

**42 IAC 1-5-6 Conflicts of interest; decisions and voting (IC 4-2-6-9)**

**42 IAC 1-5-7 Prohibition against financial interest in contract; exceptions (IC 4-2-6-10.5)**

The Secretary of the FSSA was charged by the state legislature with overseeing the creation and implementation of a non-profit corporation that would be responsible for operating the State's public cord blood bank. The Secretary was concerned about potential conflict of interest issues since at least two of the nominated board members had an ownership interest in a bank that would likely seek to contract with the board to provide administrative and processing support.

SEC found that conflicts of interest would arise for both of these board members and recommended a screen that the board and FSSA should adhere to to comply with IC 4-2-6-9(b)(1).

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The Indiana State Ethics Commission ("Commission") issues the following advisory opinion concerning the State Code of Ethics pursuant to IC 4-2-6-4(b)(1).

**BACKGROUND**

The Secretary of the State's Family and Social Services Administration ("FSSA") is charged with overseeing the implementation of the legislative mandate set forth in House Enrolled Act 1172 (the "Statute"). The Statute calls for the creation of a non-profit corporation (the "Corporation") that will form and operate a public cord blood bank in Indiana (the "Bank"). A public cord blood bank is an operation that accepts cord blood donations from anyone who desires to donate.

The Bank will accept donated umbilical cord blood, placenta, and other tissue extracted from the umbilical cord. Cord blood is the blood that remains in the umbilical cord after a baby is born and the umbilical cord is cut. These donations will be collected, processed, stored and maintained at no cost to the donors and all rights in the donations will transfer to the Bank upon donation. Donations that are of transplantable quality will be registered on the National Marrow Donor Program Registry and made available for transplant. Alternatively, those donations that are ineligible for transplant may be sold to third parties for research purposes.

The Bank will enter into a written agreement with those hospitals, clinics and birthing centers that wish to provide public cord blood banking as an option to their patients (the "Participating Hospitals"). Participation with the Bank will be solely on a voluntary basis and Participating Hospitals will be free to contract with other cord blood banks and/or entities that operate in the same or a similar field.

In addition, the Bank will contract the day-to-day management, administrative operations and tissue processing to a third party that is already equipped to perform such tasks (the "Third Party Banking Facility"). In this manner, the Bank will not require a large amount of start-up capital in order to acquire the necessary facilities as such facilities will be provided by the selected Third Party Banking Facility.

The general governance structure for the Bank consists of two Boards – a Board of Directors and an Advisory Board. The criterion for the members of the Board of Directors is defined by the Statute. The Governor appoints the Board of Directors which consists of the following:

- One president or CEO of an Indiana based hospital. *IC 12-31-1-4(a)(5)(A)*
- One research scientist with expertise in umbilical cord blood research. *IC 12-31-1-4(a)(5)(B)*
- One ethicist with expertise in bioethics. *IC 12-31-1-4(a)(5)(C)*
- One licensed physician who specializes in birthing and delivery. *IC 12-31-1-4(a)(5)(D)*
- One representative of a donor umbilical cord blood bank facility. *IC 12-31-1-4(a)(5)(E)*
- One member of the interagency state council on black and minority health established under IC 16-46-6. *IC 12-31-1-4(a)(5)(F)*

The Advisory Board is comprised of individuals who are appointed by the Board of Directors, at least half of whom must be research scientists in the area of stem cell research.

The Board of Directors of the Bank primarily functions to oversee the business decisions and overall operation of the Bank. The primary responsibilities of the Board of Directors include:

- developing various policies and procedures that are necessary for operation of the Bank, including guidelines for collecting, maintaining and receiving donations, procedures regarding patient informed consent and privacy and policies, and procedures for the education of health care professionals and donors;
- selecting an Institutional Review Board;
- establishing a set of criteria pursuant to which cord blood donations that are ineligible for transplant may be sold to third party researchers;
- appointing an Advisory Board that will be responsible for determining the allocation of the non-transplantable cord blood collected by the Bank to third parties for research purposes, as well as determining the price charged for the same on a case-by-case basis; and
- general supervision of the Third Party Banking Facility.

In addition to the aforementioned duties, it has been contemplated that the Board of Directors may also be responsible for establishing criteria for the Request for Proposal ("RFP") process associated with selecting the Third Party Banking Facility and ultimately making the final determination with respect thereto.

Since the majority of the individuals recommended for a position on the Board of Directors and the Advisory Board are professionally involved in the medical industry in Indiana and/or stem cell research, FSSA respectfully requests that the Commission issue an advisory opinion with respect to any potential conflict of interest issues that it believes may arise for the members of the Bank's Board of Directors during the initial formation of the Bank, as well as the ongoing management thereof.

In particular, the responsibility of managing the RFP process and selecting a Third Party Banking Facility is the first order of business for the Board of Directors that has been identified as potentially causing conflict of interest issues for certain Board members. This is especially true with respect to the individuals specifically discussed below.

1) A representative of a donor umbilical cord blood bank facility is the President and Chief Executive Officer of General BioTechnology, LLC ("GBT") and was appointed to the Board of Directors as required. The GBT is a for-profit entity that performs early translational research and development on cryopreservation techniques and banking procedures for biological cells and tissues. The Representative is also the Laboratory Director of the Genesis Bank ("Genesis") which is a commercial cord blood bank and processing facility that was organized independently of GBT. However, GBT employs all of the Genesis staff and owns the facilities and equipment that Genesis uses to operate. In addition to his executive involvement with GBT, the Representative is also a thirty-three percent (33%) owner of the company.

The Representative has made it clear that Genesis intends to submit an RFP to the Bank in the hopes of being selected as the Third Party Banking Facility. Furthermore, Genesis is the only commercial cord blood banking facility in Indianapolis, which is where the initial Participating Hospitals will likely be located.<sup>1</sup>

2) A professor in the Indiana University School of Medicine's Department of Pediatrics has been appointed to the Board of Directors as the required research scientist with expertise in umbilical cord blood research. The Research Scientist is a co-founder of EndGenitor Technologies, Inc. ("EndGenitor"). EndGenitor is a for-profit entity that commercializes products based on adult stem cells obtained from placenta, umbilical cord and cord blood. Further, EndGenitor's targeted consumer base comprises researchers in industry and academia.

The Research Scientist currently serves as EndGenitor's scientific consultant and is on its Board of Directors. While it is unclear whether or not the Research Scientist has any

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<sup>1</sup> As part of the Bank's roll-out strategy, it is intended that the Bank will initially limit the overall number of clinics, birthing centers and hospitals with which it contracts, as well the geography where those are located, in order to facilitate healthy and manageable growth for the Bank.

ownership interest in EndGenitor, the Research Scientist does have a five percent (5%) ownership interest in Genesis (discussed above in connection with the Representative).

### ISSUE

- (1) Would conflicts of interest arise for the Representative under the Indiana Code of Ethics given his appointment to the Board of Directors and his concurrent relationship with BioTechnology, LLC and Genesis?
- (2) Would conflicts of interest arise for the Research Scientist under the Indiana Code of Ethics given his appointment to the Board of Directors and his concurrent relationship with EndGenitor and Genesis?

### RELEVANT LAW

#### **IC 4-2-6-9**

##### **Conflict of economic interests**

Sec. 9. (a) A state officer, an employee, or a special state appointee may not participate in any decision or vote if the state officer, employee, or special state appointee has knowledge that any of the following has a financial interest in the outcome of the matter:

(1) The state officer, employee, or special state appointee.

(2) A member of the immediate family of the state officer, employee, or special state appointee.

(3) A business organization in which the state officer, employee, or special state appointee is serving as an officer, a director, a trustee, a partner, or an employee.

(4) Any person or organization with whom the state officer, employee, or special state appointee is negotiating or has an arrangement concerning prospective employment.

(b) A state officer, an employee, or a special state appointee who identifies a potential conflict of interest shall notify the person's appointing authority and seek an advisory opinion from the commission by filing a written description detailing the nature and circumstances of the particular matter and making full disclosure of any related financial interest in the matter. The commission shall:

(1) with the approval of the appointing authority, assign the particular matter to another person and implement all necessary procedures to screen the state officer, employee, or special state appointee seeking an advisory opinion from involvement in the matter; or

(2) make a written determination that the interest is not so substantial that the commission considers it likely to affect the integrity of the services that the state expects from the state officer, employee, or special state appointee.

(c) A written determination under subsection (b)(2) constitutes conclusive proof that it is not a violation for the state officer, employee, or special state appointee who sought an advisory opinion under this section to participate in the particular matter. A written determination under subsection (b)(2) shall be filed with the appointing authority.

## **IC 4-2-6-10.5**

### **Prohibition against financial interest in contract; exceptions**

Sec. 10.5. (a) Subject to subsection (b), a state officer, an employee, or a special state appointee may not knowingly have a financial interest in a contract made by an agency.

(b) The prohibition in subsection (a) does not apply to:

(1) a state officer, an employee, or a special state appointee who does not participate in or have official responsibility for any of the activities of the contracting agency, if:

(A) the contract is made after public notice or, where applicable, through competitive bidding;

(B) the state officer, employee, or special state appointee files with the commission a statement making full disclosure of all related financial interests in the contract;

(C) the contract can be performed without compromising the performance of the official duties and responsibilities of the state officer, employee, or special state appointee; and

(D) in the case of a contract for professional services, the appointing authority of the contracting agency makes and files a written certification with the commission that no other state officer, employee, or special state appointee of that agency is available to perform those services as part of the regular duties of the state officer, employee, or special state appointee; or

(2) a state officer, an employee, or a special state appointee who, acting in good faith, learns of an actual or prospective violation of the prohibition in subsection (a), if, not later than thirty (30) days after learning of the actual or prospective violation, the state officer, employee, or special state appointee:

(A) makes a full written disclosure of any financial interests to the contracting agency and the commission; and

(B) terminates or disposes of the financial interest.

## **IC 4-2-6-1**

### **Definitions**

Sec. 1. (a) As used in this chapter, and unless the context clearly denotes otherwise:

(10) "Financial interest" means an interest:

(A) in a purchase, sale, lease, contract, option, or other transaction between an agency and any person; or

(B) involving property or services.

The term includes an interest arising from employment or prospective employment for which negotiations have begun. The term does not include an interest of a state officer or employee in the common stock of a corporation unless the combined holdings in the corporation of the state officer or the employee, that individual's spouse, and that individual's unemancipated children are more than one percent (1%) of the outstanding shares of the common stock of the corporation. The term does not include an interest that is not greater than the interest of the general public or any state officer or any state employee.

## ANALYSIS

The Representative and the Research Scientist are special state appointees by virtue of their appointment to the Board of Directors, a body designated by statute that functions in a policy or an advisory role in the executive. *See* IC 4-2-6-1(a)(16). As special state appointees, the Representative and the Research Scientist are subject to the Code of Ethics including the conflicts of interest provisions set forth in IC 4-2-6-9 and IC 4-2-6-10.5. The application of both conflicts of interest provisions to each Appointee's situation are analyzed below.

### A. The Representative

#### a. *IC 4-2-6-10.5 Prohibition against financial interest in contract; exceptions*

Pursuant to IC 4-2-6-10.5, a special state appointee may not knowingly have a financial interest in a contract made by an agency. The restriction, however, does not apply to a special state appointee that does not participate in or have official responsibility for any of the activities of the contracting agency, provided certain statutory criteria are met. The term "official responsibility" has been interpreted by the Commission to refer to contracting responsibilities.

Based on the facts presented, it would appear that a conflict of interest under IC 4-2-6-10.5 would arise for the Representative. Specifically, it is apparent that Genesis intends to submit an RFP to the Bank in the hopes of being selected as the Third Party Banking Facility. Given that the President has a 33% ownership interest in GBT, which in turn owns 80% of Genesis, the Representative would have a financial interest in the contract if Genesis is selected as the Third Party Banking Facility. Because the Representative would likely have official responsibilities for the Bank in his capacity as a board member, he would be prohibited from having a financial interest in a contract made by the Bank for the Third Party Facility.

#### b. *IC 4-2-6-9 Conflict of Economic Interests*

In addition to the previous conflict of interest analysis, a separate conflict of interest would arise under IC 4-2-6-9 for the Representative if he would participate in a decision or vote in which he or his employer would have a financial interest in the outcome of the matter. In this case, Genesis intends to submit an RFP to the Bank in the hopes of being selected as the Third Party Banking Facility. It has already been established that both the Representative and his employers, GBT and Genesis, would have a financial interest in the decision of whether Genesis is selected as the Third Party Banking Facility. Accordingly, the Representative would be prohibited from participating in any Bank decision or vote, involving the drafting of the RFP or the selection of the Third Party Banking Facility.

*B. The Research Scientist*

*c. IC 4-2-6-10.5 Prohibition against financial interest in contract; exceptions*

Pursuant to IC 4-2-6-10.5, a special state appointee may not knowingly have a financial interest in a contract made by an agency. The restriction, however, does not apply to a special state appointee that does not participate in or have official responsibility for any of the activities of the contracting agency, provided certain statutory criteria are met. The term “official responsibility” has been interpreted by the Commission to refer to contracting responsibilities.

Based on the facts presented, it would appear that a conflict of interest under IC 4-2-6-10.5 would arise for the Research Scientist. Specifically, Genesis intends to submit an RFP to the Bank in the hopes of being selected as the Third Party Banking Facility. Given that he has a five (5) percent ownership interest in Genesis, the Research Scientist would have a financial interest in the contract if Genesis is selected as the Third Party Banking Facility. Because the Research Scientist would have official responsibilities for the Bank in his capacity as a board member, he would be prohibited from having a financial interest in a contract made by the Bank for the Third Party Facility.

*d. IC 4-2-6-9 Conflict of Economic Interests*

Similar to the previous analysis, a separate conflict of interest would arise under IC 4-2-6-9 for the Research Scientist if he would participate in a decision or vote in which he would have a financial interest in the outcome of the matter. In this case, Genesis intends to submit an RFP to the Bank in the hopes of being selected as the Third Party Banking Facility. The Research Scientist owns five (5) percent of Genesis. Given that he has an ownership interest in Genesis, it would appear that he would have an interest in the Bank’s decision of whether Genesis is selected as the Third Party Banking Facility. Accordingly, the Research Scientist would be prohibited from participating in any Bank decision or vote, involving the drafting of the RFP or the selection of the Third Party Banking Facility.

**CONCLUSION**

The Commission finds that conflicts of interest would arise for both the Representative and the Research Scientist under IC 4-2-6-10.5 and IC 4-2-6-9 as members of the Bank’s

Board of Directors given their concurrent relationships with BioTechnology, LLC, EndGenitor, and Genesis.

The Commission further finds that a remedy to the conflicts of interest identified herein would be permissible in accordance with IC 4-2-6-9(b)(1). Accordingly, the Commission approves and recommends that the following screening measures be implemented:

- a.* FSSA will manage the RFP process for selecting a Third Party Banking Facility and have the final decision as to which third party was selected, thereby removing any initial contracting responsibilities from the Board of Directors.
- b.* The Research Scientist will relinquish his ownership interest in the Genesis Bank and, subject to the Governor's approval, assume the Representative's projected role on the Board as the representative of a donor umbilical cord blood bank facility. (This will involve identifying another individual(s) to be recommended to the Governor to serve as the research scientist with expertise in umbilical cord blood research.)
- c.* The Representative will decline his nomination to the Board of Directors of the Bank so that General BioTechnology, LLC and/or the Genesis Bank can participate in the RFP process.
- d.* The Research Scientist shall be screened from any stage related to the RFP process including, but not limited to establishing criteria for the RFP and/or drafting the RFP.
- e.* In the event that General BioTechnology, LLC or the Genesis Bank is selected as the Third Party Banking Facility, the Research Scientist will be screened from all Board discussions and decisions that are related to the ongoing management of the Third Party Banking Facility and any contractual issues that may arise as he serves as the Medical Director for the Genesis Bank.
- f.* At the initial meeting of the Board of Directors, each Board member will make a full written disclosure of their relationships that may possibly create a conflict of interest issue (either ethical or financial) with respect to fulfilling their responsibilities as a Board member. These disclosures will be fully reviewed and analyzed for potential conflict of interest issues that have not yet been identified. Additionally, the disclosures shall be filed with the Indiana Office of Inspector General and State Ethics Commission.
- g.* For any ethical conflict of interest issues identified in light of the Board members' disclosures, screening procedures will be established in compliance with IC 4-2-6-9. Further any financial conflict of interest issues will be disclosed immediately as prescribed by IC 4-2-6-9 (b).