative Meals.** Duplicative meals (where Medtronic has provided a meal during the Medtronic activity unless the HCP's travel schedule requires missing the Medtronic activity meal).

Standard 7. Educational Items and Gifts

Part A. Educational Items. Employees may provide to HCPs/HCOs items, modest in value, that have a genuine educational function or benefit patients (e.g., journal articles, medical textbooks or anatomical models). Such items must be reported if required under local transparency laws and regulations.

Part B. Gifts. Medtronic adheres to country laws and industry codes of ethics regarding nominal gifts to an HCP/HCO or an HCP's close family member where there is a strong cultural custom. The rules around gifts are dependent on the laws and industry code of the country where the HCP resides, practices or works, or where the HCO is located. 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 monetary or non-monetary gifts to HCPs/HCOs.

For those few countries where modest cultural-courtesy gifts are allowed, some types of gifts are always prohibited, including:

- Items that could be used by the HCP/HCO (or an HCP's family members, HCO office staff members, or friends) for non-educational or non-patient-related purposes (e.g., scrubs, tablets, smart phones, laptops, or other mobile devices capable of personal or non-educational use); and
- Gifts such as cookies, wine/alcohol, flowers, chocolates, gift baskets, holiday gifts, or cash or cash equivalents - even if intended to recognize a major life event.

Standard 8. Entertainment and Recreation Prohibition

Entertainment and recreational activities are inconsistent with the appropriate business purpose of Medtronic's interactions with HCPs/HCOs. Therefore, Employees are prohibited from paying for entertainment or recreation activities for HCPs/HCOs in any form. Such activities include but are not limited to alcohol-focused events (e.g., night clubs, bar crawls), 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/HCO 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/HCOs may use Medtronic Technologies. Generally, HCPs/HCOs 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/HCOs, including:

- Presentations at medical or scientific conferences regarding clinical study 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/HCOs 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 (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/HCOs 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/HCOs (and sometimes non-HCPs/non-HCOs) 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 operating unit or geography who have appropriate knowledge and expertise. More specifically:

Part A. Information Support. Medtronic may provide HCPs/HCOs with information related to Reimbursement Activities to enhance an HCP's/HCO'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 payers or government entities for services and procedures using Medtronic Technology and any proposed regulatory changes that might impact the HCP's/HCO's decision of whether to purchase or use Medtronic Technology.

Part B. Advocacy. Medtronic may collaborate with HCPs/HCOs, their professional organizations, and patient groups to conduct joint advocacy on Reimbursement Activities. This may include providing HCPs/HCOs 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/HCOs 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/HCO 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 HCPs/HCOs with coverage, reimbursement, and health economics support as an unlawful inducement;
2. Provide coverage, reimbursement, or health economics support to patients or HCPs/HCOs that eliminates an overhead or other expense that the HCP/HCO would otherwise incur;
3. Make site-of-service recommendations to HCPs, particularly when the site of service may impact reimbursement;
4. Provide support services that have not been approved according to local requirements; or
5. Suggest ways for an HCP/HCO to:
 - a. Bill for services that are not medically necessary;
 - b. Get inappropriate reimbursement or reimbursement not in accordance with payer 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/HCOs 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/HCOs 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/HCO account representative when selling a Medtronic Technology at a reduced price or no charge. Employees may fulfill the notice requirement by giving the HCP/HCO 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 (see Related Policies).

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/HCO for use in and storage at the HCP's/HCO's patient care setting; and
 - b. To which Medtronic retains title until the product is used.Once the product is used, the HCP/HCO must be charged for the product according to the local policies and the commercial contract with the HCP/HCO. 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/HCOs that aids the use of a related Medtronic Technology. Employees may provide Support Equipment to HCPs/HCOs 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/HCO 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 (see [Global Capital Equipment Playbook](#)). In addition:
 - a. Medtronic typically retains title to the equipment;
 - b. The written agreement must address what will happen if the HCP/HCO 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 and Compliance or Legal;
- d. Medtronic must transparently and separately disclose the prices of products and the equipment to the HCP/HCO; and
- e. The written agreement must specify what happens to the equipment once the HCP/HCO fulfills the product purchase commitment (e.g., whether Medtronic will collect the equipment, the HCP/HCO will return the equipment, or the HCP/HCO will purchase the equipment).

Part B. Products or Equipment Provided for Evaluation. There are three ways that Employees may provide Medtronic Technologies to HCPs/HCOs for evaluation. In these situations, the Medtronic Technology is provided to the HCP/HCO 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/HCO. In certain circumstances, Employees may provide Demos to HCPs/HCOs for patient awareness or education.
2. **Samples.** Samples are generally products provided free of charge to an HCP/HCO for the HCP/HCO to clinically evaluate the Medtronic Technology for future purchase. Samples are intended for use by the HCP/HCO 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/HCO for the purpose of evaluation. If an HCP/HCO 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/HCO for the HCP/HCO 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:
 - i. Reasonable under the circumstances to allow an adequate evaluation as to whether the HCP/HCO wants to purchase or otherwise acquire the equipment; and
 - ii. Consistent with applicable transparency reporting requirements;

- c. Equipment must be promptly removed at the conclusion of the evaluation period unless the HCP/HCO 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 D.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/HCO’s policies and requirements, including patient privacy and credentialing requirements. Field Personnel must comply with all regional policies governing these activities. In addition, Field Personnel must comply with the following requirements:

1. **Practice of Medicine.** While 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/HCO Duties.** While providing technical support, Field Personnel must not perform duties typically expected to be performed by an HCP/HCO, such as scheduling patient appointments or accessing patient records. Similarly, Field Personnel must not fill out paperwork for HCPs/HCOs 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 labeling if the support is limited to providing information consistent with the approved product labeling.

Roles and Responsibilities

Role	Responsibilities
Employees	<ul style="list-style-type: none"> • Know and understand the rules that apply to interactions with HCPs/HCOs • Consult with appropriate regional Compliance/Legal team with questions regarding interacting with HCPs/HCOs
Corporate Office of Ethics & Compliance, Regional Compliance/Legal	<ul style="list-style-type: none"> • Provide guidance on BCS Policy questions • Provide guidance on the Global BCS Exceptions process • Develop and implement policies and procedures to ensure compliance with the Global Business Conduct Standards • Consult with Employees on appropriate sponsorships, agreements, offers, research, and information provided to HCPs/HCOs

Abbreviations, Acronyms, and Definitions

Business Meetings - Meetings between an Employee and a Healthcare Professional/Healthcare Organization 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, as determined by the standards of the country where the organization is registered.

Clinical Research - Research that involves human subjects.

Clinical Research Agreement - A written agreement documenting the Clinical Research Arrangement provided by a Healthcare Organization to Medtronic, and the payment due to the Healthcare Organization for rendering the Clinical Research Arrangement services.

Clinical Research Arrangement - An arrangement with a Healthcare Organization where Medtronic pays a Healthcare Organization to provide valuable, bona fide Clinical Research services to support Medtronic's business needs. Compensation is based on costs associated with funding the research, and a written protocol is required. Clinical Research must be approved by the responsible ethical review board, such as an institutional review board.

Collaborative Research - Research conducted jointly by Medtronic and a Healthcare Professional/Healthcare Organization 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 Agreement - A written agreement documenting the Consulting Arrangement provided by a Healthcare Professional/Healthcare Organization to Medtronic, and the payment due to the Healthcare Professional/Healthcare Organization for rendering the Consulting Arrangement services.

Consulting Arrangement - An arrangement with a Healthcare Professional/Healthcare Organization where Medtronic pays a Healthcare Professional/Healthcare Organization to provide valuable, bona fide consulting services to support Medtronic's business needs. These consulting services include advisory services, clinical consulting, pre-clinical consulting, product development consulting, and training and education consulting services. The Needs Assessment documentation process must be completed first before engaging with a Healthcare Professional/Healthcare Organization to provide these consulting 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 Medtronic legal entity that employs them.

External Research Program (ERPs) - An independent investigator-initiated study in which Medtronic is a potential supporter but is not the study sponsor. External Research Program ("ERP") is also referred to in the medical device industry as "Investigator 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 agreement in the country where the Healthcare Professional resides, practices or works, or where a Healthcare Organization is located.

Field Personnel – Employees in the field organization or who otherwise provide technical support directly to Healthcare Professionals.

General Research – Research conducted by an independent third party aimed at increasing scientific knowledge and improving scientific theory.

HCP Attendee – Healthcare Professionals who participate in Medtronic training and education activities, promotional activities (e.g., Medtronic site visits), and/or Business Meetings.

HCP Consultant – Healthcare Professionals who are delivering bona fide services to or on behalf of Medtronic under an HCP/HCO Services Arrangement.

Healthcare Organization (HCO) – “Healthcare Organization” or “HCO” collectively includes: entities engaged in the provision of healthcare, including but not limited to hospitals, universities, medical practices, home healthcare agencies, and government agencies; companies formed or owned by Healthcare Professionals to perform personal consulting services (e.g., LLC); organizations led or directed by Healthcare Professionals or in which Healthcare Professionals are members, including but not limited to patient advocacy groups, medical societies and professional organizations; any Healthcare Organization or Healthcare Professional affiliated organization, if in a position to influence the decision to purchase or use Medtronic Technologies; any other entities in a capacity to directly recommend or materially influence the decision to purchase or use of Medtronic Technologies; and any other entities within scope of transparency reporting. These entities are typically in a position to prescribe, purchase, lease, recommend, use, arrange for the purchase or lease of, or have a material influence over purchasing decisions for, Medtronic Technologies.

Healthcare Professional (HCP) – “Healthcare Professional” or “HCP” collectively includes: Healthcare Providers; any Healthcare Organization staff members or Healthcare Professional’s Relatives, if in a position to influence the decision to purchase or use Medtronic Technologies; any other individuals in a capacity to directly recommend or materially influence the decision to purchase or use of Medtronic Technologies; and any other individuals within scope of transparency reporting. These individuals are typically in a position to prescribe, purchase, lease, recommend, use, arrange for the purchase or lease of, or have a material influence over purchasing decisions for, Medtronic Technologies.

Healthcare Provider – “Healthcare Provider” collectively includes but is not limited to: physicians, non-physician practitioners, medical fellows, medical students, or healthcare providers who are government

officials, 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-conducted instruction, education, or training sessions regarding the safe and effective use of Medtronic Technologies.

Medtronic Technology - 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.

Needs Assessment - The process Medtronic uses to document in advance the Legitimate Need to engage Healthcare Professionals/Healthcare Organizations for Consulting Arrangements, including documenting an appropriate purpose for the type of Consulting Arrangement, the need for use of the Healthcare Professionals/Healthcare Organizations, and the scope of work to be conducted by the Healthcare Professionals/Healthcare Organizations.

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

Pre-Clinical Research Agreement - A written agreement documenting the Pre-Clinical Research Arrangement provided by a Healthcare Organization to Medtronic, and the payment due to the Healthcare Organization for rendering the Pre-Clinical Research Arrangement services.

Pre-Clinical Research Arrangement - An arrangement with a Healthcare Organization where Medtronic pays a Healthcare Organization to provide valuable, bona fide Pre-Clinical Research services to support Medtronic's business needs. Compensation is based on costs associated with funding the research, and a protocol, research plan or written procedure is required. Pre-Clinical Research must be approved by the responsible ethical review board when required, such as an institutional animal care and use committee.

Proctorship - A training and education session in which an HCP Consultant observes, evaluates and verbally coaches and instructs an HCP trainee during a live surgery on medical procedures in support of one or more Medtronic Technologies. The HCP Consultant may provide guidelines for use of the Medtronic Technologies, and may objectively evaluate the HCP trainee on competence in surgical techniques. The HCP Consultant is not involved in any direct patient care, performing surgery or physically engaging with the patient. The HCP trainee has the relationship with the patient and the surgery is performed by the HCP trainee at the host medical institution. The HCP Consultant may conduct the proctoring in-person or virtually.

Product Development Arrangement - Collectively refers to (1) Consulting Arrangements involving the payment of consulting services provided by Healthcare Professionals or Healthcare Organizations to support the joint development of a new/enhanced Medtronic product or therapy where the Healthcare Professionals/Healthcare Organizations contribute intellectual property important to the design of the Medtronic Technologies; and (2) Product Development Agreements involving the payment of royalties or milestones related to the novel, significant, or innovative contribution to the design of the Medtronic Technologies.

Product Development Agreement - A written agreement documenting the Product Development Arrangement related to the novel, significant, or innovative contribution to the design of Medtronic Technologies provided by a Healthcare Professional/Healthcare Organization to Medtronic, and the payment of royalties or milestones due to the Healthcare Professional/Healthcare Organization for rendering the Product Development Arrangement services.

Reimbursement Activities - Medtronic-provided coverage, reimbursement, and health economic information support given to Healthcare Professionals/Healthcare Organizations related to Medtronic Technology.

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).

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.

Services Arrangement - An arrangement with a Healthcare Professional/Healthcare Organization where Medtronic pays a Healthcare Professional/Healthcare Organization to provide a wide range of valuable, bona fide services to support Medtronic's business needs. These Services Arrangements include Consulting Arrangements, Product Development Arrangements, and Clinical Research Arrangements, and Pre-Clinical Research Arrangements.

Support Equipment - An instrument or equipment issued to Healthcare Professionals/Healthcare Organizations 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

Reference ID	Title
Medtronic.com	Code of Conduct
Medtronic.com	Code of Business Conduct and Ethics for Members of the Board of Directors
Policy Portal	Global Channel Compliance Policy
Policy Portal	Global Voice Your Concern Policy
Policy Portal	Global Travel and Expense Reimbursement Policy
Policy Portal	Global Conflicts of Interest Policy
Policy Portal	Publication & Authorship Policy
Policy Portal	External Research Program (ERP) Policy
Policy Portal	Interactions Regarding Off-Label Use Policy (U.S.)
Policy Portal	Accounting for Programmers, Other MDT Equipment, & Demos (2503)
Global Advertising and Promotional Materials SharePoint	Global Promotional Materials Policy
Global Advertising and Promotional Materials SharePoint	Global Advertising and Promotional Materials Process & Training Hub
Global Pricing and Contracting SharePoint	Global Capital Equipment Playbook
OEC Website	Global HCP Meal Limits
OEC Website	Global OEC SharePoint
OEC Website	APAC OEC SharePoint
OEC Website	Canada Legal and Compliance SharePoint
OEC Website	EMEA OEC SharePoint
OEC Website	Greater China OEC SharePoint
OEC Website	LATAM OEC SharePoint
OEC Website	US OEC SharePoint

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Documentation History

Date	Revision	Reason/Description
2012-May-01	1.0	Initial Release
2017-Aug-14	2.0	Revision
2020-Jan-21	3.0	Comprehensive review and revision to match new AdvaMed standards
2023-Sept-01	4.0	Comprehensive review and revision to incorporate the Global HCP-Related Travel, Business Courtesy & Expense Reimbursement Policy and other revisions for clarity

Procedures

N/A

FAQs

N/A

Appendices

[LATAM HCP Expenses Summary Sheet](#)

[US and Canada HCP Expenses Summary Sheet](#)