



## UNIVERSITY POLICY

**SUBJECT:** ACADEMIC AFFAIRS    **TITLE:** INVESTIGATOR CONFLICT OF INTEREST

**CODING:** 00-01-20-89:00

**ADOPTED:** 09/18/95

**AMENDED:** 02/22/06

**LAST REVIEWED:** 02/22/06

### I. PURPOSE

The University recognizes the importance and potential benefits of transferring to the private sector knowledge developed through University research and scholarship. It also recognizes the risks inherent when researchers have financial or other personal interests in their research or training activities, and the need to avoid arrangements that might compromise, or seem to compromise, the intellectual principles, independence and responsibility to the public that underlie the ethical conduct of research. Of critical importance to the University is ensuring the integrity of its research, protecting the rights and welfare of human subjects, maintaining the intellectual freedom of faculty, students, postdoctoral appointees and other trainees, and safeguarding the freedom to publish, communicate and discuss research results. Therefore, while welcoming industry sponsorship, collaboration and licensing of its technology, the University has adopted this policy for identifying and managing actual or perceived conflicts of interest that may arise in research to ensure the integrity, objectivity and freedom of inquiry of its investigators, and the safety and welfare of its human research subjects.

### II. ACCOUNTABILITY

Under the Senior Vice President for Academic Affairs, the Deans, President/CEOs of the Healthcare Units and Vice Presidents shall ensure compliance with this policy. The Research Deans shall implement this policy in the Schools, and the President/CEOs of the Healthcare Units or Vice Presidents shall implement this policy in their respective patient care or administrative units.

### III. APPLICABILITY

This policy shall apply to all University faculty, non-faculty employees, students and other individuals who, in the course of their association with the University (1) apply for or receive funds for any research or training purpose, by grant or subgrant, or by contract or subcontract, or by cooperative agreement; or (2) wish to conduct unsponsored research.

### IV. DEFINITIONS

- A. **Compelling Circumstances** are facts that convince the Conflict-of-Interest Committee (see definition below) that an interested individual with a conflict of interest should be permitted to conduct the proposed research under requirements established by the Committee. These facts may include, but are not limited to: the nature of the research, the magnitude of the financial or other personal interest, the degree to which these interests are related to the research, the extent to which these interests could be affected by the research and in the case of human subjects research, the degree of risk to the human research subjects.
- B. **Conflict of Interest** is a divergence between an investigator's financial or other personal interests and the obligation to abide by principles of the ethical conduct of research, especially the obligation to protect the rights and welfare of human subjects, such that considerations of personal gain, financial or otherwise, may influence or create the perception of influencing that investigator and compromise the objectivity or appropriate conduct of the research.

- C. **Conflict-of-Interest Committee (COIC)** is a University-wide committee whose role is to review disclosures of significant interests (see definition below) and determine if these constitute a conflict of interest and, if so, to decide how such conflicts will be managed, reduced or eliminated.

The Committee is appointed by the Senior Vice President for Academic Affairs, and comprises the Vice President for Legal Management (or designee), the Vice President for Academic Affairs (or designee), three faculty members (at least one engaged in clinical research and one engaged in laboratory research) from the New Brunswick/Piscataway Campus, three faculty members (at least one engaged in clinical research and one engaged in laboratory research) from the Newark Campus, one faculty member from the Stratford Campus, and one faculty member from the Camden Campus.

At its inception, one-half of the faculty members and all of the non-faculty members of the COIC shall serve three (3)-year terms, and the other half of the faculty members shall serve two (2)-year terms. All subsequent terms shall be for three (3) years. At its first meeting, the Chair of the Committee shall be selected from among the faculty members of the Committee by majority vote.

- D. **Financially Interested Company** means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research, or any entity acting as the agent of or with an equity interest in such an entity. This term includes companies that sponsor the research, are competitors of the sponsor, are the manufacturers or licensees of an investigational product, or the investment industry (individual stockbrokers and analysts, investment bankers, venture capital firms and investment firms).
- E. **Human Subjects Research** includes all “research” performed with “human subjects” as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.
- F. **Immediate Family** means spouse, domestic partner, children, parents, or siblings who reside in the same household.
- G. **Institutional Review Board (IRB)** is a committee established in accord with federal Common Rule (45 C.F.R. Part 46) with the authority to approve, require modifications in, or disapprove all University research activities involving human subjects.
- H. **Interest** is a financial or other personal involvement of the investigator, or his or her immediate family that could be affected by an individual’s research. Interests include, but are not limited to: income; honoraria or other payment for services; equity such as stock, stock options or other ownership rights (except interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control); patents and copyrights; contracts, licensing and other agreements; royalties (including those royalties distributed by the University); employment; and services, relationships or positions, even if uncompensated.
- I. **Investigator** means the Principal Investigator, co-principal investigator, co-investigators and any other University personnel (including faculty, non-faculty employees and students) who, in the course of their association with the University are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities, funded or proposed for funding by any sponsor, or of unsponsored research or training activities. As used herein, the term “investigator” will cover collaborators, grantors or contractors.
- J. **Research** shall, for the purposes of this policy, include training activities.
- K. **Significant Interest** means the following financial or other personal interests of the investigator, his or her spouse, domestic partner, children, parent or siblings:
1. Service as an officer, director or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service;
  2. Intellectual property rights (e.g., pending patent applications, patents, licenses, material transfer agreements, copyrights and royalties of any amount from such rights, including those royalties distributed by the University) directly related to the research;

3. Compensation, royalties, consulting fees, honoraria, gifts or other emoluments, bonuses, enrollment incentives or milestone payments, and “in kind” compensation or entitlement to same which exceed \$10,000.00 and are made directly or indirectly to the investigator by a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement between the sponsor and the University), either in the year prior to the grant application or initiation of unsponsored research and submission of the accompanying Disclosure Form, or in the twelve months following the grant application or initiation of unsponsored research;
4. Greater than 1% of the ownership of stock, assets or profits of a company which has, or seeks to have an agreement with the University, where the agreement is for the development of scientific or technological discoveries or innovations in which the University has or will have a property right.
5. Equity interests, including stock options, of any amount in a non-publicly traded financially interested company (or entitlement to the same);
6. Equity interests (or entitlement to the same) that exceed \$10,000 in a publicly-traded financially interested company;

The term “significant interest” does NOT include:

1. Salary or other remuneration from the University unrelated to the research in question;
2. Reimbursement and/or income from seminars, lectures or teaching engagements sponsored by public or non-profit entities unrelated to the research in question;
3. Reimbursement and/or income from entities unrelated to the research in question for service on advisory committees or review panels for public or non-profit entities;
4. Payments to the University, or via the University to the investigator, including salary, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;
5. Interests of any amount in publicly-traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control;
6. Stock or stock options in a publicly-traded financially interested company that does not exceed the lesser of \$10,000 or 1% of the ownership of the company.

A significant interest does not necessarily constitute a conflict of interest or the appearance of a conflict of interest as defined above.

## V. REFERENCES

- A. Code of Ethics: General Conduct [00-01-10-05:00](#)
- B. Human Subjects Research:  
Protection of Human Subjects [00-01-20-90:00](#)
- C. New Jersey state statute governing conflict of interests and agreements for the development of scientific and technological discoveries or innovations N.J.S.A. 52:130-19.1
- D. Public Health Service Objectivity in Research Rule 42 CFR Part 50, Subpart F
- E. Uniform Requirements for Manuscripts submitted to Biomedical Journals

## VI. POLICY

### A. Conduct of Research

#### 1. Disclosure of Interests

- a. Prior to the submission of applications to sponsors for funds, or prior to the commencement of unsponsored research, or prior to the execution of a licensing agreement with a publicly-traded company in which the investigator has either an equity interest that exceeds \$10,000 or a greater than one percent (1%) ownership interest, whichever is less, or prior to the execution of a licensing agreement with a non-publicly traded company in which the investigator has an equity interest of any amount, all investigators must complete and submit to the pertinent Research Dean or Vice President the University's Investigator Financial and Other Personal Interests Disclosure Form, (hereinafter "Disclosure Form", EXHIBIT), and include any such interests described in Section IV.H above for themselves and/or members of their immediate family. If the investigator has no such interest, the investigator must check the box indicating that no such interest exists.
- b. Each investigator named on the project must complete a Disclosure Form. If one or more such investigators had not been named at the time of proposal submission, a Disclosure Form or Forms must be completed subsequently by such investigator(s) and submitted to the Research Dean or Vice President as soon as such investigators are assigned to the project.
- c. In the event the research involves human subjects, all investigators must also attach the completed Disclosure Form to the protocol submitted for IRB review.
- d. All Disclosure Forms must be completed in full and in detail, with sufficient information to determine if the interests meet the definition of "significant interest," and must be signed by the investigator and the investigator's Chair or Vice President. If the investigator is a Chair, the form must be signed by the Dean. No proposal may be submitted to a funding agency, nor can unsponsored research commence, without a fully completed Disclosure Form.
- e. On an annual basis during the duration of the research, or more frequently as new interests are obtained or if the investigator's situation with respect to potential conflict of interest otherwise changes since the original disclosure, each investigator shall be responsible for completing a new Disclosure Form and submitting it to the Research Dean or Vice President and, when human subjects are involved, to the IRB. The Research Dean or Vice President shall review annual and revised Disclosure Forms as in Section VI.A.2.b-d, below.
- f. For projects involving contracts, subcontracts or collaborations with outside institutions or groups, the UMDNJ investigator must obtain written assurance from an appropriate official of that outside entity that the individuals from the outside entity participating in the project comply with the outside entity's investigator conflict-of-interest policy. If the outside entity is not an agency of the State of New Jersey, its policy must meet the requirements of the Public Health Service, pursuant to 42 CFR Part 50, Subpart F. If the outside entity is an agency of the State of New Jersey, its policy must meet the requirements of New Jersey Law, Conflicts of Interest Law, N.J.S.A. 52:13D-19.1, and of the Public Health Service pursuant to 42 CFR Part 50, Subpart F. The investigator must forward such written assurance from an appropriate official of the outside entity to the pertinent UMDNJ Research Dean, President/CEO or Vice President attached to the University's Disclosure Form. In the event the outside entity has no investigator conflict-of-interest policy, the outside entity must affirm in writing that it complies with UMDNJ's investigator conflict-of-interest policy, and the University's Disclosure Forms completed by each individual from the outside entity who will participate in the project must be attached to the Disclosure Form from the University's investigators.

2. Processing of Disclosure Forms

- a. All completed original and updated Disclosure Forms must be submitted by the investigator to the appropriate Research Dean or Vice President and, when human subjects are involved, to the IRB.
- b. The Research Dean or Vice President shall review the Disclosure Form and determine which interests, if any, are significant interests as defined in Section IV.J.
- c. Disclosure Forms that reveal no significant interests shall remain on file in the office of the Research Dean or Vice President.
- d. Whenever significant interests are disclosed, either on initial Disclosure Forms or on annual or revised Disclosure Forms, the Research Dean or Vice President shall forward the Disclosure Form to the COIC with notice to the investigator, the investigator's Chair, if any, and, when human subjects are involved, to the IRB.

3. Assessment of Significant Interests by the COIC

- a. It is the responsibility of each member of the COIC to divulge potential conflicts of interest. In the event that any member of the COIC has any real or apparent personal or professional conflicts of interest or bias with respect to the disclosure being considered, that member shall be recused. Such conflicts include, but are not limited to, involvement with the research in question, competition with the investigator, and a previous or ongoing close professional or academic relationship with the investigator, the sponsor, or competitor of the sponsor.
- b. The COIC will review all Disclosure Forms forwarded by Research Deans and Vice Presidents and make the following determinations:
  - (1) Whether the significant interests disclosed constitute or appear to constitute a conflict of interest. A conflict of interest shall be deemed to exist when the COIC reasonably decides that the significant interest could directly and significantly affect the design, conduct or reporting of the research or training activities, or have the appearance of doing so. Not all significant interests constitute or appear to constitute a conflict of interest.
  - (2) Which conditions or restrictions, if any, should be imposed upon the investigator prior to the expenditure of any funds under the award or the initiation of unsponsored research or training activities in order to manage, reduce or eliminate such conflicts of interest or appearances of conflict. Conditions or restrictions to manage, reduce or eliminate conflicts of interest include, but are not limited to:
    - public disclosure of significant interests
    - monitoring plan with independent reviewers, such as data safety monitoring board, routine on-site study review, and/or consent process with independent subject advocate/representative
    - audits of the informed consent and subject enrollment process
    - modification of the conduct of the research plan or educational activity
    - disqualification of those with significant interests from participation in all or a portion of the research or training activity
    - reduction or divestiture of significant interests
    - severance of relationships that create conflicts of interest or the appearance of such conflicts.

- (3) Whether significant interests constitute a conflict or appearance of conflict and cannot be managed, reduced or eliminated. In these cases, the research cannot proceed.
- c. In making these determinations, the COIC may:
- (1) Ask the investigator to appear before it to provide additional information to assist in the Committee's deliberations. In the event the Committee determines that the investigator has a conflict of interest or an appearance of such conflict, the investigator must present compelling circumstances that the research can go forward as proposed, or with modifications imposed by the Committee.
  - (2) Consult with individuals such as other faculty, scientists, financial experts, patents and licensing experts, IRB representatives, the pertinent Dean or Vice President, the Senior Vice President for Academic Affairs and others from inside or outside the University.
- d. COIC Decisions:
- (1) When no conflicts of interest exist or appear to exist, the Committee will inform in writing the investigator, the investigator's Chair, the Research Dean, and the Dean, President/CEO or Vice President that the research can proceed as proposed. If the research involves human subjects, the Committee will also notify the appropriate IRB.
  - (2) When conflicts exist or appear to exist, the Committee may decide that the research may not proceed, or may impose measures to reduce, manage or eliminate the conflicts, such as those described in Section VI.A.3.b.(2) as a condition of the research going forward.
  - (3) When conflicts exist or appear to exist and the Committee decides that the research can proceed as proposed or with measures to reduce, manage or eliminate the conflict or the appearance of a conflict, the Committee shall require the following disclosures:
    - (a) those investigator interests which constitute conflicts of interest in human research subjects consent forms associated with the research, and
    - (b) those investigator interests which constitute conflicts of interest to research sponsors, journal editors, co-investigators, other relevant IRBs, and in oral presentations of the research.
- e. Outcome of the COIC's decisions:
- (1) The COIC will report its decision, including an explanation of its decision and a description of conditions or restrictions, if any, in writing to the investigator(s), the investigator's Chair, the Research Dean and the Dean, President/CEO or Vice President. If the research involves human subjects, the Committee will also notify the appropriate IRB.
  - (2) If the final decision includes conditions or restrictions to manage, reduce or eliminate a conflict of interest, the investigator shall document his or her compliance with such conditions or restrictions in writing to the investigator's Chair, the Research Dean, President/CEO or Vice President, the COIC and, in cases where human subjects are involved, the IRB, prior to the expenditure of any funds under the award or the commencement of unsponsored research.

- (3) If the final decision is that a conflict of interest exists but can go forward under conditions specified, the Research Dean, President/CEO or Vice President shall report this assessment to the funding agency prior to the expenditure of any funds under the award. If the final decision includes conditions or restrictions to manage, reduce or eliminate the conflict, the Research Dean, President/CEO or Vice President shall assure the agency that the conflict of interest has been eliminated or acceptably managed or reduced.

4. Relationship between COIC and IRB

- a. In cases of human subjects research, the COIC will inform the IRB of record of its decision and reasons. The IRB may either accept the decisions of the COIC, or impose additional requirements or restrictions, and shall convey its final decision in writing to the investigator, the investigator's Chair, the Research Dean, and the Dean or President/CEO or Vice President.
- b. Where the proposed research involves human subjects and the investigator's interests are beneath the threshold of a significant interest, the IRB may request a review and recommendation from the COIC, both as to whether or not to permit that individual to conduct the proposed research and, if the research is permitted, under what terms and conditions.

B. Publication and Other Communications of Research Results

1. Contracts with research sponsors may not include provisions that prevent the investigator from independently accessing, examining, analyzing and interpreting the research data, or that restrict publication or other public communications of the methods, data and results of the research. Sponsors may be given up to thirty (30) days in which to review a manuscript, presentation or abstract that originates from the sponsored research prior to submission for publication or otherwise publicly communicated. Such review shall be limited to protection of confidential information furnished by the sponsor to the investigator, if any, or for the purpose of protection of patent or other intellectual property rights covered under the contract. The sponsor does not have the right to approve or consent to the publication or other communication of the research results.
2. In the event that the proposed publication or other communication contains patentable subject matter or confidential information, the University will, upon written request from the sponsor within the thirty (30)-day review period, delay the publication or other communication for a maximum of an additional sixty (60) days to allow the sponsor to file a patent application, or to modify the proposed publication or communication to delete sponsor-provided confidential information and/or to present the results in a manner that will not compromise such confidential information.
3. Publications should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals with regard to conflicts of interest.
4. In the case of multi-site clinical trials, the contract should state: how the results will be published; how authorship will be decided; how each investigator will have access to all data from all sites (and not simply to summary tables) in order to be able to analyze the full data independently if there is no multi-site publication within one year of the termination of the study; and that such one-year delay in publication or presentation of data results by the investigator can be waived if the investigator has a good faith belief that publication or presentation should not be delayed for reasons of public health, safety or public welfare.

C. Protection of Students, Postdoctoral Appointees and other Trainees

Contracts with research sponsors may not include restrictions on the activities of students, postdoctoral appointees or other trainees, and may not include non-disclosure provisions regarding such individuals beyond those specified above (Sections VI.B.1 and 2). Exceptions must be approved by the COIC and must be fully disclosed to all students, postdoctoral appointees and other trainees prior to their

involvement in the research. However students, postdoctoral appointees and other trainees may not, under any circumstances, be permitted to participate in research if such participation would prevent them from meeting pertinent University degree requirements, such as completion and public defense of a thesis or dissertation.

D. Enforcement and Sanctions

Non-compliance with any provision of this policy shall be subject to sanctions up to and including dismissal or termination for cause. Non-compliance shall be reported by any knowledgeable individual to the COIC, and the IRB if human subjects are involved. The COIC, and the IRB if human subjects are involved, shall investigate the allegation, reach a conclusion and recommend sanctions or dismissal of the charges to the Senior Vice President for Academic Affairs who shall have the final decision. Recommendations may also involve the notification of the sponsor and/or journal editors if non-compliance may have resulted in compromise of the integrity of the research and/or resulting publications or other communications.

E. Reports and Record Keeping:

1. The Research Dean, President/CEO or Vice President shall maintain records of all disclosures of financial and other personal interests, COIC determinations and recommendations, final decisions, actions taken to resolve conflicts of interest and the outcomes thereof for at least three (3) years from the date of submission of the final expenditure report of the project, or from the conclusion of unsponsored research, or until the resolution of any governmental or legal actions involving these records, whichever is longer.
2. Annually in January, the COIC shall summarize for the Senior Vice President for Academic Affairs all disclosures of significant interests, Committee determinations and recommendations, final decisions, actions taken and the outcomes thereof during the previous calendar year.

F. Standards set by governmental agencies will be monitored and considered in the University's routine review of this Policy.

VII. EXHIBIT

Investigator Financial and Other Personal Interests Disclosure Form

By Direction of the President:

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Vice President for Research

EXHIBIT



N  
 P/NB  
 C  
 S

**INVESTIGATOR FINANCIAL & OTHER PERSONAL INTERESTS DISCLOSURE FORM – Part 1**

PROJECT TITLE:			
PRINCIPAL INVESTIGATOR:		DEPT:	PHONE:
FUNDING AGENCY OR SPONSOR:		PROJECT AMOUNT:	START DATE:
TYPE: <input type="checkbox"/> RESEARCH <input type="checkbox"/> EDUCATION/TRAINING <input type="checkbox"/> SERVICE <input type="checkbox"/> OTHER			

**NOTHING TO DISCLOSE: CHECK "NO" COLUMN BELOW**

**I, my spouse, domestic partner, children, parents, and siblings who reside in the same household do not have any financial or other personal interests (as defined on the reverse side) that could be affected by this research or training activity.**

**DISCLOSURE TO BE MADE: CHECK "YES" COLUMN BELOW**

**I and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household DO/DOES have financial or other personal interests (as defined on the reverse side) that could be affected by this research or training activity, as itemized on Part 2 of this form.**

*I certify that the information on this form is correct; that I have read and understood the UMDNJ Policy on Investigator Conflict of Interest; that, to the best of my knowledge, all required disclosure of financial and other personal interests has been made herein; that I will complete a Disclosure Form on an annual basis during the duration of the research, or more frequently as new interests are obtained or if my situation with respect to potential conflict of interest otherwise changes since my original disclosure, and submit it to the Research Dean or Vice President; that I will comply with any conditions or restrictions imposed by UMDNJ to manage, reduce or eliminate conflicts of interest caused by my interests.*

NAME (PRINT & SIGN) <i>(see definition of "investigator" on the reverse side)</i>	NO	YES	DATE	NAME (PRINT & SIGN) <i>(see definition of "investigator" on the reverse side)</i>	NO	YES	DATE
PRINCIPAL INVESTIGATOR:				"INVESTIGATOR:"			
"INVESTIGATOR:"				"INVESTIGATOR:"			
"INVESTIGATOR:"				"INVESTIGATOR:"			
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**USE ADDITIONAL FORM(S) FOR ADDITIONAL INVESTIGATORS.**

- This project involves a contract, subcontract or collaboration with an outside institution or group.
- Attached is a written assurance from an appropriate official of this outside entity that individuals from the outside entity who will participate in this project comply with the outside entity's investigator conflict-of-interest policy and that such policy meets the requirements of the PHS (42 CFR Part 50, Subpart F).
- In the event the outside entity has no investigator conflict-of-interest policy, attached are a written assurance from an appropriate official of this outside entity that individuals from the outside entity who will participate in this project comply with UMDNJ's Investigator Conflict-of-Interest policy, plus all UMDNJ Disclosure Forms completed by these individuals.

Signature of Department Chair (or Dean if Investigator is Chair) or Vice President

\_\_\_\_\_ Date

Signature of Department Chair (if project involves more than one department)

\_\_\_\_\_ Date

**INSTRUCTIONS AND DEFINITIONS**

*EACH* "investigator," as defined below, on a research or training project must complete his/her section of the Disclosure Form which must then be submitted with the proposal to the Research Dean or Vice President, and, when human subjects are involved, to the IRB. This requirement pertains to both funded and unfunded research or training activity. If the project is to be funded, the Disclosure Form must be attached to the University's Transmittal and Approval Form for Grants and Contracts.

The term "investigator" means:

- the principal investigator,
- co-principal investigators, co-investigators, and
- any other University personnel who, in the course of their association with the University are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities funded or proposed for funding by any sponsor, or of unsponsored research or training activities. These persons may include faculty, non-faculty employees, research associates, technicians, consultants, postdoctoral fellows, graduate and other students.

*(NOTE: If one or more such individuals had not been named at the time of proposal submission, a form or forms must be subsequently completed by the(se) individual(s) and submitted by the principal investigator to the Research Dean or Vice President.)*

The term "interest" means any financial or other personal involvement of the investigator, his or her spouse, domestic partner, children, parent, or siblings who reside in the same household that could be affected by the investigator's research, including, but not limited to:

- income; honoraria or other payment for services;
- equity such as stock, stock options or other ownership rights, excluding interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control;
- patents and copyrights;
- contracts, licensing and other agreements;
- royalties (including those royalties distributed by the University);
- employment; and services, relationships or positions, even if uncompensated.

***If there is a financial or other personal interest requiring disclosure, provide on Part 2 of this form all relevant details about the relationship of the interest to the project, and sufficient information for the Conflict of Interest Committee to determine if a conflict of interest exists, and how such a conflict of interest might be managed, reduced or eliminated. Use additional pages if needed. Be as specific as possible.***

EXHIBIT



N  
 P/NB  
 C  
 S

**INVESTIGATOR FINANCIAL & OTHER PERSONAL INTERESTS DISCLOSURE FORM – PART 2**

PROJECT TITLE:		
PRINCIPAL INVESTIGATOR:		DEPT:
FUNDING AGENCY OR SPONSOR:		PHONE:
FUNDING AGENCY OR SPONSOR:	PROJECT AMOUNT:	START DATE:
TYPE : <input type="checkbox"/> RESEARCH <input type="checkbox"/> EDUCATION/TRAINING <input type="checkbox"/> SERVICE <input type="checkbox"/> OTHER		
NAME OF "INVESTIGATOR" MAKING DISCLOSURE (see definition of "Investigator" on the reverse side):		

**DISCLOSURE TO BE MADE:** (I and/or my spouse, domestic partner, children, parents, and siblings who reside in the same household **DO/DOES HAVE** financial or other personal interests (as defined on the reverse side) that could be affected by this research or training activity, as itemized below.

NATURE OF INTEREST		VALUE (DOLLAR AMOUNT)
<b>INCOME</b>	CONSULTING FEES	
	HONORARIA	
	LECTURE FEES	
	OTHER PAYMENT FOR EMPLOYMENT OR SERVICES	
	OTHER	
<b>EQUITY</b>	STOCK, STOCK OPTIONS, WARRANTS (NUMBER OF SHARES: _____)	
	OTHER OWNERSHIP RIGHTS	
<b>INTELLECTUAL PROPERTY</b>	PATENTS OR PATENT APPLICATIONS	
	COPYRIGHTS	
	ROYALTIES	
	LICENSING AND OTHER AGREEMENTS	
	CONTRACTS	
	OTHER	
<b>POSITIONS/ RELATIONSHIPS (COMPENSATED OR NOT)</b>	CORPORATE OFFICER	
	BOARD OF DIRECTORS OR TRUSTEES	
	ADVISORY BOARD	
	OTHER	

*I certify that the above information is correct; that I have read and understood the UMDNJ Policy on Investigator Conflict of Interest; that, to the best of my knowledge, disclosure of all required financial and other personal interests has been made herein; that I will complete a Disclosure Form on an annual basis during the duration of the research or more frequently as new interests are obtained or if my situation with respect to potential conflict of interest otherwise changes since my original disclosure, and submit it to the Research Dean or Vice President; that I will comply with any conditions or restrictions imposed by UMDNJ to manage, reduce or eliminate conflicts of interest caused by my interests.*

Signature of Investigator Making Disclosure	Date
Signature of Department Chair (or Dean if interested party is a Department Chair) or Vice President	Date
Signature of Department Chair (if project involves more than one department)	Date

**INSTRUCTIONS AND DEFINITIONS**

*EACH* "investigator," as defined below, on a research or training project must complete his/her section of the Disclosure Form which must then be submitted with the proposal to the Research Dean or Vice President, and, when human subjects are involved, to the IRB. This requirement pertains to both funded and unfunded research or training activity. If the project is to be funded, the Disclosure Form must be attached to the University's Transmittal and Approval Form for Grants and Contracts.

The term "investigator" means:

- the principal investigator,
- co-principal investigators, co-investigators, and
- any other University personnel who, in the course of their association with the University are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities funded or proposed for funding by any sponsor, or of unsponsored research or training activities. These persons may include faculty, non-faculty employees, research associates, technicians, consultants, postdoctoral fellows, graduate and other students.

*(NOTE: If one or more such individuals had not been named at the time of proposal submission, a form or forms must be subsequently completed by the(se) individual(s) and submitted by the principal investigator to the Research Dean or Vice President.)*

The term "interest" means any financial or other personal involvement of the investigator, his or her spouse, domestic partner, children, parent, or siblings who reside in the same household that could be affected by the investigator's research, including, but not limited to:

- income; honoraria or other payment for services;
- equity such as stock, stock options or other ownership rights, excluding interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control;
- patents and copyrights;
- contracts, licensing and other agreements;
- royalties (including those royalties distributed by the University);
- employment; and services, relationships or positions, even if uncompensated.

***If there is a financial or other personal interest requiring disclosure, provide on Part 2 of this form all relevant details about the relationship of the interest to the project, and sufficient information for the Conflict of Interest Committee to determine if a conflict of interest exists, and how such a conflict of interest might be managed, reduced or eliminated. Use additional pages if needed. Be as specific as possible.***