

ReNeuroGen LLC (DBA: rngen)
Financial Conflict of Interest (FCOI) Policy
Effective Date: [April 18th, 2017]

1. Purpose

ReNeuroGen LLC (DBA: rngen) is committed to maintaining the highest ethical standards in conducting research and ensuring transparency in NIH-funded projects. This Financial Conflict of Interest (FCOI) Policy is established in compliance with 42 CFR Part 50 Subpart F and applies to all employees, investigators, consultants, and contractors participating in NIH-funded research at ReNeuroGen LLC.

2. Scope

This policy applies to all individuals responsible for designing, conducting, or reporting research funded by the National Institutes of Health (NIH), including SBIR/STTR grants. Investigators must disclose any significant financial interests (SFI) that may present an actual or potential financial conflict of interest.

3. Definition of Financial Conflict of Interest (FCOI)

A Financial Conflict of Interest (FCOI) exists when a significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

A Significant Financial Interest (SFI) includes, but is not limited to:

- Equity interests (e.g., stock, stock options) in a publicly traded entity valued at \$5,000 or more.
- Ownership interests in a privately held entity.

- Payments (e.g., consulting fees, honoraria, royalties) exceeding \$5,000 in the past 12 months.
- Intellectual property rights (e.g., patents, licensing revenue).
- Reimbursed or sponsored travel exceeding \$5,000 annually.

4. Disclosure Requirements

- Investigators must disclose any SFI prior to engaging in NIH-funded research and annually thereafter.
- Any new SFIs acquired during the research project must be disclosed within 30 days.
- Disclosures must be reviewed by ReNeuroGen LLC's designated FCOI Official to determine if a FCOI exists.

5. Management of Financial Conflicts of Interest

If an FCOI is identified, ReNeuroGen LLC will take appropriate steps to mitigate the conflict, which may include:

- Public disclosure of the conflict in research presentations/publications.
- Modification of research plans to minimize bias.
- Divestiture of financial interests.
- Severance of relationships that create conflicts.
- Independent monitoring of research activities.

6. Reporting to NIH

ReNeuroGen LLC will report any identified FCOIs to NIH prior to the expenditure of funds and within 60 days of discovering a new FCOI. These reports will include the investigator's name, the nature of the conflict, and actions taken to manage it.

7. Public Accessibility

ReNeuroGen LLC will make this FCOI Policy publicly accessible on its website. In compliance with

NIH regulations, information concerning identified FCOIs related to NIH-funded research will be provided within five business days of a request.

To request FCOI-related information, please contact:

Email: snaylor@rngen.com

Phone: 414-420-0977

Address: ReNeuroGen LLC, 2160 San Fernando Drive, Elm Grove, WI 53122.

8. Training Requirements

All Investigators must complete NIH-compliant FCOI training prior to engaging in NIH-funded research and at least every four years thereafter. Training is also required when policy revisions occur or when an investigator is found non-compliant.

9. Non-Compliance and Enforcement

Failure to comply with this policy may result in disciplinary action, including removal from NIH-funded projects. ReNeuroGen LLC will notify NIH of non-compliance and corrective actions taken.

10. Policy Review

This policy will be reviewed annually and revised as needed to ensure compliance with NIH regulations

Approved by:

Stephen Naylor PhD

Chief Executive Officer

ReNeuroGen LLC

[March 1st 2025]