

Brandeis University

Code of Conduct and Policies and Procedures for Federally Funded Activities for the Centers for Medicare and Medicaid (CMS) Regarding Conflict of Interest and Compliance

GENERAL POLICY STATEMENT AND CODE OF CONDUCT

Founded in 1948 by members of the American Jewish community, Brandeis University is a non-sectarian institution that embodies the Jewish community's highest ethical and cultural values and its traditional commitment to education. The University that carries the name of the eminent Supreme Court Justice who stood for the rights of individuals is distinguished by academic excellence, truth pursued wherever it may lead and awareness of the power and responsibilities that come with knowledge.

The university is deeply committed to upholding the highest ethical principles in conducting its federally funded research and activities and in complying with all applicable laws, statutes, regulations and federal program requirements, as expressly required by CMS contracts. This policy is intended to increase the awareness of all members of the Brandeis community involved in CMS sponsored activities and contracts to the potential for conflicts of interest and to establish a process whereby such conflicts may be properly avoided, neutralized or mitigated. Each member of the Brandeis community has an obligation to act in the best interests of the University and must not permit outside financial and/or personal interests to interfere with that obligation. Accordingly, all employees engaged in CMS funded research, contracts or related activities are required to certify they have read, understand and agree to comply with these standards of conduct regarding disclosure of conflicts of interest and related policies and procedures.

Policies and Procedures

I. Organizational Conflict of Interest

The federal government defines organizational conflict of interest in Federal Acquisition Regulation (FAR) 2.101 as follows: "Organizational conflict of interest" means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage." Organizational conflicts of interest may be actual, potential or apparent and fall into three categories, as follows:

- A) **Unequal Access to Information**-situations in which an entity has access to non-public information (including proprietary information and non-public source-selection information) as part of its performance of a Government contract and that information may provide the entity with a competitive advantage in a later competition for a

Government contract. In these “unequal access to information” cases, the concern is limited to the risk of the entity gaining an unfair competitive advantage; there is no issue of bias.

- B) **Biased Ground Rules**-Consists of situations in which an entity, as part of its performance of a Government contract, has helped (or is in a position to help) set the ground rules for another Government contract by, for example, writing the statement of work or the specifications, or establishing source-selection criteria. In these “biased ground rules” cases, the primary concern is that the entity could skew the competition, whether intentionally or not, in favor of itself and/or its affiliates. These situations may also involve a concern that the entity, by virtue of its special knowledge of the Government agency’s future requirements, would have an unfair competitive advantage in the competition for those requirements.
- C) **Impaired Objectivity**-Consists of situations where an entity has an interest (typically financial) that may conflict with the interest of the Government to whom the entity has a contractual obligation and the entity’s work under the Government contract could give the entity the opportunity to benefit its other business interests. If the entity is using subjective judgment or giving advice, and its other business interests could be affected by that judgment or advice, the entity’s objectivity may be impaired. An example would be if the entity was evaluating itself, an affiliate or a competitor, either through an assessment of performance under another contract or an evaluation of proposals. In these “impaired objectivity” cases, the concern is that the entity’s ability to render impartial advice to the Government could appear to be undermined by its relationship with the entity whose work product is being evaluated.

II.

Personal Conflict of Interest

- A) In general, conflict of interest can arise when a Brandeis community member has the opportunity to influence the University’s research, academic or other decisions in ways that can lead to personal, family or financial advantage of any kind for him/her. In general, if a Brandeis community member or an immediate family member has a business relationship with a third party, a potential, apparent or actual conflict of interest with the University may arise. For purposes of this policy, the following definitions apply:
 - 1.) Business relationship: one in which a Brandeis community member, or member of his/her immediate family, serves as a director, officer, employee, partner, trustee or controlling stockholder of an organization, for-profit or not-for-profit, that does business with the University.
 - 2.) Financial relationship: One in which a Brandeis community member, or a member of his or her immediate family, (1) is the actual or beneficial owner of more than five percent (5%) of an organization that does business with the University; or (2) has other direct or indirect dealings with an organization that does business with the University from which the community member, or member of his or her immediate family may benefit directly or indirectly.

- 3.) Immediate family member: A spouse, domestic partner, parent, sibling or child, and in addition, any other relative living in the same household as the Brandeis community member.

B) The federal government in FAR 3.1101 defines a personal conflict of interest as follows: “Personal conflict of interest” means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee’s ability to act impartially and in the best interest of the Government when performing under the contract. (A *de minimis* interest that would not “impair the employee’s ability to act impartially and in the best interest of the Government” is not covered under this definition.) For purposes of the activities done at Brandeis on behalf of the federal government, “covered employee” means all those directly involved in performing the work, such as the project principal Investigator and her/his staff.

III. Disclosure of Conflicts

A) **Self-Reporting Obligation**-The responsibility for avoiding potential, apparent or actual conflicts of interest begins with the Brandeis community member pursuing or directly participating in CMS/Medicare research grants or contracts. If a situation arises that could present a conflict of interest, in appearance or in substance, it is mandatory that the employee make an ad hoc full disclosure to the Brandeis Medicare Compliance Officer for resolution.

B) **Annual Disclosure**- all community members involved in sponsored CMS/Medicare activities are required to submit an annual disclosure form (see Attachment A). Because any potential, apparent or actual conflict of interest is best addressed as early in the process as possible, whenever an application for funding of a CMS/Medicare sponsored project is submitted, the Principal Investigator will be required to certify that s/he has submitted a complete and accurate annual disclosure and that the new CMS/Medicare project does not present the potential for any actual or apparent conflicts of interest not already identified in the annual disclosure.

- 1) Whenever any business/financial relationships, significant financial interests or external activities change materially for those individuals engaged in CMS sponsored activities, the above described disclosures are to be updated as soon as possible, in writing. Whenever possible, those involved in such research should disclose expected changes or newly anticipated potential, apparent or actual conflicts at least thirty (30) days before they occur.

IV) Resolution of Conflicts

A) **Organizational Conflicts of Interest**-The Medicare Compliance Officer will be required to obtain and review all annual and ad hoc disclosures of Brandeis

community members to ascertain if there is an apparent, potential or actual organizational conflict of interest relative to any CMS/Medicare projects. In the event the Medicare Compliance Officer determines that a disclosure by a community member reveals a potential, apparent or actual organizational conflict of interest regarding a federal project, the Medicare compliance officer will contact the community member to do a preliminary investigation and if warranted, request that the individual immediately remove or recuse him/herself from the project until further investigation and neutralization or mitigation of any real, determined conflict of interest.

- B) Should the community member object to the resolution plan, the Medicare Compliance Officer will refer the issue to the Medicare Executive Compliance Committee and if necessary, then to the Medicare Compliance Committee of the Board of Trustees which will then determine if an organizational conflict of interest exists, determine its severity and recommend the steps necessary to resolve the conflict. Such steps may include divestiture of the financial relationship or financial interest; or recusal from the federal project.

V) The Medicare Compliance Committee

A) The Medicare Compliance Committee of the Brandeis Board of Trustees will be comprised of a majority of trustees who are not employed by Brandeis and who have no apparent, potential or actual conflicts of interest with CMS sponsored projects performed by Brandeis. The Medicare Compliance Committee will meet periodically and as necessary on an ad hoc basis to:

- 1) Review periodic reports by the Medicare Compliance Officer of conflict of interest matters, relating to CMS/Medicare sponsored projects, including but not limited to: policy changes and approvals, annual conflict of interest disclosures, identified organizational and/or personal conflicts of interest and mitigation; training activities.
- 2) Review and deliberate any contested mitigation of an identified conflict of interest related to a CMS/Medicare sponsored project.
- 3) Commission and review internal and external audits and corresponding reports of organizational conflict of interest compliance and meet with the partner and director of the audit engagements on an annual or as needed basis.
- 4) Receive ongoing training on conflict of interest and compliance as it relates to projects with CMS/Medicare.
- 5) Evaluate the Medicare Compliance Officer's performance.
- 6) Refer appropriate matters to the full board when determined necessary.

VI

The Medicare Compliance Officer

- A) The Medicare Compliance Officer will be the Brandeis Chief Legal Officer and report to the Medicare Compliance Committee and to the President. The Medicare Compliance Officer's responsibilities include:
- 1) Developing and implementing all conflict of interest policies and related compliance procedures, reviews and audits to ensure compliance with CMS/Medicare requirements.
 - 2) Ensure all appropriate Brandeis community members submit written annual conflict of interest disclosures and ad hoc disclosures when necessary.
 - 3) Review such disclosures and mitigate any potential, apparent or actual conflicts of interest.
 - 4) Report periodically to the Medicare Compliance Committee of the Board of Trustees.
 - 5) Ensure Brandeis community members involved in CMS funded projects and the Medicare Compliance Committee of the Board receive annual training on conflict of interest and compliance.
 - 6) Receive and investigate all reported ethics and compliance related complaints and reports them to the Compliance Committee. Review major gifts to the university to determine if an apparent, potential or actual conflict of interest could develop due to the donor(s).
 - 7) Coordinate external and internal audits of conflict of interest policies, procedures and related compliance and reports audit findings to the Medicare Compliance Committee of the Board.
 - 8) Chair the Executive Medicare Compliance Committee.
 - 9) In coordination with the Executive Medicare Compliance Committee and other university departments, including Human Resources, Legal and Financial Affairs, monitor compliance, update policies and ensure all conflict of interest audit findings or issues are satisfactorily resolved.

VII)

The Executive Medicare Compliance Committee

- A) The Executive Medicare Compliance Committee, comprised of selected officers, senior managers and faculty who head major university units, advises the Medicare Compliance Officer and assists in the implementation of the compliance program. Specifically, the Executive Medicare Compliance Committee would:
- 1) Quickly identify, address and raise internal issues of conflict of interest and compliance for resolution of which the Board may not be aware.
 - 2) Provide information and guidance to the Medicare Compliance Officer.

- 3) Provide guidance to the Medicare Compliance Officer but not be able to interfere with or block any actions taken, proposed or planned by the Medicare Compliance Officer.
- 4) Meet periodically and as needed.
- 5) Assist with investigations of reported non-compliance or conflict of interest.

VIII) Training, Education and Performance Assessment

- A) To ensure adequate awareness and compliance, all Brandeis community members involved with CMS funded projects will receive mandatory, annual training that addresses:
 - 1) The University's CMS/Medicare code of conduct and conflict of interest policies.
 - 2) The relevant federal acquisition (FAR) rules and regulations and updates to them.
 - 3) The compliance program requirements.
 - 4) The roles of the Medicare Compliance Officer, the Executive Medicare Compliance Committee and its members; and the Compliance Committee of the Board of Trustees.
 - 5) How to report, directly or anonymously, any ethics, conflict of interest or compliance concerns and how such reports are encouraged, investigated and resolved.
- B) New hires who will be involved with CMS sponsored projects are to be trained within 30 calendar days of hire.
- C) Individuals directly involved in CMS funded projects and subject to conflict of interest and compliance will have their annual performance review specifically address any related performance issues.

IX) Auditing and Monitoring Compliance

- A) **Internal Audit**-On a periodic basis but not less than every three years, Brandeis Internal Audit shall conduct an audit of compliance with the University's CMS/Medicare code of conduct, conflict of interest policy and related compliance procedures. The auditors, as is their usual practice, shall have full access to all records, operations and staff. At the completion of each audit, Internal Audit will follow current practice of issuing a written audit report to the Compliance Officer, members of the Executive Medicare Compliance Committee and the Compliance Committee of the Board of Trustees. The audit report will include findings, recommendations and the appropriate managers' responses to the recommendations, including when corrective action will be taken. Additionally, the auditors will ascertain whether previously agreed to recommendations, from all prior audits, have been satisfactorily implemented. To ensure a comprehensive review is performed, the CMS Compliance Program Effectiveness Self-Assessment Questionnaire (Attachment B) should be employed.
- B) **External Auditors**-On a periodic basis, as determined by the Medicare Compliance Officer, in consultation with the Executive Medicare and/or CMS Compliance Committee of the Board

of Trustees, an independent audit of the adequacy of CMS Conflict of Interest policies, procedures, monitoring and compliance will be performed. Audit results will be issued directly to the Compliance Committee of the Board, the Executive Medicare Compliance Committee, the Medicare Compliance Officer, other officers and senior managers. Accepted audit recommendations should be implemented within 60 days.

X) Enforcement and Disciplinary Guidelines

- A) Members of the Brandeis community directly involved with CMS funded projects and compliance who violate the Brandeis CMS Code of Conduct and policies and procedures will be subject to disciplinary sanctions, including immediate termination. The nature and severity of the sanctions will depend upon the specific circumstances, with consideration given to the individual's intent, whether it was an isolated instance or reflects a repeated violation, the financial effects of the violation, reputational harm and whether the violation was a single event or occurred over an extended period of time.
- B) Prospective employees who will work on CMS funded projects will be subject to background checks at time of hire to determine whether the individual were ever criminally convicted, suspended, debarred or excluded from participation in a federal program.
- C) Existing employees who are suspended from performing government research, or are under criminal investigation or indictment will be immediately removed from any direct responsibility or involvement with any CMS projects.

XI) Responding to Detected Offenses, Developing Corrective Action Initiatives and Reporting to Government Authorities

- A) The Medicare Compliance Officer shall have unfettered discretion to determine the type and nature of investigation required upon receipt of a report of non-compliance. However, should a majority of the Executive Medicare Compliance Committee vote to have an outside, independent investigation performed, the Medicare Compliance Officer will defer to this decision.
- B) Investigations should be conducted with the knowledge of the Executive Medicare Compliance Committee, which must include the head of Human Resources and his/her involvement.
- C) The Medicare Compliance Officer will commence the investigation by engaging with the alleged individual, Human Resources and Legal as necessary to ensure a fair, open review. While other departments may assist in the investigation, the Medicare Compliance Officer shall maintain oversight and final closing authority over the matter.
- D) All pertinent aspects of the investigation should be documented, including but not limited to the date and substance of the complaint, investigative actions taken, a narrative description of the resolution of the matter and the date of closure. Whenever possible, investigations should be completed within 60 days of first notice.

E) Upon determination of an act of non-compliance, corrective action will be determined as described in (X-A) preceding. Additionally, existing policies and procedures should be reassessed to determine if changes are needed or additional training warranted.

F) When a serious and/or material act of non-compliance is determined to have occurred, and there is credible evidence that the misconduct may violate criminal, civil or administrative law, The Medicare Compliance Officer will engage the Medicare Compliance Committee of the Board of Trustees to determine, among other things, if reporting to CMS or law enforcement is required.

ATTACHMENT A

ATTACHMENT B – LENGTHY AUDIT QUESTIONNAIRE NOT ATTACHED HERE