

icddr,B Conflict of Interest Policy

Statement of the Policy

Consistent with icddr,b principles of Code of Ethics, the Board of Trustees, management and staff have the responsibility of administering the affairs of icddr,b honestly, and prudently, and of exercising their best care, skill and judgment for the sole benefit of icddr,b. These persons shall exercise the utmost good faith in all transactions involving their professional duties, and they shall not use their positions with or knowledge gained there from for their personal benefit. They are always expected to act loyally, impartially, objectively in discharging their official duties with highest standard of professionalism and integrity. The interests of icddr,b must be the first priority in all decisions and actions. The Staff members shall ensure that expression of personal views and convictions does not compromise or appear to compromise the performance of their official duties or the interests of icddr,b due to any undisclosed conflict of interest.

icddr,b's policy is that the existence of conflict of interest shall be disclosed before any transaction is consummated. The Board, management and staff shall continuously securitize their transactions, outside business interests and relationships for potential conflicts and to immediately make such disclosures. Members of the Board of Trustees and staff are expected to reveal any personal, family, or business interests that they have, which, by creating a divided loyalty, could influence their judgment and hence the wisdom of decisions.

Purpose of the Policy

icddr,b adopts the Conflict of Interest (Col) Policy in order to prevent Conflicts of Interest or the appearance of such conflicts by Staff members% to establish good governance practice, maintain staff integrity, safeguard institutional resources, and promote transparency.

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icddr,b, as a nonprofit organization, may be subject to and is expected to intense public scrutiny, especially

in situations where its directors, management or staff appear to have inappropriately benefited from others directly or indirectly through access to information or from a decision over which they might have influence, or where someone might reasonably perceive such a benefit and influence to exist. icddr,b's Public Healthcare Research activities and findings also require heightened scrutiny to ensure transparency and accountability.

The conflict of interest policy establishes procedures that will offer protection against charges of impropriety involving such persons.

The policy is intended to ensure that when any actual or potential conflicts of interest arises, icddr,b has a process in place under which the affected individual will advise management or authorized official about all the relevant facts concerning the situation. The policy also establishes procedures under which individuals who have a conflict of interest will be excused from voting on such matters.

Board of Trustee members, management and staff are required to comply with the provisions of this Policy. icddr,b is committed to ensure strict adherence and any violation of any part of this policy may constitute cause for disciplinary or other administrative action pursuant to Staff Regulations and Rules and or policies under Institutional Governance Framework.

Definition of Terms

The following definitions are adopted:

"Business Entity" means a sole proprietorship, partnership, joint venture, or any other form of enterprise, whether conducted for profit or not.

"icddr,b" means International Centre Diarrheal Disease Research, Bangladesh and other entities under its control.

Staff member' means all full time, part time, seconded scientific/non-scientific employees engaged in icddr,b's business, which shall include employees at management level.

'Board' means the Board of Trustees of icddr,b constituted under section 8 of the icddr,b Ordinance 1978 **'Trustee'** means any individual member of the Board of Trustees of icddr,b

“Conflict of Interest” means any situation in which a Board or Staff member has the opportunity or appears to have the opportunity to influence icddr’s decisions or use resources or confidential or proprietary information of icddr in ways that could lead to professional, personal or financial gain, or otherwise give improper advantage to the Board or Staff member or institutions in which he or she hold official positions or Prohibited or Significant Financial Interests.

“Conflict of Interest Committee” means the committee responsible for reviewing Conflict of Interest issues relating to the Research and other Activities on such issues. The Conflict of Interest Committee is composed of one trustee appointed by Board, the Chief Operating Officer (COO), Director, RCA&S, Director, Finance, Director, Human Resources and two members from the scientific Centers appointed on the recommendation of the Centre Directors. The Committee shall be chaired by the Board appointee and the COO, in absence of the Board Appointee, shall act as the chair of the Committee.

“Family Member” means a spouse, domestic partner, child, parent, sibling, or in-law of the Board and/or the Staff Members.

Designated Official means the individual within the institution who is on behalf of icddr, responsible for the solicitation and review of disclosures of significant financial interests including those of the Staff members and their family related to the institutional responsibilities. For the purposes of this policy, the Designated Official is Director Finance.

Relevant Authority means the Board when the relevant concerned person is a Trustee of the Board and the Col Committee, acting through the Designated Official, when the concerned person is a Staff Member.

Institutional responsibilities means the Board’s, Project Investigators (PIs’) and Staff members’ professional responsibilities associated with his or her appointment or position with icddr, such as research, training, teaching, clinical activities, administration, and institutional or external professional services.

Principal Investigator means any individual who is responsible for the design, conduct, or reporting of research activities, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include scientists, senior scientists,

postdoctoral associates, consultants, fellows or trainees. The definition may also include collaborators or administrators as appropriate.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalized knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

“Research Activity” means any research which is designed and develop or contribute to Health Research that is financed in whole or in part by funds administered by icddr.

“Participate in Health Research” means, with respect to a specific research protocol, 1) acting as principal investigator for such protocol; 2) recruiting staff to such protocol; or 3) evaluating the response on such protocol.

“Personnel Action” means recruiting, hiring, sponsoring, appointing, terminating, promoting, demoting, setting compensation or other benefits, and allocating Center resources such as space and finding.

“Representative” means any member of the scientific staff, Staff Members, director or trustee of icddr.

“Transaction” is used in its broadest sense and includes, but is not limited to, loans, procuring, buying or selling goods or services, research, investigation, testing or patient care.

The term does not include the purchase by a Representative or Family Member of goods or services offered by icddr in the normal course of business.”

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Board and Staff members should conduct their affairs so as to avoid or minimize conflicts of interest, and must inform to appropriate authority when conflicts of interest arises. To that end, this policy informs such persons about situations that generate conflicts of interest related to research, training and administration and provides mechanisms for the institution to manage those conflicts of interest that arises, and describes situations that are prohibited. Every Board and Staff member has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of Conflict of Interest arises, the member affected should discuss the situation with the Designated Official.

General Conflict of Interest Provisions:

1. Prohibition on Payment for Results.

A Trustee of the Board or a Staff member shall not receive payments, gifts or hospitality from any source conditioned upon a particular research result or administrative action or that are tied to successful research outcomes or any administrative decision.

2. Limitations on Participation in Transactions Involving Financially Interested Staff Members.

A Trustee of the Board or a Staff member shall not participate in any Transaction involving icddr;b in which the Trustee or the Staff member has or receives a Significant Financial Interest unless the Transaction is reviewed and approved in accordance with this Policy after full disclosure of all relevant facts to ensure that any Conflict of Interest is managed, reduced or eliminated to prevent bias, improper influence, or misuse of icddr;b's or Government's resources.

3. Limitations on Participation in Transactions Involving Certain Business Entities.

A Trustee of the Board or a Staff member shall not participate in any Transaction between icddr;b and a Business Entity in which the Trustee or the Staff member has or receives a Significant Financial Interest, or a Business Entity of which the Trustee or the Staff member is a trustee, director or officer unless such Transaction is reviewed and approved in accordance with this Policy after full disclosure

of all relevant facts to ensure that any Conflict of Interest is managed, reduced or eliminated to prevent bias, improper influence, or misuse of icddr;b's or Government's resources.

4. Employment of Family Members.

A Family Member may be employed by icddr;b; however, icddr;b will recruit, hire, train, and compensate individuals in all job classifications as per the Staff Regulations & Rules and based solely on the applicant's qualifications, abilities or potential abilities, without any undue influence or involvement of the concerned Trustee or the Staff Member.

5. Personnel Actions Involving Family Members in official capacity.

The Board and the Staff members in conducting their official activities with a coworker, who is a Family Member, must maintain strict professional ethics and shall avoid any personal action in the office environment which may give raise to any possible Conflict of Interest.

6. Supervision of Family Members.

A Trustee or a Staff member shall not directly supervise a Family Member or any person with whom he has a family relation without having prior written approval from the relevant authority..

7. Disclosure in Publications and Presentations.

A Staff member who is the author on a paper or presentation concerning Health Research Activity must disclose any Prohibited Financial Interests held or received by that Staff member that could directly and significantly affect or be affected by the research discussed in the paper or presentation. Issues concerning the necessity and scope of disclosures under this section will be referred to the Conflict of Interest Committee through the Designated Official.

Financial Conflict of Interest Provisions:

"Financial Interest" means anything of monetary value received or held by a Trustee or a Staff member or a his or her Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, gifts exceeding \$10 and hospitality or paid authorships for other than scholarly works); any

equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests

(e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

For Trustees, Principal Investigators and other icddr;b Staff members, Financial Interest also includes any reimbursed or sponsored travel undertaken by him or her that are related to his/her institutional responsibilities. This includes travel that is paid on behalf of the concerned individual as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by icddr;b. The term Financial Interest does not include:

1. Salary, royalties or other remuneration from icddr;b;
2. Income from the authorship of academic or scholarly works or intellectual contributions.
3. Income from seminars, workshop and symposiums, lectures or teaching engagements sponsored by any government or non government institutions including but not limited to institutions of higher education, academic teaching hospitals, medical and health centers, or any research institutions that are affiliated with icddr;b subject to appropriate prior approval obtained from the Relevant Authority.
4. Income from service on advisory committees or review panels by any government or non government institutions including but not limited to institutions of higher education, academic teaching hospitals, medical and health centers, or any research institutions that are affiliated with icddr;b subject to appropriate prior approval obtained from the Relevant Authority
5. Equity interests or Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Trustee or the Staff member is not directly in control of the investment decisions made in these vehicles.

Significant Financial Interest means a Financial Interest that reasonably appears to be directly related to Trustee's, the Principle Investigator (PIs) and staff member's Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or

b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or

c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or

d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or

e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of any research activity including but not limited to PHS-sponsored research.

Prohibition on Participation in Research activity by Financially Interested Staff members

A Trustee or a Staff member may not participate in a Research protocol a) if such Research is sponsored by or is designed to test a product or service of a for-profit entity in which that concerned has or receives an undisclosed significant Financial Interest; or b) if the Conflict of Interest Committee (or the relevant authority for the Trustee, as the case maybe) determines that the Trustee or the Staff member has or receives an undisclosed significant Financial Interest in a for-profit entity that could in any way directly and significantly affect or be affected by the outcome or conduct of such Research or activity or Institutional responsibility.

Disclosure and Review Process

I. Board of Trustee Disclosure and Review.

Each individual Board of Trustee member shall make full disclosure of any actual or apparent or

potential conflict of interest, including Financial Conflict of Interest to the Full Board. Disclosures by individual member of the Board of Trustees should in particular disclose Significant Financial Interests held in entities with which icddr;b maintains a material licensing, vendor or other business relationship. The Board of Trustees or a person or persons designated by the Board of Trustees will review all disclosure by individual members of the Board of Trustees and will determine what conditions or restrictions should be imposed to ensure that any Conflict of Interest or apparent Conflict of Interest is appropriately managed, reduced or eliminated to prevent bias or other improper influence or misuse of icddr;b or government resources.

2. General Disclosure Process

Staff members will disclose to the Committee any Conflict of Interest including any Significant Financial Interests he or she may have which reasonably appears to create a Conflict of Interest. In particular, but not limited to, all Staff Members should disclose Significant Financial Interests held in entities with which icddr;b maintains a material licensing, vendor or other business relationship. Each scientific Staff members (including scientists, senior scientists, postdoctoral associates, consultants, fellows or trainee fellows) responsible for the design, conduct or reporting of research activities will disclose a) any consulting or similar relationship between the Staff member and any Business Entity; b) any Financial Interest he or she has or receives which could reasonably appear to be related to the Institutional Responsibilities; c) any positions held by that Staff member as director or officer of another Business Entity; and d) other matters as may be required by icddr;b Conflict of Interest Policy. icddr;b will require similar disclosures from all other Staff Members. Disclosures must be updated at least annually and as otherwise requested by the Col Committee or Designated Official for necessary review.

3. Review of Disclosures

- a. The Col Committee or Designated Official will review all disclosures involving Prohibited Financial Interests or potential Prohibited Financial Interests which could reasonably affect or be affected by icddr;b's activities and will recommend what conditions or restrictions

should be imposed to ensure that any Conflict of Interest or apparent Conflict of Interest is appropriately managed, reduced or eliminated to prevent bias or other improper influence or misuse of icddr;b resources.

- b. The Conflict of Interest Committee or the Designated Official, as the case may be, will recommend to the Executive Director what conditions or restrictions should be imposed to ensure that any Conflict of Interest or apparent Conflict of Interest is appropriately managed, reduced or eliminated in accordance with icddr;b's policy and applicable law to prevent bias or other improper influence or misuse of icddr;b resources. All such recommendations shall be subject to the approval of the Executive Director. If a Conflict of Interest involves the Executive Director or his/her spouse, domestic partner or dependent child, the recommendations will be reviewed and approved by the Chair of the Board of Trustees or his or her Designated Official.

4. Records Retention.

All records including disclosure forms, conflict management plans, and related documents relating to the disclosure of Conflicts of Interest and any action taken with respect thereto will be maintained for at least three years or as per icddr;b record retention policy, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

Disclosure of Financial Interests

All Staff members are required to disclose their outside financial interests as defined above to icddr;b on an annual and on an ad hoc basis, as described below. The Col Committee or the Designated Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Annual Disclosures

All Staff Members, through the Col Committee or the Designated Official must disclose their Significant Financial Interests that are related to

the Staff Member's institutional responsibilities to icddr, on an annual basis. All forms should be submitted to the Col Committee or the Designated Official by January 31st for the previous calendar year.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Staff members must disclose their Significant Financial Interests to icddr, through the Col Committee or the Designated Official, within 30 days of their initial appointment or employment.

In particular, prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Principal Investigator/Co-Investigator(s) has a Significant Financial Interest, the Principal Investigator/Co-Investigator(s) must affirm the currency of the annual disclosure or submit to the Col Committee or Designated Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. icddr may not submit any PHS-sponsored research proposal unless the Principal Investigator/Co-Investigator(s) has submitted such ad hoc disclosures.

In addition, all Staff members must submit to the Col Committee or Designated Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest

c) Travel

All Staff members must also disclose reimbursed or sponsored travel related to their Institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Col Committee or Designated Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether

the travel constitutes a Financial Conflict of Interest with the Staff members duty.

1) REPORTING TO PHS

All Staff members will report Conflicts of Interest including Financial Conflict of Interest and non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified Conflicts of Interest including Financial Conflict of Interest such that the prime awardee may fulfill their reporting obligations to the PHS.

2) MEASURES FOR NON-COMPLIANCE

a) Reporting Violations

Violations of this Policy by Staff members will be reported to the Col Committee or to the full Board where the context so warrants, for appropriate action. Violations of this Policy by the administrative Staff members responsible to administer and manage icddr resources and scientific Staff members responsible for the design, conduct or reporting of research activities will be reported to the Col Committee or Designated Official and will be addressed pursuant to this Policy. The Committee or Designated Official may seek guidance from the Executive Director for appropriate action for any Conflict or Financial Conflict of Interest in violation of this Policy. Intentional violations of this Policy by any Staff members may result in suspension or dismissal in accordance with the icddr Staff Regulations and Rules.

b) Disciplinary Action

In the event of any Staff Member's failure to comply with this Policy, the Col committee or Designated Official may suspend all relevant activities or take other disciplinary action as per Staff Regulations and Rules with approval from Executive Director until the matter is resolved or other action deemed appropriate is implemented.

The decision to impose sanctions on a Staff member because of non-compliance of this

Policy, or failure to comply with the decision of the Col committee, will be notified in writing with the right to appeal against the decision to the Board of Trustees. icddr;b will notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made to the prime awardee for reporting to PHS.

c) Retrospective Review

In addition, if the Col Committee or Designated Official determines that a Conflict or Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to a staff member's failure to disclose a Conflict or Financial Conflict of Interest or non-compliance by a Staff member with management plan under this Policy, the committee or Designated Official will complete a retrospective review of the impugned activities, including PHS-sponsored activities, to determine whether the activity conducted during the period of non-compliance was in violation of the Policy.

Documentation of the retrospective review shall include the project number, project title, PI of the project, name of the Staff member with the Conflict or Financial Conflict of Interest, name of the entity with which the Staff member has the Conflict or Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

In case of any retrospective review, icddr;b will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations, unless authorized by Executive Director. If bias or conflict is found, the icddr;b will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify

elements documented in the retrospective review, a description of the impact of the bias or conflict on the research project, if any, and the plan of action to eliminate or mitigate the effect of the identified bias or conflict.

3) TRAINING

Each Staff Member, through dissemination, must be trained on this Policy, their responsibilities regarding disclosure of any Conflict or Financial Conflict of Interest and the PHS regulations prior to engaging in research funded by PHS. At least every four years thereafter retraining through dissemination and training sessions for previously trained Staff member should be organized.

They must also complete training within a reasonable period of time as determined by the Col Committee or Designated Official in the event that this Policy is substantively amended in a manner that affects the requirements under this Policy. At the time of writing of this Policy, the responsibility of disseminating the Policy shall be vested on the Centre for Communication and Development, icddr;b and necessary training responsibility shall be vested on the Human Resources.

4) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, icddr;b, at its sole discretion, may be required to make such information available to the PHS Awarding Component and/or HHS, to a requester of information concerning Conflict or Financial Conflict of Interest related to PHS funding or to the primary entity who made the funding available to icddr;b, if requested or required. If icddr;b is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the concerned individual will be informed of this disclosure.

5) REGULATORY AUTHORITY

This Policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this Policy and the requirements, the Policy shall take precedence.