

**Financial Conflict of Interest (FCoI) Policy
for Research and Related Activities**

1. Introduction

Banaras Hindu University promote and forward such project proposals submitted by Investigators in various areas and fields related to the discovery and dissemination of knowledge that emerge from the research. Banaras Hindu University has adopted its basic policy on conflicts of interest that additional consideration has to be given to financial conflicts of interest when dealing with applications of research especially when the research is the product of collaboration of Government of India/Private funding agencies/Public Health Services(PHS)-funded research etc.

Further, the University has the Financial Conflict of Interest Policy for Research and Related Activities to ensure that employees are made aware of such conflicts, are dutiful and management. The following related procedures are not intended to substitute for compliance with Government of India rules and with regard to code of Ethics, Animal Ethics and Biosafety for public officials and employees.

2. Policy Statement and Principles

It is the intent of Banaras Hindu University to manage financial conflicts of interest of its employees as part of ongoing efforts to prevent outcomes that may be harmful to, sponsored activities, operation of regulatory compliance committees, technology transfer efforts, or the University at large. Therefore employees responsible for the designing, conduct, or reporting of sponsored Research, engaging in Technology Commercialization, and/or Related activities (Affected Employees) must report Significant Financial Interests and must work with the University to develop a plan to Manage Financial Conflicts of Interest as necessary. The Integrity of the University as a

community of scholars requires the open exchange of ideas in an atmosphere free from financial conflict and undue influence. This is especially important in those cases where relationships with external parties could lead to circumstances adversely impacting scholarly work, integrity, judgment or the conduct of sponsored activities.

Banaras Hindu University acknowledges that Affected Employees and their Immediate Family have the right to acquire personal financial assets and to establish financial relationships with outside entities. However, they also have the responsibility to manage their financial affairs and relationships in a manner that does not interfere with, or improperly influence, the performance of their professional duties and responsibilities. As long as Significant Financial Interests are disclosed and financial conflicts are managed, reduced, or eliminated; they need not be a problem.

3. Applicability

All Affected Employees of Banaras Hindu University are required to report Significant Financial Interests held by themselves or by their Immediate Family which relate to the Affected Employee's Institutional Responsibilities. This policy and accompanying procedures are intended to provide guidance to Affected Employees in disclosure of Significant Financial Interests and to Banaras Hindu University officials in the management of financial conflicts. It is not intended to substitute for compliance with code of ethics, Animal ethics or Biosafety for public officials and employees. Further, this policy supports Banaras Hindu University's compliance with U.S. Federal requirements¹ to manage and or report certain financial conflicts of interest.

4. Policy Management

Responsible Office: Office of the Dean of the Faculty

Responsible Officer: Dean of the Faculty

Responsible Executive: Vice-Chancellor

5. Definitions

¹ Public Health Service (PHS)
National Science Foundation (NSF)
Food and Drug Administration (FDA)

As per procedures for Financial Conflicts of Interest Policy for Research and Related Activities & Procedures for implementation of University's Conflict of Interest Policy as it applies to research and education activities funded by Govt. of India or any other Government (including PHS – NIH of US) or external agencies or any such collaborative research projects

- i) Authorized Institutional Representative** – is, for the purposes of the FCOI Policy and Procedures, the Vice-Chancellor, Banaras Hindu University.
- ii) Affected Employee-** Faculty as Investigator and other employees responsible for the design, conduct or reporting of sponsored Research or engaged in Related Activities. This could include, but is not limited to, tenure and non-tenure faculty, post-doctoral fellows, and/or graduate students.
- iii) Compliance Committee-** for the purposes of these procedures - the various Committees constituted for the purpose, viz., Institutional Review Boards, the Institutional Animal Ethical Committee, Institutional Ethics Committee and the Institutional Bio-safety Committee, etc.
- iv) Conflict of Interest Committee-** an *ad hoc* group of individuals convened to assist in the review of information disclosed on an Affected Employee's Disclosure Form, the determination of whether a conflict of interest exists, and the management, reduction or elimination of conflicts.
- v) Dean** – As provided in BHU Statutes.
- vi) Disclosure Form-** a form submitted by Affected Employee to the University disclosing Significant Financial Interest(s) as required by the University's FCOI Policy and these procedures.
- vii) Entity-** any domestic or foreign, public or non-public (Private) organization from which an Affected Employee (and his/her Immediate Family) receives remuneration or in which they have an ownership or equity interest.

- viii) Financial Conflict of Interest-** a set of circumstances that may create an undue risk that an individual's judgement or actions regarding a primary interest of the University may be inappropriately influenced by a secondary Financial Interest.
- ix) Financial Interest-** anything of monetary value, whether or not the value is readily ascertainable.
- x) Immediate Family-** the Affected Employee's spouse and dependent children. Throughout these procedures, Significant Financial Interest of the Affected Employee also shall include the interest of the Affected Employee's Immediate Family.
- xi) Institutional Responsibilities-** the Affected Employee's professional responsibilities on behalf of the University, including activities such research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Compliance Committees or Data and Safety Monitoring Boards.
- xii) Manage-** taking action to address a Financial Conflict of Interest, which may include, reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of sponsored Research or engagement in Technology Commercialization efforts will be free from bias.
- xiii) Management Plan-** a written document signed by the Reviewer, Affected Employee, and other appropriate individuals, such as Deans, and supervisors outlining the specific steps to be taken to address Financial Conflict of Interest.
- xiv) Related Activities-** any undertaking which has the potential to improperly influence sponsored Research or Technology Commercialization, but are not limited to: equity interest in or remuneration from a non-publicity traded entity or providing outside services of a professional nature.

- xv) Research-** a systematic investigation, study of experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.
- xvi) Retrospective Report-** a report from the University to a responsible official or agency which may be required when bias is found during a Retrospective Review.
- xvii) Retrospective Review-** a compliance review conducted by the University of a Financial Conflict of Interest that was not identified or Managed in a timely manner.
- xviii) Reviewer-** a responsible representative of the University who reviews the Disclosure Form to determine if a Significant Financial Interest is a Financial Conflict of Interest; determines what conditions or restrictions, if any, should be imposed by the University to Manage a Financial Conflict of Interest; conducts Retrospective Reviews; drafts Retrospective Reports; and ensures that FCOI reports are submitted as required. For the purposes of this policy this individual is the Dean of the Faculty or other individuals as appointed by the Authorized Institutional Representative.
- xix) Significant Financial Interest-** A Financial Interest consisting of one or more of the following interest of the Investigator (and the Investigator's Immediate Family) includes, but is not limited to (1) Equity interest in a listed Entity (on the date of disclosure) and remuneration received from the Entity (within 12 months preceding disclosure), when aggregated, exceeds Rs. 4,00,000 (or US \$5000 if the project is from outside India); (2) Equity interest of any amount in a unlisted Entity; (3) remuneration received from a unlisted Entity (within 12 months preceding disclosure), when aggregated, exceeds Rs. 4,00,000 (or US \$ 5000 if the project is from outside India); or (4) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests. "Financial Interest" does not include, interests of any

amount in diversified financial holdings, or royalties or other remuneration paid by the University.

- xx) Technological Commercialization-** Marketing, licensing, or conveyance of rights to intellectual property, technology, and know-how into the private market.

6) Procedures

i) Affected Employee Disclosure of SFI

Each Affected Employee is required to complete a Disclosure Form disclosing the Affected Employee's Significant Financial Interest which reasonable relate to the Affected Employee's Institutional Responsibilities (and those of the Affected Employee's Immediate Family) to the University's Reviewer, prior to the time of establishment of an account for sponsored Research; prior to engaging in Technology Commercialization activities; and prior to engaging in Related Activities.

Each Affected Employee is required to submit an updated Disclosure Form which includes the Affected Employee's Significant Financial Interests (and those of the Affected Employee's Immediate Family) prior to the processing of new sponsored research awards or modification to their respective scope of work; when engaging in Technology Commercialization activities; when engaging in new Related Activities and within thirty days of discovering or acquiring and unreported Significant Financial Interest for themselves (or their Immediate Family). In addition, the Authorized Institutional Official may request an updated Disclosure Form as needed to ensure compliance with the University's FCOI Policy.

ii) Review, Determination and Management

Prior to an Affected Employee expending any funds under a sponsored Research project; engaging in Technology Commercialization activities; and/or engaging in Related Activities, the Reviewer must review the affected Employee's disclosure of Significant Financial Interest and will determine whether and Affected Employee's Significant Financial Interest is a Financial Conflict of Interest. The Reviewer may convene a Conflict of Interest Committee to assist in the review, determination and management of any

Financial Conflict of Interest. The Reviewer may involve the Affected Employee in the determination of whether a Significant Financial Interest is related to funded Research projects, Technological Commercialization, or related Activities.

For any Financial Conflict of Interest, the University will take necessary actions to manage the conflict. Management of identified Financial Conflict of Interest is determined by the Reviewer and requires development and implementation of a Management Plan which will be monitored for compliance on an ongoing basis. If necessary, the Reviewer will conduct a Retrospective Review and develop and submit a Retrospective Report.

Examples of conditions or restrictions that might be imposed to Manage a Financial Conflict of Interest include, but are not limited to: public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the Research); for projects involving human subjects research, disclosure of Financial Conflicts of Interest directly to participants as determined by the Institutional Review Boards; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the Financial Conflict of Interest; modification of the Research plan; change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research; reduction or elimination of the Financial Interest (e.g., sale of equity interest); or severance of relationships that create financial conflicts

iii) Appeals Process

Within one week of notification of the Reviewer's decision, the Affected Employee must acknowledge, in writing, agreement to comply with any required Management Plan or submit a written request for reconsideration to the Authorized Institutional Representative who may recommend to the Reviewer that a requirement be amended or deleted. The Authorized Institutional Representative may not alter or remove a requirement. The Authorized Institutional Representative may add requirements to a Conflict Management Plan at his or her discretion. Based upon a response from the Reviewer, the Authorized Institutional

Representative will issue a final binding decision on the appeal. The Affected Employee has the right for a timely decision by all parties in the process. The time from submission of a written request from the Affected Employee for reconsideration to final resolution by the Authorised Institutional Representative should not exceed 30 days.

iv) Enforcement & Sanctions

The violation of this FCOI Policy shall be treated as misconduct. The Concerned Deans or the Vice-Chancellor shall utilize the standard faculty or staff disciplinary procedures or other applicable University disciplinary policies or guidelines which may result in suspension, dismissal, or severance of relationship with the University to impose sanctions for violation of the FCOI Policy and these procedures. Other sanctions may be imposed, including, but not limited to:

- a) Retrospective Review and submission of Retrospective Report to the appropriate responsible official and/or applicable sponsoring agency;
- b) Freezing expenditures from involved funds or terminating sponsored or other agreements;
- c) Revocation of the privilege for engaging in research, sponsored activities, technology transfer and commercialization and/or other scholarly activities;
- d) Removal from Compliance Committee membership, and/or
- e) Penalties if the Financial Conflict of Interest is determined to be in violation of code of ethics for public officials and employees.

v) Records Maintenance

The University, through the Authorised Institutional Representative, will maintain all Disclosure Forms, review and response documentation, and all related records of actions taken by the University with respect to disclosures of Financial Interest(s) of Affected Employees. The content of such records are considered confidential to the extent allowable by applicable law and regulations.

-:oOo:-