

## **C-Path's 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. C-Path operates mainly through public-private partnerships that work on pre-competitive, multi-stakeholder projects. Regulatory authorities act as advisors to this work. The intent is to develop methods and "tools" that ultimately receive regulatory endorsement by regulatory authorities for use in testing of new medical products.

As an organization, C-Path adheres to a policy on the acceptance of external funding and eliminating or managing conflicts of interest when engaging with other persons, organizations, and institutions. It is the intent of C-Path that each member of the C-Path 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 with, or could reasonably be perceived to conflict with, the best interests of C-Path.

### Funding and COI Policy for the Organization:

C-Path has a defined policy statement regarding its role as a Neutral Convener. It is essential that C-Path maintains its neutrality and ensures that all partnerships are aligned with our mission. Recognizing the importance of neutrality and maintaining independence and high ethical standards in health research, C-Path forms public private partnerships (i.e. consortia) and receives funding from consortia members, government institutions, donors, and foundations. Consortia members sign an agreement for participation in the consortia that ensures all work will be made public. Consortia members and stakeholders contribute knowledge, information, and data, to improve health research by combining different skills and resources in innovative ways to develop novel biomarkers, quantitative models and tools, and clinical outcome assessments.

Consortium member industry partners pay annual membership fees as part of their participation. These fees are used to fund the operations and scientific objectives defined by the consortia. A combination of in-kind resources and annual membership fees from consortia members 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 on the [c-path.org](http://c-path.org) website.

C-Path does not endorse organizations, companies, or products.

### C-Path Subsidiary Organization:

A C-Path subsidiary organization, including Critical Path Institute Stichting, is defined herein as a separate entity controlled in part or whole by C-Path, and shall adhere to C-Path's COI policy, or a newly developed policy mutually acceptable to the Board of Directors of C-Path and the controlled subsidiary, until such time as C-Path ceases to serve as its controlling agent.

### Duty to Disclose:

In connection with any actual or possible COI, any director, employee or consultant must disclose the existence of a potential COI and be given the opportunity to disclose all material

facts to the Conflict of Interest Committee (COIC) using the Employee Conflict of Interest Disclosure Form.

Determining Whether a Conflict of Interest Exists:

After disclosure of the potential COI, and all material facts, and after any discussion between the COIC and the discloser of the potential conflict, the COIC will determine if a COI exists, and what actions need to be taken as a result.

Any director, employee, or consultant to C-Path, who is engaged, or may be engaged, in outside obligations, financial interests or other relationships that may result in a COI 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 COI, to C-Path's COIC in compliance with the pertinent Conflict of Interest Policy and disclosure form.

C-Path Employee Conflict of Interest Requirements:

- Employees of C-Path will not accept honoraria, consultancies, advisory and/or board roles or gifts of \$50 or more per year from any company or entity that works with C-Path and is in the medical product development and marketing sector. Any exceptions to this must be approved in writing by C-Path's COIC.
- Employees of C-Path will not be permitted to serve on any for-profit board of directors in the medical product development/marketing sector. Any exceptions to this must be approved in writing by C-Path's COIC.
- All employees will be expected to report all real, potential, or perceived conflicts of interest to the C-Path COIC as soon as they become aware of their COI. The COIC may ask the employee to make public disclosure of any real, potential, or perceived COI or ask the employee to take corrective action(s) such as returning payments or gifts. A real, potential, or perceived COI is deemed to exist when a C-Path employee or a relative of a C-Path employee can answer "yes" to any of the following:
  - Has a financial interest in any entity in the medical product development and marketing sector where the interest is greater than 5% ownership or a value that exceeds \$5,000.
  - Has a financial interest in any entity in the medical product development and marketing sector where the value of that financial interest cannot be readily determined (for example, stock that is not publicly traded).
  - Has any other financial interest that the employee believes may interfere with, or be perceived to interfere with, their ability to act solely in the best interests of C-Path.
  - Has a proprietary interest in any aspect of C-Path's work, such as a patent, trademark, copyright, or licensing agreement.
  - Is an executive or director of any entity in the medical product development and marketing sector that are regulated by any governmental agencies, such as the FDA.
  - Has a financial interest that requires disclosure to a C-Path funding source.
  - Is paid to provide scientific and technical guidance, expertise, and/or oversight to a third party.
- All employees who administer subawards to subrecipients must comply with federal regulation requirements including 42 CFR Part 50 Subpart F (<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>).

- All employees who engage in the selection, award and administration of federal contracts must comply with federal regulation requirements including 2 CFR 200.318 (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR45ddd4419ad436d/section-200.318>) and 48 CFR Part 9.507-1 (<https://www.ecfr.gov/current/title-48/chapter-1/subchapter-B/part-9/subpart-9.5/section-9.507-1>).
- Financial interests such as mutual funds or retirement account investments over which the employee has no control in buying and selling stocks are excluded; however, any self-directed mutual funds where an employee has control over buying and selling stocks in the medical product development and marketing sector are subject to the parameters listed above.
- All real, potential, or perceived COIs must be reported on the attached Disclosure Form (Attachment A) which will be completed by each Employee upon hire, and annually thereafter. Real, potential, or perceived COIs will be reviewed by the COIC on a case-by-case basis to determine whether the COI has the potential to jeopardize C-Path's neutrality or ability to accomplish its mission, and whether the COI needs to be disclosed publicly, monitored, or eliminated, in order for the employee to remain in their position.

#### C-Path Board of Directors Conflict of Interest Requirements:

- Pursuant to Article XVI of the Bylaws of Critical Path Institute, no Director may participate in the decision-making process on any matter in which such Director, or a Relative of such Director has any Interest (a "Conflict of Interest"). The terms "Relative" and "Interest" are defined in the Bylaws as follows:
  - "Relative" means the spouse, parents, siblings, children, and domestic partners or any others sharing a financial or household relationship.
  - "Interest" means any pecuniary or proprietary interest.
- Upon learning that the Board or Advisory Board, as the case may be, is involved in a matter in which the Director believes a real or potential COI may exist, the Director shall notify the Chairperson of the Board and shall immediately withdraw from any further consideration or discussion of the issue around which the conflict exists.
- Directors who participate on any for-profit corporate, or governing boards shall be diligent in avoiding potential conflicts and report a list of all boards on which they serve, as well as report all real, potential, or perceived COIs on the attached Disclosure Form (Attachment B) which will be completed annually by each board director. Relevant disclosures are required to be reported on C-Path's annual 990 tax filing. Real, potential, or perceived COIs will be reviewed by the Board COIC on a case-by-case basis to determine whether the COI has the potential to jeopardize C-Path's neutrality or ability to accomplish its mission, and whether the COI needs to be disclosed publicly, monitored, or eliminated, in order for the director to remain in their position.

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*C-Path leads collaborations that accelerate  
drug development, advancing better  
treatments for people worldwide.*

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