



ALBANY MED  
Health System

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## **Conflict of Interest Policy**

### **PURPOSE**

The Albany Med Health System (the “System”; “Albany Med”) exists to serve the major health care needs of surrounding communities by providing medical education, biomedical research, patient care and charitable services.

Many activities undertaken in service of the System’s mission require that the public rely on the competence, professionalism and diligence of the System and its people to safeguard and promote the well-being of the community. To deserve the community trust, all Individuals’ acting on behalf of the System must avoid situations or relationships that may or may reasonably be perceived to hinder or bias our efforts due to the introduction of inappropriate or undisclosed personal benefit.

### **POLICY**

Conflicts of Interest are any action or relationship involving some value (beyond compensation from the System) accruing to an Individual, whether direct or indirect, which could reasonably have the result or give the impression that the Individual’s conduct may be affected by the potential for personal benefit. Conflicts of Interest include relationships and conduct that would lead a reasonable independent observer to conclude a Conflict of Interest may exist.

At Albany Med we recognize that events or relationships that may create the potential for a Conflict of Interest are an inevitable aspect of conducting our activities. This policy will guide each Individual and the System in avoiding, eliminating, or mitigating to an acceptable level, potential Conflicts of Interest. Every Individual is expected to educate themselves regarding potential Conflicts of Interest that may affect the performance of their duties on behalf of the System.

To aid in managing potential Conflicts of Interest, the System has adopted a three-tiered structure depending on the value and nature of the event. The three tiers include ***Nominal Events, Incidental Events, and Reportable Events and Relationships.***

However, in no instance should an Individual accept a gift or inducement in the form of cash or cash equivalents.

***Nominal Events*** – are those events where the value received by an Individual was not solicited either expressly or implicitly, and the amount received is reasonably estimated to be less than or equal to \$150.00.

- These events should be managed by the Individual taking care to be aware of any patterns that may create the potential for a perception that a Conflict of Interest exists. The Individual should maintain a record of these events, but no additional reporting is expected unless required as part of an investigation.

***Incidental Events*** – are those events where the value is received incident to required activities in the performance of an Individual’s duties to the System. Any such event and value should be minor relative to the business purpose involved and cumulatively less than \$1,000.00 from a person or entity in a calendar year.

- These events should be managed at the department level by the Individual and their manager. Normally preapproval by the manager is required. The Individual is responsible for demonstrating the event furthers System goals to a sufficient degree to warrant participation. Written documentation should be maintained by the Individual and their manager.

***Reportable Events and Relationships*** – are all other events or relationships that may create real or potential Conflicts of Interest for an Individual or for a member of an Individual’s Immediate Family.

- All Individuals must fully comply with the system administered by Corporate Compliance and Audit to provide the Committee on Audit and Compliance of the Board with the assurance that all real and potential Conflicts of Interest have been identified, eliminated or mitigated as appropriate to safeguard the System, its related entities and their missions.
  - Disclosure Requirements: Prior to the initial election of any director, and annually thereafter, such director must complete, sign and submit a Conflict of Interest disclosure statement identifying, to the best of their knowledge:
    - Any entity of which the director is an officer, director, trustee, member, owner, or employee and with which the System has a relationship and
    - Any transaction in which the System is a participant and in which the director might have a conflicted interest.
  - Selected Individuals, due to their roles and responsibilities, will also be required to complete an Annual Disclosure for themselves and on behalf of all members of their Immediate Family. In addition, all Individuals must report all potential Conflicts of Interest for themselves or any member of their Immediate Family if not previously reported or if the related facts and circumstances change.
  - Determination of Conflicts: Completed Conflict of Interest Questionnaires will be forwarded to Corporate Compliance and Audit.

Responses from questionnaires completed by directors, officers, and key persons who, by nature of their position, can exercise substantial influence over the affairs of a System entity are provided to the Committee on Audit and Compliance of Albany Med Health System's Board of Directors, and where appropriate, to the entity's Board<sup>1</sup>. The person with the potential conflict of interest may not be present at nor participate in the board or committee deliberation or vote on the matter giving rise to such conflict. In those instances where a Conflict of Interest is determined to exist, notice will be provided to the Individual notifying him/her of that determination.

- Resolving Conflicts: The Chief Compliance Officer (CCO) or his designee will work with Individuals in eliminating or reducing the impact of a Conflict to an acceptable level. In those instances where an established institutional response does not exist, the CCO will be aided by the Committee on Enterprise Compliance in resolving individual situations. Final determination of the information required and the appropriate resolution of Conflicts of Interest is vested in the Chief Compliance Officer of the System.
- Reporting/Recordkeeping: The Committee on Audit and Compliance and the entity's Board, as applicable, shall document in the meeting minutes any conflicts discussed and voted upon. Corporate Compliance and Audit will maintain a system necessary to report at least annually to the Committee on Enterprise Compliance, the Chief Executive Officer of the Albany Med Health System, and the Board Committee on Audit and Compliance on the identification and resolution of potential Conflicts of Interest. The Individual's manager is responsible for monitoring compliance with the Resolution of Conflict memoranda and reporting any noncompliance to the CCO.

**Special Situations and Duties** – in most instances reflect heightened sensitivity to the potential harm caused by certain conflicts of interest common to a healthcare or educational environment. Additional requirements relating to these and other special situations are contained in the Appendices to this Policy.

- Gifts are defined as anything of value that is given, directly or indirectly, to an Individual or group of Individuals for which the Individual or group does not give consideration of equal or greater value in return. See Appendix 4-a.
  - Gifts should never be accepted if in the form of cash or cash equivalents. In all other instances, gifts should not exceed a *Nominal Event*.
  - Gifts should never be accepted from a government employee agent representative or official, a vendor or vendor representative, or a single student or their representative.

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<sup>1</sup> COIs and related-party transactions are managed centrally within the Corporate Compliance and Audit function. However, the resolution of material conflicts of interest and all related-party transactions require acceptance by both the Committee on Audit and Compliance and the entity's Board of Trustees.

- Individuals involved in the design, conduct, oversight, or reporting of research at Albany Medical College<sup>2</sup> are required to comply with additional requirements intended to ensure that all Financial Interests are properly disclosed, managed, reduced or eliminated, and reported consistent with Federal requirements at 42 CFR Part 50 and 45 CFR Part 94. See Appendix 4-f for more specific direction.
- Individuals involved in third-party sponsored educational events, in procurement or development of a System policy directing prescribed use of products or services, or in the receipt or distribution of pharmaceutical samples should comply with the additional requirements described in Appendix 4-b, 4-c and 4-d respectively.
- Individuals acting in the capacity of Board Members, Corporate Officers, or an Interested Party as defined by the Internal Revenue Service governing Excess Benefit Transactions and New York State Not-for-Profit Corporation Law (NPCL) are also subject to additional requirements described in Appendix 4-g.
- In the event a Conflict of Interest relates to the Chief Compliance Officer, the Chief Executive Officer of Albany Med Health System will replace him in administering this policy and the Chief Compliance Officer's involvement will be restricted to only those activities involving the CCO as the Individual.

### **Education**

Corporate Compliance and Audit will develop education to increase general awareness and understanding of regulatory expectations of institutions and individuals in eliminating the detrimental effects of conflicts on interests. Corporate Compliance and Audit will assist entities and departments in the development and delivery of education specific to the unique circumstances of that unit.

### **Foundation**

This Policy is not intended and shall not be construed to limit or constrain any System entity designated as a Foundation from soliciting and accepting those gifts or charitable donations which it is legally authorized to solicit and accept. Individuals may assist the Foundation in the identification and solicitation of gifts or grants to the extent the terms of the gift or grant are not so narrowly defined as to convey unfair advantage to the Individual in benefiting from the gift. The management and disposition of gifts to the Foundation are at the sole discretion of management in compliance with relevant laws and policies.

### **Sanctions**

This Policy prohibits against any attempt by the person with the conflict to improperly influence the deliberation or vote on the matter giving rise to such conflict.

Recommendations for disciplinary actions or other responses necessary to remediate the effects of noncompliance with this Policy will be made to the appropriate parties utilizing the authorized administrative and governance processes of the System. Responses to

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<sup>2</sup>Applies to grant-funded research activities for which Albany Medical College has oversight. Any Investigator who has a financial interest from entities whose interests would reasonably appear to effect or be affected by the proposed or funded research, beyond a nominal event, should complete a Conflict of Interest disclosure consistent with this Policy.

instances of noncompliance may vary depending on the facts and circumstances up to and including termination of employment or other relationship with the System.

**Effect on other policies**

The Board of Directors of Albany Med Health System accepted, at its July 10, 2019 meeting, the delegated duty to centrally manage the TIPP Compliance Program including oversight of the Conflict of Interest Policy. Upon approval, this Policy supersedes the Conflict of Interest Policy in effect at each System Entity.

This Policy does not preclude more restrictive policies which may be adopted by the System or any System Entity including as required by law or regulation, or in the interest of effective patient care or other components of the System's mission.

Approved by the Board of Directors of Albany Med Health System: May 5, 2021

Policy Effective Date: May 5, 2021

Revised: December 14, 2022

## **APPENDICES**

### **Appendix**

### **Description**

- 1. Definitions**
- 2. Illustrative Examples of Selected Concepts**
- 3. By-law Procedures Affecting Board Members and Officers**
- 4. Special Events or Relationships**
  - 4 - a. Gifts**
  - 4 - b. Participation in Sponsored Educational Events**
  - 4 - c. Procurement and Prescribed Use Activities**
  - 4 - d. Pharmaceutical Samples**
  - 4 - e. Conflict of Commitment**
  - 4 - f. Research, Albany Medical College**
  - 4 - g. Excess Benefit Transactions**

## **DEFINITIONS**

**Albany Med Health System (the “System”; “Albany Med”)** – means Albany Med Health System and other entities over which Albany Med Health System, directly or indirectly, has direction and control including: Albany Medical Center Hospital, Albany Medical Center Foundation, Inc., Albany Medical Center Auxiliary, Albany Medical Center Kidskeller, Albany Medical College, Albany Medical College Alumni Association, Albany Medical College Funding Corporation, Albany Med Health System Staffing Alliance, LLC, The Center for Donation and Transplant, The Columbia Memorial Hospital, Glens Falls Hospital, Healthcare Partners of Saratoga Ltd., Madison Avenue Services Corporation, Saratoga Care, Inc., The Saratoga Hospital, Visiting Nurse Association of Albany, Inc., Visiting Nurses Foundation, Inc., and Visiting Association of Albany Home Care Corporation.

**Albany Medical College (the “College”)** – for purposes of research, Albany Medical College exercises oversight and direction on behalf of the entities formerly known as Albany Medical Center, including: Albany Medical Center Hospital, Albany Medical Center - South Clinical Campus, Albany Medical College, Albany Medical Center Foundation, Inc., Albany Medical Center Auxiliary, Albany Medical Center Kidskeller, Albany Medical College Funding Corporation, Albany Medical College Alumni Association, The Center for Donation and Transplant, and Madison Avenue Services Corporation.

**Board** – means the Board of Directors of any Albany Med Health System entity.

**Board Members** – means members of the Board, non-director members of Board committees, and all members of the governing boards of a System Entity.

**Cash or cash equivalent** – includes currency, coins, money orders, checks, travelers’ checks, credits, gift cards, or value in an equivalent form that would be readily accepted as an accepted means of consideration in the conduct of commerce.

**Chief Compliance Officer (“CCO”)** – means the Chief Compliance Officer of Albany Med Health System.

**Committee on Audit and Compliance** – means the Committee on Audit and Compliance of the Albany Med Health System Board of Directors.

**Conflict of Interest (“COI”, “Conflict”)** – means any potential or existing relationship or activity involving some value accruing to an Individual (including but not limited to a Financial Interest), whether direct or indirect, which could reasonably have the result, or could reasonably give the impression, that the Individual may be unable to conduct themselves in accordance with the following System expectations:

- All Individuals shall commit the time and effort necessary to perform their institutional duties and responsibilities with excellence;
- All Individuals shall conduct their duties and responsibilities in the best interests of the System, its patients, its students, its research subjects, its customers, and for the advancement of knowledge without favor or prejudice;
- Individuals shall use his/her institutional position or confidential information gained from such position, solely in the performance of System duties and only as authorized in accordance with the entity's Authority to Act or comparable document;
- All Individuals shall ensure that any interest, activity or relationship, does not impair or appear to impair their judgment in the discharge of their institutional duties;
- All Individuals shall fully disclose and manage all affiliations, relationships and activities which may give rise to Conflicts of Interest in accordance with the requirements of this Policy.

**Corporate Compliance and Audit** – means the Corporate Compliance and Audit department of Albany Med Health System.

**Faculty Member** – means a person who holds an academic appointment to the general faculty, including the voluntary faculty, of Albany Medical College.

**Financial Interest** – means an interest that does or likely could result in a monetary benefit, in cash or in kind, directly or indirectly, to the Individual now or in the future. Examples of a Financial Interest include, but are not limited to:

- Ownership of stock, stock options, or other financial instruments providing the possibility of a financial return in relation to a direct ownership interest;
- Salary or other payment for services from other than a System Entity;
- Income from service on advisory committees or review panels for public, non-profit, or for-profit entities;
- Funds obtained through lending or mortgage and/or arrangements providing the forgiveness or forbearance from debt (other than arrangements with commercial banking or lending institutions at terms available to the general public);
- Gifts, royalties, patents, pending patents, copyrights, consulting fees, honoraria, other payments or promises of payment whether immediately determinable or dependent on a future occurrence;
- Promises of ownership or other relationships offering the potential for monetary returns.

**Individual** – means all Board Members, employees, credentialed physicians, licensed independent practitioners, Faculty Members, as well as those agents, independent contractors and volunteers with recurring involvement in and influence over the goals and activities of the System.

**Individual's Immediate Family (Immediate Family)** – means spouse, domestic partner, children, parents (including in-laws), siblings, any person living in the



Individual's household or who is dependent on the Individual for on-going financial support, and any person whom the Individual is dependent on for on-going financial support.

**Investigator** – means the project director or principal investigator and any other person, regardless of title or position, who is responsible for all or part of the design, conduct, or reporting of research. Investigator includes the investigator's spouse and dependent children, significant contributors such as contractors, subcontractors, sub-grantees, collaborators or consultants and any other person regardless of title and/or position, who is named on the grant application and has a high degree of autonomy with responsibility for all or part of the design, conduct or reporting of research.

**Key Employee** – An employee of any System entity: (1) with responsibilities, powers or influence over an entity as a whole that is similar to those of officers, directors, or trustees, or (2) who manages a discrete segment or activity of an entity that represents 10% or more of the activities, assets, income, or expenses of that entity, or (3) has or shares the authority to control or determine 10% or more of an entity's capital expenditures, operating budget, or compensation for employees; and has annual reportable compensation from the system that exceeds \$150,000.

**Key Person** – Any person who is in a position to exercise substantial influence over the affairs of a System entity, including without limitation (i) persons who would be considered "disqualified" for purposes of Internal Revenue Code; or (ii) persons who would be considered "related parties" for purposes of NPCL.

**Officer** – means the president or similarly entrusted chief executive officer, and any corporate or administrative officers duly elected or approved by action of the governing body or similarly designated by the Chief Executive Officer of an Albany Med Health System Entity.

**Pharmaceutical Sample** - is defined as any free prescription medication product supplied by a pharmaceutical firm or any of its agents directly to any non-pharmacy personnel for general use or use in specifically identified patients. The product does not need to be labeled as a "professional sample" to be considered a Pharmaceutical Sample. Medications provided at no cost to System prescribers for use as part of an approved clinical trial, and controlled through a System Hospital pharmacy are not considered Pharmaceutical Samples.

**Policy** – means this Conflict of Interest Policy and Procedure including all attached appendices.

**Principal Investigator/Project Director** – is the Individual ultimately responsible for the overall research project and for ensuring that disclosure forms are submitted for all Investigators in accordance with the Policy.

**Research** – means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used here, research includes any such activity for which research funding is available from any funding source (both internal and external) including but not limited to the Public Health Service (PHS), including NIH and any other PHS Components, the National Science Foundation (NSF), industry sponsored clinical studies or research funding from private Foundations and institutional sources within the System.

**Resolution of Conflicts of Interest** (“Resolved”) - means a Conflict of Interest is eliminated, reduced or otherwise managed in accordance with the terms and intent of this Policy.

**Vendor** –means any individual or entity that has entered into, or has signified the intention to enter into, a contractual or other commercial relationship with an Albany Med Health System Entity.

Managing Potential Conflicts of Interest

Managing potential Conflicts of Interest depends on the value received and the circumstances surrounding each event or relationship. The Conflict of Interest Policy provides an escalating means of accommodating the unique facts of each case. Examples of potential Conflicts of Interest include:

Nominal Amounts  
*(Individual Level)*

- A practitioner receives a box of candy and flowers from a grateful patient at discharge

Incidental Amounts  
*(Department Level)*

- A vendor offers to cover the cost of accommodations for a team of individuals from the Center to visit other sites using vendor products under consideration.
- A member of an evaluation team receives a reusable portfolio during a vendor presentation one month and travel expenses during a site visit the following month.

Reportable Events and Relationships  
*(Institution Level)*

- In return for expert advice a practitioner receives the rights to share in future returns on an innovative medical device.
- In appreciation for lending support to a study a practitioner is promised support in gaining appointment to a prestigious board.
  - As thanks for a department's patience in working through some vendor implementation problems, the supervisor is offered accommodations for a professional development weekend sponsored by the vendor.

The examples above are summarized. The Policy should be consulted to understand the specific requirements of each approach to managing potential Conflicts of Interest.

**BY-LAW PROCEDURES AFFECTING BOARD MEMBERS AND OFFICERS**

Section 5.2 - Conflicts of Interest:

(a) No director, Honorary Director or person serving as a member of any Committee of the Corporation, officer, or employee of the Corporation, nor any such person's family member (as defined in the written policy referred to in Section 5.2(b)), shall have an interest in any purchase, sale or other financial transaction with the Corporation, any affiliate of the Corporation, or any corporation or enterprise having such an interest, except upon the prior disclosure to the Board, and then only if the Board, directly or through the Committee on Audit and Compliance, determines, after examination of all material facts and through a majority vote of disinterested directors (1) that there is no substantial or material conflict, or (2) that the arrangement is fair, reasonable and consistent with the Corporation's best interests. Unless a majority of the disinterested directors present has earlier determined that the conflict is not material, a director, Honorary Director, committee member, officer or employee with such an interest shall not be present at meetings of the Board during any discussion and vote upon such a transaction. The Board may subsequently excuse failure to bring the transaction before the Board and approve the transaction, if the Board is satisfied that the nondisclosure was inadvertent and in good faith, and if the Board also makes either of the determinations described in (1) or (2) above. Except as prohibited by applicable law and as long as the provisions of this Section are followed, the interested director, Honorary Director, committee member, officer or employee shall not be liable to the Corporation or to any creditor of the Corporation for any loss derived from the existence of such a conflict and incurred by reason of the contract, transaction, or other business, nor shall the interested director, committee member or officer be accountable on account of the conflict to the Corporation for any gains or profits realized by reason of the contract, transaction, or other business.

(b) Upon the recommendation of the President, the Committee on Audit and Compliance shall periodically review and amend a written policy to require the disclosure and to evaluate potential conflicts of interest. Such policy shall (1) be consistent with paragraph (a) above; (2) require the disclosure by interested persons, including without limitation (i) persons who would be considered "disqualified" for purposes of the Internal Revenue Code; or (ii) persons who would be considered "related parties" for purposes of the NPCL, of potential conflicts and all related material facts; (3) establish procedures for determining whether the interests of the disclosing person may result in a conflict, including prohibiting an interested director from participating in the discussion and vote on a potentially conflicting matter; and (4) include appropriate procedures for addressing a conflict of interest after having determined that it exists. The conflict of interest policy shall be administered in connection with the Corporate Compliance Plan.

## **SPECIAL EVENTS OR RELATIONSHIPS**

Special Events or Relationships define additional policies and procedures that apply to specific situations or individuals in addition to the general requirements of the Conflict of Interest Policy.

In most instances, these additional policies reflect heightened sensitivity to the potential harm caused by certain conflicts of interest common to a healthcare or educational environment. These policies will affect individuals or segments of the System depending on the persons or activities covered by each policy. The policies are intended to apply in all instances covered by each policy meaning that an Individual may be covered by one or several of the specific policies contained here.

In addition to the specific policies appended as part of Appendix 4: educators, physicians, licensed independent practitioners, researchers, and other Individuals serving in positions of trust within educational, research, and clinical environments should have a heightened awareness of the role that trust of their students, research subjects, or patients has in the performance of their duties. Consequently, those same Individuals should remain vigilant to the potential harm done from real or perceived conflicts of interest.

While this Conflict of Interest Policy and the specific directives added as part of Appendix 4 attempt to adhere to the objectives of The Joint Commission and other appropriate guiding organizations; any attempt to identify all possible areas where Conflicts of Interest may arise will be incomplete. It is incumbent therefore, on each Individual to be alert, to avoid those Conflicts of Interest that are clearly identified within this policy and those Conflicts of Interests, which while less defined, are equally inconsistent with the delivery of the System's mission in a manner deserving of community trust.

## GIFTS

### **Covered persons and activities:**

All Individuals or groups of Individuals who receive or are offered a “gift” that could reasonably be attributed to the performance of their duties or their position with the System are covered by this policy.

A “gift” is defined as anything of value that is given, directly or indirectly, to an Individual or group of Individuals for which the Individual or group does not give consideration of equal or greater value in return.

### **Requirements:**

- a) **General** – As a general rule, gifts should not be encouraged. An Individual or group of Individuals may accept a gift that is Nominal and is not in the form of cash or cash equivalents. All other gifts should be handled as follows.
- b) **Prohibited gifts** – An Individual or group of Individuals is prohibited from accepting any gift from:
  - a. A government employee, agent, representative or official
  - b. Any person where the gift is made in connection with a System business transaction
  - c. A single student where the gift is made to a Faculty Member or other Individual involved in the education of that student
  - d. A Vendor, unless receipt of the gift is specifically allowed under another provision of this Conflict of Interest Policy.
- c) **Directed Gifts** – any gifts offered or received that are neither Prohibited or acceptable under the General rule defined above:
  - a. Offers from a potential donor should be directed to representatives of the applicable Foundation.
  - b. Received gifts should be administered according to the requirements of Incidental Amounts or Reportable Events and Relationships accordingly. Individuals should be aware that the receipt of a gift that doesn’t meet the General Requirements of this appendix may result in the return of the gift or equivalent value by the System, the redirection of the gift to other System services, or the expectation of personal reimbursement by the Individual benefiting from the gift. The determination of the actions required to remedy potential Conflicts of Interests caused by the receipt of gifts is at the sole discretion of the System.

## **PARTICIPATION IN SPONSORED EDUCATIONAL EVENTS**

### **Covered persons and activities:**

Educational events include all activities that expressly or implicitly purport to advance participants knowledge or skills beyond the implementation of a single product or service. *(Presentation of single products or services are typically considered sales presentations and covered by the guidelines for Procurement and Prescribed Use Activities described in Appendix 4-c.)*

Individuals who participate in a variety of educational programs that have been sponsored in whole or in part by a third-party are covered. This may include aiding in the development or promotion of a program of education, developing materials in support of the program, presenting as part of the program or attending as a participant. Some examples of these programs include events at other academic institutions, professional conferences, government sponsored expert panels or review committees, seminars, symposia, expert training or presentations in the use of new technologies or products/services, and presentations to lay audiences. Any educational program resulting in continuing education credit must comply with the regulations of the educational accrediting body.

### **Requirements:**

- a) **Value of the Event:** The Individual and their manager are required to determine that the program and content are primarily educational in intent, design and implementation providing legitimate educational value for the participants. Further, both the Individual and supervisor must conclude that the program is relevant to the performance of duties at the System, of appropriate rigor, at a level necessary to advance the participants knowledge in this area, and sufficiently balanced in presentation to avoid the introduction of unwarranted bias. Elements of this evaluation include:
  - a. The program and the content should be predominantly directed towards the advancement of knowledge required in the performance of duties at the System.
  - b. The program should strive at all times to present a balanced representation of available options or perspectives. In those instances, where a reasonable person may conclude an unbiased presentation can't or won't be provided, full disclosure of the factors contributing to the perception of unwarranted bias should be disclosed prior to beginning the program.
  - c. The program should limit whenever possible the introduction of commercial content or labeling. Exceptions to this limitation are when the introduction of commercial content is required to accomplish the legitimate educational goals of the program. In all instances where the introduction of commercial content occurs, an equal effort should be made to introduce alternative solutions or methods in order to preserve a balanced presentation.
  - d. Program developers and presenters should demonstrate sufficient expertise through credentials or degrees, and relevant experience to conclude that the

program participant's knowledge will be significantly advanced by their attendance at this program.

- b) Disclosure by Program Planners or Presenters to Participants:** The preservation of an unbiased educational setting requires honest and full disclosure of all potentially influencing factors. Program planners and presenters should disclose all circumstances involving real, potential, or perceived support from third-party sources to safeguard the integrity of the program:
  - a.** The participating Individual should timely disclose clearly, completely and prominently the nature, source and amount of all external support received. The participating Individual should insure that all support, whether financial or in-kind, received from third-party sources is disclosed to program participants prior to the beginning of the educational activity.
- c) Compensation to Individuals:**
  - a.** Individuals should only lend their name or expertise to those types of activities that serve to enhance the reputation of the System. To this end an Individual should only participate in or otherwise allow his/her affiliation with these activities when the Individual has determined that the program and his/her participation meet the expectations of legitimate educational purpose and:
    1. All activities resulting in remuneration or financial benefit are supported by written agreements documenting all terms, conditions, and purposes of the agreement between the sponsor and the Individual.
    2. The compensation paid is consistent with fair market value for the Individual's services, and such services are both meaningful and substantive,
    3. The Individual has disclosed in advance, all relevant Financial Interests directly or indirectly related to their involvement.
- d) Support from Vendors:**
  - a.** Support for System sponsored events must be in the form of a general educational grant paid directly to a System fund.
  - b.** The System shall retain exclusive responsibility for all aspects of educational events/activities.
  - c.** Sponsors may not display commercial exhibits or distribute promotional materials in the space where the program is offered. Further the inclusion of company representatives in the program cannot be a requirement for support of any type. Vendor representatives, displays and promotional materials may be present in an adjoining space if agreed to ahead of time.
  - d.** Support can never be made directly to or earmarked specifically for an individual or individuals.
  - e.** Vendors may be acknowledged in printed materials, but specific products should not be mentioned.
  - f.** Refreshments, study materials and promotional items should be limited to those directly contributing to the stated educational objectives of the program. The provision of food should be modest, appropriate to the event and provided infrequently.





## Appendix 4 – c

### PROCUREMENT AND PRESCRIBED USE ACTIVITIES

#### **Covered persons and activities:**

Individuals involved in the evaluation, recommendation or authorization of products or services, or of policies and procedures that create an institutional incentive to use particular products or services need to be aware of the potential for bias introduced by potential Conflicts of Interest.

The commitment of System resources, directly or indirectly, requires all Individuals involved to maintain an "arms-length" independence from Vendors in both appearance and fact, and to utilize rigorous decision-making practices that insure all decisions are made in the best interests of the System.

#### **Requirements:**

- a) The following actions are required:
  - a. **Personal Incentives:** Occasionally, Vendors offer an incentive if a buyer agrees to purchase the company's goods or services. Personal incentives, e.g., merchandise, tickets to special events, food, vacation trips, etc. are considered Prohibited Gifts as described in GIFTS above and cannot be accepted under any circumstances.
  - b. **Visits by Vendor Representatives:** Individuals must act to ensure compliance with the following requirements.
    - i. All Vendor representatives must be registered and credentialed according to each Entity's policy and procedures.
    - ii. Vendor representatives from pharmaceutical, biotechnology and other industries may visit healthcare providers, researchers, and other Individuals to talk about and demonstrate their new products only upon appointment and at the request of the Individual being visited. An appointment is always required; generally, representatives are not permitted on campus on a drop-in basis or in any clinical patient diagnostic or treatment area including waiting rooms. However, nothing in this policy is intended to prohibit the involvement of trained technical representatives in clinical areas necessary for the effective delivery of patient care. Scheduled appointments are also required for Vendor visits to train physicians, researchers or others in device use or new technologies.
  - c. **Placement of Vendor Equipment at the System:** Individuals must act to ensure compliance with the following.
    - i. Vendors may offer to place a new device or piece of equipment on-campus on a trial basis. Such arrangements require notice to the Purchasing Department in advance of accepting the trial use and are required to be terminated if in the opinion of the Purchasing

Department the trial basis arrangement results in an unfair advantage in a procurement decision.

- ii.** The Vendor will be expected to deliver and retrieve the item within the designated time period not to exceed three months.
- d. Site Visits to View Vendor Products and/or Services:** Site visits to Vendors to evaluate and compare Vendor products and/or services are sometimes necessary to assist staff in making the best purchasing decision. All Individuals must comply with the requirements of this Policy in responding to and managing these activities.

## **Appendix 4 – d**

### **PHARMACEUTICAL SAMPLES**

The respective Hospital policy on Medication Management and Pharmaceutical Samples shall be followed by all Individuals as amended from time to time in accordance with the Hospital governance practices.

## **CONFLICT OF COMMITMENT**

### **Covered persons and activities:**

All Individuals are potentially affected by a Conflict of Commitment. Conflicts of Commitment are a type of Conflict of Interest where the presence of another commitment impacts the Individual's ability to conduct their duties and responsibilities in the best interests of the System. They may arise with respect to the distribution of effort between an Individual's obligations and responsibilities to the System, and his/her commitment to outside professional activities.

### **Requirements:**

Activities such as consulting, involvement with professional societies, or private practice, or educational opportunities in the Individual's area of interest or profession may be appropriate as they promote the professional development of the Individual and enrich the Individual's contributions to the System, to his/her profession, and to the various System activities and communities that the Individual serves. However, an Individual shall not participate in any activity that involves a conflict of commitment unless such activity has been approved in advance in writing by his/her manager. If such approval has been given, any terms or conditions regarding such activity will be monitored by the manager to ensure they are satisfied.

## RESEARCH

Albany Medical College (the “College”) has adopted this policy and the accompanying procedures in order to promote objectivity in the performance of research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of an “Investigator.”

### **Covered persons and activities:**

Individuals involved in the design, conduct, or reporting of research are covered by this policy. These requirements are intended to ensure that all Financial Interests are properly disclosed, managed, reduced or eliminated and reported consistent with federal requirements at 42 CFR Part 50 and 45 CFR Part 94. The requirements for Funded Research are in addition to the general requirements of the Conflict of Interest Policy.

Institutional Responsibilities of the Investigator under this policy apply to:

1. The Investigator’s professional responsibilities on behalf of Albany Medical College (refer to Conflict of Interest Policy Definitions, Appendix 1).
2. All research (including basic science and human subject research) regardless of funding source performed or proposed to be performed at the College or with the support of the College.
  - a. All “Investigators” which means the principal investigator/project director, co-investigator(s), and any other person responsible for all or part of the design, conduct, or reporting of research.
  - b. “Investigator” includes the investigator’s spouse and dependent children.
  - c. “Investigator” also include significant contributors such as contractors, subcontractors, sub-grantees, collaborators or consultants
  - d. “Any other person” regardless of title and/or position, who is named on the grant application and has a high degree of autonomy with responsibility for all or part of the design, conduct or reporting of research.
3. All Financial Interests that would reasonably appear to be affected by the research or in entities whose financial interests would reasonably appear to be affected by such research activities including:
  - a. Salary or other payments for services (e.g., seminars, lectures, teaching engagements, consulting fees or honoraria, gifts, paid authorship);
  - b. Income from service on advisory committees or review panels for public, nonprofit, or for-profit entities.
  - c. Equity interests (e.g., stocks, stock options or other ownership interests), and intellectual property rights and interests (e.g. patents,

copyrights, and royalties from such rights), upon receipt of income related to such rights and interests.

- d. Any occurrence of reimbursed travel. This includes any sponsor funded travel which is paid on behalf of the investigator and not reimbursed to the investigator.

### **Investigator and Institution Requirements:**

- **General Disclosure Requirements**

In addition to annual disclosures required by the Conflict of Interest Policy, Investigators must make a complete disclosure of Financial Interests:

- Prior to submission of a research proposal;
- And if funded, disclose within 30 days:
  - When there is a change in the previously disclosed Financial Interest during the period after submission of the proposal through the period of the research
  - When a new reportable Financial Interest arises at any time during the period after submission of the proposal through the period of the research

All Investigators must disclose their Financial Interests utilizing the Investigator Financial Interest Disclosure Form. The completed Form and all supporting documentation must be submitted with the proposal and the Sponsored Programs Review and Approval Form (Form A) to the Office of Research Affairs/Research Administration and Compliance.

- **Travel Disclosure Requirements**

Details of travel disclosure must include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The institutional official (s) determines if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest (FCOI) with any PHS/NSF funded research.

- **Determination of a Conflict of Interest**

All research related disclosures of Financial Interest will be reviewed by the College Director of Research Administration. If the Director of Research Administration (DRA) believes a potential Conflict of Interest may exist the DRA will forward the Investigator Financial Interest Disclosure Form, all supporting documentation and a recommendation to the Chief Compliance Officer for review.

- **Managing a Financial Conflict of Interest (FCOI)**

Management of an identified research related financial conflict of interest requires development and implementation of a management plan in accordance with the requirements of 42 CFR Part 50 and 45 CFR Part 94. Whenever the College implements a financial interest management plan, it will monitor the investigator's compliance with the plan on an ongoing basis until the completion of the research project.

Examples of conditions or restrictions that might be imposed to manage research conflicts of interest include but are not limited to:

- Public disclosure when presenting or publishing the research
- For research involving human subjects, disclosure of financial conflicts directly to subjects/participants addressed at a minimum within the informed research consent document
- Monitoring of research by independent reviewers
- Modification of the research plan
- Change in personnel or personnel responsibilities
- Disqualification from participation on all or a portion of the research
- Divestiture or reduction of financial interest
- Severance of relationships that create actual or potential conflicts

In addition to the above conditions or restrictions that might be imposed, the College may require other actions to mitigate or eliminate Conflicts of Interest, as it deems appropriate.

• **Reporting/Recordkeeping Requirements:**

If the research includes or proposes to include Federal funds (partial or total funding by the Public Health Service (PHS), including NIH and any other PHS Components to which the authority involved may be delegated) or if the Federally funded research is in any way reportable to FDA, the College will comply with the following Federal reporting requirements:

- Prior to spending any funds under a Federal award, the College will report to the Federal sponsor, the existence of any conflicting financial interests (as defined in 42 CFR Part 50 and 45 CFR part 94) and ensure a management plan has been implemented such that the interest has been managed, reduced, or eliminated in accordance with these regulations. The College will make information available to the Federal sponsor regarding all financial Conflicts of Interest identified in accordance with these regulations; and,
- For any new Financial Interest that the College identifies as posing a Conflict of Interest as defined in 42 CFR Part 50 and 45 CFR Part 94 subsequent to the College's initial report under the award, a report will be made and the Conflict of Interest managed, reduced, or eliminated; at least on an interim basis, within sixty days of the determination that a Conflict exists.
- Whenever a financial interest was not disclosed timely by an Investigator or was not previously reviewed or managed by the College in a timely manner during an ongoing PHS-funded research project, the College will, within sixty days, review the financial interest and if a financial Conflict of Interest exists, implement a management plan at least on an interim basis. If a Conflict of Interest exists, within 120 days of the determination, the College will complete a retrospective review to determine whether any Federally funded research was biased in the design, conduct or reporting of the research. The College will document the retrospective review and if bias is found, will promptly notify the awarding sponsor and submit a mitigation report.



- In addition to the reporting of financial Conflicts of Interest, the College may report other conflicts, as it deems appropriate.
- For any financial Conflict of Interest reported to the Federal sponsor, the College will monitor the management plan and provide annual updates for the duration of the research project period.

Prior to the expenditure of any funds under a PHS-funded research project, the College will ensure public accessibility of information concerning any significant financial interest that meets the criteria as defined in 42 CFR Part 50 and 45 CFR Part 94. The information will remain available for at least three years from the date the information was most recently updated.

Records relating to all Investigator disclosures of financial interests and the College's review of and response to such disclosures and all actions taken under this Policy will be maintained for at least three years from the date the final expenditure report is submitted to the funding agency.

The College will maintain its COI Policy via a publicly accessible Web site.

**Albany Medical College Institutional Research Committee/Board Requirements:**

Institutional Research Committee Members include Institutional Officials, Committee/Board Chairs, Committee/Board Vice-Chairs and Members of the following research review committees:

- Institutional Review Board (IRB)
  - Institutional Animal Care and Use Committee (IACUC)
  - Institutional Bio-safety Committee (IBC)
  - Controlled Substances Governing Board (CSGB)
- **Disclosure Requirements:**  
Institutional Research Committee/Board Members must disclose:
    - Any Financial Interest in entities that sponsor research
    - Any relationship (including non-financial relationships) or issues that would appear to impact the Committee/Board member's objectivity in the performance of his/her Committee/Board duties reviewing, commenting and voting on research protocols and Institutional Committee/Board standard operating policies and procedures
    - Any conflict of commitment that interferes with their ability to effectively perform their responsibilities as a Committee/Board Member

**Additional Disclosure Process for Institutional Committee /Board Members:**

- Institutional Committee/Board Members shall complete a Committee/Board Disclosure Questionnaire annually and amend same at any time there is a new reportable conflict.

- Institutional Committee/Board Members are responsible for immediately reporting any protocol specific conflicts to the Institutional Committee/Board Chair prior to review and discussion of the protocol.
- **Resolving a Committee/Board Conflict of Interest:**

The Institutional Committee/Board Chair will determine and document any protocol specific conflict, whether the member will be able to participate in the discussion and voting, that the conflict was communicated to the Committee/Board and any related action taken as part of the meeting minutes. All potential Conflicts of Interest must be reported to the Director of Research Administration and the Chief Compliance Officer.

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Questions concerning compliance with any of the requirements included in Appendix 4-f should be directed to the Dean's Office, Director of Research Administration (DRA) of the Albany Medical College. The Dean's Office/DRA will conduct or provide training of researchers on this policy applied to research activities prior to engaging in PHS-funded research at least every four years, and as otherwise required by federal regulation.

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## **EXCESS BENEFIT TRANSACTIONS**

### **Covered persons and activities:**

In order to safeguard the tax-exempt status of the System entities, increased scrutiny is required to insure relationships and transactions involving persons or parties (Interested Parties) having the potential to influence the actions of the System and its entities do not result in excess benefit to those parties beyond what would have been received at fair market value.

For purposes of this section Interested Parties include:

- Any director, principal officer or member of a committee with governing board delegated powers
- Any employee:
  - with responsibilities, powers or influence over an entity as a whole that is similar to those of officers, directors, or trustees, or
  - who manages a discrete segment or activity of an entity that represents 10% or more of the activities, assets, income, or expenses of that entity, or
  - has or shares the authority to control or determine 10% or more of an entity's capital expenditures, operating budget, or compensation for employees, and
  - has annual reportable compensation from the System that exceeds \$150,000.
- Any person who was in a position to exercise substantial influence over the affairs of an entity at any time during the five-year period ending on the date of the transaction by virtue of a substantial ownership or investment interest, or a compensation arrangement in any entity, trust or venture with which the System has a business relationship, is contemplating a transaction or arrangement, or has been the beneficiary of a substantial level of gifts from that person, family members or related entities.

### **Requirements:**

Preservation of the tax-exempt status of System entities requires all activities and relationships further the tax-exempt purposes of the organization and do not unduly benefit an individual or group of individuals.

This requires that all relationships and transactions by the System and each of its entities be on the basis of fair market value defined as the price at which property or the right to use property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell, or transfer property or the right to use property, and both having reasonable knowledge of relevant facts. For purposes of this standard; compensation includes all forms of cash and non-cash payments or benefits provided in

exchange for services or goods, direct and indirect remunerations, gifts or favors. Examples include salary and wages, bonuses, severance payments, deferred payments, retirement benefits, fringe benefits, and other financial arrangements or transactions such as personal vehicles, meals, housing, personal and family educational benefits, below-market loans, payment of personal or family travel, entertainment, and personal use of the organization's property.

- **Disclosure Requirements:**

Any Interested Party has a duty to disclose all material facts and circumstances for review by the Committee on Audit and Compliance of the Albany Med Health System prior to soliciting or engaging in any activities that may result in the exchange of financial assets between any entity of the System and the individual, related entities or members of their family. In addition to those persons included in the definition of Immediate Family of this policy, for the purpose of this section family members also include ancestors, grandchildren, great grandchildren, and spouses of brothers, sisters, children, grandchildren, and great grandchildren.

*Annual Statements* – Each person covered by this section is required to annually sign a statement which affirms such person:

- Has received a copy of the Conflicts of Interest policy,
- Has read and understands the policy,
- Has agreed to comply with the policy, and
- Understands the System entities are charitable and in order to maintain their federal tax exemption each entity must engage primarily in activities which accomplish one or more of its tax-exempt purposes.

- **Resolving a Conflict of Interest**

*Excess Benefit Transactions* – In those instances where a transaction or arrangement results in economic benefit to an Interested Party beyond the consideration that would be paid under like facts and circumstances between disinterested parties with sufficient knowledge to engage in an arm's-length exchange; an excess benefit transaction is deemed to have occurred.

When an excess benefit transaction occurs the Interested Party that benefits beyond the fair market value will be expected to return the compensation in excess of fair market value to the System. In all instances, the terms of the transaction or arrangement will be amended to comply with the rules and regulations of the U.S. Internal Revenue Service requiring the avoidance of transactions or arrangements resulting in excess benefit transactions prior to any future exchange or encumbrance of the finances of the System.

- **Reporting/Recordkeeping Requirements:**

*Proceedings* – The minutes of the Committee on Audit and Compliance of the Albany Med Health System and entity Board meeting where the transaction is voted upon shall contain:

- The names of persons who disclosed or otherwise were found to have a potential conflict of interest under this section, the nature of the potential conflict, any

action taken to determine whether a conflict of interest was present, and the committee's decision as to whether a conflict of interest, in fact, existed.

- The names of all persons present for discussions and votes relating to the transaction or arrangement, the content of the discussion, including any alternatives to the proposed transaction<sup>3</sup> or arrangement, and a record of any votes<sup>4</sup> taken in connection with the proceedings.
- Notice to all other committees with board delegated powers of identified conflicts of interest and actions taken or required to be taken.

*Periodic Reviews* – At least annually, a periodic review will be completed of selected transactions and arrangements involving the System and Interested Parties which shall, at a minimum, include:

- Whether the compensation and benefits are reasonable based on comparison to reliable sources of transactions or arrangement of like facts between disinterested parties and as the result of arm's length bargaining.
- Whether partnerships, joint ventures, or other arrangements conform to the System's written policies, relevant laws and regulations are properly recorded, reflect reasonable investment or payments for goods and services, further charitable purposes and do not inure impermissible private benefit or in an excess benefit transaction.

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<sup>3</sup> NPCL Section 715 requires the consideration of alternative transactions to the extent available.

<sup>4</sup> NPCL Section 715 requires approval by not less than a majority vote of the directors or committee members present at the meeting.