



**MONTEFIORE HEALTH SYSTEM  
ADMINISTRATIVE POLICY AND PROCEDURE**

SUBJECT: CONFLICT OF INTEREST NUMBER: JH20.1  
OWNER: DEPARTMENT OF COMPLIANCE  
EFFECTIVE: 10/15 REVIEW/REVISED: 4/21 SUPERSEDES: 10/15

CROSS-REFERENCE: Administrative Policies: JP30.1: Ethical Relations with Suppliers – Honoraria, Payments in Connection with Educational Activities; JF10.1: Charitable Contributions; Fundraising; JP54.1: Medical Vendor Representative; JE16.1: Ethical Conduct, Legal Compliance, Fraud and Misconduct; JR20.1: Ethical Relations with Suppliers and Other Third Parties Privately Sponsored Research/Programs; JP30.1: Political Activity; MHS Code of Conduct; MHS Supplier Guidelines, Information for Vendors and Sales Representatives; AECOM BIOT-POL-2018-001. Official Policy on Intellectual Property and Licensing Agreements; Montefiore Health System Conflict of Interest Policy: Trustees, Officers & Key Employees (*in development*)

*Administrative Policy and Procedure JH 20.1 for Montefiore Health System replaces Montefiore Medical Center Administrative Policy and Procedure JH 20.1 that was effective 05/93 and all subsequent versions.*

**Purpose:**

This Conflicts of Interest Policy is issued by resolution of the Board of Trustees of Montefiore Health System, Inc. (“MHS”), pursuant to Article XI of the Bylaws of MHS, and by resolution of the Board of Trustees of Montefiore Medical Center (MHS and Montefiore Medical Center collectively defined as “Montefiore”), pursuant to Article V, Section 5.12, of the Bylaws of Montefiore Medical Center.

The purpose of this Policy is to ensure that all institutional decisions are made solely to promote the best interests of Montefiore and Montefiore’s patients without favor or preference based on personal considerations, and to provide for the highest standards of ethical conduct with respect to the actions and business relationships of all Montefiore associates, including employed providers and businesses, with which Montefiore does business with and where such obligations are contractually stipulated.

This Policy was developed to provide guidance on a variety of conflicts of interest and commitment that may arise across Montefiore and to describe the procedures adopted for addressing these conflicts of interest. It is Montefiore’s goal to promote disclosure of potential conflicts so that Montefiore and Covered Persons can comply with all applicable federal and state laws, rules and regulations and ethical obligations, as well as internal policies and procedures.

This Policy is divided into several sections. First is a section which defines the key terms used throughout this Policy. Next is a general policy that applies to all Covered Persons. Following are sections applicable to specific members of the Montefiore community who may be in positions which entail special fiduciary responsibilities to Montefiore, or who are in positions in which conflicts of interest or commitment are more likely to arise or are subject to unique ethical or regulatory requirements.

**Scope:**

This Policy applies to all associates of Montefiore, including employed physicians, and to each not-for-profit affiliate and subsidiary of Montefiore that does not have its own Board-adopted Conflicts of Interest Policy, including, but not limited to, The Care Management Organization, Montefiore Information Technology, the Montefiore Medical Group, the Montefiore Home Health Agency (“Covered Persons”). Non-employed providers who are members of the medical staff at Montefiore must comply with provisions of this policy related to disclosure of potential conflicts and the requirements for resolution of conflicts, to the extent such Policy provisions are within the scope of their obligations to Montefiore and its patients. Businesses are required to comply with this Policy to the extent Policy provisions are within the scope of their contractual or legal obligations to Montefiore.

As set forth in Section V below, individuals conducting research at Montefiore must comply with Albert Einstein College of Medicine (“Einstein”) policies regarding conflicts of interest in research and requirements for Public Health Service (“PHS”) -funded research grants and cooperative agreements.

## Section 1. Definitions

**Business:** A “Business” is any person, business, organization, association or entity that (1) is in the business of manufacturing or distributing or selling drugs, diagnostic or therapeutic equipment or devices, or any other supplies, items or services that are of the nature or type that Montefiore purchases for use in the conduct of its activities, whether or not the Business currently is or has ever been a Montefiore vendor; (2) otherwise has or is seeking to do business or have a financial relationship with Montefiore; or (3) any entity with which Montefiore has a referral relationship.

Examples include billing consultants, pharmaceutical and medical device manufacturers, nursing homes, durable medical equipment distributors, real estate companies, environmental services companies, parking garage services, etc.

**Clinical Personnel:** All Montefiore associates, medical staff and other contracted personnel who are involved, directly or indirectly, with the provision of patient care, including, but not limited to, physicians and other providers.

**Competitor:** An organization that is engaged in commercial or economic competition with Montefiore.

**Conflict of Commitment:** Any situation where an individual engages in external activities, whether paid or unpaid, that burden or interfere with their primary obligations to Montefiore or create the appearance of doing so.

**Conflict of Interest:** Any relationship or interest that could interfere, directly or indirectly, with an individual’s objectivity in performing their duties on behalf of Montefiore or creates the appearance of doing so.

**Conflict of Interest Advisory Committee:** A standing committee consisting of the, the Senior Vice President & Chief Medical Officer, the Senior Vice President & General Counsel and the Vice President & Counsel, Compliance. The purpose of the committee is to review Conflicts of Interest and determine the appropriate resolution, including developing Conflict of Interest Management Plans. All decisions of the Conflict of Interest Advisory Committee are subject to approval of the President and Chief Executive Officer.

**Conflict of Interest Disclosure Survey (“Disclosure Survey”):** A Montefiore-specific role-based paper or electronic questionnaire and certification designed to facilitate accurate and comprehensive disclosure of actual or potential Conflicts of Interest by Covered Persons.

**Conflict of Interest Management Plan:** An individual plan designed to manage, reduce or eliminate a specific Conflict of Interest. Such plans may include, but are not limited to, the following: (i) public disclosure (e.g., publications, presentations, consent forms); (ii) restrictions on equity; (iii) limiting the individual's role and responsibilities; (iv) increased oversight; (v) divestiture; or (vi) termination of relationships.

**Covered Persons:** This Policy applies to all associates of Montefiore, including employed physicians, and to each not-for-profit affiliate and subsidiary of Montefiore that does not have its own Board-adopted Conflicts of Interest Policy.

**Family Member:** An individual's spouse/domestic partner, parents, siblings, and children. This term also includes any trust, organization or enterprise over which the individual and/or their Family exercises a controlling or significant interest.

**Financial Interest:** Anything of value including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, gifts, loans, leases); equity interests (e.g., stocks, stock options, partnership interests); intellectual property rights (e.g., patents, copyrights, royalties, licenses, investment in unregistered products such as mobile apps); and service (whether compensated or unpaid) as an officer, manager or member of a board of directors, or other fiduciary or managerial role or other special relationship with a Business that has the potential for material gain. This term does not include salary and other remuneration received directly from Montefiore or publicly-traded mutual funds or similar diversified financial holdings. Situations where a Covered Person holds equity in a Business formed to develop a product or other IP for market or other financial gain, but where the product or other IP has not yet been brought to market or otherwise generated revenue must still be disclosed and are subject to review and potential Conflict Management Plans.

**Institutional Review Board ("IRB"):** Committee that approves, monitors and reviews research involving human research subjects for the purpose of protecting the rights and welfare of the human research subjects. The Montefiore IRB serves as the IRB for the member entities of the Montefiore Health System except where not-for-profit affiliates and subsidiaries of Montefiore have implemented their own IRB's.

**Research:** Any systematic investigation of scientific inquiry designed to develop or contribute to general knowledge. Research shall include, but is not limited to, the following activities: (i) designing; (ii) directing or serving as an investigator; (iii) performing laboratory experiments; (iv) soliciting consent from research subjects or making eligibility determinations; (v) analyzing or reporting data; and (vi) preparing, contributing to or submitting manuscripts or abstracts related to the research.

**Speakers' Bureau:** a consulting arrangement in which an individual, usually a subject matter expert, agrees to serve as a paid speaker at company-sponsored events. Participation in Speakers' Bureaus is strictly prohibited unless such participation has been preapproved by the Conflict of Interest Advisory Committee.

## **Section II. General Conflict of Interest Policy**

### **A. General Standard**

All Covered Persons have an obligation to make decisions and conduct the affairs of Montefiore in a way that promotes the best interests of Montefiore and its patients and avoids a Conflict of Interest or the appearance of a Conflict of Interest. All Covered Persons must refrain from using their Montefiore position, responsibilities and knowledge for inappropriate personal gain.

All Covered Persons are responsible for knowing, understanding and complying with this Policy, and to ensure compliance of Family Members where applicable. All Montefiore Vice Presidents and Chairpersons are responsible for implementing this Policy within their respective departments and facilitating the disclosure, review and resolution of any Conflict of Interest. Any Covered Person with questions concerning this Policy or its application should contact the Department of Compliance for guidance.

## **B. Disclosure and Reporting Process**

**1. New Hires and Appointments:** Upon employment, new associates shall be informed of this Policy by the Department of Human Resources. New attending physicians shall be informed of this Policy by the Medical Staff Credentialing Office.

**2. Obligation to Comply:** It is the responsibility of all Covered Persons to familiarize themselves with this Policy and to comply with the following procedures.

**3. Disclosure of Conflicts of Interests:** Covered Persons are required to complete and submit the appropriate role-based Conflict of Interest Disclosure Survey (“Disclosure Survey”) as set forth below:

**a)** All associates must complete a Disclosure Survey prior to beginning work at Montefiore, and thereafter as requested by the Department of Compliance.

**b)** All credentialed providers must complete a Disclosure Survey prior to initial appointment and subsequently prior to recredentialing.

**c)** Conflict of Interest Disclosures to the IRB in connection with research applications will be forwarded to the Department of Compliance by the applicable IRB.

**d)** Recipients of PHS-funded research grants and cooperative agreements must also comply with the reporting requirements of the Einstein “Policy on Disclosing Financial Conflicts of Interest in Research,” which includes PHS conflict of interest requirements. See Section V below.

**e)** All Covered Persons must update their role-based Disclosure Survey to disclose any activity, personal, or familial interest that may lead to a Conflict of Interest that arises at any time after filing the Survey, within thirty (30) days of becoming aware of the possibility of a Conflict of Interest.

**f)** Medical staff and other Clinical Personnel must disclose and receive approval prior to making any contractual agreement to participate in any activities that could constitute a Conflict of Interest.

**4. Responsibility for Accuracy:** It is the Covered Person’s responsibility to provide all pertinent information on the Disclosure Survey to enable full review and analysis of the circumstances, and to otherwise cooperate with the Department of Compliance in its review and management of any actual or potential conflict. Montefiore reserves the right to request additional information or supporting documentation.

Medical Staff and other Clinical Personnel are personally responsible for review and dispute management of any publicly posted information about payments they may have received from Businesses pursuant to The Physician Payments Sunshine Act (PPSA) of 2010 and any other relevant state or federal laws enacted following the implementation of this Policy.

### **C. Administrative Responsibility**

Montefiore has designated the Vice President & Counsel, Compliance to be the compliance officer (“Compliance Officer”) for this policy. The Compliance Officer will consult with the Conflict of Interest Advisory Committee and/or the Compliance Committee of the Board of Trustees as advisable in addressing specific Conflicts of Interest, in developing policies and procedures, or as otherwise appropriate. All Conflict of Interest Management Plans and disciplinary decisions pursuant to the Policy shall be developed in consultation with the Conflict of Interest Advisory Committee. The Compliance Officer shall report quarterly and/or as indicated based on disclosures received, to the Conflict of Interest Advisory Committee regarding the Conflict of Interest program and related activities.

### **D. Resolution of Conflicts**

**1. Disclosure Survey Review:** The Compliance Officer will review submitted Disclosure Surveys and take appropriate action. Appropriate action may include providing guidance to manage a Conflict of Interest, developing a Conflict of Interest Management Plan for approval by the individual designated by the President and Chief Executive Officer, directing an investigation and/or referring the Disclosure Survey to the Conflict of Interest Advisory Committee and/or the Compliance Committee of the Board of Trustees. To the extent that further investigation is required, the Compliance Officer shall direct such investigation and develop recommendations as to the resolution of any Conflict. Such appropriate actions by the Compliance Officer, the Conflict of Interest Advisory Committee, the President and Chief Executive Officer or duly empowered designee and/or the Compliance Committee of the Board of Trustees, shall be documented and communicated in writing to the Covered Person involved.

**2. Review of Other Information:** The Compliance Officer may review additional information in connection with ascertaining actual or potential Conflicts of Interests among Covered Persons, including but not limited to periodic review of publicly available information on payments by the medical industry to Clinical Personnel, forwarded Conflict of Interest Disclosures submitted to the IRB and/or Einstein in connection with Research applications or other academic activities, inquiries or reports to the Compliance hotline or Department of Compliance concerning potential Conflicts, or other auditing or monitoring review. The Covered Person shall cooperate with such review and shall provide copies of all relevant documentation as reasonably requested.

**3. Conflict of Interest Management Plan:** A Conflict of Interest Management Plan (the “Plan”) will be developed and implemented based on specific facts and circumstances involved in a potential or actual Conflict of Interest presented. Collaboration with the Covered Person is encouraged where possible to ensure a fair but effective plan to manage the Conflict.

In general, unless otherwise authorized in the Plan, Covered Persons with a Conflict of Interest may not take part in any decisions to which the Conflict relates. Prohibited activities include, but are not limited to:

- a) Submitting, signing, or authorizing a purchase order to make purchases from the Business;
- b) Negotiating or entering into contracts with the Business on behalf of Montefiore;
- c) Supervising or administering the performance and activities under a contract or relationship with the Business, or monitoring the business performance of the Business under the contract; and
- d) Participating in patient care decisions or research activities or giving lectures at Montefiore that relate to the Conflict.

Where management of a Conflict is impractical or ineffective, the Conflict of Interest Advisory Committee and/or the Compliance Committee of the Board of Trustees may prohibit or otherwise limit the Covered Person from engaging in the activity giving rise to the Conflict of Interest, consistent with applicable law.

**4. Enforcement:** The Compliance Officer, in consultation with the Conflict of Interest Advisory Committee and/or the Compliance Committee of the Board of Trustees, as appropriate, shall review all potential violations of this Policy and determine whether a breach has occurred. Potential violations may include: (i) failing to report; (ii) providing incomplete or inaccurate information; (iii) failing to update a disclosure form when required to do so; (iv) failing to cooperate with an investigation of a potential Conflict of Interest; or (v) failing to abide by a Conflict of Interest Management Plan.

All Covered Persons who violate this Policy may be subject to discipline, up to and including termination and removal or non-renewal of appointment to the medical staff, or other affiliation with Montefiore, subject to the approval of Conflict of Interest Advisory Committee, Operations and/or the Compliance Committee of the Board of Trustees.

**5. Document Retention:** The Compliance Officer shall maintain all Conflict of Interest Disclosure Forms, Conflict of Interest Management Plans and related documentation for a period of at least six (6) years.

**6. Training:** The Compliance Officer shall ensure that all Covered Persons receive training on the Conflict of Interest Policy.

**7. Auditing and Monitoring:** All Conflicts of Interest disclosed under this Policy shall be subject to auditing and monitoring by the Compliance Officer, in consultation with the Conflict of Interest Advisory Committee and/or the Compliance Committee of the Board of Trustees, as appropriate. Monitoring shall include review of activity in connection with Conflict of Interest Management Plans.

**8. Confidentiality:** To the extent possible and as permitted by law, Disclosure Surveys submitted pursuant to this Policy and additional information or materials provided in support will be kept confidential and provided to the Conflict of Interest Advisory Committee, Compliance Committee of the Board of Trustees, the applicable IRB, the Albert Einstein College of Medicine, the Covered Person's supervisor or chairman, and other individuals on a need-to-know basis. Montefiore will, however, comply with applicable laws which may require public posting or disclosure, electronically or through other media, of certain information concerning payments by specified Businesses to providers of health care services or other requirements.

#### **E. Areas of Potential Conflict of Interest and/or Commitment**

It is impossible to anticipate and describe every circumstance that might create a Conflict of Interest and that must, therefore, be disclosed. The following are illustrations of activities that might give rise to a Conflict of Interest and that must be disclosed. They do not comprise an exclusive list. **Please refer more specifically to later role-based Sections of this Policy, as applicable, for additional guidance on disclosure and management of specific types of conflicts.**

##### **1. Ownership, Control or Management of a Business or Competitor:**

Being connected directly (as owner, trustee, partner, officer, director, participant, licensee, shareholder, stock option holder, manager, or recipient of any compensation of value) or indirectly (as a Family Member, silent partner, etc.) with any Business or Competitor or otherwise being in a position to influence or direct the activities of a Business or Competitor or to refer patients to/from the Business must be disclosed.

These financial interests do not include interests in entities listed on a national stock exchange or traded over the counter, provided the Covered Person and Family Members do not own in the aggregate 5% or more of the entity's outstanding shares unless special circumstances exist.

**2. Consulting Arrangements:** A consulting arrangement exists between a Covered Person and an entity when the Covered Person is compensated by the entity in exchange for providing services or advice utilizing his or her professional knowledge and expertise related to his or her professional field or discipline. The Covered Person providing services might function as a speaker, scientific or advisory board member, or focus group member for the entity, or otherwise play a role in providing endorsement, marketing, public relations or advertising services to an entity.

All consulting arrangements involving an associate or employed physician, regardless of amount of compensation, must satisfy the following conditions (a) the arrangement is set out in writing; (b) there is a legitimate need for the services; (c) the services are actually provided; (d) the compensation is at fair market value; and (e) all of the above characteristics are documented prior to payment.

Any anticipated or existing consulting arrangement between an associate or employed physician must be disclosed in advance to and approved by the associate's or employed physician's supervisor or Department Chair, as applicable, and timely disclosed in the Disclosure Survey. Clinical Personnel also must comply with later role-based Sections of this Policy.

**3. Outside Employment:** Engaging in outside business or employment that interferes with an associate or employed physician's ability to fulfill his or her employment obligations to Montefiore is prohibited as a Conflict of Commitment. Such activities are subject to prior review and approval by the associate's or employed physician's supervisor or Department Chair, as applicable.

**4. Community Service Activities:** Nothing in this Policy prohibits any Covered Person from serving as an unpaid outside director, trustee or other volunteer to a not-for-profit corporation or organization or any civic or public interest or social welfare organization as a community service, provided that such position does not conflict with the Covered Person's responsibilities at Montefiore and is disclosed to the Covered Person's supervisor (for associates and employed physicians) and/or the Compliance Officer. Such activity must not involve the use of Montefiore's name or endorsement in a manner that would conflict with Montefiore's interests or activities.

**5. Gifts and Other Benefits:** Covered Persons may not solicit or accept payments, loans, services, or gifts or favors ("Gifts"), for their own personal use or benefit, or for the benefit of a Covered Person's Family Member, from a Business or Montefiore competitor. It is expected that any Gift that is offered or given to a Covered Person is unsolicited. If a Covered Person should receive a Gift from a Business or Montefiore Competitor, the Covered Person must promptly report it to the Compliance Officer, who will arrange for its return, or for its donation to Montefiore through the Montefiore Office of Development.

Notwithstanding the foregoing and if not otherwise prohibited under the Montefiore Medical Vendor Representative Policy, unsolicited, de minimis non-cash gifts whose aggregate value per year from any Business does not exceed \$250 are not required to be reported or refused. When possible, divisible gifts (candy and the like) should be shared with other employees, particularly those who have interactions with the giver, both out of fairness and to avoid any appearance of favoritism.

**6. Business Meals and Entertainment:** Unless otherwise prohibited under the Montefiore Medical Vendor Policy, occasional business meals and related entertainment are permitted if they are of reasonable value and if there is a Montefiore benefit in accepting them. Meals and entertainment can result in a Montefiore benefit if attended with the giver or a representative of

their company; attendance with only Montefiore associates or with only family members does not result in a Montefiore benefit.

**7. Business Travel Reimbursement:** Reimbursement for reasonable costs of business travel of an Montefiore associate or employed physician by a Business or Competitor is only allowable under the following limited circumstances: 1) the Montefiore associate or employed physician is a bona fide speaker or panelist at a conference or meeting sponsored by the Business or Competitor; 2) the Montefiore associate or employed physician is receiving specialized clinical or technical training by the Business or Competitor which is more practically provided at an offsite location; 3) the Montefiore associate or employed physician is performing functions pursuant to a consulting arrangement approved in accordance with this Policy and within approved financial limits; or 4) reimbursement for travel is pre-approved by the Compliance Officer. Any travel for which an associate or employed physician anticipates seeking reimbursement from a Business or Competitor must be disclosed to and approved in advance by the Covered Person's supervisor or Department Chair, as applicable. Any such travel must be consistent with Montefiore Administrative Policy JF06.1, Travel and Employee Business Expense Reimbursement.

**8. Debts/Loans:** Any existing or proposed debt owed directly or indirectly by a Covered Person or Family Member to a Business or a Montefiore Competitor must be disclosed to the Compliance Officer. (A loan from a bank or other qualified lending institution at interest rates and on terms prevailing in the market at the time the loan was made does not create a Conflict of Interest.)

**9. Patents, Intellectual Property, and Royalties:** Associates and employed physicians must report any outside commitment they are considering or engaged in that creates intellectual or tangible property rights, such as patent ownership or licensing to an organization other than Montefiore. Such reportable circumstances include provision of financial or other support by a non-Montefiore entity for the utilization by the entity of intellectual property (e.g., inventions, know-how), tangible property (e.g., research materials) or original works of authorship (e.g., computer software, but not textbooks) of that associate's or employed physician's academic work or the work of another person who reports to the Covered Person. See Albert Einstein College of Medicine's Official Policy on Intellectual Property and Licensing Agreements, available from the Albert Einstein College of Medicine Office of Biotechnology and Business Development, for additional information.

Work product created or developed in the capacity as an associate or employed physician of Montefiore or any of its affiliates or subsidiaries shall be the property of Montefiore.

Royalties in excess of \$5,000 received by providers for any medical products or devices that are, or could be potentially prescribed, ordered or used within the scope of the providers' clinical practice must be disclosed to the providers' chairperson, department head or immediate supervisor on an annual basis. Any increase in such royalties received that would represent an increase of either 50% from the providers' previous COI disclosure will require the submission of an updated disclosure form by the provider.

**10. Montefiore Property; Confidential or Privileged Information:** All materials, equipment, goods, products, designs, plans, ideas, data and records of Montefiore, whether or not written, are the property of Montefiore and are "Proprietary Materials." No Covered Person may give or disclose any Proprietary Materials to any person or entity for purposes other than to promote the interests of Montefiore. Further, confidential or privileged information may not be disclosed for any purpose, except as may be required by valid order of a court or governmental agency of competent jurisdiction or as approved by the Office of Legal Affairs.

**11. Insider Trading:** Covered Persons shall not use confidential information obtained from their employment at Montefiore to speculate or invest in the securities of any entity or to speculate or invest in real estate, commodity markets, or other business ventures. Covered Persons must refrain from sharing such information with Family Members or others to participate in such

activities. If in doubt as to whether an activity is prohibited, the Covered Person should consult with their personal attorney.

**12. Use of Montefiore Facilities, Equipment, and Working Hours:** Covered Persons may not use their time and/or efforts during normal working hours to promote non-Montefiore interests, nor use Montefiore facilities or equipment for such purposes, except in conformity with Human Resources Policy and Procedure VII-4 (Solicitations and Distribution of Literature, Products and Services).

**13. Use of Position:** Covered Persons may not use their positions at Montefiore for their own inappropriate personal benefit or for the benefit of a Family Member, friend or business associate. Decision-making with respect to a particular Business may only be made in consideration of Montefiore interests and may not be influenced in any way by a Covered Person's personal interests.

**14. Use of Montefiore Name:** Using Montefiore's name, logo, or other identifying marks in outside private business or employment or misrepresenting oneself as an agent of Montefiore is prohibited. Unless otherwise agreed in a specific conflict of interest management plan, Covered Persons may list their Montefiore title and affiliation as identification only. Using Montefiore's name or the fact of the covered person's position in the covered person's private business or employment, or sponsorship of a political party or cause, or otherwise in a way that implies Montefiore endorsement of private services, business, equipment or supplies is prohibited.

**15. Gifts to Supervisors:** Associates shall not offer or give any gift to their direct or indirect supervisor except a gift of de minimis value. Supervisors shall not solicit, request or demand any gift from associates who report directly or indirectly to him or her.

## **Section III. Education and Clinical Care**

### **A. Scope**

This Section applies to all Clinical Personnel, including but not limited to physicians, nurses, residents, students and fellows, involved in clinical care and education instruction or administration. This Section further supplements the applicable provisions of Sections I and II of the Policy.

### **B. General Standard**

Health care providers and other Clinical Personnel owe patients undivided loyalty and uncompromised decision-making that is in the best interest of the patient. Collaborations and interactions with a Business may be beneficial to Montefiore, its patients, physicians and associates. Interactions with a Business must be conducted in a manner that avoids or minimizes even the appearance of a Conflict of Interest. In addition, employed Clinical Personnel must conduct any activities with a Business in a manner which will avoid any Conflict of Commitment.

Montefiore requires Clinical Personnel to disclose all relationships with any Business, scientific or medical non-profit organizations and medical education and communication companies, including but not limited to: All payments or other remuneration received from a Business in connection with consultancies, authorship and writing medical literature; payments or other remuneration received from Industry in connection with Research; patents, royalty payments, licenses and similar arrangements with Industry; and any other Financial Interest in a Business. Further, Montefiore limits or prohibits certain arrangements with Business which have the potential to compromise objectivity in patient care, research or commitment to Montefiore.

### **C. Conflict of Interest Disclosure**

**1. Medical Staff:** All providers seeking credentialing or recredentialing by Montefiore as a member of the medical staff, must complete a Disclosure Survey prior to initial appointment and subsequently prior to recredentialing. Credentialing and recredentialing applications are not considered complete and will not be processed until a completed Disclosure Survey Certification is submitted to the Credentialing Office. The preferred method of completion is electronic; however, a paper form may be requested and completed in lieu of electronic completion upon request to the Department of Compliance.

**2. Other Clinical Personnel:** All other Clinical Personnel must complete a Disclosure Survey prior to beginning employment at Montefiore, and thereafter as requested by the Department of Compliance.

**3. Continuing Duty to Disclose:** All Clinical Personnel must update their role-based Disclosure Survey to disclose any activity or personal interest that may lead to a Conflict of Interest that arises at any time after filing the Disclosure Survey, within thirty (30) days of becoming aware of the possibility of a Conflict. Montefiore reserves the right to request a revised Disclosure Survey any time.

**4. Prior Approval from Department Chair or Supervisor:** All Covered Persons subject to parts 1 and 2 of this section must disclose and seek approval for potential conflicts of interests that would be subject to this policy from their Department Chair or Supervisor pre-hire and subsequently prior to making any sort of contractual or other commitment to engage in any activities that substantively would constitute a potential conflict of interest.

#### **D. Conflict of Interest Resolution**

Completed Clinical Personnel Disclosure Surveys shall be forwarded to the Compliance Officer. The Compliance Officer shall consult with the Conflict of Interest Advisory Committee and the Compliance Committee of the Board of Trustees to determine appropriate action on any Conflict, as set forth in Section II, above. All decisions shall be documented and communicated to the Clinical Personnel involved. Requests for modifications or exceptions to this Policy must be directed to the Compliance Officer, who will consult the Conflict of Interest Advisory Committee for a decision.

#### **E. Clinical Care Conflicts**

**1. Section IIE Application:** This Section is supplemental to Sections I and II; Clinical Personnel must be familiar with and comply with all requirements for Conflict of Interest Management and Disclosure as set forth in Sections I, II and Section III, including specific areas of potential Conflicts described in Section IIE.

**2. Montefiore Medical Vendor Policy Application:** This Section is consistent with and is supplemental to the Montefiore Medical Vendor Representative Policy. Clinical personnel must be familiar with and comply with all applicable requirements as set forth in the Medical Vendor Policy.

**3. Clinical Personnel Activities:** In addition to the specific areas of potential Conflicts described in Section IIE and the Medical Representative Vendor Policy, employed Clinical Personnel must comply with the following:

**a) Consulting arrangements:** Montefiore Clinical Personnel are highly accomplished professionals and are recognized for their expertise within the health care industry. As such, they may be valuable contributors in research and in the development and implementation of new forms of treatment for patients; therefore they are frequently requested by Businesses to serve as

consultants. Consulting arrangements may take many forms, including but not limited to provision of services as a speaker, scientific or advisory board member, or focus group member for the entity, or providing endorsement, marketing, public relations or advertising services to an entity.

All consulting arrangements involving Clinical Personnel, regardless of amount of compensation, must satisfy the following conditions (a) the arrangement is set out in writing; (b) there is a legitimate need for the services; (c) the services are actually provided; (d) the compensation is at fair market value; and (e) all of the above characteristics are documented prior to payment.

Any anticipated or existing consulting arrangements otherwise in compliance with this Policy must be disclosed to and approved by the Clinical Personnel member's supervisor or Department Chair, as applicable, and timely disclosed in the Disclosure Survey. With regard to their personal potential consulting arrangements, Department Chairs must disclose and receive approval from the Conflict of Interest Advisory Committee prior to entering into any consulting arrangement otherwise in compliance with this Policy.

After careful consideration and in recognition of the evolving regulatory and professional standards in connection with provider/industry relationships, Montefiore has established the following guidelines for consulting arrangements, effective as of **January 1, 2014**:

**i. Scientific or advisory board participation:** Clinical Personnel may serve on scientific or advisory boards in a bona fide arrangement that comply with provisions of Section IIE of this Policy, provided that any anticipated or existing arrangement is disclosed to and approved by the Clinical Personnel member's supervisor or Department Chair, as applicable, and timely disclosed in the Disclosure Survey.

**ii. Speaking arrangements, including "Speakers' Bureaus":** Montefiore does not permit employed Clinical Personnel to participate in so-called "Speakers' Bureaus" funded by Businesses.

**iii. Expert witness testimony:** Clinical Personnel may serve as expert witnesses in situations that do not involve Montefiore directly, conflict with Montefiore's business interests, or otherwise represent a potential conflict of interest as defined by this policy.

**iv. Other consulting activities:** Other types of consulting arrangements will be reviewed and approved on a case-by-case basis by Supervisors and Chairpersons, as well as in the Compliance Officer review and evaluation of a Disclosure Survey. Consulting arrangements with the potential to facilitate institutional and patient care goals through collaboration with a Business may be approved, or approved with modification, where appropriate. In some circumstances, having Montefiore contract directly with a Business for the services of Employed Clinical Personnel will decrease the potential for a Conflict and will be recommended in a Conflict of Interest Management Plan.

**v. Other considerations:** Other factors may impact the potential for a Conflict of Interest to arise in connection with consulting arrangements and may be considered in requests for approval by Supervisors or Chairpersons, as well as in the Compliance Officer review and evaluation of a Disclosure Survey. Those factors include, but are not limited to: any ongoing or planned research related in any way to a consulting arrangement which may impact objectivity of the proposed consultant; Montefiore reputation or business interests, including purchasing decisions and contracts with Business that may be adversely impacted by the consulting arrangement; referral relationships; and the potential for a Conflict of Commitment.

**b) Writing and Publication Activities:** Medical literature should be transparent as to all authors and contributors to the document. This is especially important when a Business sponsors, funds, contributes or otherwise influences medical literature. All documents must include full disclosure as to the role of each author, contributor and sponsor.

Employed Clinical Personnel may not be designated as an author of a publication in which he or she has not provided substantive content (“ghostwriting”). Additionally, all individuals who contribute to a literature piece should be acknowledged as such, including employees or agents of a Business. Clinical Personnel must maintain editorial independence at all times.

**c) Remuneration, Equity and Ownership Interests:** As noted above, all remuneration provided to Clinical Personnel related to an approved arrangement with a Business should be at fair market value in relation to the services provided. Montefiore recognizes that in some circumstances, particularly with start-up pharmaceutical or medical device companies, a Business may seek to compensate employed Clinical Personnel through granting of an equity or ownership interest in the Business in exchange for services provided. Granting of an equity interest presents a difficulty in quantifying the fair market value of the payments received and creates the possibility of a windfall to Clinical Personnel many times beyond the present value of their services. Nevertheless, given the need to overcome barriers for collaboration to potentially enhance patient care, and in light of current industry standards, Montefiore will consider arrangements involving remuneration through equity or ownership interests on a case-by-case basis. All such arrangements must be directed to the Compliance Officer, who will consult the President and Chief Executive Officer or duly empowered designee for a decision.

#### **4) Support for Educational Activities**

**a) General Standards:** Providing accurate, unbiased and comprehensive education is a critical component of Montefiore’s mission. With that goal, educational programs that take place at Montefiore facilities or are planned or hosted, in whole or part, by Montefiore and its employed Clinical Personnel either onsite or offsite are educational in nature and should not be used or influenced for promotional or marketing purposes. Financial support provided by Business for Montefiore educational programs may not be restricted or otherwise have any “strings attached.” Financial Support for Montefiore educational programs should be made with the approval of and directly to the Albert Einstein College of Medicine Center for Continuing Medical Education. Clinical Departments or employed Clinical Personnel may not receive educational funds directly from any Business, including funding for informal departmental education or offsite provider or patient educational sessions.

Businesses may not influence or provide advice regarding program topic, format, faculty, participants, or content. Disclosure shall be made at each educational program of any Business support or faculty relationships with Businesses. In addition, any educational program that is accredited must comply with all standards set forth by the accrediting body.

Industry representatives may not attend Montefiore educational programs held in clinical areas with direct patient care including, for example, grand rounds. See also, Montefiore’s Office of Continuing Medical Education policy on conflicts of interest.

#### **b) Scholarships and Other Funding for Residents, Fellows and Clinical Personnel-in-Training**

Clinical Personnel may not accept scholarships or other funds directly from a Business for participation in or attendance at a conference or meeting.

## **SECTION V. OTHER APPLICABLE POLICIES**

### **A. Research**

The Einstein and BRANY Institutional Review Boards have conflict of interest and disclosure policies that cover potential conflict of interest in connection with research and provide for a Conflict of Interest disclosure process.

**1. PHS-Funded Research:** Individuals conducting PHS-funded research at Montefiore must comply with the requirements of 42 CFR Part 50 Subpart F and 45 CFR Part 94 and the Albert Einstein College of Medicine policies regarding conflicts of interest in research, including the Albert Einstein College of Medicine Comprehensive Conflicts of Interest Policy. This policy is located at <http://www.einstein.yu.edu/administration/conflict-of-interest/policies/> and contains information on disclosure requirements for PHS-funded research grants and cooperative agreements.

**2. Public Accessibility:** As required by federal law, Montefiore will make available certain information concerning financial conflicts of interest to any requestor. Requests for such information must be in writing and should be addressed to:

Vice President & Counsel, Compliance  
Montefiore Medical Center  
111 East 210<sup>th</sup> Street  
Bronx, New York 10467

The request must specify the name of the investigator and/or the PHS funded grant to which the request pertains. Responses will be mailed no later than 5 business days following receipt in the Department of Compliance.

**3. Human Subjects Research:** Individuals submitting a protocol to the IRB must comply with the Einstein Policy on Conflicts of Interest in Research, which is located at <http://www.einstein.yu.edu/administration/conflict-of-interest/policies/>.

Any information collected under these Einstein policies that suggest an actual or potential Conflict of Interest must be promptly shared with the Compliance Officer at Montefiore.

**B. CME**

The Center for Continuing Medical Education has a conflict and disclosure policy regarding all Continuing Medical Education (CME) programs and provides for a Conflict of Interest disclosure process. Any information collected under the CME policy that suggests an actual or potential Conflict of Interest must be promptly shared with the Compliance Officer at Montefiore. The Center for Continuing Medical Education is responsible for the review of any publicly posted information regarding CME payments received by Montefiore and for the dispute of any inaccurate information.

**C. Pharmacy**

The Pharmacy has a disclosure statement for use in proposing drugs for inclusion in the formulary. Any information collected under the Pharmacy disclosure procedures that suggest an actual or potential Conflict of Interest must be promptly shared with the Compliance Officer at Montefiore.