

Charitable Organization

“Ukrainian Institute for Public Health Policy”

POLICY AND PROCEDURE

Subject:	<u>RESEARCH CONFLICT OF INTEREST POLICY</u>	Minutes No. <u>14</u> of the Board meeting
Reviewed by:	<u>Prof. Sergii Dvoriak M.D.</u> Board designee	Effective Date: <u>02/04/2015</u>
Approved by:	<u>Tetiana Kiriazova Ph.D.</u> Director	

UIPHP RESEARCH CONFLICT OF INTEREST POLICY

1. PURPOSE

The purpose of this Policy is to (1) promote objectivity, ethical and bias-free environment, (2) provide general guidance for managing financial conflict of interest, as well as (3) ensure compliance with any applicable regulations in any Research conducted by UIPHP while furthering UIPHP's statutory objectives and tasks.

2. POLICY

2.1. UIPHP's policy is that all Investigators (as defined below) cannot have any financial interest that can be reasonably expected to bias the design, conduct or reporting of Research. All Investigators who are conducting Research must disclose significant financial interests.

2.2. This Policy is complementary to the general UIPHP's Conflict of Interest Policy, which means that the general UIPHP's Conflict of Interest Policy shall be applied to all Investigators at the same time with this Policy to ensure proper discharge of their duties in the best interests of UIPHP (e.g. regarding the obligation to disclose any conflict of interests not falling under this Policy but subject to the general UIPHP's Conflict of Interest Policy), unless one can reasonably conclude based on this Policy that it excludes or makes unnecessary application of the general UIPHP's Conflict of Interest Policy.

3. DEFINITIONS

For the purposes of this Policy the following terms have the following meaning:

3.1. **COI Administrator** means an UIPHP official designated by UIPHP Director to administer disclosure of FCOI, submission of FCOI reports and related issues within UIPHP or a separate Research as per this Policy. Unless otherwise decided by the Director, for the purpose of this Policy functions of COI Administrator shall be fulfilled by the Institutional Review Board Secretary.

3.2. **Disclosure of significant financial interests (SFI)** means an Investigator's disclosure of significant financial interests to UIPHP.

3.3. **Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of Research.

3.4. **FCOI report** means UIPHP's report of a financial conflict of interest to a PHS Awarding Component.

3.5. **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.

3.6. **Institutional responsibilities** means an Investigator's professional responsibilities on behalf of UIPHP, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.

3.7. **Investigator** means a project director or a principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, or proposed for such funding, which may include, for example, collaborators or consultants. If the role of an individual is unclear and that individual is listed as an Investigator, compliance with all training and filing requirements will be expected. Staff or trainees, who merely implement a protocol developed by an Investigator, recruit participants and/or collect and handle data under supervision, but are not key to the design, conduct or reporting of Research are not considered Investigators for purposes of this Policy.

3.8. **Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

3.9. **PD/PI** means a project director or a principal Investigator of a Research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this Policy.

3.10. **PHS Award(s)** means any grant, contract, award, or sub-award issued or awarded by the United States Public Health Service (PHS) and its agencies, including Centers for Disease Control and Prevention, National Institutes Health etc., and their sub- agencies.

3.11. **PHS Awarding Component** means the organizational unit of the PHS that funds the Research.

3.12. **Research** means a systematic sponsor-funded investigation, study or experiment designed to develop or contribute to generalizable 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).

3.13. **Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by UIPHP in the grant application, progress report, or any other report submitted to the PHS by UIPHP under this Policy.

3.14. **Significant financial interest** means:

3.14.1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(a) 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 the UAH equivalent of \$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, corporate rights or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(b) 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 the UAH equivalent of \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, corporate rights or other ownership interest); or

(c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.14.2. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's institutional responsibilities, once the UAH equivalent of \$5,000 threshold in value of travel from a single non-exempt entity has been reached; provided, however, that this does not apply to travel that is reimbursed or sponsored by a state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3.14.3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by UIPHP to the Investigator if the Investigator is currently employed or otherwise appointed by UIPHP, including intellectual property rights assigned to UIPHP and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or teaching engagements sponsored by a state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

13.15. **Sponsor-funded** means financed based on UIPHP's contract or agreement with any national, foreign or international governmental or private entity, whether for-profit or not.

13.16. **UIPHP** means CHARITABLE ORGANIZATION "UKRAINIAN INSTITUTE ON PUBLIC HEALTH POLICY".

13.17. Any other terms (if used in the general UIPHP's Conflict of Interest Policy) shall be construed in accordance with the general UIPHP's Conflict of Interest Policy (e.g. Institutional Review Board, etc.).

4. PROCEDURES

4.1. Submission of FCOI Disclosure Forms.

4.1.1. FCOI disclosure under this Policy is required in the following instances:

- before application for a Research;
- annually within Research duration;
- in case a new significant financial interest arises.

4.1.2. At the time of development of a new Research application, PD/PI is responsible for identifying all Investigators and designating their role. PD/PI is also responsible for ensuring the accurate completion and timely submission of FCOI Disclosure Forms by all Investigators no later than the time of application. No proposal for sponsor funding can be submitted unless all Investigators named in the proposal have submitted a Disclosure Form.

4.1.3. Each Investigator who is participating in Research shall submit an updated disclosure of significant financial interests annually during the period of Research, not later than December 15 of the current year. Such disclosure shall include any information that was not disclosed initially to UIPHP, or in a subsequent disclosure of significant financial interests, and shall include updated information regarding any previously disclosed significant financial interest.

4.1.4. Each Investigator who is participating in Research shall submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

4.1.5. FCOI Disclosure Forms shall be submitted to COI Administrator describing the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) as of the date of disclosure. COI Administrator will routinely run management reports to determine those Investigators who have not submitted an annual Disclosure Form and will notify the individual and/or UIPHP's Director, as necessary.

4.1.6. With regard to travel included in SFI, the following information must be provided:

- Identity of the sponsor/organizer;

- Destination;
- Duration;
- Purpose of trip;
- Relationship to institutional responsibilities; and
- Estimated value of expenses.

4.2. Review of FCOI Disclosure Forms.

4.2.1. Any SFI documented in the Disclosure Form shall be reviewed to determine whether such interests relate to Research and, if so related, whether the significant financial interest is a financial conflict of interest. This review will be conducted upon receipt of the Disclosure Form and the proposal or protocol. A SFI is related to Research when it is reasonably determined that the SFI could be affected by Research or is in an entity whose financial interest could be affected by Research. A financial conflict of interest exists when it is reasonably determined that the significant financial interest could directly and significantly affect the design, conduct, or reporting of Research.

4.2.2. If a Disclosure Form comprises description of any SFI, COI Administrator shall submit it for the Institutional Review Board review and assessment.

4.2.3. The assessment will require access to the funding application, progress reports, and any other technical and programmatic documentation, and may also require scientific, legal or any other relevant expertise, for which purpose the Institutional Review Board may require submission of the relevant documentation, interview the relevant staff, including the Investigator, invite various experts, analyze corporate structure and affiliation of the entities included in the Disclosure Form, etc.

The following potential red flags may be utilized to make FCOI determinations regarding travel:

- International travel;
- Inclusion of an Investigator's spouse or family;
- Travel that appears unnecessary in terms of location, duration or scheduled recreational activities;
- Travel for a duration beyond typical timeframes necessary for the intended purpose of the travel;
- Many trips from one entity in a short period of time.

4.2.4. The rationale supporting the resulting determination will be documented and maintained by COI Administrator.

4.3. FCOI Management.

4.3.1. If a FCOI is determined to exist, a management plan that specifies the actions that have been/will be taken to manage such FCOI^[SEP] shall be developed, endorsed and implemented by the Institutional Review Board. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of FCOI (e.g., when presenting or publishing Research);
- For Research projects involving human subjects research, disclosure of FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of Research against bias resulting from FCOI;
- Modification of Research plan;

- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of Research;
- Reduction or elimination of the financial interest (e.g., sale of an interest); or
- Severance of relationships that create financial conflicts.

4.3.2. COI Administrator will provide a copy of the management plan to the Investigator. The Investigator will be required to submit a confirmation of or a grounded rebuttal to the plan to COI Administrator within three (3) days. The Investigator's rebuttal will be considered by the Institutional Review Board whose decision shall be final and binding.

4.3.3. Expenditure of any funds under a PHS Award or for Research that is funded by sponsors that adhere to PHS FCOI regulations shall not take place prior to or be put on hold until submission of FCOI report (see Section 5 "REPORTING" below).

4.3.4. COI Administrator is responsible for monitoring Investigator compliance with the management plan on an ongoing basis until the completion of Research. Such monitoring may include several approaches, based upon the specific details of the plan:

- Self-certification of compliance by the Investigator with periodic requests by COI Administrator for confirmation that the plan is being followed;
- Monitoring by PD/PI;
- Review of publications/presentations for required disclosures and requesting submission of press releases prior to issuance;
- Periodic audits based upon sampling algorithm or other risk based model to spot check Investigator compliance with the plan.

4.3.5. Whenever, in the course of an ongoing Research, an Investigator who is new to participating in Research discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, or UIPHP identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by UIPHP during an ongoing Research (e.g., was not timely reviewed or reported by a Subrecipient) COI Administrator shall within sixty (60) days ensure that such a disclosure is reviewed and determined as a FCOI, as well as a management plan, on at least an interim basis, is implemented in accordance with this Section. Depending on the nature of the SFI, the Institutional Review Board may determine that additional interim measures are necessary with regard to the Investigator's participation in Research between the date of disclosure and the completion of the review.

5. REPORTING

5.1. UIPHP's reporting on FCOI shall follow the provisions of the relevant contract or agreement for Research. The following provisions of this Section shall apply only to PHS Awards.

5.2. The following reports shall be prepared and submitted by COI Administrator to PHS Awarding Component under a PHS-funded Research project:

- Initial FCOI report;
- Subsequent FCOI report;
- Annual FCOI report;
- Retrospective review and mitigation report.

5.3. Initial FCOI report regarding any Investigator's SFI found by UIPHP to be conflicting together with the management plan implemented shall be submitted prior to expenditure of any funds under

a PHS-funded Research project. In cases in which UIPHP identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, a FCOI report shall not be submitted.

5.4. For SFI that UIPHP identifies as conflicting subsequent to the initial FCOI report during an ongoing PHS-funded Research project (e.g., upon the participation of an Investigator who is new to the Research project), a subsequent FCOI report together with the management plan implemented shall be submitted within sixty (60) days. Where such FCOI report involves a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by UIPHP, a retrospective review shall be completed and, if bias is found, the PHS Awarding Component should be notified promptly and a mitigation report submitted to the PHS Awarding Component (see sub-clause 5.7. below).

5.5. Initial and subsequent FCOI reports shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of UIPHP's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project/Contract number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Nature of the financial interest (e.g., consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (value ranges are permissible), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded Research and the basis for UIPHP's determination that the financial interest conflicts with such Research; and
- A description of the key elements of UIPHP's management plan, including:
 - Role and principal duties of the conflicted Investigator in Research;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in Research;
 - 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.

5.6. For any FCOI previously reported, an annual FCOI report that addresses the status of the FCOI and any changes to the management plan shall be submitted for the duration of the PHS-funded Research project in the time and manner specified by the PHS Awarding Component. The annual FCOI report shall specify whether FCOI is still being managed or explain why FCOI no longer exists.

5.7. Whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined to constitute a FCOI, failure by UIPHP to review or manage such a FCOI, or failure by the Investigator to comply with a FCOI management plan, COI Administrator shall, within one hundred and twenty (120) days of the UIPHP's determination of noncompliance, ensure that the Institutional Review Board completes a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. Determination of bias may be based on:

- Review of enrollment;
- Assessment of systemic protocol deviations;
- Assessment of Research design;
- Interviews with the Research staff;
- Any other actions the Institutional Review Board may deem fit.

The retrospective review shall be documented with the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, COI Administrator shall update the previously submitted FCOI report, specifying the actions that will be taken to manage FCOI going forward.

If bias is found, COI Administrator will notify the PHS Awarding Component promptly and prepare and submit a mitigation report to the PHS Awarding Component.

The mitigation report must include (1) the key elements documented in the retrospective review above; (2) a description of the impact of the bias on the Research project and (3) UIPHP's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Depending on the nature of the FCOI, the Institutional Review Board may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date that FCOI or the Investigator's noncompliance is determined and the completion of the retrospective review.

6. COMMUNICATION AND TRAINING

6.1. This Policy will be available on UIPHP's website and shall be communicated to any Investigator prior to engaging in Research. The following provisions of this Section shall apply only to PHS Awards.

6.2. COI Administrator will respond in writing to any requestor within five (5) business days of a request, of information concerning any SFI disclosed that meets the following criteria:

- SFI was disclosed and is still held by the Investigator;
- UIPHP has determined that SFI is related to the PHS-funded Research; and
- UIPHP has determined that SFI is a FCOI.

The response shall include the following: (1) the Investigator's name; (2) the Investigator's title and role with respect to the Research project; (3) the name of the entity in which SFI is held; (4) the nature of SFI; and (5) the approximate value of SFI (value ranges are permissible), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The response shall also include a note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of UIPHP's identification of a new FCOI.

Information concerning SFI's shall remain available, for responses to written requests for three (3) years from the date that the information was most recently updated.

6.3. Each Investigator shall complete training regarding disclosure of significant financial interests prior to engaging in Research related to any PHS Award and at least every four years, and immediately when any of the following circumstances apply:

- UIPHP revises this Policy in any manner that affects the requirements of Investigators;
- An Investigator is new to UIPHP; or
- UIPHP finds that an Investigator is not in compliance with this Policy or management plan.

7. SUBRECIPIENTS (this Section applies only to PHS Awards)

7.1. For PHS funded Research and for Research funded by organizations that follow PHS policy

that is carried out through a sub-recipient (e.g., subcontractors or consortium members), UIPHP's Finance and Administrative Department shall ensure that a written agreement with the subrecipient provides for terms that establish whether this Policy or that of the subrecipient will apply to the subrecipient's Investigators. In the latter case the subrecipient shall certify as part of the agreement that its policy complies with relevant Federal regulations applied to PHS Awards.

7.2. The agreement referenced above shall in any case specify the following time periods for the subrecipient to report all identified FCOI's to UIPHP's COI Administrator: (1) at the time of the initial agreement execution, prior to expenditure of funds; (2) On an annual basis, before December 15; and (3) within thirty (30) days of any subsequently identified SFI.

8. ADMINISTRATIVE PROVISIONS

8.1. UIPHP will maintain this Policy up-to-date, written and enforced, in compliance with all applicable requirements, available on its public website.

8.2. UIPHP will maintain adequate enforcement mechanisms for this Policy.

8.3. UIPHP will maintain for a period of three (3) years from the date of final expenditures report submitted, unless another requirement applies to retain the information for a longer time frame, records relating to all Investigator disclosures of financial interests and UIPHP's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI) and all actions under this Policy or retrospective review, if applicable.

8.4. UIPHP will certify, when required by the sponsor, in the grant application or contract proposal, that UIPHP:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI's with respect to all Research projects for which funding is sought or received;
- Shall promote and enforce Investigator compliance with these requirements, including those that pertain to disclosure of SFI's;
- Shall manage FCOI's and provide initial and ongoing FCOI reports consistent with the applicable requirements;
- Agrees to make information available, promptly upon request, to the Department of Health and Human Services (HHS) relating to any Investigator disclosure of financial interests and UIPHP's review of, and response to, such disclosure, whether or not the disclosure resulted in determination of a FCOI; and
- Shall comply fully with the COI requirements.

9. NON-COMPLIANCE AND SANCTIONS

9.1. All instances in which an Investigator has failed to comply with this Policy or a management plan appears to have biased the design, conduct or reporting of the Research must be reported immediately to COI Administrator or to the Institutional Review Board.

9.2. In cases where disciplinary or a civil law (for consultants) or any other legal action is necessary in opinion of the Institutional Review Board and depending on the facts and circumstances of each case, UIPHP's Director may take one or more of the following actions:

- Reprimand;
- Suspension;
- Dismissal;

- Contract termination (for consultants);
- Referral for criminal prosecution;
- Demand of reimbursement to UIPHP for any losses or damages resulting from the failure to comply with this Policy.

9.3. If the failure of an Investigator to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, COI Administrator shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

9.4. UIPHP will comply with any further action required by the PHS agencies on how to maintain appropriate objectivity in PHS-funded Research projects, including submission or permission of on site review of, all records pertinent to compliance with this Policy, suspending the Research or other enforcement action, until the matter is resolved.

9.5. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by UIPHP as required, UIPHP shall require the Investigator involved to disclose FCOI in each public presentation of the results of Research and to request an addendum to previously published presentations.

9. ROLES AND RESPONSIBILITIES

Role/Position	Responsibility
<i>Investigator</i>	<ul style="list-style-type: none"> ● Disclose SFI ● Complete and submit FCOI Disclosure Forms at the time of submission of an application, annually and within thirty (30) days of discovering a new SFI ● Submit confirmation or rebuttal of management plans within three (3) days and comply with final, binding management plan ● Certify compliance with management plan, as necessary ● Complete training, as required
<i>PD/PI</i>	<ul style="list-style-type: none"> ● Properly identify Investigators and their roles on Research ● Ensure the accurate completion and timely submission of Investigators' FCOI Disclosure Forms ● Monitor Investigators' compliance with required management plans
<i>COI Administrator</i>	<ul style="list-style-type: none"> ● In collaboration with Institutional Review Board, provide support, guidance and training for the establishment of the Research Conflict of Interest administrative processes, contributes to the establishment of relevant policies and procedures ● Collect FCOI Disclosure Forms from Investigators and reports on FCOI from subrecipients, coordinate and document their review and processing ● In the event that a FCOI is determined to exist, coordinate and document a management plan development and endorsement ● Monitor compliance with management plans ● Prepare and submit necessary reports on FCOI to Research sponsors, update them, coordinate and document retrospective review ● Collect information on non-compliance with this Policy, coordinate and document any resulting action ● Coordinate and ensure responding to requests on FCOI information ● Notify and follow up with Research sponsors on FCOI issues ● Run management reports to determine those Investigators who have not submitted an annual Disclosure Form and notify the individual and/or

	<p>UIPHP's Director, as necessary</p> <ul style="list-style-type: none"> ● Coordinate and plan FCOI training activities
<i>Institutional Review Board</i>	<ul style="list-style-type: none"> ● Review disclosed SFI's and determine whether they are Research related and FCOI ● Develop and implement management plans to manage FCOI, any other interim measures, review rebuttals of management plans and make final, binding determination ● Complete retrospective reviews of Investigator's activities and Research projects ● Collect and review information on non-compliance with this Policy
<i>Finance and Administrative Department</i>	<ul style="list-style-type: none"> ● In collaboration with COI Administrator, determine whether the subrecipient shall apply this Policy or that of the subrecipient, introduce necessary changes to the contract/agreement draft ● In collaboration with COI Administrator, put a hold on Research expenditures, as necessary
<i>Director</i>	<ul style="list-style-type: none"> ● Designate COI Administrator ● Institute disciplinary or other proceedings against an Investigator, when necessary

10. ATTACHMENTS

Attachment 1 – FCOI Disclosure Form

To the Institutional Review Board

FCOI Disclosure Form

Research project name:

Investigator's name:

Investigator's position/title/role:

1) Do you, as an Investigator, your spouse and/or dependent children have any significant financial interest (for definition see sub-clause 3.14. of the Research Conflict of Interest Policy) related to your responsibilities within UIPHP?

<input type="checkbox"/>	NO
<input type="checkbox"/>	YES

2.1) If yes, please, name the entities with which you have the significant financial interest:

2.2) If yes, please, describe the nature of the significant financial interest (e.g. salary, consulting fee, sponsored travel etc.) and how it is related to your responsibilities:

2.3) If yes, please indicate the value of the significant financial interest (in USD equivalent):

<input type="checkbox"/>	0-4,999
<input type="checkbox"/>	5,000-9,999
<input type="checkbox"/>	10,000-14,999
<input type="checkbox"/>	15,000-19,999
<input type="checkbox"/>	More than 20,000
<input type="checkbox"/>	Value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

I confirm that I have read, understood and followed UIPHP Research Conflict of Interests Policy. I confirm that all data provided in this FCOI Disclosure Form are reliable and complete. I promise to update information stated in this FCOI Disclosure Form in case of any significant changes in the provided data or of a new significant financial interest, and at least annually.

Signature:

Date: