

Company Name	MGS
Process/Policy Name	Financial Conflict of Interest
Purpose	Establish guidelines for disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Federal grant-funded research
Scope	Applies to Federal grant-funded research
Last Update	January 2021 – Effective Immediately

Policy & definitions

MGS (the Company) is committed to ensuring that research is conducted with the highest scientific and ethical standards and without bias. This policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest (FCOI) in Federal grant-funded research. The Company has created this written and enforced policy to identify and manage FCOIs with respect to Federal grant funds received or sought. It is intended to comply with the requirements of

- 42 Code of Federal Regulations (CFR) CFR 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*, as implemented in the 2011 Final Rule for grants and cooperative agreements
- 45 CFR 94, *Responsible Prospective Contractors*

MGS will promote and enforce investigator compliance with the above named regulations’ requirements. The Company will identify and manage FCOIs and provide initial and ongoing FCOI reports to NIH, as appropriate. When requested, the Company will promptly make information available to NIH relating to any investigator disclosure of financial interests and the Company's review of, and response to, such disclosure, whether or not the disclosure resulted in the Company's determination of an FCOI.

An FCOI is defined to be the significant financial interest (SFI) of an investigator that could directly and significantly affect the design, conduct, or reporting of research. SFI exists if the value of remuneration received by the individual and individual’s spouse or dependent children that reasonably appear to be related to the individual’s Company responsibilities exceeds, or will potentially exceed, \$5,000 in aggregate.

An "investigator" is someone:

- Defined as the Principal Investigator (PI) and any other person, regardless of title or position
- Who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding
- Which may include collaborators, consultants, contractors, etc.

This policy is applicable to each individual who is planning to or is participating in research activity that is either partially or wholly supported by Federal funds. Each such individual must:

- Disclose his or her SFIs in non-MGS entities that are related or could be potentially related to the individual's professional responsibilities on behalf of MGS
- Comply with a FCOI management plan, if a FCOI is identified
- Undergo FCOI training at least once every four years

Collaborators, consultants, or contractors receiving Federal grant compensation from MGS in excess of \$5,000 in aggregate are also subject to this policy.

The Company will incorporate in its written agreements with subrecipients terms that

- Establish whether the FCOI policy of the Company or that of the subrecipient will apply to subrecipient investigators
- Include time periods to meet disclosure and FCOI reporting requirements (so that the Company is able to effectively meet its own timely reporting requirements to NIH)

Each investigator will receive FCOI training prior to engaging in NIH-supported research and at least every four years. Additional training and inquiry of investigators for nondisclosed potential significant financial interests will be completed as necessary.

This policy will be made publicly available on MGS's website and updated within 30 days when revisions occur. Policy revisions are communicated to identified investigators immediately.

Disclosure of individual financial interests

Ultimate determinations and communications of investigator status are the responsibility of the PI for each grant. The determination is made and documented prior to incurring any costs for a new grant and continues throughout the life of the grant. If any of following questions can be answered "YES" for individuals involved in grant spending, they are considered an investigator:

- Is the individual the PI or Co-PI or this grant?
- Is the individual responsible for the design, conduct, and/or reporting of the research?
- Is the individual responsible for the programmatic outcomes?

An FCOI Policy Compliance and Disclosure Certification is completed annually by each individual identified as an investigator. This standard form requires the disclosure of significant financial interests related to the grant research completed by the individual. Individuals are also required to immediately disclose a new or newly identified significant financial interest throughout the remainder of the year directly to the grant's PI.

Any instance of significant financial interest that is disclosed by investigators is reviewed by the CEO and evaluated to determine if an FCOI exists. Any potential financial conflict of interest that comes to the CEO's attention throughout the life of the grant, but has not been disclosed, will be discussed with the individual investigator immediately and evaluated for significance and disclosure.

Management and reporting of individual financial conflicts of interest (FCOI)

For each disclosure that is determined to be an FCOI,

- The CEO will design and ensure the implementation of a management plan to address the FCOI; investigators with an identified FCOI must comply with the management plan
 - When determining a management action plan, the following actions are considered:
 - Public disclosure of FCOI (e.g., when presenting or publishing the research)
 - Disclosure of FCOI directly to human subjects research participants
 - Monitoring of research by independent reviewer
 - Modification of the research plan
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
 - Reduction or elimination of significant financial interests (e.g., sale of an equity interest)
 - Severance of relationships that create financial conflicts
- For NIH awards, the Company will report the FCOI to the NIH awarding institute through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module
 - When reporting an FCOI, the Company will include the following information:
 - The name of the investigator with the FCOI
 - The name of the entity with which the investigator has an FCOI
 - The nature of the FCOI
 - The value of the financial interest
 - Description of how the financial interest relates to the Federally funded research and why the Company determined that the financial interest conflicts with such research
 - Description of the key elements of the Company's management plan, including
 - Role and principal duties of the conflicted investigator in the research project
 - Conditions of the management plan
 - 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 annual FCOI report will be submitted to the NIH each year within a competitive segment or until the Company reports that the FCOI no longer exists. The annual FCOI report will include the status of the FCOI originally reported and any changes to the management plan.

Noncompliance with policy

Individuals that are identified as investigators that are found to not be in compliance with this policy may be subject to discipline including, without limitation, suspension or termination of employment or contract.