POLICY ON

DISCLOSURE OF SIGNIFICANT

FINANCIAL INTEREST

RESEARCH FOUNDATION FOR
MENTAL HYGIENE, INC.
150 Broadway, Suite 301
Menands, New York 12204

27 February 2004

RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC.
POLICIES ON DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST

RFMH is committed to carrying out its functions in a manner that promotes confidence in the integrity of the organization. RFMH employees and any person representing or acting on behalf of the Foundation should not have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction or professional activity or incur any obligation of any nature, which is in substantial conflict with the proper discharge or his/her duties in the best interest of the Foundation.

Attached are policies governing disclosure of significant financial interest for:

I. PHS and NSF grants, contracts, subcontracts and cooperative agreements and all other non-clinical applications/agreements that are not subject to the FDA requirements.

II. FDA regulated studies and all other clinical applications/agreements that are not subject to the PHS or NSF requirements.

Both sets of policies require disclosure of significant financial interest by investigators (includes sub-investigators, spouses and dependent children) and review by a conflict of interest committee appointed by the Institute (facility) Director. If a potential conflict is identified it may be managed, eliminated or the investigator can be removed from the study.

Many investigators covered by these policies are New York State employees and are therefore also subject to the provisions of the State Ethics Law. The RFMH policies do not address obligations under the State Ethics Law. You should consult with your state personnel office or counsel's office if you have any questions about state requirements.

I. POLICY ON DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST FOR PHS AND NSF FUNDED APPLICATIONS/AGREEMENTS AND NON-CLINICAL APPLICATIONS/AGREEMENTS

BACKGROUND:

On July 11, 1995, the Department of Health and Human Services and the National Science Foundation published in the Federal Register the Final Rule and Notice of Regulations on Objectivity in Research; Investigator Financial Disclosure Policy. (42 CFR Part 50 and 42 CFR Part 94.) The purpose of this policy, as stated in the regulation, is to "promote objectivity in research by establishing standards to insure there is no reasonable expectation that the design, conduct or reporting of research funded under Public Health Service (PHS) or National Science Foundation (NSF) grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator." This policy places the responsibility for disclosure and management of conflicting financial interests on the Investigator and his/her Institution that is seeking federal assistance.

EFFECTIVE DATE:

October 1, 1995

APPLICABILITY:

All PHS and NSF grants, contracts, subcontracts and cooperative agreements submitted on or after the effective date of the policy and all organizations and investigators participating in the research. RFMH will also apply the requirements of this policy to all non-clinical applications/agreements that are not subject to the FDA policies in Section II.

DEFINITIONS:

- RESEARCH – a systematic investigation designed to contribute generalizable knowledge relating broadly to public health including behavioral and social science research and encompassing basic and applied science and product development.

- INVESTIGATOR – the principal investigator and any other person responsible for the design, conduct or reporting of PHS funded research. For the purpose of compliance with this policy, Investigator includes spouse and dependent children.

- INSTITUTION – any domestic or foreign, public or private entity or organization (excluding federal agencies). For purposes of this policy, Institution shall mean any Research Institute or facility requesting federal support for a research activity where the Research Foundation for Mental Hygiene, Inc. (RFMH) is the applicant organization.

- SIGNIFICANT FINANCIAL INTEREST (SFI) – anything of monetary value, including but not limited to, salary or other payments, (consulting fees or honoraria) that when aggregated for the Investigator, the Investigator's spouse and dependent children over the next twelve months is expected to exceed $10,000; equity interests,

(stock, stock options, or other ownership interests)[1] and intellectual property rights (patents, copyrights and royalties from such rights).

It Does Not Include:

- Salary, royalties, or other remuneration from the Institution.
- Income from services on advisory committees or review panels for public or non-profit entities.
- Equity interests in business or entities if the value of such interests do not exceed $10,000 and does not represent more than five percent ownership interests for any one enterprise or entity when aggregated to include the investigator, spouse and dependent children.
- Salary (from other than Institution), royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

- AWARDING COMPONENT – The organizational unit of the sponsoring agency that funds the research.

REQUIREMENTS: Each Institution must:

- Inform each investigator of the Institution's policy for identifying and managing SFI and the Investigator's responsibility for reporting.

- Designate an institutional official(s) to solicit and review financial disclosure statements from each investigator who is planning to participate in PHS and NSF funded research.

- Require that the Investigator provide a listing of SFI prior to submission to the funding agency and that it will be updated during the period of the award either annually or as new SFI are obtained.

- Provide guidelines to identify SFI and take such actions as necessary to insure SFI will be managed, reduced or eliminated.

- Maintain records of all financial disclosures and of all actions taken by the Institution with respect to each SFI for at least three years from the date of submission of the final expenditure report or until resolution of any action taken by the sponsoring agency, whichever is longer.

- Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

- By signing the Application Face Sheet, the Institute certifies that:

    - There is a written and enforced process to identify, manage, reduce or eliminate SFI.

[1] The value of stock, stock options or other ownership interests are determined by referring to public prices or other reasonable measures of fair market value.

- Prior to the Institution's expenditure of any funds under the award, the Institution will report to the Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this policy.

- It will notify the awarding component of the identification, management or elimination of any conflicting interest that originates or becomes known after the award, within 60 days of its identification of the conflicting interest.

- It agrees to make available to the funding agencies, upon request, all SFI information identified by the Institution and how those interests have been managed, reduced or eliminated.

- It agrees to allow confidential on site review of records pertinent to these certifications.

IMPLEMENTATION:

Each Institute Director will establish a Conflict of Interest Review Committee (CIRC) to review all financial disclosures and determine whether a Conflict of Interest exists and, if so, determine what actions should be taken by the Institute to manage, reduce or eliminate the Conflict of Interest. Existing Ethics Committees may be used for this purpose, however, it is recommended that the Committee include at least one individual with administrative, financial or legal experience.

- Each Investigator is required to disclose the following Significant Financial Interests:

    - Any Significant Financial Interest that would reasonably appear to be directly and significantly affected by the research activities funded or proposed for funding by PHS or NSF.

    - Any Significant Financial Interest of an Investigator in an entity whose financial interest would reasonably appear to be directly and significantly affected by the research activities funded or proposed for funding by PHS or NSF.

- Significant Financial Interest must be disclosed prior to the time a proposal is submitted and must be updated by the Investigator during the period of the award as changes occur or as new reportable Significant Financial Interests arise.

- If it is determined by the CIRC that a Significant Financial Interest exists, the Investigator, in cooperation with his/her Department Head, will develop and present to the CIRC a Resolution Plan that details proposed steps which will be taken to manage, reduce or eliminate any actual or potential Conflicts of Interest presented by a Significant Financial Interest. At minimum, the Plan shall address such issues as:

    - Public Disclosure of Significant Financial Interest.
    - Review of the research protocol by independent reviewers.
    - Monitoring of Research by independent reviewers.

- Where the CIRC deems it appropriate, the CIRC shall review the Resolution Plan and approve it, add conditions or restrictions, including, but not limited to, the following:

    - Modifications of the Research Plan.
    - Disqualification from participation in all or a portion of the funded research activity.
    - Divestiture of Significant Financial Interest.
    - Severance of relationships that create actual or potential conflicts of interest.

- If the CIRC determines that imposing such conditions or restrictions would be inequitable, or that the potential negative impacts that may arise are outweighed by the interests of scientific progress or public health and welfare, then the CIRC will refer the matter to the Institute's Director, who in consultation with agency officials, will make the final decision regarding resolution. This may include disclosure of the particulars of the SFI to the awarding component and request for advice or resolution.

- The approved Resolution Plan shall be incorporated into a Memorandum of Understanding that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Memorandum of Understanding shall be signed by the Investigator and the Investigator's Department Head. Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated *prior to expenditure of funds,* or they will be disclosed to the sponsoring agency for action.

- Records of the Investigator's financial disclosures and of actions taken to manage actual or potential conflicts of interest, shall be retained by the RFMH Administrative Office until three years after the later of the submission of the final expenditure report, or the resolution of any government action involving those records.

- Whenever an Investigator has violated this policy or the terms of the Memorandum of Understanding, the CIRC shall recommend sanctions which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. If the violation results in a collateral proceeding under the Institution's policies regarding misconduct in science, then the CIRC shall defer a decision on sanctions until the misconduct in science process is completed. The CIRC's recommendations on sanctions shall be presented to the Institute Director who shall take appropriate disciplinary action. **NOTE:** If the Investigator is an employee of New York State, the disciplinary action to be taken will be consistent with the due process rights available to the employee under the Civil Service Law or labor agreements.

September 14, 1995
Revised February 27, 2004

PROCEDURE

RESPONSIBLE INDIVIDUAL/ UNIT	ACTION
Grants Administration Office	Distributes copy of policy to all investigators and staff affected by the policy.
Principal Investigator	Determines which staff will be involved in the design, conduct or reporting of the research. Insures that all staff involved in the design, conduct or reporting of the research are aware of their responsibilities to Disclose Significant Financial Interest.
Principal Investigator/Project Staff	Review Disclosure Policy and determine if Significant Financial Interest or other Conflicting Interest exist or may exist in the future.
Principal Investigator	If no Significant Financial Interests exists, completes the Investigator Assurance Regarding Significant Financial Interest form (Attachment I) and forward with the grant application to the Grants Administration Office.
Principal Investigator/Project Staff	If Significant Financial Interest exists, or may potentially exist, complete the Significant Financial Interest Disclosure form (Attachments II) seal in an envelope marked “Confidential” and forward with the application to the Grants Administration Office.
Grants Administration Office	Forwards sealed Significant Financial Interest Disclosure form to Conflict of Interest Review Committee (CIRC)

Conflict of Interest Review Committee (CIRC)	Reviews Significant Financial Interest Disclosure. Determines what actions are necessary to manage, reduce or eliminate Significant Financial Interest. Directs the Investigator and the Department Head to develop a resolution plan, and incorporate it into a Memorandum of Understanding (MOU).
Investigator and Department Head	Prepare MOU detailing the action to be taken to reduce, eliminate or manage the Significant Financial Interest (SFI). Sign MOU and forward to CIRC
Conflict of Interest Review Committee	Review MOU to insure appropriate action will be taken to reduce, eliminate or manage SFI. Develop monitoring plans as necessary Maintains file of MOU's Notifies Grants Administrative Office, by letter, that SFI has been identified and that action will be taken prior to expenditure of funds against the award, to manage, reduce or eliminate SFI. This letter should not include the details of the SFI or the MOU.
Grants Administrative Office	Forwards CIRC determination letter to awarding component prior to expenditure of funds against the award.

Attachment I

RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC.

INVESTIGATOR ASSURANCE REGARDING SIGNIFICANT FINANCIAL INTEREST

Investigator/Employee_____

Department_____

Project Title_____

Funding Agency_____

The proposed project including relationships with any co-investigators, contractors, consultants, or others does not require the disclosure of Significant Financial Interest. All individuals that will be involved in the project have been informed of Research Foundation for Mental Hygiene, Inc., policy and Federal regulations and have provided complete disclosure regarding this matter.

Sign:_____ Date:_____

Attachment II

RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC.

SIGNIFICANT FINANCIAL INTEREST DISCLOSURE

(Applicable to all PHS, NSF and other non-clinical Proposals)

Investigator/Employee Name_____

Department_____

Project Title_____

Funding Agency_____

I have a financial interest to disclose: [ ] Yes (please complete the entire form) [ ] No (sign the form)

I am disclosing the following Significant Financial Interests SFI (check one) and attaching supporting documentation (in an envelope marked "confidential") that identifies the business enterprise or entity involved and the nature and amount of the interest.

(Significant Financial Interests (SFI)) is defined as interests valued at greater than $10,000 and an equity or ownership interest of more than five percent by an investigator and the investigator's spouse or dependent children. (See policy statement for exclusions.)

_____ Salary or other payment of services (e.g., consulting fees or honoraria).

_____ Equity interests (e.g., stocks, stock options, or other ownership interests).

_____ Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

_____ Other significant financial interest of the Investigator that possibly could affect or be perceived to affect the results of the research activities funded or proposed for funding.

Further, I Agree:

- To update this disclosure, during the pendency of the award, either on an annual basis or as new reportable Significant Financial interests is obtained.
- To cooperate in the development of a Memorandum or Understanding (MOU) that constitutes a conflict of interest "resolution plan."
- To comply with any conditions or restrictions imposed by the Institute to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signed:_____ Date:_____
(original signature only a "per" signature is not acceptable.)

Endorsements:

I have reviewed the Significant Financial Interest disclosure and believe that it will be possible to develop and execute, prior to award, an Memorandum of Understanding to manage, reduce, or eliminate any actual or potential conflict of interests and, therefore, I recommend that the proposal be submitted to the agency at this time.

Department/Unit Head: _____ _____

Signed **Date**

_____ _____

Signed **Date**

II. POLICY ON DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST FOR CLINICAL RESEARCH

Background

On February 2, 1998, the Food and Drug Administration published in the Federal Register, the Final Rule on Financial Disclosure by Clinical Investigators (21 CFR Part 54). The FDA regulation is intended to ensure that financial interests and arrangements of clinical investigators that could affect reliability of data submitted to FDA in support of product marketing are identified and disclosed by the sponsor of any drug, biological product, or device marketing application. This policy, effective February 2, 1999, requires the sponsor of any drug or device marketing application, to submit for all clinical investigators who participated in the study, a certification that no financial conflicts exist or a disclosure of the existing financial conflicts. The Investigator and Institution are required to provide the sponsor with the information needed to complete certification and disclosure statements.

The FDA policy encourages applicants and investigators to minimize such financial arrangements or to ensure that studies are well designed and managed in such a way, as to eliminate the possibility of bias due to the existing financial arrangements. Similar financial disclosure policies were implemented by PHS and NSF in 1995. The PHS/NSF policy requires the Institution to evaluate financial interests and determine whether there are conflicting interests that must be managed, reduced or eliminated. These differences warrant the development of specific policies to separately address FDA and PHS/NSF requirements.

Additionally, RFMH requires investigators (as defined below) for non-FDA regulated clinical studies that are not subject to the PHS/NSF requirements to submit information on significant financial interest on the FDA form for consideration and oversight by the conflict of interest committee and Institute (facility) Director.

FDA Financial Disclosure Policy

Definitions

Covered Clinical Study - any study of a drug, biological product or device in humans submitted in a marketing application or reclassification petition, that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or that make a significant contribution to the demonstration of safety. An applicant may consult with FDA as to which studies are subject to the financial disclosure requirements.

Clinical Investigator (Investigator) - any listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

Applicant - the party who submits a marketing application to FDA for approval of a drug, device, or biologic product. The applicant is responsible for submitting the appropriate certification and disclosure statements. This is generally the pharmaceutical or industry sponsor, although occasionally it may be the Investigator.

Sponsor - the party supporting a particular study at the time it was carried out. In most cases, the applicant and sponsor will be the same entity.

Institution - for purposes of this policy, Institution shall mean any research institute or facility participating in a clinical study where the Research Foundation for Mental Hygiene, Inc. (RFMH) is the contracting organization.

Financial Interests Requiring Disclosure:

- **Compensation affected by the outcome of clinical studies** - compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
- **Significant equity interest** - any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds $50,000 during the time the clinical investigator is carrying out the study and for one year following completion of the study.
- **Proprietary interest in the tested product** - property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

- **Significant payments of other sorts** - payments made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than $25,000, exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation of honoraria) during the time the clinical investigator is carrying out the study and for one year following the completion of the study.

Requirements

The applicant is responsible for making the appropriate certification or disclosure statements to the FDA.

- The applicant must submit a list of all clinical investigators who conducted covered clinical studies, identifying those clinical investigators who are full time or part time employees of the sponsor.
- The applicant must completely disclose or certify information concerning the financial interests of a clinical investigator who is not a full time or part time employee of the sponsor.
- The clinical investigator must provide the sponsor with sufficient information needed to allow subsequent disclosure or certification. The investigator will promptly update this information if any relevant changes occur in the course of the investigation of for 1 year following completion of the study.
- The applicant shall submit for all clinical investigators, for whom the certification applies, a completed Form FDA 3454 verifying the absence of financial interests.
- The applicant shall submit for all clinical investigators, for whom a disclosure is necessary, a completed Form FDA 3455 disclosing completely and accurately the following:
    - Any significant payments of other sorts from the sponsor of the study, such as a grant to fund ongoing research, compensation in the form of equipment, a retainer for ongoing consultation, or honoraria;
    - Any proprietary interest in the tested product held by any clinical investigator;
    - Any significant equity interest in the sponsor of the study;
    - Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests or payments.

Implementation

The intent of the FDA rule is to make the agency aware of payments and financial arrangements that could lead to the introduction of bias into the clinical trial process, so that this information can be taken into consideration during the review process and to discourage such practices. It is expected that the reporting requirements will prompt sponsors of studies to consider potentially problematic financial arrangements and interests in the early stages of product development and consider how to minimize such potential sources of bias in their studies. The intent is not to ban certain financial arrangements, but rather when they exist, to subject such studies to closer scrutiny and evaluation.

Because FDA is only requiring disclosure of the financial interest and not to manage or eliminate it, the process differs from the PHS/NSF policy.

- Each Investigator is required to disclose certain financial interests such as: compensation that may be higher for a favorable outcome than for an unfavorable outcome; significant equity interest in the sponsor; proprietary interest in the product; or other significant payments. This will be done on the RFMH FDA Disclosure Form (attachment 2).
- The Investigator will submit the form directly to the RFMH. If the Investigator discloses

financial interests, the information will be passed on the Conflict of Interest Review Committee (CIRC) within the appropriate Institute.

- The RFMH FDA Disclosure Form will be submitted to the Sponsor by the RFMH along with the fully executed agreement or when requested by the Sponsor. The Investigator must update this information if any relevant changes occur during the course of the study and for one year following completion of the study.
- The FDA will evaluate the information disclosed to determine the impact on the reliability of the study. FDA may consider the size and nature of the disclosed financial interest including the increase in value if the product is approved, as well as steps that have been taken to minimize bias.
- The FDA will also take into account the design and purpose of the study. Studies may be designed in a way that may adequately protect against any bias created by a disclosable financial interest.
- If the FDA determines that a financial interest of an Investigator raises questions about the integrity of the data, the FDA will take any action deemed necessary to ensure the reliability of the data including:
    - Initiating agency audits of the data derived from the Investigator in question;
    - Requesting that the Applicant submit further analyses of data, to evaluate the Investigator's data on overall study outcome;
    - Requesting that the Applicant conduct additional independent studies to confirm the results of the questioned study;
    - Refusing to treat the Study as providing data that can be the basis for an agency action.

Recordkeeping

The applicant who has submitted a marketing application must keep on file certain information pertaining to the financial interests of clinical investigators who conducted studies on which the application relies. These records must be retained for two years after the date of approval of the application and they must be available to any properly authorized officer or employee of the FDA. The documents must include:

- Complete records showing any financial interest paid to a clinical investigator by the sponsor of the covered study.
- Complete records showing significant payments of other sorts, made by the sponsor to the clinical investigator.
- Complete records showing any financial interests held by the clinical investigator.

Records of investigator financial disclosure and of actions taken to manage actual or potential conflicts of interest, shall be retained by the RFMH Administrative Office until two (2) years following the approval of a marketing application or according to the terms of the clinical study agreement, whichever is longer.

Whenever an Investigator has violated this policy, the CIRC shall recommend sanctions which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. If the violation results in a collateral proceeding under Institution's

policies regarding misconduct in science, then the CIRC shall defer a decision on sanctions until the misconduct in science process is completed. The CIRC's recommendations on sanctions shall be presented to the Institute Director who shall take appropriate disciplinary action. **NOTE:** If the Investigator is an employee of New York State, the disciplinary action to be taken will be consistent with the due process rights available to the employee under Civil Service Law or labor agreements.

RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC.
FDA Financial Disclosure by Clinical Investigators

Investigator/Employee Name_____

Investigator Phone_____Department/Institute_____

Project Title_____

Sponsor_____

According to FDA regulations, Investigators must disclose the following types of financial arrangements:

- Compensation that could be higher for a favorable outcome than for an unfavorable outcome, compensation in the form of an equity interest or tied to the sales of the product, such as a royalty interest.
- Significant equity interest in the Sponsor, including any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally a non publicly traded corporation) or any equity interest in a publicly traded corporation that exceeds $50,000 during the time the Study is conducted and for one year following completion of the Study.
- Proprietary interest in the product, including but not limited to, a patent, trademark, copyright or licensing agreement.
- Significant payments to the Investigator or Institution to support activities of the Investigator with a value of more than $25,000 (excluding the costs of conducting the clinical study or other clinical studies) during the time the Study is conducted and for one year following completion of the Study.

The term Investigator refers to any listed or identified Investigator or Subinvestigator who is directly involved in the treatment or evaluation of research subjects, and includes the Investigator's spouse and dependent children.

The above financial arrangements exist in reference to this project (check one)

☐ Yes

☐ No

If the yes box is checked, supporting documentation should be attached in a confidential envelope that identifies the nature of the arrangement and amount of the interest.

Further the Investigator Agrees:

- To update this disclosure during the pendency of the award and for one year following completion of the study, as new reportable significant financial arrangements are obtained.
- To provide the Sponsor of the Study, working through the Institute and RFMH, with sufficient accurate information to allow the sponsor to complete their required certifications and disclosures.
- To provide the RFMH with information requested by the Applicant, Sponsor or the FDA regarding the conduct of the Study.

Signed:_____ Date:_____
(Original signature only – "per" signature is not acceptable.)

Endorsements (for affirmative disclosure only):
I have reviewed the significant financial disclosure and agree to assist the RFMH in providing requested information.

Department/Unit Head:_____ Date:_____

_____ Date:_____