International Mammalian Genome Society, Inc. Conflict of Interest Policy

Brief:

Promoting objectivity in Research is defined in 42 CFR 50 Subpart F (https://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm). The IMGS President is responsible for research-related financial conflicts of interest (FCOI). Defined in 42 CFR 50.603, (https://www.govinfo.gov/app/details/CFR-2007-title42-vol1/CFR-2007-title42-vol1-sec50-603) disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

What is a Financial Conflict of Interest (FCOI)?

Conflicts of interest in research are present when Significant Financial Interests directly affect, or could appear to affect, the professional judgment of a researcher when designing, conducting, or reporting research.

Who needs to disclose?

All IMGS investigators (Grant PI and COO) must disclose at least annually.

What is considered an SFI?

An SFI is present when any of the following are received by an Investigator or their Immediate Family Member:

- Combined income or equity exceeding \$5,000 in a publicly traded company
- Income exceeding \$5,000 or any equity in a privately held company

When do I disclose?

At proposal submission, principal investigators submit the disclosure form at the end of this document, hould a conflict be reasonably expected to:

- Have a direct and significant impact on the design, conduct or reporting of the sponsored project or
- Undermine IMGS Investigator's obligation to IMGS or to the sponsor.

Why do I need to disclose?

Federal regulations require IMGS to have policies in place to promote objectivity in research for which Public Health Service (PHS) grants or cooperative agreements are sought, <u>42 CFR Part 50</u> Subpart F, as well as to address IMGS's Conflict of Interest and Commitment.

COI COMMITTEE

The IMGS President reviews the reporting forms to determine whether a significant financial interest is related to the investigator's IMGS research and whether it constitutes an FCOI. Once an FCOI has been identified, the IMGS President recommends a management plan and implementation mechanisms for monitoring. Should the need arise, a Conflict of Interest Committee can be established.

Detailed:

Summary: The International Mammalian Genome Society (IMGS) has an obligation to the public at large to conduct its activities properly. Accordingly, the IMGS must provide clear standards aimed at preventing financial conflicts of interest from compromising its objectivity in the performance of its responsibilities. This policy on Institutional Conflict of Interest (the "Policy") concerns conflicts that arise from the IMGS's financial relationships with external entities. It is intended to provide guidance to the IMGS Investigators (Grant PI and COO) to enable them to recognize and deal with institutional conflicts of interest, both real and perceived, that may arise in the course of relationships between the IMGS as an institution and private entities outside of the IMGS.

I. CONTEXT

The COI Policy here is in regard to the IMGS and the securing of funds from, but not limited to, NIH. The Grant PI and COO are employees of other institutions, but this policy is specifically in regard to IMGS. IMGS's mission of hosting an annual conference and trainee mentoring is well served through the creation of collaborations with people and entities outside the IMGS that better enable all concerned to meet the challenges of an increasingly complex world. Collaboration, particularly where external financial sponsorship is involved, may result in the creation of inherent tensions between the IMGS's role as an independent host, and the interest of the parties to the collaboration in achieving a positive outcome. Where such tensions have or appear to have the potential to interfere with independent decision- making on the part of IMGS investigators, or to compromise the objectivity of conference decisions, the IMGS must examine whether a conflict of interest exists.

The IMGS's policy is to comply with all laws and regulations affecting its activities. This policy on conflict of interest and commitment is intended to satisfy compliance requirements and guide IMGS investigators in avoiding those situations that can result in a conflict of interest or commitment. This Policy defines institutional conflicts of interest, provides examples and sets out rules for the guidance of IMGS investigators. It is hoped that by increasing awareness of the potential for such conflicts and providing a process to address them, this Policy will both protect the integrity of the IMGS and will encourage IMGS investigators to enter into and conduct IMGS activities involving engagement with outside entities with transparency, confidence and integrity.

II. DEFINITIONS

For the purposes of this Policy, the following definitions apply.

Sponsored Projects are projects that support conference activities funded by sponsors whose funds are administered by the IMGS.

IMGS Personnel/Investigators includes the Grant PI and IMGS COO.

Conflicts of Interest in Sponsored Projects are defined in two major categories.

An <u>Individual</u> Conflict of Interest in a Sponsored Project occurs when a person engaged in the project has a professional or financial interest that might adversely affect, or appear to a reasonable person to adversely affect, the IMGS's responsibility to the public, to the safety of human subjects participating in the sponsored project, to the sponsor, or to the integrity of research, creative, and scholarly activities.

Some, but by no means all, examples of situations that may create an individual conflict of interest in a sponsored project include:

- Serving as an investigator on a sponsored project that is either sponsored by a company or related to the company's products where the investigator is receiving royalties, consulting fees, or has equity (or stock options or a future "inventor's share") in the same company.
- Issuing a subcontract for work to an outside entity in which the investigator on the sponsored project has a financial interest.
- Receiving personal payments conditioned upon a particular decision of conference venue or other conference supply.

An <u>Institutional</u> Conflict of Interest in a Sponsored Project arises when the reputational or financial interests of the IMGS, or an IMGS official acting within his/her authority on behalf of the IMGS, may influence or appear to influence processes for the design, conduct, review, reporting or oversight of the sponsored project, possibly affecting the IMGS's responsibility to the public or to the sponsor.

Examples of activities in which an institutional conflict of interest may arise include:

- Situations in which the IMGS has an equity stake in an organization seeking to support a conference.
- Situations in which the IMGS, its Presidents, or members of the Secretariat (board) have a considerable financial stake in the outcome of a sponsored project.

III. POLICY STATEMENT

The International Mammalian Genome Society (IMGS) has an obligation to the public at large to conduct its activities properly. Accordingly, the IMGS must provide clear standards aimed at preventing financial conflicts of interest from compromising its objectivity in the performance of its responsibilities. This policy on Institutional Conflict of Interest (the "Policy") concerns conflicts that arise from the IMGS's financial relationships with external entities. It is intended to provide guidance to the IMGS Investigators (Grant PI and COO) to enable them to recognize and deal with institutional conflicts of interest, both real and perceived, that may arise in the course of relationships between the IMGS as an institution and private entities outside of the IMGS.

The Policy requires that IMGS Investigators make disclosures of significant financial interests at the time a proposal for sponsored project support is developed for submission to a potential sponsor and at least annually after awarded. Furthermore, IMGS Investigators are required to make ad-hoc disclosures of any significant financial interests within 30 days from which they arise and during the period in which a sponsored project is active. Following disclosure, if a bona fide conflict of interest is determined to exist, a management plan will be developed to manage the conflict. IMGS Investigators must comply with the management plan that has been developed to manage the conflict of interest in the sponsored project.

Finally, IMGS Investigators engaged in or managing sponsored projects are required to take conflicts of interest training prior to engaging in research, at least once every four years, and immediately when any of the following circumstances apply: the IMGS revises this Policy and related procedures in ways that affect the requirements of IMGS Investigators, the IMGS finds that IMGS Investigators are not in compliance with this Policy, or the IMGS Investigators are new to the IMGS. This Policy applies regardless of where the sponsored project activities are conducted.

IV. POLICY IMPLEMENTATION

The IMGS President administers this policy, ensuring it remains consistent with federal regulations, and has primary responsibility for overseeing the process for managing conflicts of interest in sponsored projects.

Disclosure Statement. Each IMGS investigator with a perceived Conflict of Interest shall submit a disclosure statement listing all organizations with which he or she is affiliated that may be related to the financial operation of the organization and describe the nature of the affiliation, as defined below. An IMGS investigator is deemed to be "affiliated" with an organization if he or she or a member of his or her family is a director, officer, trustee, partner, employee, or agent of such organization or receives a direct or indirect financial benefit from such organization. An organization is deemed "related" to the financial operation of the society if it receives monies from the society either directly or indirectly or if it contributes monies to the IMGS. Thus, this excludes academic institutions, not-for-profit research entities, other Professional Societies. The term "family" is deemed to include an individual's immediate family and members of that person's household.

- 1. Administration. The IMGS President shall be responsible for administration of this policy. All disclosures under this policy and any amendments to such disclosures shall be directed in writing to the IMGS President. Issues under this policy shall be reported to the IMGS President for appropriate action. Information disclosed under this policy shall be held in confidence by the IMGS President except where, in the IMGS President's judgment, the best interests of the IMGS require further disclosure. The results of this review process shall be reported annually to the IMGS Secretariat by the IMGS President.
- 2. Restraint on Participation. An IMGS Investigator who is aware of or has been found to have a conflict of interest in any proposed transaction or other matter involving the IMGS shall refrain from participating in consideration of the proposed transaction. An IMGS Investigator, who is also an active Secretariat Member who is aware of or has been found to have a conflict of interest in any proposed transaction or other matter involving the IMGS

shall not vote on the matter. The minutes of the meetings of the IMGS Secretariat shall show every instance where an IMGS Investigator having a conflict of interest disclosed the same and abstained from voting on the matter.

- 3. Advance Determinations. Any IMGS Investigator who is uncertain about a possible conflict of interest in any matter may request the IMGS President to determine whether a possible conflict exists. The IMGS President may refer the question of potential conflict to counsel for an opinion before making a determination.
- 4. **Reporting to NIH.** Initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation to the NIH will be submitted via the eRA Commons FCOI Module for the Institution as required by the regulation and as stated in 42 CFR 50.604.
- 5. **Maintenance of records.** Records will be maintained for at least three years from the date the final expenditure is submitted to PHS (NIH), or, where applicable, from other dates specified in 45 CFR 75.362 for different situations.
- 6. **Enforcement Mechanisms and Remedies and Noncompliance** will be performed according to 42 CFR 50.604(j) and 42 CFR.605.
- 7. **Public Accessibility Requirements.** This policy is available at imgs.org.

V. EFFECTIVE DATE

This Policy on Managing Conflicts of Interest in Sponsored Projects shall be effective April 5, 2021.

International Mammalian Genome Society, Inc. Conflict of Interest Disclosure Statement

TO: International Mammalian Genome Society President

Your Name (printed)

FROM: **PART A: Required Training** ____ I certify that I have received and understand the contents of the IMGS policy. **PART B: Significant Financial Interest** ____ To the best of my knowledge, there do NOT exist circumstances involving me or a member of my family that may be construed as a conflict of interest within the meaning of the Conflict of Interest Policy. **PART C: Significant Financial Interest Disclosure** _I am (or a member of my family is) affiliated with the following organizations that may be related to the financial operation of the International Mammalian Genome Society (as defined in the Conflict of Interest Policy): Name of Organization Nature of Affiliation Name

Signature

Date