

Policy for Managing Conflicts of Significant Financial Interests

I. INTRODUCTION

A. GENERAL POLICY

The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of Naprogenix, Inc. ("Naprogenix") and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Sponsored research includes funding support (grants/cooperative agreements/contracts) from Public Health Service (PHS), HHS (United States Department of Health and Human Services), National Institute of Health (NIH), and any other entity (Federal, state, or organization) outside of Naprogenix. PHS refers to

Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

This Financial Conflict of Interest (FCOI) policy is to adhere with the Public Health Service (PHS) and National Institutes of Health (NIH) Federal regulations as outlined in 42 CFR 50, Subpart F, "*Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*" along with the additional requirements of the 2011 Revised Financial Conflict of Interest (FCOI) Regulation amending the 1995 PHS regulation (and the companion regulation at 45 CFR 94, "*Responsible Prospective Contractors*," imposing similar requirements for research contracts) as published in Federal Register (July 11, 1995 and August 25, 2011) and NIH Grants Policy Statement.

Under PHS final rules on *Objectivity in Research* (Federal Register, July 11, 1995 and August 25, 2011), each investigator is required to disclose a listing of her/his *Significant Financial Interests* (SFI), as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding by PHS. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, Naprogenix will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias owing to the conflict of interest. This policy statement is intended to satisfy current Federal rules for disclosure with regard to projects funded by PHS as well as other Federal agencies and State of Kentucky statutes involving conflict of interest situations.

B. SCOPE

This policy and the associated procedures are applicable to all sponsored research program activity at Naprogenix, Inc. carried out by Naprogenix employees, investigators, consultants, scientists, trainees, technicians and other agents or research collaborators as well as to any research subrecipients, consortium, subawards, and subcontracts with research institutes, consortiums, and universities regardless of job title. These procedures will be followed whenever Naprogenix, Inc. or its employees submit a request for funding from any external agency, whether it is PHS or another Federal/State agency.

C. PURPOSE

The purpose of this policy on Financial Conflict of Interest (FCOI) is to follow the PHS & NIH Federal regulations of having an up-to-date, written and enforced administrative process to identify and manage FCOI that shall 1) promote and enforce investigator compliance with regulations; 2) manage FCOI and provide initial and ongoing FCOI reports; 3) agree to make FCOI and SFI information (including related Institutional reviews and determinations) available to PHS or other Federal/State agency, promptly, upon request; and 4) fully comply with regulation's requirements.

D. RESEARCH AND THE MISSION STATEMENT

The Mission Statement for Naprogenix, Inc. states:

Harnessing the power of genomics and high throughput molecular pharmacological screens to access the chemical diversity of native plant species and known medicinal plants. The purpose is to discover novel active compounds useful in their own right, or as leads for agrochemicals, food, health, and well-being industries.

Such Naprogenix research is facilitated and made possible through external funding from public and private sources. It is Naprogenix's responsibility to assure the integrity of all aspects of such sponsored research while, simultaneously, taking care not to discourage the development of external funding opportunities. The purpose of this document is to identify situations where potential conflicts of significant financial interest are likely to arise and to establish a process whereby such conflicts are either avoided or at least equitably resolved to the satisfaction of all concerned parties.

E. MANAGING CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST

This document articulates Naprogenix policy on the management or elimination of conflicts of significant financial interest between outside constituencies and the associated funded activities carried out by Naprogenix. While this policy focuses upon avoiding or at least managing, conflicts of significant financial interest, its primary purpose is to promote compliance with the standards of Objectivity in Research (42 CFR Part 50 Subpart F).

