MAIMONIDES MEDICAL CENTER

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SUBJECT: CONFLICTS OF INTEREST IN HUMAN RESEARCH & PHS FUNDED RESEARCH

I. POLICY

Consistent with current law and to ensure the safety and welfare of human subjects participating in research at Maimonides Medical Center ("Medical Center") and the integrity of data collection, it is Medical Center policy that Investigators and Research Officials may not make any decisions regarding research in relation to which they possess a conflict of interest. This policy is intended to: 1) assist Investigators and Research Officials in determining when they have conflicts of interest in research; and 2) to guide them in disclosing all potential conflicts and, as appropriate, cooperating in the management or elimination of conflicts. This policy also defines the process to manage and potentially eliminate any existing conflicts of interest related to research at the Medical Center. Finally, this policy addresses the disclosure, management and reporting components of financial conflicts of interest, related to Public Health Service-supported research as set forth in 42 CFR Part 50.[1]

To guard against holdings and interests that could result in potential Institutional conflicts of interest at the Medical Center any Investigator, IRB member, or Research Official who learns of any significant corporate investments or other interests of the Medical Center (or any of its affiliated entities) in research projects or products, Sponsors of research and/or in any other research-related organizations, must promptly disclose their awareness of such investments or interests to the Research Integrity Officer, either in person or in writing, and must cooperate with any inquiry into the nature and scope of any such corporate investments.

II. DEFINITIONS

A. Financial Conflict of Interest: A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a research project and could directly and significantly affect the design, conduct or reporting of research.

B. Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable, including but not limited to any of the following: investments; stock or other equity ownership; stock options or warrants to purchase stock or equities; patent, royalty or intellectual property interests;

[1] These amendments were released through the Department of Health and Human Services Final Rule, 76 FR 53.256 (August 25, 2011)..

directors' fees; consulting fees; and income, remuneration in cash or kind, emoluments, benefits, gifts, honoraria, travel reimbursement, paid authorship, goods or services. Financial Interest does not include holdings in mutual funds or other equity funds in which day-to-day control of investments is held by a person not covered by this Research Conflict of Interest Policy.

C. Immediate Family: Spouse or domestic partner, and dependent children.

D. Investigators: for the purpose of this policy, Investigators are
   i. any professional research staff member involved in exercising independent judgment in research design, enrollment, data collection and gathering, analysis and/or preparation for publication, including the Principal Investigators, Co-Investigators, and Key Personnel, listed on an IRB Application;
   ii. anyone who is planning to receive or is receiving PHS funds for research, including whether the Medical Center is the direct recipient of the PHS funds or is participating in the research as a sub-contractor or sub-recipient of PHS funding from another institution. This includes (including any type of NIH-funding mechanism such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award, with the exception of a Phase I SBIR/STRR application;
   iii. anyone who is planning to submit or is submitting Phase I SBIR/STRR applications[2] when the activities of Phase I also require an IRB application;
   iv. anyone who meets the definition of a Principal Investigator, Co-Investigator, Key Personnel, or anyone who participants in PHS (including NIH) funded research.

E. Leadership Role: Employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees or board of directors, (ii) an officer, (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees or of a board of directors, whether remunerated or non-remunerated, or (iv) paid advisor for a research Sponsor or research-related entity.

F. Public Health Service Funding: Funding received from the Public Health Service (PHS) of the U.S. Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including but not limited to: the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration,

[2] Phase I SBIR/STRR applications do not require disclosure reporting at the time of grant application; however, disclosure is only required by the Medical Center if an IRB application is required for the project (i.e., also meets the definition of human research under 45 CFR 46).

Health Resources and Services Administration, and the National Institutes of Health (NIH).

G. Research Officials: All medical and administrative staff in offices that oversee or have discretionary authority over the funding or performance of research at the Medical Center, including without limitations: the Office of the General Counsel; the Office of Grants and Contracts; the Office of Research Administration; members of the IRB; IRB administrators: all executive level administrators, such as the President and Vice Presidents of the Medical Center; Department Chairs; Division Chiefs and Finance officials who make decisions that directly affect research.

H. Significant Financial Interest ("SFI"): A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's immediate family) that reasonably appears to be related to the Investigator's institutional responsibilities and includes one or more of the following, with exceptions noted below:
   1. With regard to any publicly-traded entity, a SFI exists for these Investigators (or their immediate family) if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000.[3]
   2. With regard to any non-publicly traded entity, a SFI exists for these Investigators (or their immediate family) if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000.
   3. Intellectual property rights and interests (e.g. patents, copyrights, and royalties[4] from such rights), upon receipt of income related to such rights and interests, in the 12 months preceding the disclosure, when aggregated, exceeds $5,000
   4. Any payments made directly to an Investigator related to the accrual of patients to a clinical trial (e.g., recruitment incentives).[5]

[3] For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

[4] Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are subject to the $5,000 threshold. Royalties paid to the Investigator (or his/her spouse and dependent children) that satisfy the definition of SFI must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by the Medical Center and are licensed or potentially licensed through the Medical Center (i.e., they are not personally owned by the Investigator), they are considered remuneration from the Medical Center and would not be considered a SFI of the Investigator. Royalties received by the Investigator from the Medical Center are excluded from the definition of SFI if the Investigator is currently employed or otherwise appointed by the Medical Center. Unlicensed intellectual property that does not generate income is also excluded from the definition of SFI. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to disclosure requirements.

[5] Payments made to the Medical Center related to accrual of patients are not included.

5. Salary, consulting or advisory fees, speaking fees, travel[6] reimbursements, or gifts received from an entity other than the Medical Center, including other employment relationships in the 12 months preceding the disclosure.
6. 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.
7. A Blind Trust, when the original known value exceeds $5,000.
8. Foreign Investments, Stock Options, or Bonds that exceed $5,000 when aggregated over the preceding 12 months.
9. Any remuneration to a Corporate Officer or member of the Board of Directors that exceed $5,000 when aggregated over the preceding 12 months.
10. SFI does not include the following types of financial interests:
    a) salary, royalties, or other remuneration paid by the Medical Center to the Investigator if the Investigator is currently employed or otherwise appointed by the Medical Center;
    b) intellectual property rights assigned to the Medical Center and agreements to share in royalties related to such rights
    c) any ownership interests in an Institution held by the Investigator, if the Institution is a commercial or for-profit organization
    d) 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;
    e) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 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;
    f) income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.
    g) travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

[6] Investigators 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 the Investigator's institutional responsibilities and the specific details of the disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The COIC 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.

I. Sponsor: An entity that is sponsoring or funding research and the entity's affiliates and subsidiaries, and any entity that monitors research, collects or arranges data for research or otherwise performs any services related to or supporting research, including assisting in applications or responses to the Food and Drug Administration (FDA).

III. RESPONSIBILITY

A. Annual Conflict of Interest Disclosure Form

1. Investigators

All Investigators must complete and submit a Conflict of Interest Disclosure Form ("Disclosure Form") in IRB Manager or using the paper form as follows:

a) No later than at the time of application for PHS-funded research (except if this is for a Phase I SBIR/STRR application).
b) Prior to the approval of an initial IRB application, continuing IRB review, or IRB review of a closure, if the annual COI has expired or there is none on file for the period.
c) Within 30 days of discovering or requiring a new SFI.
d) Annually.

In addition to completing the Disclosure Form, Investigators that are planning or currently participating in PHS-funded research projects will be required to complete a training, to be made available by the Medical Center, which addresses financial conflicts of interest. The initial training is valid for four years and must be repeated at least every four years thereafter during the period of the PHS research award.

If a co-investigator is an employee of another institution, they can provide the adjudication of conflict of interest from their institution in lieu of using the Maimonides Medical Center disclosure forms, provided their institution provides a statement to the IRB that their policy complies with the 42 CFR part 50, Subpart F. The Maimonides Medical Center IRB can require the Maimonides Medical Center COI disclosure forms, if requested.

COI disclosure forms are not required for clinical personnel listed on a Humanitarian Use Device (HUD) IRB application when the HUD is intended for clinical purposes only; however, disclosures are required when the HUD is used in a clinical trial.

2. Research Officials

Once per year, all Research Officials must complete and submit to the Research Integrity Officer a Disclosure Form, which will be maintained by the Research Integrity Officer as a record of each Research Official's research-

related Financial Interests and Leadership Roles. In the Disclosure Form, Research Officials must disclose their own research-related Financial Interests and Leadership Roles, as well as those of their Immediate Family. Within 30 days of any new appointment to a position as a Research Official, that newly appointed person must complete and submit the Disclosure Form to the Research Integrity Officer.

All Research Officials must sign an Annual Confidentiality Pledge.

B. Obligation to Keep Current the Investigator / Research Official Conflict of Interest Disclosure Form and Obligation to Keep Current the Disclosed Information

1. If at any time after submitting a Disclosure Form, one or more Financial Interests or Leadership Roles of an Investigator or Research Official or of an Investigator's or Research Official's Immediate Family in any research or health care-related organization changes in any material way, the Investigator or Research Official must promptly notify the IRB or Research Integrity Officer, respectively, of that change by submitting an updated Disclosure Form. Investigators must submit an updated Investigator Disclosure Form to the IRB annually. If an Investigator discovers or acquires a new significant financial interest (e.g. through purchase, marriage or inheritance) during the award period, the Investigator must submit an updated Conflict of Interest Disclosure Form within 30 days to the IRB after discovery or acquisition. A new SFI is a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a "new" SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

2. If at any time after making a disclosure of a potential research-related institutional investment or interest, an Investigator, IRB member, or Research Official becomes aware of any additional significant investments of the Medical Center, the Investigator, IRB member, or Research Official must promptly notify the Research Integrity Officer of their new knowledge.

IV. PROCEDURES

A. IRB and Conflict of Interest Committee (COIC) review:

The disclosure forms are reviewed at the following times:

1. Whenever a form is submitted to the IRB

2. Initial IRB review of a new study
3. Continuing IRB review of a previously approved study
4. IRB review of a closure of a previously approved study

The IRB Administrative Staff will review the disclosure forms and forward any reported financial or leadership interests to the IRB Chair or designate. The IRB Chair or designate will determine if there are any SFI or whether to send the disclosure to the Conflict of Interest Committee (COIC). The IRB Chair may seek consultation from the convened IRB as deemed appropriate; however, all SFI and all institutional conflicts must be reviewed by the COIC. If the COIC determines that the conflict may pose a risk, the COIC will develop a management plan for the Investigator and research study to reduce the risk of the conflict affecting the results or integrity of the research.

The COIC will consider whether those Financial Interests and/or Leadership Roles of an individual with a SFI constitute one or more conflicts of interest in regard to research. COIC shall be composed of the IRB Chair (who shall sit as the chair of the COIC), the Corporate Compliance Officer, and one member not from the IRB appointed by the President of the Medical Center, and shall be advised by an attorney from the Office of General Counsel.

The COIC may request additional information or discuss the matter in person with one or more members of the COIC. A conflict of interest will be deemed to exist whenever a Financial Interest qualifies as a "Significant Financial Interest." If one or more conflicts of interest are identified in this process, then the COIC shall assess the degree of risk posed by the conflicts in regard to research integrity and the safety and welfare of human research participants, and recommend a plan to manage those conflicts. Generally, the greater the Financial Interests, the greater the potential risk that the conflicts may inappropriately influence research outcomes and/or research participant safety and welfare. The COIC will make its recommendations to the IRB for the IRB to consider at the time the study undergoes either initial or continuing review. The IRB may modify those recommendations as it deems appropriate, but may only strengthen the recommendations, not weaken them. The IRB cannot approve such a protocol without considering the recommendations of the COIC.

The same process as described above will be used in determining whether disclosures of Financial Interest by Investigators meet the threshold of a Significant Financial Interest ("SFI"). Similarly, a subsequent determination will be made via the aforementioned process of whether or not this SFI constitutes a Financial Conflict of Interest ("FCOI"). In making this determination, the designated Institutional Official (i.e. the IRB Chair), will adhere to the definition of Significant Financial Interest ("SFI") for Investigators as defined above to determine whether the SFI could affect or be

affected by the funded research or is held within an entity whose financial interest could be affected by the research.

If the Medical Center identifies that an SFI was not disclosed in a timely manner, the IRB Chair shall, within 60 days of discovery, review the SFI, determine whether or not it is related to the funded research, determine whether a financial conflict of interest exists and, if so, institute an appropriate management plan.

Whenever a financial conflict of interest is not identified or managed in a timely manner, either by the Investigator or Medical Center, the Medical Center will complete and document a retrospective review (within 120 days of discovery) of the Investigator's activities and the funded research project to determine whether any funded research conducted during the period of non-compliance was biased in the design, conduct or reporting of such research.

Regarding institutional conflicts of interest, the COIC shall meet to consider whether awareness of significant institutional investments or interests by the disclosing Investigator, IRB member, or Research Official could potentially bias research being conducted or reviewed at the Medical Center. COIC shall develop recommendations for the management of those conflicts and shall report those recommendations to the Audit and Legal Committee of the Board of Trustees, as well as to the IRB and the Institutional Official for Research. Either the Audit and Legal Committee or the IRB may strengthen the COIC's recommendations, but may not weaken them. Those recommendations must be implemented by the IRB, in its consideration and approval of the terms and conditions of any human research, and by the Medical Center itself, acting through its Institutional Official.

B. Compelling and Necessary Exceptions for Investigators

The COIC may consider "compelling and necessary" exceptions that would allow the Medical Center to host research, with special oversight measures, notwithstanding one or more conflicts of interest created through significant institutional investments or interests. Additionally, the COIC may consider "compelling and necessary" exceptions that would allow an Investigator with a conflicting "Significant Financial Interest" and/or Leadership Role (or whose Immediate Family member has a conflicting "Significant Financial Interest" and/or Leadership Role) to conduct research, with appropriate oversight and management, at the Medical Center. This may be allowed to occur in circumstances where that Investigator has special expertise regarding the particular drug, device method or therapy under investigation; where the Medical Center has special facilities or equipment that are unavailable at most other institutions that allow or facilitate the proposed research; and/or where the Investigator or the Medical Center is particularly well situated to enroll study subjects because of the patient population and/or catchment area of the Medical Center or of the Investigators themselves.

C. Requirement to disclose financial conflict of interest in each public presentation of certain PHS funded clinical trials

Whenever a PHS-funded clinical trial's purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and has been designed, conducted, or reported by an Investigator with a financial conflict of interest the Investigator involved must disclose the financial conflict of interest in every public presentation or publication, including an addendum to any previously published presentations (e.g., new financial conflict of interest reported for a previous presentation).

D. Recommendations Regarding the Management or Elimination of Conflicts of Interest for Investigators

The COIC recommendations, and the IRB determinations regarding those recommendations, will be calibrated to correspond to the seriousness of the conflict of interest, and the likelihood that the conflict of interest could in fact influence persons to make inappropriate, unfair or unwise decisions in their conduct or oversight of human subject's research. Whenever an Investigator or a member of his/her Immediate Family holds a "Significant Financial Interest" in research that is being conducted by the Investigator, COIC shall normally recommend, and the IRB shall normally adopt, a requirement that the Investigator disclose his/her conflict of interest to every subject participating in the research, both orally during the informed consent process and in writing in the research consent form or information sheet, as applicable. The following conflict of interest disclosure language is an example of the kind of disclosure that may be recommended by COIC and required by the IRB:

Every research scientist and physician at Maimonides Medical Center who is connected to a research study must disclose any and all financial interests they and their immediate family members have in private companies or entities that may be related to that study. A Conflict of Interest Committee at Maimonides which reviews such financial interests has concluded that one or more of the researchers conducting this study do in fact possess certain financial interests in, or relationships with, companies funding or associated with the study. [insert some degree of specific disclosure here, if warranted, as to the nature of the interests and the conflict management strategies that have been adopted to manage those interests]. However, after considering this information, the Committee has concluded that there are no conflicts of interest that, when considered together with the conflict of interest management strategies discussed above, can be reasonably expected to influence the way you will be treated in this study or the way this study will be conducted. If you

would like more information about Maimonides' review process generally, or in regard to the conflicts of interest that were determined to exist in relation to this study, please ask the researchers or the research coordinator and they will assist you. You may also ask Maimonides' patient advocate, who also can arrange for you to have this information; the patient advocate may be reached at (718) 283-7212. If, because of this information, you choose not to participate in this study, that decision will have no effect on your continued health care at Maimonides. Participation in all research, including this study, is entirely voluntary, and you may withdraw your participation at any time.

Additional methods of controlling or managing conflicts of interest include, but are not limited to:

(i) Eliminating the conflict by referring the study to non-conflicted Investigators;
(ii) Divesting or sequestering the conflicting Significant Financial Interest;
(iii) Eliminating the Leadership Role;
(iv) Referring the study to another site at which Investigators are not conflicted;
(v) Severance of relationships that create financial conflicts;
(vi) Requiring that investments posing a conflict of interest in a research study be "frozen" for a designated period of time lasting beyond the termination of the study, with the Investigator allowed neither to sell nor transfer those interests until the end of that time period, thus providing for a forced attenuation of the research study and its results from the Investigator's conflicting Significant Financial Interest;
(vii) Disclosing the conflicting Financial Interest, Significant Financial Interest and/or Leadership Role to staff members working on the project, the IRB, Sponsors and/or journals and other publications or when presenting the research;
(viii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias which may include monitoring of the research participant recruitment, enrollment, and/or the informed consent processes;
(ix) Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting;
(x) Modification of the research plan;
(xi) Arranging for strengthened review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made;
(xii) Adopting procedures for the updating of information relating to the conflict, if it appears that the conflict might change in any appreciable way over the course of a research study;
(xiii) Requiring that a non-conflicted Co-Investigator obtain informed consent from study participants;
(xiv) Requiring a change of personnel or personnel responsibilities; and/or

(xv) Disqualifying of personnel from participation in all or a portion of the research.

The COIC will put into place measures to monitor Investigator compliance with the recommended management plan. The key elements of the Institution's management plan may include but are not limited to the following:

(i) The role and principal duties of the conflicted Investigator in the research project;
(ii) Conditions of the management plan;
(iii) How the management plan is designed to safeguard objectivity in the research project;
(iv) Confirmation of the Investigator's agreement to the management plan;
(v) How the management plan will be monitored to ensure Investigator compliance; and
(vi) Other information as needed.
(vii) Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the PHS Agency.

E. Review by the Research Integrity Officer of Research Officials' Disclosures

Whenever a Research Official indicates in a Disclosure Form that he or she or his or her Immediate Family possesses Financial Interests and/or Leadership Roles in research being conducted at the Medical Center, the Research Integrity Officer will consult the COIC, which shall be advised by an attorney from the Office of the General Counsel, to determine whether those Financial Interests and/or Leadership Roles constitute one or more conflicts of interest in regard to that research. For this purpose, COIC may ask that the Research Official provide additional information or discuss the matter in person. A conflict of interest will be deemed to exist whenever a Financial Interest held by a Research Official or a member of his/her Immediate Family qualifies as a "Significant Financial Interest." If one or more conflicts of interest are identified in this process, then COIC shall inform the Research Official that he or she may not oversee or make any decisions regarding the research in relation to which the conflict of interest exists. If the Research Official insists on maintaining authority or discretion over the research in question, he or she may do so only by eliminating the Financial Interest and/or Leadership Role that was determined to pose a conflict of interest, and by re-submitting to the Research Integrity Officer for reconsideration by the COIC an updated Disclosure Form certifying that the Financial Interest or Leadership Role has been eliminated.

V. REPORTING AND PUBLIC AVAILABILITY OF INFORMATION ON INVESTIGATORS' FINANCIAL CONFLICTS OF INTEREST

If any Investigator with PHS funding is found to have a financial conflict of interest, the Medical Center will submit to the PHS agency providing the funds for the PHS research project a Financial Conflict of Interest Report, which includes the steps the Medical Center is taking to manage or eliminate the FCOI, unless the FCOI is eliminated prior to award expenditures. Any subsequent discoveries of FCOIs among Investigators with PHS funding after distribution of the initial report will similarly be reported to the referenced PHS agency within 60 days. The elements of the report will be consistent with those outlined in Title 42 Part 50.605(b)(3). In addition, the Medical Center will provide annual reports to the relevant PHS funding agency that addresses the status of previously reported FCOIs and any changes to the relevant management plan.

Prior to the Medical Center's expenditures of any funds under a PHS-funded research project, the Medical Center will ensure public accessibility via written response to any request within 5 business days, of information concerning any SFI disclosed to the Medical Center that a) was disclosed and still held by the Investigator; b) is considered by the Medical Center to be related to the PHS-funded research; and c) is a financial conflict of interest. This information will remain available to the requestor for at least three years from the date the information was most recently updated. At a minimum, the information shared with the requestor will include: the Investigator's name, title and role with 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, unless the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If a Medical Center Investigator is a sub recipient of PHS award and has a SFI, the SFI must be reported to the primary awardee and published on their website (or be made publically available upon request). If an Investigator with a SFI in a PHS funded project is from an external institution, the external Investigator must comply with his/her institution's policy as well as the Medical Center policy.

VI. CONFIDENTIALITY AND RECORD-KEEPING

All financial and other information disclosed by Investigators to the COIC, the IRB and the IRB staff will be maintained in the strictest of confidence. All financial and other information disclosed by Research Officials to the Research Integrity Officer will be maintained in the strictest of confidence. COIC, IRB members and the Research Integrity Officer must pledge in writing (using the Maimonides Medical Center Confidentiality Pledge) to use or disclose Investigator or Research Official financial and other information only as necessary to carry out their designated functions. Information from the Disclosure Form will be shared with the Research Integrity Officer, and may also be shared with other institutional officials such as one or more persons from the

Office of the General Counsel, the Corporate Compliance Officer and/or the Medical Center's President. Any institutional official to whom disclosure is made will also be required to sign the Confidentiality Pledge. All other uses or disclosures of Investigator or Research Official information will require the written authorization of the Investigator or Research Official who is the subject of that information. However, Investigators may be required to disclose their Financial Interests and/or Leadership Roles to the subjects enrolled in their study if such disclosure is directed by the IRB.

Records relating to all Investigator disclosures or financial interests and the review of such disclosures and all actions under this policy, including any applicable retrospective review, are maintained for at least 6 years from the date the final expenditure report is submitted to PHS, or 6 years from the date of a research study closure for non-PHS studies, or until the completion and resolution of all issues that arise from any litigation, claim, negotiation, financial management review, or audit that is started before the 6 year expiration, whichever is longer. The Medical Center will make any of these reports available to the PHS funding agency upon request.

VI. REMEDIES, AUDITS, AND SANCTIONS FOR NON-COMPLIANCE

All persons employed by or affiliated with the Medical Center are expected to comply with this policy and to assist the COIC in its work. A Disclosure Form may be audited for the purpose of verifying whether the individual truthfully and accurately disclosed his or her Financial Interests and/or Leadership Roles to the IRB or Research Integrity Officer. An Investigator may also be audited for the purpose of verifying whether the Investigator is complying with the actions, if any, that were specified by the IRB. An Investigator who does not comply with the IRB's determinations on these issues or a Research Official who is found to have failed to disclose, or to have misrepresented the nature or quantity of his or her research-related Financial Interests and/or Leadership Roles, or those of his or her Immediate Family, will face potential sanctions. These sanctions may include: formal admonition or censure; suspension or termination of the Investigator's eligibility for grant applications and/or IRB approval; non-renewal of medical staff appointment; and/or dismissal.

If an Investigator fails to comply with this policy or the recommended management plan set forth by the COIC, which has resulted in a subsequent bias in the design, conduct or reporting of the research, the Medical Center will immediately recommend corrective action to the Investigator(s), including directives for maintaining appropriate objectivity in the research and prompt notification to the PHS funding agency for PHS funded research. The Medical Center will comply with any subsequent recommended corrective actions from the PHS funding agency, including suspension of funding or other enforcement actions as necessary until the matter is resolved.

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

VII APPLICABILITY; COORDINATION WITH OTHER POLICIES AND REGULATIONS

This Policy is not intended to supersede or replace any other regulations or policies of the Medical Center, including the Policy on Conflicts of Interest (AD-108).

This policy is coordinated with Institutional Review of Research, Including Research Involving Human Research Participants (RES-7). Disclosures are reviewed for all IRB applications for human research.

This policy does not replace financial disclosures required of Clinical Investigators to be reported to the FDA under Title 21 CFR 54, related to submission of a marketing application for a human drug, biologic product, or a device.

VIII. CONTROLS

The Corporate Compliance Officer and the Vice President for Legal Affairs shall monitor compliance with this policy.

Each investigator is informed of this policy prior to engaging in any research and whenever the policy is revised.

Annual disclosures are tracked in IRB Manager™. Reviews and determinations are documented in this system and reminders will automatically be sent by the system to remind Investigators and Research Officials at least 30 days prior to their reporting anniversary.

If a Disclosure Form is delinquent at the time the review is due, the investigator will be notified by the IRB.

This policy must be made publically available on the Maimonides Medical Center website.

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Kenneth Gibbs
President & CEO

REFERENCES:

TITLE 42 CFR F (76 FR 53283) - PROMOTING OBJECTIVITY IN RESEARCH

NIH Grants and Funding: Financial Conflict of Interest (website: available 04/14/2015)

NIH Financial Interests Frequently Asked Questions (website: updated 6/19/2014)

PART 46 (56 FR 28012, 28022; 66 FR 56778; 43 FR 53655; 48 FR 9818; 74 FR 2405)—PROTECTION OF HUMAN SUBJECTS

TITLE 21 PART 54 (63 FR 5250)—FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

AD-108

INDEX: RES 21

ORIGINATING DEPARTMENT: Research Administration

Attachments:
A. Conflict of Interest Disclosure Form
B. Annual Research Confidentiality Pledge