
Progentec Diagnostics, Inc.

Conflict of Interest Policy



Date Effective: 10/27/2017

CONFLICT OF INTEREST POLICY

PROGENTEC DIAGNOSTICS INC.

Policy on Conflicts of Interest And Disclosure of Certain Interests

This conflict of interest policy is designed to help directors, officers, and employees of Progentec Diagnostics, Inc. ("Progentec"), identify situations that present potential conflicts of interest and to provide Progentec with a procedure that, if observed, will allow a transaction to be treated as valid and binding even though a director, officer, or employee has or may have a conflict of interest with respect to the transaction. In the event there is an inconsistency between the requirements and the procedures prescribed herein and those in federal or state law, the law shall control. All capitalized terms are defined in Part 2 of this policy.

1. Conflict of Interest Defined. For purposes of this policy, the following circumstances shall be deemed to create Conflicts of Interest:

A. Outside Interests.

(i) A Contract or Transaction between Progentec and a Responsible Person or Family Member.

(ii) A Contract or Transaction between Progentec and an entity in which a Responsible Person or Family Member has a Material Financial Interest or of which such person is a director, officer, agent, partner, associate, trustee, personal representative, receiver, guardian, custodian, conservator, or other legal representative.

B. Outside Activities.

(i) A Responsible Person competing with Progentec in the rendering of services or in any other Contract or Transaction with a third party.

(ii) A Responsible Person's having a Material Financial Interest in; or serving as a director, officer, employee, agent, partner, associate, trustee, personal representative, receiver, guardian, custodian, conservator, or other legal representative of, or consultant to; an entity or individual that competes with Progentec in the provision of services or in any other Contract or Transaction with a third party.

C. Gifts, Gratuities and Entertainment. A Responsible Person accepting gifts, entertainment, or other favors from any individual or entity that:

- (i) does or is seeking business with, or is a competitor of Progentec; or
- (ii) has received, is receiving or is seeking to receive a loan or grant, or to secure other financial commitments from Progentec;

- (iii) is a charitable organization;

under circumstances where it might be inferred that such action was intended to influence or possibly would influence the Responsible Person in the performance of his or her duties. This does not preclude the acceptance of items of nominal or insignificant value or entertainment of nominal or insignificant value that are not related to any particular transaction or activity of Progentec.

2. Definitions.

A. A Conflict of Interest is any circumstance described in Part 1 of this Policy.

B. A Responsible Person is any person serving as an officer, employee or member of the board of directors of Progentec.

C. A Family Member is a spouse, domestic partner, parent, child, or spouse of a child, brother, sister, or spouse of a brother or sister, of a Responsible Person.

D. A Material Financial Interest in an entity is a financial interest of any kind that, in view of all the circumstances, is substantial enough that it would, or reasonably could, affect a Responsible Person's or Family Member's judgment with respect to transactions to which the entity is a party. This includes all forms of compensation. (The board may wish to establish an amount that it would consider to be a "material financial interest.")

E. A Contract or Transaction is any agreement or relationship involving the sale of purchase of goods, services, or rights of any kind, the providing or receipt of a loan or grant, the establishment of any other type of pecuniary relationship or review of a charitable organization by Progentec. The making of a gift to Progentec is not a Contract or Transaction.

3. Procedures.

A. Before board or committee action on a Contract or Transaction involving a Conflict of Interest, a director or committee member having a Conflict of Interest and who is in attendance at the meeting shall disclose all facts material to the Conflict of Interest. Such disclosure shall be reflected in the minutes of the meeting.

B. A director or committee member who plans not to attend a meeting at which he or she has reason to believe that the board or committee will act on a matter in which the person has a Conflict of Interest shall disclose to the chair of the meeting all facts material to the Conflict of Interest. The chair shall report the disclosure at the meeting and the disclosure shall be reflected in the minutes of the meeting.

C. A person who has a Conflict of Interest shall not participate in or be permitted to hear the board's or committee's discussion of the matter except to disclose material facts and to respond to questions. Such person shall not attempt to exert his or her personal influence with respect to the matter, either at or outside the meeting.

D. A person who has a Conflict of Interest with respect to a Contract or Transaction that will be voted on at a meeting shall not be counted in determining the presence of a quorum for purposes of the vote. The person having a conflict of interest may not vote on the Contract or Transaction and shall not be present in the meeting room when the vote is taken, unless the vote is by secret ballot. Such person's ineligibility to vote shall be reflected in the minutes of the meeting. For purposes of this paragraph, a member of the board of directors of Progentec has a Conflict of Interest when he or she stands for election as an officer or for re-election as member of the board of directors.

E. Responsible Persons who are not members of the board of directors of Progentec or who have a Conflict of Interest with respect to a Contract or Transaction that is not the subject of board or committee action, shall disclose to the Chair or the Chair's designee any Conflict of Interest that such Responsible Person has with respect to a Contract or Transaction. Such disclosure shall be made as soon as the Conflict of Interest is known to the Responsible Person. The Responsible Person shall refrain from any action that may affect Progentec's participation in such Contract or Transaction.

In the event it is not entirely clear that a Conflict of Interest exists, the individual with the potential conflict shall disclose the circumstances to the Chair or the Chair's designee, who shall determine whether there exists a Conflict of Interest that is subject to this policy.

4. Confidentiality.

Each Responsible Person shall exercise care not to disclose confidential information acquired in connection with such status or information the disclosure of which might be adverse to the interests of Progentec. Furthermore, a Responsible Person shall not disclose or use information relating to the business of Progentec for the personal profit or advantage of the Responsible Person or a Family Member.

5. Review and Acknowledgment of Policy.

A. Each new Responsible Person shall be required to review a copy of this Policy and to acknowledge in writing that he or she has done so.

B. Each new Responsible Person shall annually complete a disclosure from identifying any relationships, positions, or circumstances in which the Responsible Person is involved that he or she believes could contribute to a Conflict of Interest arising. Such relationships, positions, or circumstance might include service as a director of or consultant to a not-for-profit organization, or ownership of a business that might provide goods or services to Progentec. Any such information regarding business interests of a Responsible Person or a Family Member shall be treated as confidential and shall generally be made available only to the Chair, the Executive Director, and any committee appointed to address Conflicts of Interests, except to the extent additional disclosure is necessary in connection with the implementation of this Policy.

C. This policy shall be reviewed annually by each member of the Progentec board of directors. Any changes to the policy shall be communicated immediately to all Responsible Persons.

6. Provisions Concerning Financial Conflict of Interest in Research

Progentec is committed to performing medical research with integrity and openness and objective research is a cornerstone of Progentec's policy. This section of the policy is specifically designed to identify any financial interests that could bias research at Progentec and to monitor and manage those situations to ensure that investigators' financial interests have no bearing on the research conducted at Progentec.

A. Investigator Annual Disclosure

1. Upon initial employment or affiliation with Progentec and on an annual basis thereafter, each Investigator (defined as any individual, regardless of title, who is responsible for the design, conduct, or reporting of research at Progentec) must complete and submit a Financial Disclosure Statement.

2. Investigators also have an ongoing obligation to update their disclosures within 30 days whenever there is a change in status from their previously submitted disclosures.

B. Conflicts of Interest

1. Conflict of Interest Determination

If Progentec determines that an Investigator possesses a Conflict of Interest (defined as a financial interest that is related to the Investigator's research at Progentec and that could directly and significantly affect the design, conduct, or reporting of that research), Progentec shall refer that Conflict to its Conflict of Interest Committee.

2. Conflict of Interest Committee Membership

The CEO and General Counsel will serve on the Committee in an ex officio capacity and will determine the membership of the Committee, which may be drawn from members of the community, the Progentec Board of Directors, and Progentec staff.

3. Conflict of Interest Committee Responsibility

The Committee will review the Conflicts referred to it and will recommend steps to manage, reduce, or eliminate those Conflicts. The Committee will make recommendations to the CEO, who will report those recommendations to the Progentec Board of Directors for final action.

C. Managing Conflicts of Interest

Examples of strategies for managing Conflicts of Interest include:

1. Disclosure of financial interests to lab personnel and collaborators
2. Disclosure of financial interests in publications and posters
3. Disclosure of financial interests to audiences at conferences and seminars
4. Disclosure of financial interests to any human subjects participating in research studies
5. Appointment of an independent peer reviewer to monitor research
6. Modification of research plans
7. Disqualification of the Investigator from participating in research
8. Limitation of the Investigator's role in research
9. Divestiture of financial interests

D. Ongoing Training Requirements for Investigators

All Investigators must complete initial conflict of interest training and update their training at least every four years after their initial training. This training will be a requirement and will be satisfied by the completion of Progentec's online tutorial(s) and/or NIH web-based training (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) will be used. Employees must save and print the FCOI Certificate as proof of completion.

E. Reporting to Federal Agencies

1. Prior to expending any funds under a federal award, Progentec will report to the federal agency the existence of any Financial Conflict of Interest. A Financial Conflict of Interest exists when Progentec, through its designated officials, reasonably determines that an Investigator's Significant Financial Interest (as defined and explained below) is related to a federally funded research project and could directly and significantly affect the design, conduct, or reporting of the federally funded research project.

2. In determining whether an Investigator possesses a Significant Financial Interest, remuneration includes payments for services, receipt of consulting fees, honoraria, paid authorship, royalties, and intellectual property, as well as the value of any reimbursed or sponsored travel.

3. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when

aggregated, exceeds \$5,000.

4. With regard to any non-publicly traded entity, a Significant Financial Interest exists: (a) if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000; or (b) when the Investigator or the Investigator's spouse or dependent children holds any equity interest in the entity.

5. Types of interests specifically excluded from the definition of Significant Financial Interest are:

a. Income from investment vehicles such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in the vehicle;

b. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels for federal, state, or local government agencies, U.S. institutions of higher education, nonprofit academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education; or

c. Intellectual property rights or royalty shares assigned by Progentec to the Investigator.

F. Reporting FCOI to PHS Awarding Component (e.g., the NIH)

1. The information Progentec shall submit to the federal funding agency (via eRA Commons) about a Financial Conflict of Interest shall include:

a. Grant/contract number

b. Name of the principal investigator or project director

c. Name of the Investigator with the Financial Conflict of Interest

d. The name of the entity with which the Investigator has the Financial Conflict of Interest

e. Statement regarding whether the Financial Conflict of Interest was managed, reduced, or eliminated

f. The nature of the Significant Financial Interest involved (e.g., equity, consulting fees, travel reimbursement, honoraria)

g. Value of the Significant Financial Interest within one of the following ranges: \$0-4,999; \$5,000-9,999; \$10,000-19,999; amounts between \$20,000-100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or including a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value

h. A description about how the Financial Conflict of Interest relates to the federally funded research and the basis for Progentec's determination that the Significant Financial Interest conflicts with that research

i. A description of the key elements of Progentec's Financial Conflict of Interest management plan, with that description including the following information:

1) Role and principal duties of the conflicted Investigator in the federally funded research project

2) Conditions of the management plan

3) How the management plan is designed to safeguard objectivity in the research

project

- 4) Confirmation of the Investigator's agreement to the management plan
- 5) How the management plan will be monitored to facilitate Investigator compliance
2. Progentec will provide annual reports to the federal funding agency for any

previously reported Financial Conflict of Interest.

- a. The annual report will specify whether the conflict is still being managed, describe any changes to the management plan, or explain why the conflict no longer exists.

- b. As required, Progentec will provide annual reports to the funding agency for the duration of the project period, including extensions with or without funds.

G. Public Disclosure

1. Progentec shall make its Financial Conflict of Interest in Research Policy publicly accessible via its website.

2. Progentec will also post on its website the following information regarding any identified Financial Conflict of Interest:

- a. The name of the Investigator

- b. The title and role of the Investigator in the federally funded research project

- c. The name of the entity in which the Significant Financial Interest is held

- d. The nature of the Significant Financial Interest

- e. Value of the financial interest within one of the following ranges: \$0-4,999; \$5,000-9,999; \$10,000-19,999; amounts between \$20,000-100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or Including a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value

H. Non-Compliance and Enforcement

1. If an Investigator fails to comply with this policy and such failure implicates federally funded research, within 120 days of determining such non-compliance, Progentec must complete a retrospective review of the Investigator's activities and research. This review will document Progentec's determination as to whether there existed any bias in the design, conduct, or reporting of the federally funded research.

2. If bias is found, Progentec must submit a mitigation report addressing: the impact of the bias on the research project, including the extent of the harm done; any qualitative and quantitative data to support any actual or future harm; whether the project is salvageable; and the actions Progentec has taken or will take to eliminate or mitigate the effect of the bias. Depending on the nature of the Financial Conflict of Interest, Progentec may determine that additional interim measures are necessary regarding the Investigator's participation in the research until the completion of the retrospective review.

3. If an Investigator violates this policy or fails to comply with a written management plan, he or she will be subject to disciplinary action that may include, but may not be limited to, suspension of the ability to submit new grant applications, limitations on or suspension of current funding, and termination of employment.

I. Records

1. Financial Disclosure Statements and Descriptions of Financial Interest shall be maintained by Progentec for a period of at least three years.

2. Where a Financial Conflict of Interest management plan has been created that relates to federally funded research, Progentec will retain a copy of any financial conflict of interest report filed with a federal agency for a period of at least three years after submission of the final expenditures report or, for federal research contracts, three years after final payment.

J. Subrecipient compliance

When working with a subrecipient, Progentec will put in place a written agreement with the subrecipient to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed; and (b) in either case, clarify the timeline for disclosure and reporting.

Conflict of Interest Acknowledgment
Form

Please describe below any relationships, positions, or circumstances in which you are involved that you believe could contribute to a Conflict of Interest (as defined in Progentec's Policy on Conflicts of Interest) arising.

I hereby certify that the information set forth above is true and complete to the best of my knowledge. I have reviewed, and agree to abide by, the Policy of Conflict of Interest of Progentec that is currently in effect.

Signature: _____ Date: _____

Printed Name: _____