

FCOI REPORT – SECTION 3

Grant Number: 2R44AA025804-03

Principal Investigator(s): JOHN M. LITTLETON, MD

Project Title: *Novel modulators of the dopamine transporter for alcohol and nicotine use disorders*

Name of Investigator with the FCOI: Dr. Greg A. Gerhardt

Name of the entity with which the investigator has an FCOI: Quanteon, LLC

Nature of the financial interest: Equity Interest - Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)

Annual Value: \$7,500 (\$5,000 - \$9,999)

Section 3. Include a description of the key elements of the Institutions management plan, including:

- A) **Role and principal duties of the conflicted Investigator in the research project:** Dr. Gerhardt is a co-investigator on this award. He will be responsible for testing lobinaline N-oxides and novel metabolites for activity on dopamine clearance in rat brain in vivo.
- B) **Conditions of the management plan:** The conditions of the management plan include the following:
 - a. Oversight for data analysis and manuscript preparation will be provided by Dr. Gerhardt's oversight committee.
 - b. Dr. Gerhardt will formally inform, in writing, all participants in the research project, including students, postdoctoral fellows, faculty, and staff, of the existence of a conflict.
 - c. Dr. Gerhardt will disclose his financial interest in any presentation or publication resulting from the research.
 - d. Dr. Gerhardt will provide to his COI oversight committee copies of any presentations/publications from research that is impacted by his financial conflict for review prior to release.
 - e. Dr. Gerhardt will disclose to his COI oversight committee plans for all patents generated from the project. All intellectual property will go through UK.
 - f. The COI oversight committee must submit to the Office of Sponsored Projects Administration a brief annual report which outlines the review activities conducted during the year, including reviewing any presentations/publications before release, any patent applications, and research results for bias. The oversight committee is also required to contact, at least via email, any University personnel involved with the projects and remind them of contact personnel should any issues arise during the conduct of the research.
 - g. Company activities will be maintained separately and will not use university resources.

- C) **How the management plan is designed to safeguard objectivity in the research project:** The FCOI management plan is designed to safeguard objectivity in the research project as it incorporates both the formation of an oversight committee which monitors the research activities during each year and the written notification to research personnel. The oversight committee reviews any presentations and publications to ensure that a disclosure of Dr. Gerhardt's significant financial interest is present as well as any potential patent disclosures. In addition, the members of Dr. Gerhardt's oversight committee will have independent access to the original data. Dr. Gerhardt is also required to disclose his significant financial interest in writing to all University personnel who are involved in the research project.
- D) **Confirmation of the Investigator's agreement to the management plan:** Dr. Gerhardt signed the conflict of interest management plan and this serves as his agreement to the plan.
- E) **How the management plan will be monitored to ensure Investigator compliance:** Investigator compliance with the management plan is monitored by the local oversight committee. This committee will meet at least annually to review the project. The Chair of Dr. Gerhardt's local oversight committee will sign an annual report form to signify the completion of the annual review. This report is then reviewed by the central Research Conflict of Interest Committee at the University of Kentucky.

FCOI REPORT – SECTION 3

Grant Number: 2R44AA025804-03

Principal Investigator(s): JOHN M. LITTLETON, MD

Project Title: *Novel modulators of the dopamine transporter for alcohol and nicotine use disorders*

Name of Investigator with the FCOI: Dr. Susan Barron

Name of the entity with which the investigator has an FCOI: Naprogenix, Inc.

Nature of the financial interest: Spouse Equity Interest – Spouse holds equity/ownership in non-publicly traded entity (e.g., stock, stock option, or other ownership interest)

Annual Value: \$0 (\$0-\$4,999)

Description of Financial Interest: Naprogenix issued a subaward to University of Kentucky (UK) for their NIH-funded SBIR “*Novel Modulators of the Dopamine Transporter for Alcohol and Nicotine Use Disorders*” 2R44AA025804-03. The UK subaward PI is Dr. Greg Gerhardt, with co-PI’s Dr. Barron, Dr. Littleton, Dr. Bardo, and Dr. Lynn. Dr. Barron is now the subaward PI of a scope account for her own project.

Section 3. Include a description of the key elements of the Institutions management plan, including:

- A) **Role and principal duties of the conflicted Investigator in the research project:** Dr. Barron is a co-investigator on this award. She will be responsible testing lobinaline N-oxide for activity in simple rodent behavioral paradigms for value in alcohol and nicotine use disorders.
- B) **Conditions of the management plan:** The conditions of the management plan include the following:
 - a. Oversight for data analysis and manuscript preparation will be provided by Dr. Barron’s oversight committee.
 - b. Dr. Barron will formally inform, in writing, all participants in the research project, including students, postdoctoral fellows, faculty, and staff, of the existence of a conflict.
 - c. Dr. Barron will disclose her financial interest in any presentation or publication resulting from the research.
 - d. Dr. Barron will provide to her COI oversight committee copies of any presentations/publications from research that is impacted by her financial conflict for review prior to release.
 - e. Dr. Barron will disclose to her COI oversight committee plans for all patents generated from the project. All intellectual property will go through UK unless otherwise agreed with UK OTC.

- f. The COI oversight committee must submit to the Office of Sponsored Projects Administration a brief annual report which outlines the review activities conducted during the year, including reviewing any presentations/publications before release, any patent applications, and research results for bias. The oversight committee is also required to contact, at least via email, any University personnel involved with the projects and remind them of contact personnel should any issues arise during the conduct of the research.
 - g. Company activities will be maintained separately and will not use university resources.
- C) **How the management plan is designed to safeguard objectivity in the research project:** The FCOI management plan is designed to safeguard objectivity in the research project as it incorporates both the formation of an oversight committee which monitors the research activities during each year and the written notification to research personnel. The oversight committee reviews any presentations and publications to ensure that a disclosure of Dr. Barron's significant financial interest is present as well as any potential patent disclosures. In addition, the members of Dr. Barron's oversight committee will have independent access to the original data. Dr. Barron is also required to disclose her significant financial interest in writing to all University personnel who are involved in the research project.
- D) **Confirmation of the Investigator's agreement to the management plan:** Dr. Barron signed the conflict of interest management plan and this serves as her agreement to the plan.
- E) **How the management plan will be monitored to ensure Investigator compliance:** Investigator compliance with the management plan is monitored by the local oversight committee. This committee will meet at least annually to review the project. The Chair of Dr. Barron's local oversight committee will sign an annual report form to signify the completion of the annual review. This report is then reviewed by the central Research Conflict of Interest Committee at the University of Kentucky.
- F) **Other Information:** This FCOI report includes a failure to comply with the regulation. The subrecipient failed to identify the conflict in a timely manner. The research COI committee met to review project materials. Due to delays in the preceding project components, there are no data or publications yet. Given the limited information available, the committee finds that there is no reasonable basis on which to conclude that bias has occurred in the design, conduct or reporting of the research. No mitigation plan is required.