

Berkshire Biomedical Corporation – Financial Conflict of Interest (FCOI) Policy

The Public Health Service (PHS) regulation at 42 CFR Part 50, Subpart F is designed to promote objectivity in PHS-funded research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grant awards (includes NIH) is not biased by any conflicting financial interests of an Investigator. The regulation places the responsibility for the identification and management of Investigators' FCOI with Berkshire Biomedical Corporation (Berkshire), which oversees the Investigator's activities. The NIH, as the grantor agency, has primary responsibility for overseeing compliance with these requirements, and BERKSHIRE, an institution that is a recipient of NIH funding and supporter of this regulation, has responsibility for ensuring that all Investigators, including those at subawardee Institutions and vendors, that are paid with grant funds comply with these requirements. Herein states BERKSHIRE'S FCOI policy.

Definitions:

Co-Investigator: A person who is responsible for the design, proposal, conduct, or reporting of research funded by PHS. This person could be an employee or consultant of BERKSHIRE, or an employee or consultant of BERKSHIRE'S subawardee institutions or vendors.

FCOI: A financial conflict of interest exists when the BERKSHIRE reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

Institution: The recipient of NIH funds, herein BERKSHIRE.

Investigator: The principal investigator and any other person who is responsible for the design, proposal, conduct, or reporting of research funded by PHS, including the Investigator's spouse and dependent children.

Significant Financial Interest: A financial interest consisting of one or more of the following interests of the Investigator that reasonably appears to be related to the Investigator's institutional responsibilities.

- i. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- ii. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

This definition does not include the following types of financial interests:

- i. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- ii. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- iii. 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 these vehicles;
- iv. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- v. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

Vendor: A contract research organization (CRO) that conducts work for BERKSHIRE and is paid for that work with NIH funding.

Policy:

BERKSHIRE strives to create a research environment that promotes objectivity in research by establishing standards for the design, conduct and reporting of NIH-funded research to determine if bias could result from a financial conflict of interest (FCOI). This policy is applicable to all Investigators as well as any other Co-Investigator(s). Note that Investigators or Co-Investigators from other subawardee institutions or vendors will be bound by the FCOI policies of their respective employers, and overseen by and reported to BERKSHIRE.

Each Investigator or Co-Investigator that is an employee of BERKSHIRE must undergo FCOI training provided by NIH every 4 years, and comply with this policy by disclosing any significant financial interest in outside entities that would be or appear to be related to the grant funded work conducted or overseen by the Investigator. The institutional official (SO) at BERKSHIRE is responsible for the general administration and enforcement of this policy while the Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed. Records of all FCOI training and reporting are kept on file for 3 years.

Nondisclosure of Significant Financial Interests, either prior to or during the award, will subject the employee to disciplinary action by BERKSHIRE.

Reporting:

Investigators or Co-Investigators have an ongoing obligation to disclose Significant Financial Interests throughout the awarded project period. Investigators or Co-Investigators must update financial disclosures of Significant Financial Interests to their Institutions within thirty (30) days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

The FCOI report must contain a description of the key elements of the Institution's management plan, including the following:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Following a disclosure, and in accordance with this FCOI policy, the institutional official at BERKSHIRE will have sixty (60) days to review the disclosure, determine if further information is needed, including a determination or disclosure of monetary value, determine whether the Significant Financial Interest is related to NIH-funded research, and determine whether a FCOI exists, and if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI.

Action:

In the event that a disclosure is determined to be a FCOI by the institutional official, BERKSHIRE will submit an FCOI report to the grants administrator at the institute at NIH from which the funding was received within the 60-day review period.

Managing FCOIs:

Examples of ways that BERKSHIRE may manage FCOIs by employees are the following:

- Publicly disclose of the FCOI (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.);
- For research projects involving human subjects research, disclose FCOI directly to the participants;
- Appoint an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modify of the research plan;
- Monitor the research using independent reviewers;
- Change personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduce or eliminate the financial interest (e.g., sale of an equity interest); or
- Sever the relationship(s) that create the FCOI