



## **Karamedica Inc. Financial Conflict of Interest Policy**

### **Introduction**

This document establishes policies on individual conflicts of interest. It is the policy of Karamedica, “the Company,” to ensure that personnel avoid situations in which personal interests may affect, or have the appearance of affecting, their professional judgment in exercising their duties or responsibilities, or in conducting or reporting research. This policy provides guidance to help personnel manage situations in their personal affairs, employment outside the Company’s, and financial activities that may appear to conflict with their responsibilities and to ensure the Company and its employees comply with applicable federal laws when participating in research funded by the Public Health Service (PHS). The Company’s personnel should promptly disclose the circumstances of any situation that might be covered by this policy. This policy applies to any Company member acting as Investigator or as a Senior/Key personnel on any PHS research project and any Sub-recipient of that project.

### **Procedure Statement(s)**

This procedure is designed to comply with PHS regulations (42 CFR Part 50 Subpart F, Promoting Objectivity in Research, 45 CFR Part 94, Responsible Prospective Contractors). These standards and procedures are intended to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator FCOIs. The Company’s Conflict of Interest Policy implements the requirements of these federal regulations.

### **Availability of the Policy**

The Company will maintain an up-to-date written, enforced policy on financial conflicts of interest that complies with applicable regulations, including any federal financial conflict of interest regulations. The policy will be posted and available via the Company’s publicly accessible website. The Company will inform covered individuals of the policy and of their responsibilities regarding disclosure. The Company will inform covered individuals in the event the policy is revised and updated.

### **Who is Covered by this Policy?**

The conflict of interest policy applies to members of the Board of Directors and employees that are involved in PHS-funded research projects or are applying for PHS funding.

### **Disclosure Requirements**

By the time a proposal is submitted to PHS, all investigators, senior or key personnel requesting PHS funding—whether grant, cooperative agreement, or contract—are required to have submitted to the

Company Official (CO) a Financial Interest Disclosure Form. These completed forms either indicate that the investigators, senior or key personnel, has no significant financial interests (SFI) or includes a listing of known SFIs (and those of the spouse and dependent children) in entities whose financial interests would reasonably appear to be affected by the research for which PHS funding is sought. Financial disclosures must be updated by all investigators, senior or key personnel on an annual basis during the award period or as new reportable SFIs are obtained, whichever occurs first.

### **Responsibilities**

#### **PHS-Funded Investigators/Senior/Key Personnel:**

- Must complete FCOI training prior to engaging in a PHS research project and thereafter, every four years.
- Must complete and submit to the CO a Financial Interest Disclosure Form prior to working on PHS-funded projects.
- Must update the Financial Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.
- Must follow management plan as prescribed by the CO for FCOIs.

#### **Sub-Recipient:**

- Must complete and submit to the CO a Sub-Recipient FCOI disclosure form prior to working on PHS funded projects.
- Sub-recipient organization will certify that it has a PHS FCOI compliant policy in place or that it intends to have one in place at the time of the award or that it will abide by The Company policy.
- Sub-recipient organization will certify that the investigators, senior and/or key personnel will complete required training.

#### **Company Official (CO):**

- Must record and review all Financial Interest Disclosure forms from PHS-funded researchers to determine whether a FCOI exists.
- Must provide required information concerning FCOIs to the expenditure of PHS funds, and must update such information at least annually and within 60 days of changes to Statement of Financial Interest Disclosure forms, whichever occurs first.
- Must prepare the Public Financial Conflict of Interest Disclosure Form, including the following information, for reported FCOIs such that it can be made publicly available upon request:
  - ☐ Project/Contract number
  - ☐ Investigator's name
  - ☐ Investigator's title and role with respect to the research project
  - ☐ Name of the entity in which the relevant significant financial interest (SFI) is held
  - ☐ Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.)
  - ☐ Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.)
- For reported FCOIs, must develop a FCOI management plan to include: role and principal duties of the Investigator with the FCOI; how the FCOI Management Plan is designed to safeguard objectivity in the PHS research project; confirm that Investigator agrees with the FCOI

Management Plan; and how the FCOI Management Plan will be monitored.

- Must maintain for three years records of all Statement of Financial Interest Disclosure form records and FCOI Management Plans.
- Maintains the FCOI Policy and Procedure on the The Company's external website.
- Must ensure compliance with FCOI policy and procedures.
- In cases where a potential FCOI exists, assists in the development and implementation of FCOI

Management Plan for FCOI is developed in consultation with the CO and Investigator. The FCOI Management Plan must be completed in advance of the Company's spending PHS funds and a summary of the management plan must be included in the FCOI Report.

### **SFI Review Process**

The CO reviews each SFI received from Company personnel. If necessary, the CO collects additional information from the disclosing individual and/or from other individuals who possess relevant information. The CO determines whether the disclosed financial interests are significant, whether they are related to the individuals research responsibilities at the Company, and whether a management plan is required. In conducting this review, the CO considers factors such as the value of the individual's financial interest and how it could affect their ability to objectively complete their research with the Company.

If a significant financial interest is deemed to be a financial conflict of interest, the CO will develop a management plan in consultation with the Investigator. The goal of the management plan is to reduce or eliminate the financial conflict of interest, which can include reducing or eliminating the financial conflict of interest and to ensure that the design, conduct and reporting of research will be free from bias. The management plan may include, but is not limited to: (1) requiring the individual to recuse him/herself from particular decisions or activities related to the research, (2) requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (e.g. relevant review bodies, research sponsors, co-investigators, journals to which manuscripts about the research are submitted, media, etc.), (3) requiring others to review decisions in which the individual participates, (4) requiring the individual to reduce, modify or eliminate a financial interest (e.g. divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments), (5) requiring the individual to vacate a position, (6)

### **Reporting**

The Company will comply with federal regulations regarding reporting of financial conflicts of interest (e.g. by submitting FCOI reports to the awarding institution, as required). The Company will comply with federal FCOI regulations regarding making publicly available information on identified FOCIs held by investigators and key personnel on PHS-funded research projects.

### **Record Keeping**

The Company complies with federal regulations regarding maintaining records relating to all disclosures of financial interests and the Company's review of, and response to, such disclosures.

### **Confidentiality**

All disclosures or information obtained in reviewing a potential FCOI is kept confidential, except where disclosure is required by federal regulations.

### **Sanctions**

Failure to comply with the Company's FCOI policy includes failing to submit a required disclosure, providing false information, omitting required information, failing to maintain confidentiality, failure to carry out duties prescribed by these policies, and refusal or failure to comply with a management plan adopted under these policies. A failure to comply with these policies may result in a decision by the CO to suspend the research project or to refuse to approve a new research project for the individual who fails to comply.

A failure to comply is also subject to: (1) formal admonition, (2) ineligibility of the individual to apply for federal research grants, (3) additional sanctions per research funding agency (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of function per application federal regulations (note: the Company will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective action), and/or (4) termination of employment.

### **Definitions:**

For the purposes of this procedure, the following definitions apply:

- Company Official means the individual within the Company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's family related to the Investigator's Company Responsibilities.
- Company Responsibilities means the Investigator's responsibilities associated with his or her Company appointment or position, such as research, teaching, administration, and internal and external professional committee service.
- Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consulting fees, paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership interest), intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for 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.
- Investigator means the Project Director (PD) or 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 the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.
- Sub-recipient means any party that has entered into an Agreement with The Company as a sub-grantee, subcontractor, collaborator, contractor, or consultant.
- Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Company Responsibilities, and is:
  - a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
  - b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
  - c) if with a non-publicly-traded company, is an equity interest of any value during the 12-

month period preceding or as of the date of disclosure; or  
d) income related to intellectual property rights and interests not reimbursed through The Company.

The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Company 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 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; or 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.