

 <p>BROWN Alpert Medical School</p>	<p>Mission, Planning, Organization, and Integrity</p>	<p>POLICY NO.: 01-00, includes: Policy No.: 01-01 Policy No.: 01-02.01 Policy No.: 01-02.02</p> <hr/> <p>Effective Date: July 1, 2020</p>
---	--	---

1.0 Policy Purpose

The purpose of this policy is to govern patient and student safety and ensure the preparedness of those who teach, supervise, and assess students of the Warren Alpert Medical School of Brown University (AMS). This policy contains policies and guidelines related to the following:

- Continuous Quality Improvement (Element 1)
- Conflict of Interest Policies (Element 2)

Such policies are in place to ensure compliance with Liaison Committee on Medical Education (LCME) requirements for re-accreditation and correspond to elements of Standard 1 (Mission, Planning, Organization, and Integrity).

2.0 To Whom the Policy Applies

All AMS community members.

3.0 Policy Statement

3.1 Continuous Quality Improvement (Policy No. 01-01)

Quality Improvement Policy:

The Warren Alpert Medical School of Brown University (AMS) engages in continuous quality improvement (CQI) around the medical education program. The Alpert Medical School and Continuous Quality Improvement (AMS-CQI) committee has primary responsibility for CQI. AMS-CQI committee is comprised of the Senior Associate Dean for Medical Education, the Associate Dean for Medical Education (Chair), the Associate Dean for Student Affairs, the Associate Dean for Diversity and Multicultural Affairs, the Assistant Deans for Medical Education (Years 1 and 2), the Director of Assessment and Evaluation, and the LCME Coordinator.

This policy requires monitoring of all LCME standards and reporting out (to the MCC) of the status of compliance with LCME Standards.

To meet the requirements of this policy, the AMS-CQI Committee reviews the entire medical school and medical education programs on an ongoing basis. The Associate Dean for Medical Education (Chair), the Director of Assessment and Evaluation and the LCME coordinator have primary responsibility for staffing the AMS-CQI Committee, which reports to the Senior Associate Dean for Medical Education. The Senior Associate Dean for Medical Education then reports recommendations to the Dean’s Leadership Council, which is empowered to make decisions on

how best to ensure the ongoing CQI processes at the medical school and has core responsibility and authority to manage the CQI effort. In conjunction with key stakeholders at AMS, such as the Executive Dean for Administration, the Senior Associate Dean for Academic Affairs and the Associate Dean for Clinical Affairs, this Committee regularly reviews LCME Standards, identifies any gaps that may exist in these standards, and works to remedy these gaps through the Dean's Leadership Council. In addition, this Committee reviews data pertaining to the AMS's strategic plans, to ensure these plans are carried out effectively, as well as data specifically related to LCME standards.

The Senior Associate Dean for Medical Education then reports recommendations to the Dean's Leadership Council, which is empowered to make decisions on how best to ensure the ongoing CQI processes at the medical school and has core responsibility and authority to manage the CQI effort. In conjunction with key stakeholders at AMS, such as the Executive Dean for Administration, the Senior Associate Dean for Academic Affairs and the Associate Dean for Clinical Affairs, this Committee regularly reviews LCME Standards, identifies any gaps that may exist in these standards, and works to remedy these gaps through the Dean's Leadership Council. In addition, this Committee reviews data pertaining to the AMS's strategic plans, to ensure these plans are carried out effectively, as well as data specifically related to LCME standards.

The AMS-CQI Committee is responsible for the initial, ongoing review of the program competencies (Nine Abilities) and medical education program objectives (sub-Abilities), including their linkage.

See [Appendix C](#) for AMS Committee structure and AMS-CQI's relationship to other committees.

3.2 **Conflict of Interest Policies (Policy No. 01-02.01 and Policy No. 01-02.02)**

3.2.1. **The Warren Alpert Medical School of Brown University Conflict of Interest and Commitment Policy – Reporting and Review Process (Policy No. 01-02.01)**

Purpose

This policy establishes the reporting and review process The Warren Alpert Medical School of Brown University (Medical School) employs pursuant to Section 5 of the [Brown University Conflict of Interest and Commitment Policy](#) (University COI Policy), as amended from time-to-time.

Section 5.1 of the University COI Policy requires individuals to disclose potential, actual, or perceived conflicts of interest to their University Representative. The Dean of Medicine and Biological Science (Dean) or the Dean's designee is the University Representative for Academic Appointees in the Division of Biology and Medicine (Division). The Dean has established the Medical School Conflict of Interest Committee (Committee) and has designated to the Committee the authority to oversee and execute the reporting and review process contemplated by the University COI Policy.

Committee Structure

The Committee is composed of the Senior Associate Dean for Academic Affairs (Chair), Senior Associate Dean for Medical Education, Senior Associate Dean for the Program in Biology, and the Associate Dean for Clinical Affairs. The Committee may include other individuals at the discretion of the Dean of Medicine and Biological Science.

Commitment to Compliance

The Division will provide all Academic Appointees in the Division with links to the University COI Policy and this process document when Academic Appointees receive their appointment or reappointment letters. By accepting a faculty appointment, Academic Appointees acknowledge that they have received the University COI Policy and attest that they will comply with the University COI Policy, as it may be amended from time to time, for the duration of their appointments.

Additionally, all Academic Appointees who evaluate Medical School students through the Oasis system must attest annually to receipt of and compliance with the University COI Policy and to this reporting process.

Reporting Process

Academic Appointees in the Medical School who are not employed by Brown University must report any potential, perceived, or actual conflicts of interest or conflicts of commitment as defined in the University COI Policy to the Committee at the time of appointment and at the time of reappointment via a form, a link to which will be provided to Academic Appointees. Academic Appointees who evaluate Medical School students are required to submit conflict of interest forms annually via the Oasis system. All Academic Appointees must report conflicts of interest to the Committee as they arise, by submitting the form.

Information reported to the Committee includes the following:

1. The nature of the potential, perceived, or actual conflict of interest;
2. Whether the conflict has been disclosed or reported to another entity and, if so, to which entity or entities; and
3. Whether a management plan for the conflict exists and,
 - a. if so, information on the how the conflict is being managed, or
 - b. if not, information on how the conflict could be managed.

Academic Appointees who are not employed by Brown must report to the Committee in addition to any other reporting obligations that may be required by the individual's employer or institution.

Please click here to be routed to the reporting form: <Insert>

Review Process

The Committee will review reported conflicts quarterly and as otherwise necessary or appropriate. After reviewing a reported conflict, the Committee may request further information or conduct an investigation. Upon completing its review, the Committee will make a determination about the conflict in writing, and may make related recommendations. Recommendations could include implementing a plan to manage the conflict (*i.e.*, a conflict of interest management plan).

Consequences for Non-Compliance

Academic Appointees who do not comply with the University COI Policy, the reporting process discussed above, or the recommendations of the Committee are subject to the consequences stated in the University COI Policy, loss of their appointments, and/or other consequences at the discretion and upon decision of the Dean, including, for Housestaff¹, being reported to the appropriate Graduate Medical Education office.

Definitions

Capitalized terms take the definitions assigned them in this document or, if undefined in this document, the definitions set forth in the University COI Policy. Conflict of interest and conflict of commitment take the definitions set forth in the University COI Policy.

Related Information

Questions regarding the contents of this document should be directed to the Senior Associate Dean for Academic Affairs.

This document and the University COI Policy are available on the Brown BioMed Faculty Administration website, located at <https://www.brown.edu/about/administration/biomed/faculty-affairs/>.

¹ Housestaff are Academic Appointees who are physicians in training. Housestaff include interns, residents, and fellows who care for patients under the direction of attending staff in a hospital or other setting, including an outpatient facility.

3.2.2 **Medical Student Conflict of Interest Policy (Policy No. 01-02.02)**

The Warren Alpert Medical School of Brown University (“AMS”) Student Conflict of Interest Policy (the “Policy”, for purposes of Policy No. 01-02.02) is the policy specifically in place for AMS students. Faculty and resident housestaff are covered by Brown University’s Conflict of Interest (“COI”) Policy, in addition to any non-Brown employer’s COI policy.

Rationale

The primary goal of this Policy is to create a learning environment at AMS that will promote the practice of evidence-based medicine. While pharmaceuticals and medical devices are vital to medical care and the public, the industry has a fiduciary responsibility to deliver profits to its shareholders. The conflict between these financial interests and the ideals of medicine require close monitoring by the medical profession and its institutions of learning.

The trust placed in the medical profession by the public is subject to the perception that physicians are unduly influenced by the pharmaceutical and device industries.

Gifts from Industry

AMS students cannot accept any form of gift from Industry (including educational industry, such as third-party vendors for licensing exam preparation), any of its representatives, or from faculty/residents who may have received these materials, regardless of the size, nature, type, or dollar value of the gift. Accordingly, AMS students cannot accept promotional materials (*e.g.*, pens, notepads, clocks) from Industry, any of its representatives or from faculty/residents who may have received these materials. Students may not receive remuneration from industry to promote its product within the medical school, in through any mechanism.

AMS students may not accept or attend any meals directly funded by Industry, whether on or off the Brown University Campus, nor may AMS students accept complimentary tickets to sporting, entertainment, or other events or any other hospitality from Industry, even if invited by faculty or residents. Notwithstanding this restriction, AMS students may attend Accreditation Council for Continuing Medical Education (ACCME) accredited events.

AMS students may not accept any remuneration or gift from Industry in exchange for participating in or attending Continuing Medical Education (“CME”) activities. AMS’s Office for Continuing Medical Education, the AMS Senior Associate Dean for Academic Affairs, the AMS Associate Dean for Clinical Affairs, and the AMS Senior Associate Dean for Medical Education are responsible for ensuring that educational programs that students may attend are free of any actual or perceived conflict of interest.

AMS students must not interact with Industry representatives to the extent possible, with the understanding that sometimes this may not be possible.

The below list, although not exhaustive, provides examples of prohibited activities. Exceptions are made for official sanctioned events through AMS. Please contact the AMS Senior Associate Dean of Academic Affairs or the AMS Senior Associate Dean for Medical Education with any questions.

Prohibited Activities (in any setting, including conferences)

- Attending any meals directly funded by Industry, unless attendees pay for their own meal
- Accepting complimentary tickets to sporting, entertainment, or other events or any other hospitality from Industry
- Accepting any form of gift from Industry or any of its representatives, regardless of the size, nature, type, or dollar value of the gift
- Interacting with Industry

Site Access by Industry Representatives

Interactions with Industry

AMS strictly limits AMS student interactions with Industry in order to remove any potential conflicts of interest from medical education and patient care. Industry representatives are not allowed on the Brown University Campus; in addition, students are also not allowed to meet with Industry representatives off campus. In addition, AMS Students may not accept or respond to attempts by Industry to initiate direct contact, such as by e-mail or phone. In these situations, AMS students should notify an appropriate faculty member (such as the Senior Associate Dean for Medical Education, the Associate Dean for Medical Education or the Associate Dean for Student Affairs) that contact was initiated. Failure to abide by this policy may result in a professionalism form for a student.

AMS students should always seek out evidence-based unbiased sources of information about products, drugs, and devices.

Specific requirements for AMS Faculty and Housestaff at Community Teaching Sites

AMS recognizes that enforcing a procedure governing Industry interaction with students is particularly challenging with non-Brown employed AMS Faculty and Housestaff who are dispersed throughout Rhode Island, Massachusetts, and elsewhere. To ensure compliance with this Policy, students must not engage with Industry representatives at these sites, to the extent possible.

To preserve the integrity of the education program, AMS will abide by the requirements below in educational offerings for students. This list is not exhaustive and any questions should be directed to the Senior Associate Dean for Medical Education, the Associate Dean for Medical Education or the Associate Dean for Student Affairs.

In order to provide an educational atmosphere that is free of industry influence, AMS will also require the following from faculty who teach students:

- All lecturers in the pre-clerkship curriculum (years MD1 and MD2) must begin PowerPoint and other presentations used in or for the pre-clerkship curriculum with the appropriate “disclosure” slide. *See Appendix A.* Guidelines for these disclosures follow standard CME practice.
- All lectures given during the clinical years (MD3 and MD4) must begin PowerPoint and other presentations with a disclosure of conflicts of interest slide. Clerkship directors will ensure this is consistent throughout each clerkship. In addition, Clerkship directors and faculty supervisors for other clinical rotations will ensure that students do not attend Industry-sponsored conferences unless approved in writing by either the AMS or an AMS affiliate’s CME office.
- Content on the impact of Industry, direct marketing to patients, and other related issues is incorporated into the pre-clerkship and clinical curricula.
- Applications for summer assistantships (summer between years MD1 and MD2) include a COI form that must be completed by the student’s designated AMS mentor. *See Appendix B.* Applications will not be considered without a completed form.

See [Appendix A](#) for information on presentation slide requirements and [Appendix B](#) for the summer assistantship student COI form and related information.

Monitoring and Compliance

All AMS students will receive links to this Policy annually through Oasis. AMS students will be asked to attest to receiving the policies and to confirm that they will adhere to such policies.

Definitions

AMS Faculty: Individuals holding Brown University Division of Biology and Medicine faculty, faculty affiliate, or Housestaff officer titles.

AMS Student: For purposes of this Policy, AMS Student includes, but is not limited to, MD students, PLME students, PhD students, and other graduate students.

Community Teaching Sites: Any site outside the main hospital-affiliated campuses where sessions are held with AMS Students.

Conflict of Interest:

- An **actual conflict of interest** involves a direct conflict between (1) an individual’s official duties and University responsibilities and (2) a competing interest or obligation, whether personal or involving a third-party.
- A **perceived conflict of interest** occurs where it could reasonably be perceived, or give the appearance, that a competing interest could improperly influence the performance of an individual’s official duties and University responsibilities.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable, and not limited to payments or fees for services outside of AMS compensation such as:

- Any form of compensation; consulting, honoraria, or expert testimony; equity interests such as stocks, stock options, deferred benefits or other ownership interests;
- Intellectual property rights including named inventor on a patent or patent assignee, copyrighted material and benefits accruing from such rights; royalty or milestone payments from Brown or an outside entity; and
- Gifts

Housestaff: Physicians in training (*i.e.*, interns, residents, and fellows) who care for patients under the direction of the attending staff. House in this context refers to a hospital as these physicians are most often employed by a hospital. However, housestaff subject to this Policy may also care for patients in other settings, including outpatient facilities.

Industry: Any for profit entity that markets, develops, sells, distributes, or provides education regarding its products, drugs, devices, or other healthcare-related materials or items.

Sessions: Period of time when students are engaged in education, formal or informal mentorship, or clinical care with AMS Faculty or Housestaff.

References

1. Elliott, C. The drug pushers. *Atlantic Monthly* April 2006. <http://www.theatlantic.com/doc/200604/drug-reps>
2. Wazana, A. Is a gift ever just a gift? *JAMA*. 2000;283:373-380.
3. Molloy W, Strang D, Guyatt G, et al. Assessing the quality of drug detailing. *J Clin Epidemiol*. 2002;55:825-832
4. McCormick, B., et al. Effect of restricting contact between pharmaceutical company representatives and internal medicine residents on post training attitudes and behavior. *JAMA*. 2001.286(16):1994-1999.
5. Blumenthal D. Relationships between academic institutions and industry in the life sciences--an industry survey. *N Engl J Med*. 1996;334(6):368-73.

4.0 Definitions

For the purpose of this policy, the terms below have the following definitions:

- 4.1 **AMS:** The Warren Alpert Medical School of Brown University
- 4.2 **AMS-CQI:** Alpert Medical School and Continuous Quality Improvement committee is responsible for ensuring ongoing compliance with LCME Standards and for overall continuous quality improvement of the medical school.
- 4.3 **COI:** Conflict of Interest
- 4.4 **COLE:** Committee on the Learning Environment affirms the medical school's commitment to shaping a culture of teaching and learning that is rooted in respect for all.

4.4 **MCC:** The Medical Curriculum Committee oversees the review of curricular content and integration, and evaluation of the medical education program to ensure continuous oversight of such program. (Formerly “MDCC.”)

4.5 **OME:** Office of Medical Education

5.0 **Responsibilities**

All individuals to whom this policy applies are responsible for becoming familiar with and following this policy. University supervisors are responsible for promoting the understanding of this policy and for taking appropriate steps to help ensure compliance with it.

Responsibilities include the department/office of the subcommittee responsible for the Standard; for Standard 1, this is primarily the Office of the Dean of Medicine and Biological Sciences.

6.0 **Consequences for Violating this Policy**

Failure to comply with this and related policies is subject to disciplinary action, up to and including suspension without pay, or termination of employment or association with the University, in accordance with applicable (e.g., staff, faculty, student) disciplinary procedures.

Brown’s Ethics and Compliance Reporting System allows anonymous and confidential reporting on matters of concern, including privacy issues, through the EthicsPoint platform.

Failure to comply with this policy will be referred to either the COLE executive committee or the Medical Curriculum Committee.

7.0 **Related Information**

The following information complements and supplements this document. The information is intended to help explain this policy and is not an all-inclusive list of policies, procedures, laws and requirements.

7.1 **Related Forms:**

- Data Collection Instrument for Standard 1: Mission, Planning, Organization, and Integrity, as submitted to the LCME in July 2020. (See also 6.1.b of Data Collection Instrument.)
- The Warren Alpert Medical School of Brown University Conflict of Interest and Commitment Policy – Reporting and Review Process (approved March 16, 2020).
- The Warren Alpert Medical School of Brown University Student Conflict of Interest Policy, including Appendix A (Required Disclosure Slides) and Appendix B (Summer Assistantship COI Form) (approved by MCC on April 15, 2020).

7.2 **Other Related information:**

- **LCME Standard 1: Mission, Planning, Organization, and Integrity.** A medical school has a written statement of mission and goals for the medical education program, conducts ongoing planning, and has written bylaws that describe an effective organizational structure and governance processes. In the conduct of all internal and external activities, the medical school demonstrates integrity through its consistent and documented adherence to fair, impartial, and effective processes, policies, and practices.

- Standard 1, Element 1: Strategic Planning and Continuous Quality Improvement. A medical school engages in ongoing strategic planning and continuous quality improvement processes that establish its short and long-term programmatic goals, result in the achievement of measurable outcomes that are used to improve educational program quality, and ensure effective monitoring of the medical education program's compliance with accreditation standards.
- Standard 1, Element 2: Conflict of Interest Policies. A medical school has in place and follows effective policies and procedures applicable to board members, faculty members, and any other individuals who participate in decision-making affecting the medical education program to avoid the impact of conflicts of interest in the operation of the medical education program, its associated clinical facilities, and any related enterprises.

8.0 Policy Owner and Contact(s)

8.1 **Policy Owners:** Office of the Dean of Medicine and Biological Sciences

8.2 **Policy Approved by:** Dean of Medicine and Biological Sciences, MCC (for medical student COI policy)

8.3 **Subject Matter Contact:** Office of the Dean
Brown University
Box G-A1
91 Waterman Street
Providence, RI 02912
Telephone: 401-863-3330
Fax: 401-863-3431
Email: Dean_of_Biology_and_Medicine@Brown.edu

9.0 Policy History

9.1 **Policy Effective Date:** July 1, 2020

9.2 **Policy Last Reviewed:** June 17, 2020 (Pol. No. 01-01); March 16, 2020 (Pol. No. 01-02.01); April 15, 2020 (Pol. No. 01-02.02)

9.3 **Policy Update/Review Summary:** Pol. No. 01-01 revised to reflect new committee structure (approved by MCC on June 17, 2020). Pol. No. 01-02.01 approved by Dean of Medicine and Biological Sciences on March 16, 2020. Pol. No. 01-02.02 approved by MCC on April 15, 2020.

The text for Policy Nos. 01-02.01 and 01-02.02 is pulled from the formal documents containing conflict of interest policies (reporting and review process, and student COI documents). The text is provided in full in each policy section. Appendices A and B herein correspond to the appendices in the full student COI policy document. See also 7.1 above.

Formatted to comply with new University Policy template.

Key Words: conflict, interest, continuous, quality, improvement

Appendix A

Required Disclosure Slides

*(from The Warren Alpert Medical School of Brown University
Student Conflict of Interest Policy Form, Appendix A)*

DISCLOSURE

The commercial entities with which I/we have relationships do not produce health-care related products or services relevant to the content I am presenting.

DISCLOSURE

I/we have no financial relationship with a commercial entity producing health-care related products and/or services.

DISCLOSURE

I/we disclose the following financial relationships with commercial entities that produce health-care related products or services relevant to the content I am presenting:

COMPANY	TYPE OF RELATIONSHIP	CONTENT AREA (IF APPLICABLE)

Appendix B

Summer Assistantship COI Form

(from The Warren Alpert Medical School of Brown University
Student Conflict of Interest Policy Form, Appendix B)

To view more information on Summer Assistantships and to complete the summer assistantship COI form, please go to <https://www.brown.edu/academics/medical/education-programs/student-enrich-ops/fundings/summer-assistantships>.



BROWN
Alpert Medical School

Alpert Medical School – Summer Funding Policy

Subject: Conflict of Interest

Issuing Department: BioMedical Education

Original Policy Date: July 29, 2009

Latest Revision Date: October 6, 2016

I. Purpose:

Alpert Medical School (AMS) is committed to pursuing its mission and conducting its affairs in accordance with the highest professional and ethical standards. This commitment includes the avoidance and management of potential conflicts of interest.

II. Eligibility:

This policy applies to all persons who serve as a mentor to a medical student as part of the Summer Assistantship (SA) and Basic & Translational Research (BTR) Programs.

III. Policy:

Persons who agree to serve as a mentor to an AMS student under the auspices of the SA or BTR Programs should not use their positions, or the work of the medical student mentee, for personal gain or for the benefit of an entity in which the faculty member has a financial interest.

It is the policy of AMS to require that mentors disclose business practices or conduct that could constitute a conflict between their research interests and the interests of the medical student mentee and AMS.

IV. Definition:

“Conflict of Interest” as it relates to mentors means either engaging in conduct or entering into business or private or personal relationships, whether by way of investments, outside employment service, personal relationships, or any other obligation or relationship, which could cause one to use his or her position and influence for personal gain or for the benefit of others (such as family members or other business entities with which such person is associated) instead of the benefit or best interest of the medical student mentee.

V. Mentor Responsibilities under this policy:

It shall be the responsibility of all mentors to disclose situations that may give rise to a Conflict of Interest. Conflict of Interest disclosure statements must be completed and submitted as part of the medical student’s funding application process. All disclosure statements will be reviewed and maintained by the Review Committee.

It shall be the responsibility of the mentor to update or complete a new conflict of interest disclosure statement if a situation occurs, resulting in a Conflict of Interest or potential Conflict of Interest, which has not been previously disclosed.

Examples of Conflicts of Interest or potential Conflicts of Interest include, but are not limited to collaboration on a project in the context of the faculty mentor

1. holding a substantial ownership or financial interest in the distributors of a drug, device or other product that is the subject of a medical student’s summer project;
2. serving as a consultant to the entity developing the product under review;
3. serving as a trustee, director or officer of the distributor of said product;
4. acting as an influential employee of an organization whose product is under review; or
5. accepting gifts, loans, travel, services, entertainment or other favors from such an organization whose product/drug is under review.

CONFLICT OF INTEREST DISCLOSURE STATEMENT

1. Is the proposed work with the medical student mentee one in which you conduct, supervise or otherwise control research sponsored by a Business Entity, in which you or a Family Member has an Ownership or Financial Interest, and/or serve as an officer or director?

Yes No

If yes, please identify the Business Entity and the nature of your relationship.

2. Is the proposed work with the medical student mentee one in which you conduct, supervise or otherwise control research sponsored by a Business Entity from which you or a Family Member derives compensation, consulting fees, speaker fees, honorarium, etc?

Yes No

If yes, please provide the name of the business entity, as well as the form and amount of annual compensation.

3. Is the proposed work with the medical student mentee a clinical trial or other research where dissemination of results adverse to the sponsoring entity is restricted or in which obtrusive control of a protocol or research plan is exercised by the sponsoring entity?

Yes No

If yes, please identify the trail or research project and the sponsoring entity.

4. Other Matters: If you are involved in activities or have business relationships that are not addressed by the queries above, but should be disclosed because they represent a conflict, please describe below.

Mentor Name (print)

Title/Position

Mentor Signature
(electronic signature preferred)

Date

Medical student mentee (print name)

Appendix C

AMS-CQI Committee Structure and Relationship to Other AMS Committees

