Policies and Procedures

SUBJECT: Conflict of Interest and Commitment Policy
POLICY #: 804.0
PROCESS OWNER: Business Affairs

PURPOSE / OVERVIEW / INTENT:

The purpose of this policy is to protect the integrity and credibility of activities related to research and to maintain public trust and confidence in MRN and its employees. The Conflicts of Interest and Commitment policy addresses the crucially important responsibilities of safeguarding research objectivity, protecting MRN researchers who may be exposed to conflict of interest situations, and enabling compliance with applicable laws and other regulatory requirements. Research activities occurring at MRN shall not be adversely affected by financial or other interests of persons involved in those activities.

The MRN recognizes the importance of relationships between MRN staff and other organizations, and seeks to encourage such relationships. These relationships can give rise to significant discoveries and to the translation of those discoveries into useful products. Productive relationships with other organizations also inspire new avenues of inquiry and provide opportunities to test research. The MRN permits employees to engage in external activities, subject to certain limitations. Although such outside activities are often compatible with an employee’s MRN duties, they may in some cases lead to conflicts of commitment with regard to an employee’s MRN responsibilities, or misuse of organizational resources. Separately, conflicts of interest arising from an employee’s external interests or activities can make it difficult for him/her to perform their MRN duties impartially. Therefore, this policy is used to reaffirm MRN’s dedication to the key principles in the organization’s Code of Conduct and to clarify the overriding professional obligations of all employees of MRN with respect to external activity, including outside employment and use of organizational resources.

DEFINITIONS:

Clinical Trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (such as drugs, treatments, devices, or new ways of using known drugs, treatments or devices).

Conflict of Commitment, which may also be called conflict of effort or conflict of obligation, occurs when the time or effort that an employee devotes to external activities interferes with his or her MRN responsibilities, or when an employee makes inappropriate use of MRN resources in the course of an external activity.

Conflict of Interest is a situation in which private or personal interests have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not the likelihood. A conflict of interest can arise naturally from an employee’s engagement with the world outside of MRN and the existence of a conflict of interest does not necessarily imply wrongdoing on anyone’s part. When conflicts of interest do arise, however, they must be recognized, disclosed and either eliminated or properly managed. Disclosing the required information at the earliest possible time will afford the best protection of a person’s interest. Conflicts of interest may take many forms. For the purposes of this policy, they will be addressed under two classifications:
• Financial Conflicts of Interest (FCOI; related to the performance of federal research under 42 CFR Part 50, Subpart F and/or 45 CFR Part 94) occur when an employee’s obligations to MRN, including research activities, could be compromised by his or her external agreements, particularly financial agreements that provide research funding, other funding or compensation. The regulations stipulate that outside work is reportable if representing compensation greater than a specified threshold or if representing a significant ownership or management interest in a private enterprise. Ideally, an FCOI-related disclosure will be made by an employee prior to their acceptance of a qualifying outside work commitment and/or relationship. If the reporting threshold is not reasonably foreseeable in advance, disclosure must be made in the course of events as the relevant triggers are approached. MRN policy requires an FCOI disclosure to an appropriate Institutional Official (IO) prior to submission of any proposal.

• General Conflicts of Interest occur when an employee or immediate family member receives personal benefit from the employee’s MRN position in a manner which may inappropriately influence the employee’s judgment, compromise the employee’s ability to carry out their MRN responsibilities, or damage the organization’s integrity. It is the responsibility of each employee to identify and disclose potential conflicts of interest to their supervisor. Supervisors will work with the appropriate IO and other MRN management, as needed, to manage or resolve the conflict and create appropriate documentation.

External activity means involvement with any person, trust, organization, enterprise, government agency, or other entity that is not associated with or under the control of LRRI/MRN.

Human Subject refers to any living individual about whom the investigator conducting research obtains data through direct intervention or interaction, or identifiable private information.

Inventor is any person who has created intellectual property in which MRN has any right or interest, including but not limited to patents, trademarks, copyrights, trade secrets, or know-how.

Investigator refers to the Principal Investigator, co-investigators or any other person responsible for the design, conduct or reporting of research funded by NIH or proposed for such finding, such as Investigators working for subgrantees/contractors/subcontractors/collaborators. The term Investigator includes the Investigator’s spouse, domestic partner and dependent children.

IRB is the Institutional Review Board, also known as an independent ethics committee (IEC) or ethical review board (ERB). This committee has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.

Management Plan is a written plan for the management, reduction, or elimination of potential conflicts of interest relating to an individual’s institutional responsibilities. Possible management of conflict of interest may include, but is not limited to, public disclosure of the significant financial interest, monitoring of the research by independent reviewers, modification of research plans, divestiture of the significant financial interest, and severance of the relationships that created the conflict.

Non-Sponsored Research refers to research that is supported through discretionary funds, research endowment, unrestricted gift accounts, or is unfunded.

PHS Awarding Component is the organizational unit of the Public Health Service that funds research subject to 42 CFR 50 subpart F, entitled “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.”

Principal Investigator is the investigator who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.

Research is a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social science research. The term encompasses basic and applied research and product development.
Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse, domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- Salary, royalties or other payments for services such as consulting fees or honoraria, 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, meets or exceeds $5,000.
- Reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Note the exclusions to travel related disclosures that are listed in the section below.
- Equity interests such as stocks, stock options, or other ownership interests if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, meets or exceeds $5,000, or when the Investigator (or the Investigator’s spouse, domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) in a non-publicly traded entity;
- Intellectual property rights such as patents, copyrights, and royalties from such rights.

Significant Financial Interest does not include the following:

- Salary, royalties, or other remuneration from MRN to the Investigator if he/she is currently employed or otherwise appointed by MRN
- 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, and service on advisory 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.
- 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.

Sponsored Research refers to research that is partially or fully, proposed or funded by federal, foundation, or corporate sources.

GUIDELINES / GENERAL RULES / POLICY:

**Training.** All employees, investigators, and subcontractors are required to review and document willingness to comply with this policy. A copy of the policy will be provided to all new employees and investigators and annual reminders will be sent to ensure compliance with ongoing disclosure responsibilities. At the time of application, within 30 days of change in status of investigator, including subrecipient investigator, upon revision of this policy, or at least every four (4) years, training will be provided to all employees and investigators on any change in requirements or definitions.

**Gratuities.** No investigator may accept, under circumstances that might reasonably be interpreted as an attempt to influence him/her in the conduct of his/her duties, any gratuity or special favor from individuals or organizations with whom MRN is doing business.

**Use of Privileged Information.** Employees will not use for personal gain or make other improper use of privileged or business-sensitive information that is acquired in connection with their employment. In this connection, the term "privileged or business-sensitive information" includes, but is not limited to, information relating to technological and scientific developments, medical or personnel records of individual, legal, accounting, business development or marketing interests.
Disclosure Obligation. MRN staff must be cautious to prevent unresolved conflicts of interest in relationships that might undermine the credibility of their work or damage their personal reputations or that of MRN. However, conflicts of interest may occur when an investigator’s research responsibilities compete with his or her private financial interests, raising questions of objectivity and improper gain. Conflicts of interest are inevitable and do not imply any impropriety on the part of the investigator. Disclosing potential conflicts of interest, financial and otherwise, at the earliest possible time will afford the best protection of an investigator's interests. Early disclosure is a key factor in protecting an investigator’s reputation and career from potentially embarrassing or harmful allegations of inappropriate behavior. Investigators are encouraged to disclose any situation that could conceivably be viewed as a conflict of interest or a reportable financial interest, and to favor more rather than less disclosure. Prior to participating in a research activity, anyone having a significant financial interest related to the activity shall report the interest to the FCOI Official, who will be responsible for reviewing reports, determining if a conflict exists, and instituting an adequate plan for the management of any potential conflicts of interest, communicating the conflict to the IRB and, if applicable, submitting any necessary reports to the sponsoring agency. Conflicts of interest and commitment will be reported using the COI Disclosure Form.

FINANCIAL CONFLICTS OF INTEREST

Disclosure Requirements. It is the responsibility of the PI of a research project to identify and report all investigators who have a Significant Financial Interest (SFI) requiring reporting under this policy. It is the responsibility of the PI to ensure that investigators who anticipate participation, or are already participating in research, report a SFI.

SFI shall be reported by an Investigator under the following circumstances:
- when a proposal for a research project is submitted to the Office of Research Contracts;
- within 30 days of discovering or acquiring a new SFI;
- when requested by the Institution.

On the submission of non-competitive continuations PIs are required to certify that:
- there are no SFI changes since the original competitive application and the project is compliance with any and all management plans (if any) issued;
- new SFI reports have been submitted to the FCOI Official, using the COI Disclosure Form.

The COI Disclosure Form is to be completed and submitted to the FCOI Official for disclosure of a significant financial conflict of interest.

Ongoing Disclosure Responsibilities. Disclosure requirements apply for the duration of the research. Investigators must disclose any of the following that occur during the sponsored MRN research within 30 days of discovery:
- new SFI that would reasonably appear to be affected by the research;
- new situation that could call into question the investigator's professional commitments in undertaking the research or the investigator's primary allegiance to MRN;
- a significant change to a previously reported disclosure;
- a new investigator added to the project (must submit disclosure forms).

Review of FCOI Reports. The FCOI Official will assess whether an actual or potential conflict exists and work with the investigator to determine how it should be resolved or managed. All disclosures will be reviewed when a proposal has been funded. The review must be completed before any expenses are incurred under an award or before any research can begin. Investigators shall fully cooperate with requests by the FCOI Official for additional information and documentation to support their SFI reports. If an SFI is identified that was not previously disclosed by an Investigator, the FCOI Official will review the disclosure, make a determination regarding presence of FCOI and implement a management plan, if appropriate, within sixty days of discovery.

If the FCOI Official determines after an initial review of a disclosure that no conflict of interest exists, the assessment will be concluded. Proposed research activities will only be approved if the FCOI Official determines that they can be conducted in compliance with HHS regulations 42 CFR part 50 subpart F (grants) and 42 CFR part 94 (contracts), NSF regulation 60 FR 35820–35823 July 11, 1995, and if an adequate Management Plan can be implemented.
If the FCOI Official determines a conflict exists, he/she will continue to work with the investigator to determine how the conflict might be managed or resolved to best protect the investigator, research participants, MRN and the research results. The FCOI Official will provide notice to the MRN Executive Committee of any reported SFI relating to MRN research.

**Monitoring of FCOI.** Whenever MRN identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the FCOI Official shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; and determine whether a financial conflict of interest exists. If it is determined that a FCOI exists, the FCOI Official will implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be taken to manage the FCOI going forward.

- Whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a FCOI management plan, MRN shall, within 120 days of the determination of noncompliance, 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 noncompliance, was biased in the design, conduct, or reporting of such research. MRN will document the retrospective review which shall include all of the following key elements: (1) Project number; (2) Project title; (3) PI or contact PI if a multiple PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a FCOI; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review. The findings should note the following:
  - Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
  - Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amts between $20K-$100K by increments of $20K; amts above $100K by increments of $50K or a statement that a value cannot be readily determined;
  - A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research.

Based on the results of the retrospective review, if appropriate, MRN shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, MRN will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and MRN'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).

**Participation in Business Negotiations.** No investigator having a significant financial interest in a commercial or non-profit organization outside MRN may participate in negotiating the terms and conditions of any agreement between MRN and that organization on behalf of either party.

**Participation in Administration of Agreements.** No investigator having a significant financial interest or a management position in a commercial or non-profit organization outside MRN may have primary responsibility for administering an agreement between MRN and that organization on behalf of either party.

**Clinical Trial Investigators.** No one may participate as a PI in a clinical trial sponsored by a start-up commercial or non-profit organization in which he or she has any equity or intellectual property interest, holds a management position, or serves on the organization's Board of Trustees.

**Financial Interests in Competitors and Competitive Products.** Investigators shall be considered as having a financial interest for the purposes of this policy if they have any interest of economic or monetary value in a business that produces a competing product that could reasonably appear to affect or to be affected by the particular research activity under consideration.
Clinical Trials of MRN or MRN Technology. No person shall participate in a clinical trial involving technologies licensed by MRN if that person has a substantial equity interest in the licensee or intellectual property interest in the technology without a full conflict of interest review and implementation of the management plan. When MRN has either a substantial equity interest in the licensee or an intellectual property interest in the technology, funding for clinical trials will not be accepted without a full conflict of interest review and a review of the management plan being implemented.

Conflicting Management Roles in Outside Organizations. No person may simultaneously serve in key management positions for both MRN and an outside organization on the same research project. For purposes of this guideline, key management positions shall include PI and any other role in which the person has the authority to make or recommend significant business, contractual, or financial decisions relating to the research project. In no event may an investigator act as PI for both MRN and an organization contracting with MRN with respect to a research project unless another MRN employee, not in a direct reporting relationship to the conflicted investigator, has been designated by MRN to be responsible for all business, contractual, and financial decisions relating to the outside organization.

Compliance with Federal Regulations. All research activity undertaken at MRN shall be conducted in compliance with the following federal regulations:

- U.S. Department of Health and Human Services’ Objectivity in Research Regulations 42 CFR part 50 subpart F (grants) entitled “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought”
- 42 CFR part 94 (contracts) entitled “Responsible Prospective Contractors”

Management Plan and Closing Letter. The FCOI Official in consultation with the investigator, if appropriate, shall determine, first, if a management plan is required, and if so, the terms, conditions and restrictions, that are required as part of a Management Plan. The management plan shall be conveyed in a closing letter with copies to the CEO, CFO, President and other persons deemed appropriate. Copies of COI management plans will be provided to the MRN Research Committee for the purpose of internal departmental review and also to the appropriate IRB office for consideration.

Management Plans should, at a minimum, include:

- Role and principal duties of the conflicted Investigator in the research project;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the investigator’s agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance;
- Other information as needed.

The Management Plan may require that one or more of the following actions are taken in order to manage, reduce, or eliminate a potential conflict of interest:

1. Disclosing Significant Financial Interests, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
2. Monitoring of research by independent researchers and/or reviewers, unbiased individual or committees;
3. Placing copies of research data with a neutral party;
4. Disqualifying specific individuals from participation in all or a portion of the research;
5. Requiring that the Significant Financial Interest be divested, restructured, or placed in blind trust;
6. Modifying or severing the relationships that create potential conflicts of interest;
7. Changing terms of agreement relating to the research;
8. Requiring that Investigator participation in the recruitment or consent of subjects in human subject research be prohibited or restricted;
9. Requiring non-participation in any business transactions between MRN and parties to agreements involving sponsored research.

All investigators subject to a Management Plan shall report annually or more frequently if required by a management plan. These reports shall be provided directly to the FCOI Official.
MRN shall take such actions as deemed reasonable to audit and/or monitor compliance with Management Plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connections with such Management Plans.

**Subcontractor Compliance.** MRN’s subcontractors are required to notify the ORC of the existence of any conflicting interest identified by the subcontractor. Subcontractors must certify and ensure that any reported conflicting interest has been managed, reduced or eliminated in accordance with 42 CFR Part 50 and/or 42 CFR Part 94.

If a subcontractor identifies a conflicting interest subsequent to the initiation of the subcontract, the following actions must be performed within forty-five (45) days of identification of the interest:

1. The subcontractor must notify ORC of the conflicting interest;
2. The conflicting interest must be managed, reduced or eliminated in accordance with 42 CFR Part 50 and/or 42 CFR Part 94.

The ORC will notify the FCOI Official of any conflicting interests identified by a Subcontractor and of any assurances provided by the subcontractor. The FCOI Official will notify the PI and if appropriate, the IRB, of any conflicting interests identified by a subcontractor. The PI and FCOI Official will determine whether continued participation by the subcontractor is appropriate, and may seek consultation of the funding agency if appropriate.

**Summary Disposition Procedures.** The FCOI Official may implement reasonable and appropriate summary procedures for the disposition of matters involving compliance with this policy. These may include written approvals for annual reports, renewals, and no-cost extensions where the FCOI Official reasonably determines that the facts and circumstances pertaining to the matter being approved have not materially changed since the date of the original review and approval. All such summary approvals shall be documented.

**Annual Management Plan Reporting.** All Investigators and inventors subject to a Management Plan shall report annually or more frequently if required by a management plan. These reports shall be provided directly to the FCOI Official.

**Sanctions and Remedies for Violation of Policy.** Whenever a person has violated this policy, including failure to submit a required report of financial interests or failure to comply with the requirement of a management plan, FCOI Official shall report violators to the President/CEO. The President/CEO shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to:

1. suspending expenditures on a research account,
2. instituting disciplinary measures to include suspension or termination, and
3. other actions deemed necessary.

If criminal conduct has been detected, MRN shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making necessary modifications to this policy.

**Record Keeping.** All SFI Reports submitted to FCOI Official will be treated confidentially. Records of/related to SFI reporting shall be retained by the FCOI Official for a period of no less than three (3) years after the date of submission of the final expenditures report to PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

**Federal Reporting.** Prior to the expenditure of any funds under an award, annually and following a retrospective review, the FCOI Official shall disclose to the PHS Awarding Component the existence of any reported SFI which requires reporting according to 42 CFR Part 50. The FCOI Official will ensure the PHS Awarding Component that the interest has been managed, reduced, or eliminated in accordance with 42 CFR Part 50. Any disclosure of conflict of interest received from a subrecipient will be reviewed by the FCOI Official and sent to the appropriate NIH-awarding entity as required by regulation.

When any SFI (as defined by 42 CFR Part 50) is identified after the initial report under an award, within 60 days of that identification the interest will be managed, reduced, or eliminated and an updated disclosure will be made to the PHS awarding component in accordance with 42 CFR Part 50.
The PHS Awarding Component will be promptly notified if:
- bias is found with the design, conduct, or reporting of PHS-funded research including a mitigation report, if deemed appropriate; or
- an Investigator fails to comply with this policy or an established FCOI management plan.

Auditing and Oversight. The FCOI Official shall take such actions as deemed reasonable to audit and/or monitor compliance with Management Plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with Management Plans.

Public Accessibility. MRN’s FCOI policy will be posted on the Institution’s public website. Information for any identified FCOIs of senior/key personnel that is related to PHS-funded research will be made available, upon request, within 5 calendar days of a written request for information. This information shall 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 significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible; e.g. $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, if appropriate. This information will remain available for three (3) years from the date the information was most recently updated.

GENERAL CONFLICTS OF INTEREST

External Activities. Employees should generally not engage in private employment outside their official working hours or accept consultantships if such employment will:
- Compete with any research work conducted at or by MRN;
- Interfere with the proper and effective performance of the duties of their MRN position;
- Create or appear to create a conflict of interest situation;
- Subject MRN to public criticism or embarrassment.

See below for further clarification.

Generally Permissible External Activities. Permissible external activities are divided into two categories.

*Category I* activities are generally allowable, and are accepted as integral to an employee’s professional growth. These activities constitute a public service that is recognized as beneficial to MRN, as well as to the individual employee. Employees are encouraged to pursue *Category I* activities if their MRN duties permit. In general, these activities are uncompensated, are performed on an employee’s own time, and represent readily manageable commitments, within the framework of full-time employment. Examples include:
- Serving on a federal, state, or local government agency, committee, panel, or commission;
- Serving as a committee member or as an officer of a professional society;
- Reviewing journal manuscripts, book manuscripts, or grant/contract proposals;
- Presenting talks to community organizations or academic lectures to students.

*Category II* activities are unlikely to raise issues of conflict of commitment and are ordinarily allowable compensated and/or uncompensated external activities. These are activities do not typically represent MRN and are understood to be pursued on an employee's own time. If compensated, MRN FCOI requirements apply with respect to reporting. Examples include:
- Providing consulting services or engaging in professional practice where such activities are through the employee’s single-member professional corporation or sole proprietorship. Providing such services through other entities, such as an employee of another entity, is a *Category III* activity (addressed below);
- Serving on the board of directors of an outside entity;
- Acting in an editorial capacity for a professional journal;
- Providing expert testimony in administrative, legislative, or judicial proceedings;
- Developing scholarly communications in the form of books, movies, television productions, and similar works, including those that result in financial gain.
External Activities That Are Ordinarily Not Permitted or That Require Prior Approval. Category III activities are compensated outside professional activities, which common sense and good judgment would indicate are likely to raise issues of conflict of commitment or conflict of interest. Therefore, such activities will not be permitted; or, they will only be approved in conjunction with a conflict of commitment mitigation plan. Examples include:

- Serving as a salaried employee with a non-MRN entity. This does not include consulting for or serving on the board of directors of an outside entity, as addressed under Category II.
- Conducting a contract or grant outside the MRN that would ordinarily be administered under the auspices of the organization.

Managing External Activities. Employees in part-time status, less than 0.75 FTE, may accept outside employment (Category III external activity) that does not create a conflict of commitment, conflict of interest, SFI, or interfere with their professional obligations to MRN. Outside employment engagements must be coordinated in advance between an employee and MRN management and the arrangements fully documented in writing.

Category I or II activities that result in the award of an honorarium to the employee are allowable, but must be reported as indicated in this policy. This policy does not apply to activities that are conducted as part of a joint venture between the employee and MRN. In such cases, a written agreement will establish the responsibilities of each party, as well as sharing of costs and profits.

When contemplating opportunities for compensated non-MRN work, such as consulting to a business organization, employees are encouraged to consider coordinating potential engagements as a contract through MRN. Depending on the variables of an employee’s particular MRN commitments and the requirements of financial sponsors, efforts beyond 1.00 FTE may possibly be accommodated. For instance, employees may work up to 1.20 FTE, so long as their level of effort on certain federal awards does not exceed 0.99 FTE. Office of Research Contracts’ staff can provide a definitive level-of-effort determination for specific situations. Standard MRN business provisions will apply to such arrangements, consistent with organization’s normal practices for similar activities. Discussion with and approval by the MRN Chief Executive Officer is required.

External activities not related to MRN responsibilities shall take place outside of the employee’s designated work schedule or during periods of authorized paid time off (PTO).

Employees shall make clear that, when engaging in Category II and Category III external activities, they are acting and speaking in their individual capacity and not as representatives or agents of the MRN, as appropriate.

Employees shall not disclose any non-public or proprietary information concerning MRN’s operations (e.g. information categorized as MRN Proprietary, Privileged, or Trade Secret in the Information Security Policy), except that this provision shall not affect any person’s right to report suspected illegal activity under applicable law.

Use of MRN Resources. Although MRN permits employees to engage in external activities, use of any MRN resources in the furtherance of such outside employment is strictly prohibited. This prohibition is in line with MRN’s stewardship obligations to prevent use of resources acquired through federal sponsorship for personal benefit or gain. Attachment A provides examples of prohibited use of resources.

Exception: MRN may choose to allow use of resources for selected activities judged to advance or be compatible with the organization’s mission. Requests of use of resources may be submitted by either internal or external entities. They must be made in writing to the Research Operations Department (researchops@mrn.org). Requests will be reviewed by the Executive Committee and a determination made based on the following criteria:

- Nature of the requesting organization (generally, only nonprofit entities will be eligible);
- Purpose of activity and the potential to advance MRN aims;
- Whether MRN employees can participate in the activity and the benefit of that participation;
- Potential impact of activity on MRN operations and staff.

All requests will receive a written reply, either approval or disapproval (with an explanation). Attachment B provides an expanded discussion of allowed uses through this exception.
This is a copy of the official, signed Policy on file.

Allowable Use of Resources – De Minimis Uses by MRN Employees. Employees may use their personally-assigned MRN resources on a limited basis for personal benefit, so long as the requirement is incidental, there is little or no cost to MRN, and it does not disrupt other employees, or cause other employees to make unauthorized use of resources. Attachment C provides a more complete listing of allowable use of resources.

Use of office supplies, other consumables, copying and printing for personal purposes does not fall under the de minimis provisions; their use creates an expense for the organization that is at odds with MRN’s care requirements for property.

Employees seeking consideration under de minimis use for a more than incidental requirement -- for instance a student using their MRN-assigned computer after hours to prepare a term paper -- should make their request in advance of the requirement to their supervisor or, in the absence of this individual, to the CEO. Requests will be considered in light of MRN’s overall stewardship obligations and those found to avoid waste or improper use of resources will be approved. Although each and every request need not be formally documented, individuals charged with supervising others should do so actively, making sure those who are supervised have an adequate understanding of their obligations and are meeting these obligations with respect to allowable use of resources. The concept of de minimis use has no application to outside professional work; employees engaging in outside work may not draw upon MRN resources to enable or advance performance of work for non-MRN entities.

Reporting Violations of Policy. Employees who are aware of or have reason to suspect a violation of this policy should report the situation as soon as possible. Reports can be made to their supervisor, unless there is reason to believe the supervisor may be involved with the possible violation. As an alternate, it is appropriate to make reports to the IO under the policy for Reporting of Non-Compliance with Laws, Regulations, or Organization Policies.

It is the responsibility of MRN management to address all reports of variances from policies. Additionally, MRN management must address perceived conflicts of commitments that may result from employee activities. Such conflicts are readily recognized in the apparent reduction of an employee’s time and energy devoted to MRN activities.

Disciplinary Action. Employees who violate published MRN policies with respect to external work, use of MRN resources, or conflict of interest are subject to appropriate disciplinary or corrective action, including termination.

REFERENCES:

Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)
Responsible Prospective Contractors (45 C.F.R. Part 94)

REVISION HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVISION</th>
<th>DESCRIPTION OF CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/12/2012</td>
<td>0</td>
<td>Original Release</td>
</tr>
</tbody>
</table>
This is a copy of the official, signed Policy on file.

Attachment A. Responsibility Matrix

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>• Report Significant Financial Interests using the Conflict of Interest Disclosure Form under the following circumstances: (a) when a proposal for a research project is submitted to the OCR, (b) when a Significant Financial Interest arises during the course of research, and (c) annually.</td>
</tr>
<tr>
<td></td>
<td>• Identify all investigators who share responsibility for the design, conduct or reporting of a project, and are required under this policy to report significant financial interests.</td>
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<tr>
<td></td>
<td>• Ensure investigators submit their disclosure forms.</td>
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<tr>
<td></td>
<td>• Ensure investigators’ prompt reporting of new or increased SFI.</td>
</tr>
<tr>
<td></td>
<td>• Ensure newly hired or transferred Investigators submit disclosure forms.</td>
</tr>
<tr>
<td></td>
<td>• If subject to a management plan, comply with this plan and provide an annual report (or more frequently, if required) directly to the FCOI Official.</td>
</tr>
<tr>
<td>Investigators</td>
<td>• Report Significant Financial Interests using the COI Disclosure Form under the following circumstances: (a) when a proposal for a research project is submitted to the ORC, (b) within 30 days of when a Significant Financial Interest arises during the course of research, and (c) annually.</td>
</tr>
<tr>
<td></td>
<td>• Prompt reporting of new or increased SFI to the FCOI Official.</td>
</tr>
<tr>
<td></td>
<td>• If subject to a management plan, comply with this plan and provide annual report (or more frequent, if required) to the FCOI Official.</td>
</tr>
<tr>
<td>Office of Research Contracts (ORC)</td>
<td>• Notify FCOI Official of any SFI indicated on disclosure forms.</td>
</tr>
<tr>
<td></td>
<td>• Notify FCOI Official of any indicated changed SFI status on disclosure forms.</td>
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<tr>
<td></td>
<td>• Place hold on all project accounts in which a report was made until notified by FCOI Official that the potential conflict was eliminated, reduced, or otherwise adequately managed.</td>
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<td></td>
<td>• Obtain notification of any existing conflicting interest identified by subcontractors and obtain written assurances from subcontractors that SFIs have been disclosed and managed.</td>
</tr>
<tr>
<td></td>
<td>• Notify FCOI Official of both subcontractor conflicting interests and subcontractor assurances.</td>
</tr>
<tr>
<td>FCOI Official</td>
<td>• Review MRN SFI reports.</td>
</tr>
<tr>
<td></td>
<td>• Determine the terms, conditions, and restrictions, if any, that are required as part of a management plan.</td>
</tr>
<tr>
<td></td>
<td>• Provide President/CEO and CFO with notification of any management plans put into place.</td>
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<tr>
<td></td>
<td>• Provide FCOI reports by an MRN subcontractor to the PI for review.</td>
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<td></td>
<td>• Retain records on reports for a period of no less than three (3) years.</td>
</tr>
<tr>
<td></td>
<td>• Take actions as deemed reasonable to audit and/or monitor compliance with management plans.</td>
</tr>
<tr>
<td></td>
<td>• Report violations of this policy, including failure to make a required report of financial interests or failure to comply with the requirements of a Management Plan to the President/CEO of MRN.</td>
</tr>
<tr>
<td>President/CEO (or his/her designee)</td>
<td>• Institute appropriate sanctions or discipline for investigators or inventors violating this policy.</td>
</tr>
</tbody>
</table>
Attachment B. Prohibited Use of MRN Resources for non-MRN activities

Although MRN permits employees to engage in outside professional work, use of MRN resources in the furtherance of such non-MRN activities is strictly prohibited. Examples of prohibited use include:

- Using MRN laboratories, laboratory supplies, equipment, or hardware to conduct experiments or carry out projects for outside work;
- Using MRN cost centers (i.e., services for which there is a charge) for tests, assays, or analyses that are part of an outside work assignment for free;
- Transferring or using MRN-owned intellectual property and/or data as part of an outside work assignment (See MRN's Intellectual Property Policy);
- Using MRN supplies/consumables to conduct outside work;
- Obtaining assistance from other MRN employees to carry out or discuss an outside work project.

Attachment C. Exception to Prohibited Use of MRN Resources for non-MRN activities

As stated in the policy, MRN may choose to allow use of resources for selected activities judged to advance or be compatible with the organization's mission. Examples of potential exceptions to prohibited uses include:

- Using an MRN conference room for a CPR class for an outside non-profit organization, which MRN employees can attend;
- Allowing a collaborator to use an MRN conference room to conduct an interview with members of the media on topics that help inform the community about neuroscience research;
- Allowing school groups to tour MRN laboratories to promote educational objectives.

If there is doubt about the applicability of an anticipated activity, employees should consult the CEO for guidance.

Attachment D. Allowable Use of Resources

Employees may use their personally-assigned MRN resources on a limited basis for personal benefit, so long as (1) there is little or no additional cost to MRN; (2) any use is reasonable in duration and frequency; (3) the use does not interfere with the performance of the official duties of either the employee, or other employees; (4) the use does not disrupt or distract from the conduct of MRN business due to volume or frequency; (5) the use does not disrupt other employees and does not obligate them to make unauthorized uses of resources; (6) the use does not compromise the security or integrity of property, information, or software; and (7) the use does not violate any other MRN policy.

The following are examples of limited uses of resources for approved outside work by employees that are permitted under this policy if reasonable in duration, frequency, and impact on business operations:

- Using a personally-assigned MRN computer and email account to perform online banking during a lunch break;
- Doing research of personal interest after work hours using MRN Internet access, providing no additional charges are incurred;
- Drafting a letter after work hours using a personally assigned computer.

Note: Employees should be aware, consistent with MRN's Computer Services Policy, MRN has the right to monitor and review any activity on its resources. Personal business of a truly confidential nature should not be conducted on MRN-owned equipment.