RESEARCH CONFLICT OF INTEREST

I. POLICY STATEMENT

RRI is committed to upholding integrity across all research activities. This policy establishes the standards for identifying, disclosing, and managing individual conflicts of interest to ensure that personal or financial interests do not compromise—or appear to compromise—the objectivity, credibility, or ethical conduct of RRI-affiliated research.

Compliance is mandatory for all personnel engaged in RRI-sanctioned research activities. The policy promotes proactive disclosure as a protective measure and supports risk-based oversight aligned with federal regulatory frameworks, including those set forth by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services (HHS).

II. SCOPE AND APPLICABILITY

This policy applies to all individuals engaged in the design, conduct, or reporting of research overseen by RRI, including:

- Employees, contractors, and volunteers
- External collaborators when RRI is the primary awardee or IRB of record

Research engagement includes:

- **Design**: Protocol development, hypothesis generation, methodology, or analysis planning.
  Examples: PI, Co-Investigator

- **Conduct**: Direct interaction with participants or data, including recruitment, informed consent, data collection, or intervention delivery
  Examples: Research Coordinator, Clinician, Technician
- **Reporting**: Post-data collection activities including analysis, manuscript preparation, and dissemination of findings
  Examples: Analyst, Presenter, Author

III. DEFINITIONS

- A **Conflict of Interest (COI)** arises when personal, financial, or professional circumstances may compromise or appear to compromise objectivity or integrity of a person's research responsibilities.
- A **Significant Financial Interest (SFI)** includes:
  - Ownership of publicly traded stock or dividends exceeding $5,000 within the past 12 months
  - Any equity interest in privately held companies
  - Annual income over $5,000 from intellectual property rights such as royalties or licensing agreements
  - Sponsored travel over $5,000 annually from a single entity (excluding approved government or academic resources
- **Financial relationships** include any monetary benefit received from an external organization, such as payments, investments, or sponsorships. Roles requiring disclosure include consulting, advisory positions, board membership, and other leadership or fiduciary functions.
- **Family members** covered under this policy include spouses, domestic partners, parents, children, siblings, stepchildren, and legal dependents.

IV. DISCLOSURE REQUIREMENTS

A. When to Disclose:

- **Initial Disclosure:** Required upon initial affiliation or onboarding with RRI
- **Annual Updates:** Mandatory submission on an annual basis.
- **Changes in Circumstances:** Any change in financial or personal circumstances within 30 days.

Disclosures must be submitted to Human Resources or the IRB Office.

B. What to Disclose:

- **Significant Financial Interests (SFIs)**, including:
  - Publicly traded stock exceeding $5,000 annually
  - Private equity interests, regardless of value
  - Income over $5,000 from intellectual property rights annually
  - Sponsored travel exceeding $5,000 from a single source within a year.
- **Research-Related Associations:**
  - Financial or advisory relationships with entities providing research funding.
  - Participation in research evaluating proprietary products (e.g., drugs or devices).
- **Procurement and Clinical Usage:**
  - Involvement in procurement, purchase, or decision-making related to external companies' products.

- Use, prescription, or implantation of proprietary products as part of clinical duties.

- **Payments and Compensation:**
  - Payments for consultancy, advisory roles, board membership, or participation in speaker programs.
  - Travel sponsored by outside entities (excluding approved U.S. government or academic institutions)

C. Do Not Report:

- Compensation, royalties, or other payments received from RRI
- Income generated through mutual funds or retirement accounts, as long as the investigator does not control the investment decisions
- Honoraria, service payments, or travel support provided by U.S. federal, state, or local government agencies; U.S. institutions of higher education; or affiliated research institutes, teaching hospitals, or medical centers.

V. REVIEW AND OVERSIGHT

RRI employs a streamlined review process appropriate to its size and structure. Annual disclosures are received by the IRB Administrator or the Human Resources Administrator. If a potential conflict is identified, the Chief Executive Officer (CEO) conducts a targeted evaluation of its relevance and potential to affect research outcomes.

Conflicts requiring mitigation are referred to the RRI Board of Directors in consultation with external legal counsel. Together, they develop formal Management

Plans that outline appropriate oversight, activity restrictions, and monitoring protocols.

Risk assessments are based on the nature and scope of the disclosed activity, applicable financial thresholds, and the likelihood or appearance of influence over research integrity

For federally regulated research:

- NIH/PHS-sponsored studies require annual disclosures and updates within 30 days of acquiring new interests.
- FDA-regulated protocols are reviewed at initial IRB submission and during continuing review.

VI. MANAGEMENT PLANS

When a conflict of interest requires mitigation, RRI will convene an ad hoc committee composed of appropriate administrative leadership and external counsel to evaluate the circumstances and recommend a tailored Management Plan. These plans are designed to preserve research integrity, maintain transparency, and fulfill institutional and regulatory obligations.

Mitigation strategies may include modification of research responsibilities, recusal from specific decisions or study components, independent review of data, or periodic compliance reporting. Each plan will be proportionate to the nature and extent of the disclosed interest and the individual's research role.

All Management Plans are reviewed and approved by the RRI Board of Directors, in coordination with external legal counsel, and are documented for institutional tracking.

The committee approach ensures flexibility, scalability, and appropriate oversight based on risk and relevance.

VII. IRB RECUSAL PROTOCOLS

IRB members must recuse themselves from any protocol review, discussion, or vote when an actual or perceived conflict is present. Recusals are documented in the meeting minutes and must reflect abstention from both deliberation and decision-making. Physical or virtual absence during relevant agenda items is required.

VIII. TRAINING AND CERTIFICATION

All individuals subject to this policy are required to complete conflict of interest (COI) training approved by RRI prior to engaging in any research activity. This training ensures awareness of institutional obligations and alignment with federal regulations. Certification must be renewed every three years through the CITI Program, and personnel must affirm the accuracy of their disclosures via physical or electronic signature.

Changes in financial, personal, or professional circumstances that could impact conflict status must be reported within 30 calendar days using the Conflict of Interest Disclosure Form. Completed training records and signed attestations are retained by Human Resources and the IRB office in accordance with RRI's records management policy and applicable federal audit standards.

X. ROLES AND RESPONSIBILITIES

RRI employs a coordinated compliance framework to support the effective implementation of this policy across research teams and administrative units.

Entity	Responsibility
Investigators	Submit accurate disclosures and comply with Management Plans
IRB Chair & Administrator	Verify disclosures, document recusals, maintain review records
Chief Executive Officer	Conduct targeted evaluations, recommend mitigation
Board of Directors	Approve Management Plans and ensure institutional oversight
Human Resources & IRB Office	Maintain records, support training and audit readiness
Department Administrators	Ensure compliance prior to and during study engagement

XI. NONCOMPLIANCE

Noncompliance with this policy—including failure to disclose relevant conflicts of interest, implement an approved Management Plan, or meet procedural requirements—may result in administrative or disciplinary action.

Initial reviews are conducted by the IRB Chair in coordination with IRB Administrator and appropriate department leadership. As warranted, the Chief Executive Officer may escalate concerns to the RRI Board of Directors, which determines corrective measures in consultation with external legal counsel.

Corrective actions may include personnel measures, suspension of research activities, or withdrawal of institutional support. Human Resources is responsible for documenting

outcomes and ensuring consistency with institutional policy and applicable labor regulations.

When required, records are shared with sponsors or agencies for compliance purposes.

XII. RECORDKEEPING AND RETENTION

All COI documentation is managed and retained according to RRI's data retention policy and federal audit protocols. This includes signed disclosure forms (authenticated via electronic or physical signature), approved Management Plans, IRB meeting minutes that reflect recusal decisions, and training completion records.

Access to these materials is limited to designated compliance personnel, and all records are maintained in an audit-ready state to ensure alignment with FDA Bioresearch Monitoring requirements and NIH policy standards.

XIII. ACKNOWLEDGMENT

By signing the COI Disclosure Form, individuals acknowledge that they have reviewed and understood this policy, certify that their disclosures are complete and accurate, and agree to submit timely updates and comply with any assigned Management Plans.

XIV. REFERENCES

- RRI Conflict of Interest Policy (Rev. 3.24.2025)
- 42 CFR Part 50 Subpart F – Promoting Objectivity in Research
- FDA BIMO Compliance Program Manual 7348.809
- NIH Grants Policy Statement
- CITI Program COI Training Guidelines