NIH FCOI Policy

07/01/2021

**UPDATED**

**RAM Medical Innovations, Inc. Company-Wide Policy: Government Awards Financial Conflict of Interest Disclosures**

Reference # RAMFCOI001

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| Updated On: | July 1, 2021 |
| Next Review Date: | June 30, 2024 |
| Approval Date: | July 1, 2021 |
| Approved By: | Mubin Syed  |

# PURPOSE AND SCOPE:

# RAM Medical Innovations, Inc. (“RAM”) strives to create a research climate that promotes objectivity in research by establishing standards such that the design, conduct and reporting of Public Health Service (PHS), including NIH, and/or Government Award funded research is free from bias resulting from financial conflict of interest (FCOI). Further, RAM strives to ensure that all PHS- and Government Award-funded research meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could harm patients, the reputation of RAM, the governmental agency providing the funding, and/or external partners.

# As RAM must comply with government regulations when making expenditures with Government Awards, this policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards. This policy is intended to comply with the requirements of federal regulations, including , but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (the “PHS FCOI Rules”) as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the “Financial Conflict of Interest Rules”).

This policy applies to all RAM personnel, including employees, sub-recipients, consultants, or any other covered organizations or persons, who are planning to or are participating in research activity that is either partially or wholly supported by PHS funds. All personnel must:

1. Disclose any significant financial interests (SFI) in non-RAM entities that would appear to be related to his or her professional responsibilities on behalf of RAM;
2. Comply with RAM’s Management Plan, if a FCOI is identified; and
3. Undergo FCOI training, at least once every four years.

Disclosure of SFI is essential for RAM to determine if an FCOI exists, and, if an FCOI exists, to assess how the FCOI will be managed and reported in full compliance with government regulations.

Capitalized terms used herein have their assigned meanings or the meanings assigned in Section 2 below.

# DEFINITIONS: The following terms have their assigned meanings:

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| ***Management*** ***Plan***:  | The document specifying the actions to be taken to manage a Financial Conflict of Interest consistent with government regulations.  |
| ***External Partner***:  | A consultant, subcontractor, or sub-recipient performing work under a Government Award who is not employed by RAM. |
| ***Financial Conflict of Interest (FCOI***):  | A significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project. |
| ***Government Award***:  | Government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that RAM receives directly from government agencies or indirectly from pass through entities. Government Awards do not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)). |
| ***Immediate Family Member***:  | A spouse, domestic partner, child or step-child, parent or step-parent, or sibling or step-sibling. |
| ***Investigator:*** | 1. For PHS-funded research: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
2. For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.
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| ***Institutional Responsibilities*:**  | An Investigator’s professional responsibilities on behalf of RAM, which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. |
| ***Public Health Service (PHS*):**  | A division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA). |
| ***Research:***  | 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. |
| ***Remuneration*:**  | Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships). |
| ***Significant Financial Interest (SFI):*** | Anything of monetary value, whether the value is readily ascertainable, that: 1) is related to the Investigator’s Institutional Responsibilities, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committed memberships, and service on panels; and 2) belongs to the Investigator or any Immediate Family Member of the Investigator. |

# POLICY:

It is the policy of RAM to comply with the Financial Conflict of Interest Rules to ensure that the work performed under Government Awards is carried out in a manner that is free from any bias which may result from financial conflicts of interest. All Investigators for Government Awards must disclose any Significant Financial Interests (SFI) to RAM Investigators, must complete or update a disclosure survey at least annually during the period of the award, and must disclose any new SFIs within thirty (30) days of discovering or acquiring the SFI. Investigators also must ensure that the disclosure survey is completed or updated no later than the time of application for a Government Award.

***Significant Financial Interest***

The following Significant Financial Interests must be disclosed:

* With regard to any publicly traded entity, 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); 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.
* With regard to any non-publicly traded entity, 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 Immediate Family Member) holds any equity interest (e.g., stock, stock option, or other ownership interest).
* Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
* 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. The disclosure will include, at a minimum, the following details: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) the trip duration. (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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.).

Significant Financial Interests do not include:

* Financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet both of the following tests:
	+ The financial interest does not exceed $5000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
	+ The financial interest does not represent more than a five percent ownership interest in any single entity.
* Salary, royalties, or other remuneration from RAM (or the institution that currently employs any non-RAM key personnel)
* Salary, royalties, or other payments that, when aggregated for the Investigator and his/her Immediate Family Members, are not expected to exceed $5,000 during the next 12 month period.
* 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.
* 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.
* 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.
* Unlicensed intellectual property owned by the Investigator that does not generate income. Note that Intellectual property owned by RAM is excluded.

An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest.

## Disclosure Review; Sponsored Projects Administrator; Research Compliance Oversight Committee (RCOC)

If the Sponsored Projects Administrator determines that an SFI constitutes a Financial Conflict of Interest (FCOI), RAM will establish and monitor a Management Plan to manage or eliminate the conflict of interest. RAM has nominated a Sponsored Projects Administrator to serve as the conflict of interest institutional official. The Sponsored Projects Administrator shall be responsible for managing RAM’s conflict of interest policy for Government Awards and soliciting and reviewing disclosures of SFIs.

RAM has further established a Research Compliance Oversight Committee (RCOC) to act as the Conflict of Interest Committee for purposes of Government Awards. The RCOC will regularly evaluate compliance with this policy and will review the effectiveness of the Sponsored Projects Administrator’s conflict of interest management program, including a review of the implementation and effectiveness of these procedures.

No Government Award funds may be expended unless the Sponsored Projects Administrator has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of a Management Plan that has been adopted and implemented in accordance with the procedures set forth in this policy.

## Duty to Cooperate

If the Conflict of Interest Official requests additional information from an Investigator to assess whether a SFI constitutes a Financial Conflict of Interest (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a Management Plan is implemented in connection with a SFI, the Investigator must comply with the Management Plan. Compliance with the requirements of this policy is a condition of employment with RAM for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

## Education

Investigators must complete training regarding this policy and the applicable regulations at the following times: (i) upon becoming an Investigator for RAM; (ii) before performing work under a Government Award; (iii) when this policy is revised to alter the responsibilities of an Investigator; (iv) and at least every four years.

## Public Posting of Policy; Public Accessibility

This policy will be posted on a publicly accessible Internet site for RAM at <http://www.rammedicalinnovations.com/about>

Further, RAM makes available information concerning identified FCOIs held by senior/key personnel (as defined in the applicable regulations), public accessible prior to expenditure of funds. The information will: (a) include the minimum elements provided in the regulations, (b) be posted on a public website or made available within 5 days of a written request, (c) be updated, at least annually, (d) be updated, within 60 days of a newly identified FCOI, and (e) remain available in accordance with RAM’s document retention policy as contained herein.

## Reporting of Financial Conflicts of Interest for PHS-Funded Projects

The Sponsored Projects Administrator will ensure that an appropriate Management Plan has been implemented. Before the expenditure of any funds under a PHS-funded project and within sixty (60) days of subsequently identifying a Financial Conflict of Interest, the Sponsored Projects Administrator will report to the PHS awarding component all Financial Conflicts of Interest that have not been resolved. The report will include the elements required under the Financial Conflict of Interest Rules. For subsequently identified FCOIs, the Sponsored Projects Administrator will conduct a retrospective review to determine whether the PHS-funded project was affected by the financial conflict of interest, and if bias is found, will submit a mitigation report to the PHS awarding component. The Sponsored Projects Administrator also will provide an annual FCOI report that addresses the status of any previously reported FCOIs and Management Plans related to an ongoing PHS-funded project.

As a part of the Management Plan, the Sponsored Projects Administrator will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Personnel with an identified FCOI must comply with the Management Plan.

## External Partners

Any individual or organization acting as an External Partner to RAM on a PHS-funded award must either: (1) have an FCOI policy that meets the requirements of the Financial Conflict of Interest Rulesor (2) follow this policy.

* Organizations with their own policy will certify that the policy meets the requirements of the Financial Conflict of Interest Rules by submitting an External Partner Financial Conflict of Interest Disclosure form or registering with the FDP Clearinghouse <https://fdpclearinghouse.org/> before submission of the Government Award. The Sponsored Projects Administrator will verify registration with the FDP Clearinghouse before submission. The contract with RAM will contain language requiring compliance with the organization’s FCOI Policy.
* External Partners without their own FCOI policy are required to follow this policy. The contract with RAM will contain language requiring compliance with RAM’s Government Awards FCOI Policy.

## Procedure

This procedure is for use by RAM personnel (including External Partners that do not have their own FCOI policy).

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| **Step** | **Who** | **Action** |
|  | Investigators | * Before the expenditure of funds under a Government Award, Investigators must complete the training on RAM’s Government Awards FCOI Policy.
* All external investigators must complete FCOI training required under the policy.
* Training can either be completed using the NIH FCOI tutorial found at: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> or CITI COI training found at: <https://about.citiprogram.org/en/homepage/> .
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|  | Investigators | * Training must be documented by submitting the Government Award FCOI Training Certification form to the Sponsored Projects Administrator.
* The required training is valid for four years; however, Investigators are required to certify annually that they understand and have complied with their responsibilities under RAM’s Government Awards FCOI Policy.
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|  | Investigators | * After the training is completed, the Investigator will complete the Government Award FCOI Questionnaire. This survey must be completed no later than the time of application for a Government Award and before any funds are expended. It also must be updated as required by the policy.
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|  | PI | * The principal investigator/project director will complete the Government Award Approval form, which requires verification that those meeting the definition of Investigator and External Partners have been informed of the requirement to comply with this policy.
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|  | Investigator | * The Investigator must report and update their Government Award FCOI Questionnaire when he/she is a recipient of sponsored travel. The Investigator will disclose: the purpose of the trip; the name of the entity that paid for the travel; the travel destination; the duration of the trip; the dates of the travel; and if known, the approximate value of the Sponsored Travel.
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|  | Sponsored Projects Administrator | * The Sponsored Projects Administrator will receive and review all Investigator SFI disclosures.
* The Sponsored Projects Administrator will determine if any SFIs related to PHS-funded research.
* The Sponsored Projects Administrator will determine if an FCOI exists.
* If the Sponsored Projects Administrator determines a FCOI exists, he/she will create a draft Management Plan. The draft Management Plan will be presented to the Research Compliance Oversight Committee (RCOC) for consideration and approval. The RCOC will act as the Conflict of Interest Committee for purposes of Government Awards.
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|  | Sponsored Projects Administrator | * The actions taken by the RCOC will be documented in the RCOC meeting minutes. The Sponsored Projects Administrator will ensure that Management Plans are properly implemented and will monitor compliance with Management Plans on an ongoing basis. The RCOC will review the status of established Management Plans at intervals determined by the RCOC and indicated in the Management Plan, and will have oversight responsibility for the enforcement of Management Plans and compliance with this policy.
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|  | Investigator | * Each Investigator under a Management Plan must comply fully and promptly with the Management Plan, and each person identified in the Management Plan as having responsibility for monitoring compliance with the Management Plan must carefully and fully monitor that compliance.
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|  | Sponsored Projects Administrator | * For PHS-funded projects, the Sponsored Projects Administrator will disclose the FCOI and Management Plan to the PHS awarding component before the expenditure of any federal funds.
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|  | Sponsored Projects Administrator / RAM | * For PHS-funded projects, RAM will make FCOI information available to those who submit a request by sending an email to mubinsyed@aol.com or by writing the Sponsored Projects Administrator at the address below. Responses will be sent within five business days.
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|  | Sponsored Projects Administrator / RAM | * RAM will keep records related to FCOI and the related Management Plan for the longer of at least three years after:
	+ the date of creation;
	+ the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement;
	+ the date of final resolution of any investigation, audit, or similar action involving the records;
	+ the date required to be in compliance with RAM’s Record Retention policies; or
	+ The other dates specified in 45 CFR 75.361, where applicable.
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|  | RCOC  | RCOC will regularly evaluate compliance with this policy and will review the effectiveness of the Sponsored Projects Administrator’s conflict of interest management program, including a review of the implementation and effectiveness of these procedures. |
|  | RCOC | The RCOC will send initial, annual, and revised FCOI reports, including all reporting elements required by applicable regulations, to the NIG for the Institution and its sub-recipients, if applicable, as required by the regulations. Reports should be considered, consistent with applicable regulations, (a) prior to expenditure of funds, (b) within 60 days of identification for an Investigator who is newly participating in the project, (c) within 60 days for new, or newly identified, FCOIs for existing Investigators, (d) at least annually to provide the status of the FCOI and any changes to the Management Plan, if applicable, until the completion of the project, and/or (e) following a retrospective review to update a previously submitted report, if appropriate. |
|  | Sponsored Projects Administrator / RAM | The Sponsored Projects Administrator must promptly notify NIH if bias is found with the design, conduct, or reporting of NIH-funded research and submit a Mitigation Report in accordance with the regulations. |
|  | Sponsored Projects Administrator / RAM | The Sponsored Projects Administrator must promptly notify NIH if an Investigator fails to comply with this policy or a Management Plan appears to have biased the design, conduct, or reporting of the NIH-funded research.  |

**Sponsored Projects Administrator Procedure for External Partners with their own PHS Rule policy**

1. The principal investigator/project director will complete the Government Award Approval form, which requires them to inform any External Partner if they need to comply with the Financial Conflict of Interest Rules.
2. Prior to any application submitted by RAM for a Government Award, the Sponsored Projects Administrator must receive confirmation the External Partner has a FCOI policy that meets the Financial Conflict of Interest Rules.
3. The External Partner will have two options to verify they have a FCOI:
	1. Register with the FDP Clearinghouse, <https://fdpclearinghouse.org/>. At this time, this website is acting as a central registration location for many colleges. RAM will accept this method of verification. Registration is free and you may contact the Sponsored Projects Administrator if you have questions.
	2. Submit the External Partner Financial Conflict of Interest Disclosure.

# ENFORCEMENT

# Personnel may be subject to discipline, including without limitation termination, for non-disclosure of SFI or non-compliance with this policy.

# The Sponsored Projects Administrator shall complete and document retrospective reviews within 120 days of RAM’s determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulations.

# In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported as required by the regulations, the Investigator involved must (a) disclose the FCOI in each public presentation of the results of the research and (b) request an addendum to previously published presentations.

# AMENDMENT/TERMINATION

This policy may be amended or terminated at any time. Here is the revision history

# CONTACT INFORMATION

If you have questions regarding this policy, please contact:

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