

INSTITUTIONAL CONFLICT OF INTEREST POLICY

Overview:

Critical Path Institute (C-Path) is a 501(c)(3) organization incorporated in Arizona whose mission is to create innovative collaborations in research and education that enable the safe acceleration of the process for developing new medical products. **It exists to serve the Food and Drug Administration's (FDA) Critical Path Initiative** through consortia composed of pharmaceutical company researchers who work on pre-competitive projects in drug development. The FDA and European Medicines Agency (EMA) act as advisors to this work. The intent is to develop methods and "tools" that are ultimately qualified by the FDA and EMA for use in testing of new medical products.

As an organization, C-Path adheres to a policy on the acceptance of external funding and conflict of interest when engaging with other persons, organizations and institutions. It is the intent of C-Path that each member of the Board of Directors, any committee, task force or advisory body, employees, professional consultants, and volunteers understand and respect their duty to place the best interests of C-Path first in all dealings, and that they shall take no action that conflicts or could reasonably be perceived to conflict with the best interests of C-Path.

Funding and COI Policy for the Organization:

It is essential that C-Path maintain neutrality and ensure that all partnerships are aligned with the scientific and health mission of C-Path and the FDA. Recognizing the importance of neutrality and maintaining independence and high ethical standards in health research, C-Path receives funding from local governments, donors and foundations, and competitive grants (FDA, Science Foundation Arizona, and Agency for Healthcare Research and Quality (AHRQ)). To accomplish its work, C-Path creates and maintains consortia whose members include commercial entities that are developing products regulated by the FDA. Consortia member companies sign a common legal agreement for participation in the consortia that ensures all work will be made public with FDA approval. Currently, the consortia contribute knowledge and information to improve health research by combining different skills and resources in innovative ways to work on biomarkers, disease models, and survey instruments.

Consortium member companies pay research support fees as part of their participation. The research support fees range from \$10,000 to \$25,000 per year depending on the consortium. These fees are used exclusively to support the operations of the consortia, are kept separate from C-Path funds and are deposited into accounts unique to each consortium. The funds in each of these accounts are controlled solely by each consortium's coordinating committee which is composed of representatives of the member companies. Consortia support includes but is not limited to professional project management, meeting expenses, clinical trials to verify findings, and for contracting research organizations to do specific work for the consortia. Their contribution of in-kind resources and research support fees enable the consortia to accelerate the results of their work to benefit the public good. C-Path's full, independently-audited, annual accounting of revenues and expenses is available and maintained as a permanent record in its annual report. Copies of these reports can be obtained by contacting the Institute at 520.547.3440, or info@c-path.org.

C-Path does not endorse organizations, companies or products. It engages in no commercial or for-profit activities, and does not act as a philanthropic agency for other organizations or events.

C-Path Subsidiary Organizations

C-Path subsidiary organizations, defined herein as a separate entity controlled in part or whole by C-Path, shall adhere to C-Path's conflict of interest policy, or a newly developed policy mutually acceptable to the Boards of Directors of C-Path and the controlled subsidiary, until such time C-Path no longer serves as its controlling agent.

C-Path Created Organizations

C-Path created organizations, defined herein as a separate entity that originated as an outcome of C-Path's work and is not controlled by C-Path, is independently incorporated, has self-governing Boards and bylaws, and autonomous business operations and policies, are excluded from this conflict of interest policy. The C-Path Board of Directors will oversee the creation of new organizations and review C-Path created organizations as appropriate in its annual review to ensure no conflicts of interest exist for C-Path or any of its employees.

Definitions:

Employee: anyone working part-time or full-time, not serving as a professional consultant, and receiving financial remuneration from C-Path

Consultant: anyone self-employed or employed by a company under contract to provide professional services to C-Path on a limited or temporary basis to lend their expertise to a specific project.

Relevant Financial Interest: an investment or equity in any entity that is greater than 5% ownership or exceeds \$10,000 in value

Conflict of Interest: Conflict of Interest (COI) is any situation in which an individual or corporation, either private or governmental, is in a position to exploit a professional or official capacity in some way for their personal or corporate benefit

Relative: any spouse, parent, sibling, child and domestic partner or any other sharing a financial or household relationship with the employee

Process:

Any director, employee, or consultant to C-Path, who is engaged, or may be engaged, in outside obligations, financial interests or other relationship that may result in a conflict of interest or commitment which could affect the objectivity of that individual's decisions and/or effectiveness of their performance will disclose any involvement or potential involvement in any activity by them or their close relative(s), that may be considered a conflict of interest, to C-Path's Conflict of Interest Committee, using C-Path's Employee Conflict of Interest Disclosure Form.

C-Path Conflict of Interest Committee: The Conflict of Interest Committee is responsible for reviewing disclosures of potential conflicts of interest reported by any director, employees or consultants, for determination and management of potential conflicts of interest. The Conflict of Interest Committee will work with the Director of Contracts, Legal Services & Compliance, to document written conflict of interest determinations, and management plans. This team is comprised of three voting individuals with sufficient seniority and ability to exercise independent judgment in such matters. Conflict of Interest Committee Members will be appointed by C-Path's Chief Executive Officer ("CEO"). Non-voting, ex officio representatives may be invited to participate in Conflict of Interest Committee meetings, at the discretion of the Conflict of Interest Committee, to provide expertise as necessary and appropriate to reviews and determinations.

Duty to Disclose: In connection with any actual or possible conflict of interest, any director, employee or consultant must disclose the existence of a potential conflict of interest, and be given the opportunity to disclose all material facts to the Conflict of Interest Committee using the Employee Conflict of Interest Disclosure Form.

Determining Whether a Conflict of Interest Exists: After disclosure of the potential conflict of interest, and all material facts, and after any discussion between the Conflict of Interest Committee and the discloser of the potential conflict, the Conflict of Interest Committee will determine if a conflict of interest exists, and what actions need to be taken as a result.