

Corporate Template	MacroGenics, Incorporated	
Title: <b>Conflict of Interest in Federally Funded Research</b>		
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## **Conflict of Interest in Federally Funded Research**

### **1. Purpose and Scope**

MacroGenics, Inc. (also referred to as "Company") relies on government grants and contracts for funding of various projects within the Company. In these endeavors, as with all others involving scientific research, the Company seeks to ensure that the research is conducted on an objective basis. For that reason, this Policy is established to identify and manage conflicts of interest involving research supported by government funding.

This Policy applies to all employees, as well as agency and contract personnel (collectively, "Personnel").

All Personnel are required to (1) familiarize themselves with this Policy and the FCOI Regulations and (2) refrain from participating in government grants, contracts, and research upon the identification of any conflicts of interest could interfere with their objectivity.

All individuals other than Company Personnel acting on behalf of the Company, including subrecipients, are subject to the FCOI policies of their employer, provided that where this Policy or other Company policies impose more stringent requirements, this Policy and/or Company policies shall govern.

### **2. Policy Terminology**

- **FCOI Regulations**

All applicable federal and state laws pertaining to financial conflicts of interest, including but not limited to 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94.

- **Financial Conflict of Interest**

A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of federally funded research.

- **Investigator**

The Principal Investigator, co-Principal Investigator, and any other person who is responsible for the design, conduct or report of a federally funded grant or contract who may or may not be an employee of MacroGenics.

- **Significant Financial Interest**

Anything of monetary value, including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other corporate ownership interests); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights). A significant financial interest is not:

- Salary, royalties or other remuneration from MacroGenics;

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- Any ownership interest in MacroGenics;
- Income seminars, lectures or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both or the following test: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% interest in any single entity; or
- Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next funded twelve-month period.

### **3. Conflict of Interest in Federally Funded Research**

#### *3.1. Investigator Disclosure*

Before any application seeking award of a federal grant or contract is submitted, the Investigators for that grant or contract must disclose a listing of Significant Financial Interests (and those of his/her spouse and dependent children) to the individual that could be reasonably expected to bias or influence the design, conduct or reporting of research and its results to be conducted under the federal grant or contract. The listing will be provided to Human Resources.

Disclosures are a mandatory, ongoing obligation. The Investigator shall provide an SFI listing at least annually, and within 30 days of discovering or acquiring a new SFI.

#### *3.2. Resolution Plan*

In the event a conflict of interest for an Investigator for a federal grant or contract is identified, a Resolution Plan will be written and implemented to manage the conflict prior to award of the federal grant or contract. The Investigator will be required to sign the Resolution Plan and a copy of the Plan will be maintained in Human Resources' records. Special consideration will be given for research involving human subjects in accordance with 45 CFR, part 46. Actions to be taken under the Resolution Plan may include:

- Public disclosure of Significant Financial Interests
- Monitoring of research by independent reviewers
- Modification of the federal grant's or contract's research plan
- Disqualification from participation in the portion of the project that is affected by the Significant Financial Interest

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- Divestiture of Significant Financial Interests
- Severance of relationships that create actual or potential conflict

### 3.3. *Documentation and Record Maintenance*

Submissions by employees regarding possible conflicts of interest and Resolution Plans that result from such submissions will be maintained by Human Resources.

All FCOI-related records shall be maintained in accordance with the retention periods required by Company policy, regulation, and/or contract, whichever period is longer.

### 3.4. *Reporting*

In accordance with the FCOI Regulations, the Company will provide initial, ongoing, and annual FCOI reports to the required government officials. FCOI reports will be submitted prior to the expenditure of funds, and FCOIs identified during the period of award will be submitted within 60 days of identification.

### 3.5. *Accessibility and Transparency*

In accordance with FCOI Regulations, this Policy shall be made publicly available on MacroGenics' website. Should the Company identify an FCOI held by senior or key personnel (as defined by FCOI Regulations), the Company shall make the required information available within five business days of a written request for such information.

## **4. Interpretation and Enforcement**

Potential violations of this Policy will be investigated by Human Resources. Penalties for violation of the Policy may affect the Investigator's yearly performance review, result in termination of employment or result in other penalties. Further guidance as to what may constitute a significant financial interest will be provided to employees upon their request to Human Resources.

## **5. Training**

All Investigators must undergo training with respect to this Policy, related Company policies, and the applicable rules and regulations that govern FCOIs prior to engaging in any research. This training shall occur:

- When an Investigator joins MacroGenics;
- When this Policy is revised in a manner that affects Investigators' obligations;
- When an Investigator is found not in compliance with the Policy or the Resolution Plan; and
- Every at least once every four years.

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**6. Revision History**

Revision #	Effective Date	Reason
00		Updating in Policy on Policy Format on MasterControl
01		Updating based on Legal Guidance