RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC. (RFMH)

FINANCIAL CONFLICT OF INTEREST POLICY

RFMH is committed to carrying out its functions in a manner that promotes confidence in the integrity of the organization. No officer, director, employee or agent of RFMH shall 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 that is in substantial conflict with the proper discharge of their duties in the best interest of RFMH. RFMH's Conflict of Interest Policy can be found in the RFMH Corporate Policy Manual Section 2.2 available at: http://corporate.rfmh.org/corporate_info/corporate_policy_manual.pdf

This RFMH Financial Conflict of Interest Policy provides more detailed requirements for addressing issues relating to potential Financial Conflict of Interest in research. It incorporates the provisions of:

- 42 CFR Part 50 and 45 CFR Part 94 which were issued by National Institutes of Health (NIH) to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants, cooperative agreements or under PHS contracts will be free from bias resulting from Investigator financial conflicts of interest; and

- 21 CFR Part 54 which was issued by the Food and Drug Administration (FDA) 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. The sponsor of any drug or device marketing application must 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.

Table of Contents

1 APPLICABILITY

This Policy applies to all research and related activities supported by funds administered through the Research Foundation for Mental Hygiene, Inc. (RFMH).

2 DEFINITIONS

Contractor means an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

Disclosure of Significant Financial Interests means an Investigator's disclosure of Significant Financial Interests to RFMH.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct (including data collection and analysis), or reporting of research.

FCOI report means RFMH's report of a Financial Conflict of Interest to a PHS Awarding Component.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable and would include an intellectual property right or interest, whether or not any income has yet been received in respect of that right or interest.

> Financial Interest does not include the following: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), 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 federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of RFMH an associated state agency (OMH, OPWDD, OASAS) and any affiliated academic institution. Professional responsibilities include all clinical, administrative, research and academic activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as an Institutional Review Board or Data and Safety Monitoring Board.

Institutional Official for the purposes of this policy means the persons or committees appointed by the Directors of the New York State Psychiatric Institute (NYSPI), Nathan Kline Institute (NKI) and Institute for Basic Research (IBR) to ensure disclosure and review of disclosures under this policy at each location and the person appointed by the Managing Director of RFMH to ensure disclosure and review of disclosures under this policy for Central Office and all locations other than NYSPI, NKI and IBR.

Investigator means the project director or principal investigator and any other person, regardless of title or position and including key personnel, who is responsible for the design, conduct (including data collection and analysis), or reporting of research which may include collaborators or consultants.

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.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research and encompassing basic and applied science and product development.

Senior/key personnel means the Project Director/Principal Investigator and any other person identified as senior/key personnel in a grant application, progress report or other report submitted to PHS or other Sponsor and any person identified as key personnel in a contract proposal and contract.

Significant Financial Interest (SFI) means

> (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 appear to be related to the Investigator's Institutional Responsibilities:
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> > (i) 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 $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, directorships, executive roles and other special relationships with business having the potential for personal financial gains); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) 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 $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

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

(2) Investigators also must disclose the occurrence of 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research. Travel reimbursed by RFMH or DMH is not required to be disclosed.

(3) The term *Significant Financial Interest* does not include the following types of Financial Interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), 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 federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3 TRAINING

All Investigators must be provided with a copy of this Policy and must complete training regarding the Policy and its implementation prior to participating in research and at least every four years.

Training must also be completed immediately:

- if this Policy is revised in any manner that affects the requirements of Investigators;
- for any Investigator new to RFMH
- for any Investigator found to be not in compliance with this Policy or a management plan

4 SUBRECIPIENTS

When RFMH enters into agreements with subrecipients, including subcontractors and consortium members, for PHS-funded research RFMH will include in each agreement terms that establish whether the RFMH Financial Conflict of Interest Policy or the Subrecipient's Financial Conflict of Interest policy will apply to the Subrecipient's investigators.

If RFMH's Policy applies, subrecipients must disclose Significant Financial Interests at time periods sufficient to enable RFMH to comply timely with its review, management and reporting obligations.

If the Subrecipient's policy will apply:

- the subrecipient must certify that its policy complies with 42 CFR Part 50 or 42 CFR Part 94, as applicable;
- the agreement must specify the time period for the subrecipient to report all identified financial conflicts of interest to RFMH. The time period shall be sufficient to permit RFMH to provide timely (before expenditure of funds and within 60 days of any subsequently identified FCOI) FCOI reports, as necessary, to PHS.

5 SUBMISSION AND REVIEW OF DISCLOSURES

RFMH will designate an Institutional Official(s) to solicit and review disclosures of Financial Interests that reasonably appear to be related to the Investigator's Institutional Responsibilities from each Investigator who is planning to participate in or is participating in research funded through RFMH. The Director of each Research Institute (NYSPI, NKI and IBR) shall designate an appropriate person or committee to be the Institutional Official responsible for ensuring that disclosures are obtained from each such Investigator and for the review of such disclosures. The responsible Institutional Official for all other locations shall be appointed by the Managing Director of RFMH.

Investigators who are planning to participate in research funded through RFMH must disclose to the applicable Institutional Official their Financial Interests (and those of their spouse and dependent children) related to the Investigator's Institutional Responsibilities. Financial Interests are considered related to the Investigator's Institutional Responsibilities when those Financial Interests are derived from or associated with an external entity engaged in activities that:

- relate even broadly to the same or reasonably similar subject matter as the Investigator's Institutional Responsibilities, AND/OR
- include activities that the Investigator knows or should have known involve the same patients, clients or research subjects that the Investigator interacts with as part of Institutional Responsibilities.

All Financial Interests involving pharmaceutical companies, biotechnology companies, medical equipment or supplies manufacturers and distributors and all intellectual property rights, including patents, royalties and licensing agreements are considered to be related to RFMH/DMH employment and must be disclosed under this policy.

5.1 Submission Prior to Application for Funding or Negotiation of an Agreement

Each Investigator must disclose to the appropriate Institutional Official the Financial Interests of the Investigator, the Investigator's spouse and the Investigator's dependent children related to the Investigator's Institutional Responsibilities no later than the time an application is submitted for research funding. The disclosure should include any Financial Interests existing during the prior 12 months and, for Financial Interests related to the application or

agreement, those that existed from the time study planning began and any Financial Interests that are reasonably anticipated to arise in the future, including subsequent to the current research.

5.2 Submission of Updated Reports

At least annually each Investigator must submit an updated disclosure of Financial Interests (including those of the spouse or dependent children). Such disclosure shall include any information that was not previously disclosed and any updated information, e.g. an updated value of equity interest.

In addition, each Investigator must submit an updated disclosure of Financial Interest (including those of the spouse or dependent children) within 30 days of discovering or acquiring such an interest.

The Institutional Official for the Investigator's location will determine the schedule for submitting updated annual reports which may be based on the anniversary of the original submission date, a fixed date for all investigators at the location or other schedule.

5.3 New Investigators and New Disclosures

In the course of an ongoing research project if an Investigator is added to the project and discloses a Financial Interest or an existing Investigator discloses a new Financial Interest the designated Institutional Official must review the disclosure within 60 days, make the determinations described in "Review of Disclosures" below and, if a FCOI is found to exist implement, on at least an interim basis, a management plan that specifies the actions that have been and will be taken to manage the FCOI. Interim measures may be taken as necessary during the period of review.

5.4 Review of Disclosures

The Institutional Official shall determine for each Financial Interest :

1. Whether the Financial Interest is related to a specific funded project or application for funding. A Financial Interest is **related** when the Financial Interest: could be affected by the research or related activity; or is in or derived from an entity whose Financial Interest could be affected by the research or related activity; and

2. If related, whether the Financial Interest poses a conflict of interest or a potential conflict of interest; and
3. Whether the Financial Interest is a Significant Financial Interest.

If the Financial Interest is related, poses a conflict or potential conflict of interest and is a Significant Financial Interest, it is a **Financial Conflict of Interest (FCOI).**

A **Financial Conflict of Interest** (FCOI) exists when the appropriate Institutional Official reasonably determines that the Financial Interest is a Significant Financial Interest and could directly and significantly affect the design, conduct, including data analysis, or reporting of the research. FCOI's are not ordinarily allowable and in most cases will be eliminated rather than managed before the research or related activity is permitted to commence.

Note: If the Financial Interest is related and poses a conflict or potential conflict of interest but is not a Significant Financial Interest, the appropriate Institutional Official will take actions as appropriate to manage or eliminate the Financial Interest. Such conflicts are not ordinarily allowable and in most cases will be eliminated rather than managed before the research or related activity is permitted to commence.

6 FAILURE TO TIMELY DISCLOSE OR REVIEW OR FINDING OF NON COMPLIANCE WITH A FCOI MANAGEMENT PLAN

If a Financial Interest was not disclosed timely by an Investigator or was not timely reviewed, the designated Institutional Official must review the Financial Interest within 60 days and make the determinations in "Review of Disclosures" above. If a FCOI is found to exist the designated Institutional Official shall, within the 60 day period, implement, on at least an interim basis, a management plan that specifies the actions that have been taken and will be taken to manage the FCOI going forward.

The following steps must be taken if a FCOI is not identified or managed in a timely manner, including failure of an Investigator to disclose a Financial Interest that is determined to be a FCOI, failure by RFMH to review or manage a FCOI, or failure of the Investigator to comply with a FCOI management plan:

- Within 120 days RFMH shall complete 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 non-compliance, was biased in the design, conduct or reporting of the research.
- The retrospective review must be documented, including but not limited to:
    - 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, composition of the review panel, documents reviewed; and
    - Conclusions of the review.

Based on the results of the retrospective review, if appropriate, RFMH shall update the previously submitted FCOI report and specify any actions that will be taken to manage the FCOI going forward. If bias is found, RFMH will promptly notify the PHS Awarding Component and submit a mitigation report to the PHS Awarding Component. The report must include the documentation elements described above and a description of the impact of the bias on the research project and RFMH's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

RFMH may implement interim measures during the period in which the retrospective review is being conducted.

7 MANAGEMENT OF CONFLICTS OF INTEREST

The appropriate Institutional Official shall take actions as necessary to manage or eliminate Financial Conflicts of Interest, including any subrecipient Investigator Financial Conflict of Interest when the subrecipient must comply with RFMH's financial conflicts of interest policy rather than the subrecipient's policy.

Management of an identified Financial Conflict of Interest requires the development and implementation of a management plan and, if necessary a retroactive review and a

mitigation report. Adequate enforcement mechanisms, including sanctions, to ensure Investigator compliance shall be included in the plan. Management plans must be developed and implemented before any expenditure of PHS funds on the project.

Management plans may include, but are not limited to:

1. Public disclosure of FCOI, e.g. when presenting or publishing the research ;
2. For research involving human subjects, direct disclosure to research participants;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or
7. Severance of relationships that create financial conflicts.

Investigator compliance with monitoring plans must be monitored on an ongoing basis until the completion of the research.

8 RECORD RETENTION

Records relating to all investigator disclosures of Financial Interests and the review of and responses to such disclosures (whether or not a disclosure resulted in a determination of Financial Conflict of Interest) and all actions under this policy or retrospective review shall be kept for at least three years from the date the final expenditures report is submitted to PHS or such other date as may be required by PHS, or for research funded by other sponsors, the date on which the final report is submitted to the sponsor or the research is completed or is terminated, whichever is later. For Covered Clinical Studies records must be kept for a minimum of two years following the approval or withdrawal of a marketing application or according to the terms of the clinical trial agreement, whichever is longer.

9 PHS CERTIFICATION

For each application for PHS funding (including contract proposals), except SBIR Program Phase I applications, RFMH is required to certify that:

- it has an up–to-date, written and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which PHS funding is sought or received,
- it promotes and enforces Investigator compliance with the PHS regulations
- it will manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component ,
- it agrees to make information available, promptly on request, to the HHS relating to any Investigator disclosure of Financial Interests and RFMH's review of and response to the disclosure regardless of whether the disclosure resulted in a determination of Financial Conflict of Interest, and
- it will fully comply with 42 CFR 50 Subpart F and/or 45 CFR Part 94, as applicable.

10 PUBLIC ACCESSIBILITY

Policy document: An up-to-date copy of this Policy must be posted on the RFMH Corporate website.

Investigator FCOI:
Prior to expending any funds under a PHS-funded research project, RFMH will ensure public accessibility by responding in writing within 5 business days to any person or entity who submits a written request for information about a Significant Financial Interest that meets all of the following criteria:

1. The SFI was disclosed and is still held by the senior/key personnel,
2. The SFI is related to PHS-funded research, and
3. The SFI is a FCOI.

The information made available must include: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI 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. Reports of dollar values may be made in ranges ($0 – $4,999, $5,000 - $9,999, $10,000 - $19,999,

amounts between $20,000- $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000.

Written responses must note that the information provided is current as of the date listed and is subject to updates on at least an annual basis and within 60 days of RFMH's identification of a new FCOI, which should be requested subsequently by the requestor.

Information regarding FCOIs and made available on request shall remain available for at least 3 years from the date that the information was most recently updated.

11 REPORTING – INITIAL REPORTS

Prior to expending any funds under a PHS-funded research project, RFMH will provide the PHS Awarding Component with a FCOI report regarding any Investigator's SFI that is found to be a FCOI and ensure that a management plan has been implemented. If an identified FCOI has been eliminated prior to expenditure of PHS funds reporting is not required.

If a FCOI is identified subsequent to RFMH's initial report to PHS for an ongoing project, e.g., when a new investigator joins a project, RFMH will report to the PHS Awarding Component within 60 days and ensure that a management plan has been implemented.

If a FCOI report involves a SFI that was not disclosed timely by the Investigator or, for whatever reason, was not previously reviewed or managed by RFMH (e.g., was not timely reviewed or reported by a subrecipient), RFMH will conduct a retrospective review as described above (See Section : FAILURE TO TIMELY DISCLOSE OR REVIEW FCOI, OR FINDING OF NON COMPLIANCE WITH A FCOI MANAGEMENT PLAN.) If bias is found, RFMH shall promptly notify the PHS Awarding Component and submit a mitigation report to the PHS Awarding Component.

Any FCOI report will include sufficient information to enable the PHS Awarding Component to understand the nature, and extent of the financial conflict, and to assess the appropriateness of RFMH's management plan. The report must include:

1. Project Number;
2. Principal Investigator (PI)/ Project Director (PD) or Contact PD/PI name if a multiple PD/PI model is used;
3. Name of the Investigator with the FCOI;

4. Name of the entity with which the Investigator has a FCOI;
5. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the Financial Interest Reports of dollar values may be made in ranges ($0 – $4,999, $5,000 - $9,999, $10,000 - $19,999, amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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.
7. A description of how the Financial Interest relates to the PHS-funded research and the basis for RFMH's determination that the Financial Interest conflicts with the research;
8. A description of the key element of the management plan, including:
    a. Role and principal duties of the conflicted Investigator in the research project;
    b. Conditions of the management plan;
    c. How the management plan is designed to safeguard objectivity in the research project;
    d. Confirmation of the Investigator's agreement with the management plan;
    e. How the management plan will be monitored to ensure Investigator compliance; and
    f. Other information as needed.

12 REPORTING – ANNUAL REPORTS

For each report to PHS of a FCOI RFMH shall provide the PHS Awarding Component with an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. This annual report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. Annual reports must be made for the duration of the project period, including no cost extensions.

13 REMEDIES

If an investigator has failed to comply with this Policy (RFMH's FCOI Policy) or a financial management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, RFMH must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component may take appropriate action or require RFMH to enforce any applicable corrective actions prior to an award or the transfer of a PHS grant(s).

The PHS Awarding Component and/or HHS may inquire at any time into any Investigator disclosure of Financial Interests and RFMH's review of and response to such disclosure, regardless of whether the disclosure resulted in a determination of a FCOI.

RFMH must permit HHS to review all records pertinent to reviews under this policy for PHS-funded research. HHS will keep records confidential to the extent permitted by law. The PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that RFMH has not managed the FCOI in compliance with 42 CFR 50. The PHS Awarding Component may impose special award conditions, suspend funding, or take other enforcement actions as necessary until the matter is resolved. If 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 RFMH, RFMH shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

RFMH shall take additional actions as deemed appropriate, which may include restrictions on the ability to submit funding applications through RFMH and, for RFMH employees, disciplinary actions up to and including termination.

14 ADDITIONAL REQUIREMENTS FOR FDA REGULATED COVERED CLINICAL STUDIES

14.1 Definitions under FDA Regulations 21 CFR 54

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 implementing FDA requirements under 21 CFR 54, 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

14.2 Additional Disclosure Requirements for Covered Clinical Studies

For Covered Clinical Studies under 21 CFR 54 Investigators must be careful to include and to clearly identify in their disclosure any:

- 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 an 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.

14.3 Reporting for Covered Clinical Trials

Investigators and RFMH are responsible for reporting to the party who plans to submit a marketing application to FDA ("Applicant") certification and disclosure statements covering the items required by 21 CFR 54 and described above in Section: Submission and Review of Disclosures. Typically the Applicant is a commercial sponsor. However, in the unlikely event that the Investigator and/or RFMH is the Applicant then the Investigator must consult with the appropriate Institutional Official to ensure that FDA requirements will be met. Further information can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1&utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=21 CFR 54 regulations&utm_content=2

15 EFFECTIVE DATE

This Policy shall become effective on August 24, 2012 for all PHS funded grants and cooperative agreements (including noncompeting continuations) with an issue date of the Notice of Award on or after August 24, 2012. For all other activities that fall within the scope of this policy the RFMH Policy on Disclosure of Significant Financial Interests dated 27 February 2004 shall remain in effect for each activity until all Investigators for that activity, as defined in the revised Policy, have met the requirements of the revised Policy but no later than August 23, 2013. Institutional Officials may require compliance with the revised policy at their location prior to August 23, 2013.

16 PROCEDURES AND FORMS

Please consult with your local RFMH Business Office for instructions and forms implementing this Policy at your location.