1. Purpose

The purpose of this policy is to ensure that research funded by federal sponsors is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI). The 2011 revised regulations are 42 CFR Part 50 Subpart F, “Promoting Objectivity in Research” and 45 CFR Part 94, “Responsible Prospective Contractors”, which set requirements for promoting objectivity in Public Health Service (PHS)-funded research for grants, cooperative agreement, and research contracts, respectively. The regulations and this policy do not apply to SBIR or STTR Phase I applications or awards.

This policy is intended to implement the applicable regulatory requirements for federally funded research. For PHS/NIH-funded research, this policy implements the requirements of 42 CFR Part 50 Subpart F and NIH guidance. For research sponsored by a federal agency, Reselute will apply this policy together with any applicable agency-specific requirements. Where sponsor requirements differ from or are more stringent than this policy, the sponsor-specific requirements will govern.

Reselute, Inc. (“Reselute”, “The Institution”) adopts this policy for all Investigators (as defined below) engaged in federally funded research for which FCOI requirements apply. It establishes processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in federally supported research.

2. Applicability

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. This policy applies to individuals who meet the regulatory definition of “Investigator” (as defined below) who are planning to participate in or who participate in PHS/NIH-funded research.

For research funded or proposed for funding by other federal agencies, Reselute will apply this policy together with any applicable agency-specific requirements. Where the applicable federal agency imposes requirements that differ from or are more stringent than this policy, the agency-specific requirements will govern.

3. References

1. 42 CFR § 50 Subpart F - Promoting Objectivity in Research
2. 45 CFR § 94 - Responsible Prospective Contractors
3. NIH Grants Policy Statement, § 4.1.10 – Financial Conflict of Interest
4. NIH Grants Policy Statement, § 15.2.1 – Written Agreements for Consortium/Subrecipient Arrangements
5. SOP-040 Document Control and Change Control
6. SOP-180 Control of Records

4. Definitions (42 CFR 50.603)

For the purpose of these policies and procedures, the following definitions apply:

4.1 Financial Conflict of Interest (FCOI): A significant financial interest that Reselute’s designated officials determine is related to federally funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of federally funded research.

4.2 Financial Interest: Anything of monetary value, whether or not its value is readily ascertainable.

4.3 Institutional Responsibilities: The professional responsibilities of an Investigator on behalf of Reselute, which may include activities such as research, research consultation and collaboration, product development, product testing and validation, development of datasets, models, or systems, publication and communication of research results, fundraising, business development, and other professional services performed on behalf of Reselute. These responsibilities also extend to institutional committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

4.4 Designated Official (DO): The individual(s) appointed by REselute to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOI. The DOs include the Chief Executive Officer (CEO), Chief Technology Officer (CTO), Clinical Affairs, and a Quality representative.

4.5 Institution: Any public or private organization, domestic or foreign (excluding a federal agency) that is applying for or receives, federal research funding.

4.6 Investigator: The Project Director (PD) or Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, or research proposed for such funding, which may include, for example, collaborators or consultants. The institution determines who is responsible for the design, conduct, or reporting of federally funded research. Reselute will consider the individual's role, rather than the title, of those individuals involved in the research and the degree of independence in carrying out the work when determining who is responsible for the design, conduct, or reporting of federally funded research.

4.7 Manage: Means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

4.8 Research: Means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in the applicable regulation, the term includes activities for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, and federally funded research supported by other federal sponsors to the extent the sponsor's requirements apply.

4.9 PHS-Funded Research: Any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

4.10 PHS: The 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).

4.11 NIH: The biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

4.12 Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by Reselute in a grant application, progress report, or other report submitted to NIH under the FCOI regulation. For this policy, the term applies specifically to public accessibility requirements imposed by the applicable sponsor.

4.13 Significant Financial Interest (SFI): A domestic or foreign (non-United States) financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:

4.13.1 Publicly traded entity: An SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

4.13.2 Non-publicly traded entity: An SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

4.13.3 Intellectual property (IP) rights and interests (e.g., patents, copyrights): An SFI exists upon receipt of income greater than $5,000 in the twelve months preceding the disclosure that are related to such rights and interests. Includes royalties from such rights, and agreements to share in royalites related to licensed IP rights.

4.13.4 Reimbursed or sponsored travel: Investigators must disclose any reimbursed or sponsored travel related to their Institutional Responsibilities in excess of $5,000. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly, where the exact cost may not be known. The disclosure must cover the previous 12 months and include, at minimum, the purpose, sponsor or organizer, destination, and duration of each trip. Updated disclosure of reimbursed or sponsored travel must also be submitted within 30 days of each occurrence.

The disclosure requirement does not apply to travel that is reimbursed or sponsored by:

- a Federal, state, or local government agency located in the United States;
- a United States institution of higher education;
- an academic teaching hospital;
- a medical center; or
- a research institute affiliated with a United States institution of higher education.

The term "Significant Financial Interest" does not include, and therefore Investigators are not required to disclose, the following types of financial interests:

- Salary, royalties, or other remuneration paid by Reselute to the Investigator if the Investigator is currently employed or otherwise appointed by Reselute, including intellectual property rights assigned to Reselute and any agreements to share royalties related to those rights.
- Any equity interest in Reselute since Reselute is a commercial or for-profit organization.
- Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.
- Income from service on advisory committees or review panels for a U.S. Federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

5. Significant Financial Interest (SFI) Disclosure Requirements

5.1 Investigators will disclose their SFIs that are related to their "Institutional Responsibilities" as defined in the policy. The disclosure will not be limited to an Investigator's research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation. The Investigator SFI Disclosures will be retained by the Company as part of the record maintenance requirements.

Investigators are required to disclose SFIs at the following times:

5.1.1 At the time of application: Each Investigator must disclose their SFI(s) to the FCOI Committee no later than the time of application for federally funded research. Any new Investigator who joins the project after the application has been submitted or during the course of the research must disclose their SFI(s) promptly and before participating in the

project, using the Reselute Significant Financial Interest Disclosure Form or another Company-approved mechanism.

5.1.2 **Annual disclosure during the award**: Each Investigator participating in research under a federal award must submit an updated SFI disclosure at least annually during the award period. The annual disclosure must include any new information that was not previously disclosed, including SFIs associated with federally funded projects transferred from another institution, and updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

5.1.3 **Ad-hoc basis during the award**: Each Investigator participating in federally funded research must submit an updated SFI disclosure within 30 days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel subject to disclosure must also be submitted within 30 days of each travel occurrence.

6. Review of SFI Disclosures

6.1. Reselute's Designated Officials (DOs), consisting of the Chief Executive Officer, Chief Technology Officer, Clinical Affairs representative, and Quality representative, will be responsible for reviewing all SFI disclosures and making determinations of FCOI. In cases where it is determined that one of the DOs has a disclosed SFI related to the research under review, or where additional independence is warranted, that DO will recuse himself or herself from the review and determination. The remaining non-conflicted DOs will conduct the review and determination. Any recusal will be documented.

Each SFI will be evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI).

The SFI disclosures will be reviewed as described below:

6.1.1 **Prior to the issuance of a new award or before any expenditure of any awarded funds (e.g., during Just-in-Time stage):** The DOs will review the Investigator's SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.

6.1.2 **Annual SFI disclosure:** As part of the annual disclosure process, Investigators must provide updated information on any previously disclosed SFIs (e.g., revised value of an equity interest). The DOs will review these updates to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.

6.1.3 **Ad hoc basis during award period:** If a new Investigator joins a project or an existing Investigator acquires or discovers a new SFI during the project, the DOs will, within 60 days:

6.1.3.1 Review the disclosure;

6.1.3.2 Determine whether the SFI is related to the PHS/NIH-funded research;

6.1.3.3. Determine whether an FCOI exists; and, if so,

6.1.3.4. Implement, on at least an interim basis, a management plan.

6.1.3.5. An FCOI report will be submitted to NIH within 60 days of identifying the FCOI.

7. Relatedness of SFIs to Federally Funded Research and FCOI

7.1 **Relatedness Test:** The FCOI Committee is responsible for assessing the relatedness of SFIs to federally funded research and determining when they constitute an FCOI. An SFI is considered "related" when the Committee reasonably determines that:

7.1.1. The SFI could be affected by the federally funded research, or

7.1.2. The SFI is in an entity whose financial interests could be affected by the federally funded research.

7.2 Investigator Involvement: The FCOI Committee may consult with the Investigator when assessing whether an SFI is related to the research. The Committee makes the final determination.

7.3 Designated Officials FCOI Determination: An FCOI exists when the FCOI Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the federally funded research ("significantly" meaning that the financial interest would have a material effect on the research).

8. Management of SFIs that Pose an FCOI

8.1 When an FCOI is identified, the DOs will determine and implement management strategies to ensure the research is conducted objectively. Examples of management conditions include, but are not limited to:

8.1.1. Public disclosure of the FCOI, including disclosure in publications and presentations;

8.1.2. For human subjects research, disclosure of the FCOI directly to participants;

8.1.3. Appointment of an independent monitor capable of protecting the design, conduct, and reporting of the research from bias;

8.1.4. Modification of the research plan;

8.1.5. Change in personnel or responsibilities, or disqualification from all or a portion of the research;

8.1.6. Reduction or elimination of the financial interest; or

8.1.7. Severance of relationships that create the FCOI.

The DOs will communicate the determination and the management plan in writing to the Investigator and will require the Investigator to comply with the management plan.

No expenditure on a federally funded award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan, when such a requirement applies. The DOs will monitor Investigator compliance with each management plan on an ongoing basis until completion of the federally funded research project.

9. Monitoring Investigator Compliance

Reselute will monitor Investigator compliance with the management plan for the duration of federally funded research project.

When the Institution's FCOI policy applies to subrecipient Investigators, the Institution will monitor subrecipient Investigator compliance with the management plan.

As part of this monitoring process, the DO may request and review documentation demonstrating compliance with required FCOI disclosures, including publications, presentation materials, abstracts, posters, and written communications to study personnel. Investigators must provide copies of such materials, including relevant emails or other written disclosures, to the DO for recordkeeping. These records will be maintained to document compliance with the management plan and to support institutional review and audit activities.

10. Public Accessibility of the FCOI Policy and FCOIs

10.1 FCOI Policy: Reselute shall make this FCOI policy publicly accessible per the applicable federal requirements. For PHS/NIH funding, Reselute shall post the policy on its publicly accessible website (https://reselutemedical.com/about-us/) and submit a copy through the eRA Commons Institution Profile Module, as required. Reselute shall satisfy any additional public-access requirements imposed by other federal sponsors.

10.2 Identified FCOIs Held by Senior/Key Personnel: Before any funds are spent under a PHS/NIH award, Reselute will ensure public accessibility, by providing a written response within five business days to requests for information about any SFI that meets all three of the following criteria:

10.2.1. The SFI was disclosed and is still held by Senior/Key Personnel (the PD/PI and any other individual identified by Reselute as senior/key personnel in the application, progress report, or other NIH submission).

10.2.2. Reselute has determined that the SFI is related to the PHS/NIH-funded research.

10.2.3. Reselute has determined that the SFI constitutes an FCOI.

When applicable, Reselute will make available at least the following information:

10.2.4. Investigator's name;

10.2.5. Investigator's title and role with respect to the research project;

10.2.6. Name of the entity in which the SFI is held;

10.2.7. Nature of the SFI; and

10.2.8. Approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures.

10.2.9. The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of Reselute's identification of a new FCOI, which should be requested subsequently by the requestor.

10.2.10 If Reselute uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of receiving or identifying an additional SFI of Senior/Key Personnel related to the PHS/NIH-funded research that was not previously disclosed; or a new SFI being disclosed by Senior/Key Personnel joining the project and determined by the DOs to be related and an FCOI. Information on SFIs subject to public accessibility will remain available for at least three (3) years from the most recent update.

11. Reporting Identified FCOIs

11.1 Prior to spending any funds under a PHS/NIH-funded award, Reselute will submit an identified FCOI report to NIH, in accordance with the FCOI regulations, for any Investigator's SFI determined to be an FCOI. Reselute will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

Reselute will designate an institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports to NIH.

FCOI reports are submitted only when an award is active and an FCOI has been identified (i.e., no award means no FCOI report, and no FCOI means no FCOI report).

The NIH eRA Commons FCOI Module User Guide provides instructions for preparing and submitting FCOI reports.

Reselute will submit the following types of reports as explained below:

11.1.1. Initial (Original) FCOI Reports: The report must include all information required under 42 CFR 50.605(b)(3). When an FCOI is identified, the Original Report will be submitted as described below:

Prior to the expenditure of funds: If an FCOI is identified at the time a new NIH award is issued, the FCOI SO will submit an "Original" FCOI report (2011 FCOI) through the eRA Commons FCOI Module before any funds are spent.

Within 60 days of identifying a new FCOI during the award: If an FCOI is identified during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project), Reselute must submit an Original FCOI report within 60 days of identifying the FCOI.

11.1.2. Annual FCOI Reports: For the duration of an award, including any extensions with or without funds, Reselute must submit an annual FCOI report to NIH. This report will indicate whether each previously reported FCOI is still being managed or no longer exists and describe any changes to the management plan, if applicable.

The annual report must be submitted at the same time as the Research Performance Progress Report (RPPR) or multi-year progress report, and at the time of any grant extension, following NIH guidance. NIH creates the opportunity for the FCOI SO to submit the Annual report 75 days prior to the next budget period start date for continuation awards. NIH will notify Reselute by email when an annual report is due.

Annual FCOI reports are not required at grant closeout.

11.1.3. Revision (or Mitigation) FCOI Reports: After completing a retrospective review, Reselute will submit a Revision report to NIH if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred.

Types of FCOI Report Summary Chart for NIH

Report	Content	Required When
New FCOI Report (Initial Submission)	Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan	Prior to expenditure of funds on a new award; or within 60 days of identifying any new FCOI during the award period
Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable	Annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension
Revised FCOI Report	If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report	Following a retrospective review when noncompliance with the regulation is identified, if applicable
Mitigation Report	Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions	After a retrospective review when bias is found

12. Investigator Training

Each Investigator will be informed of Reselute's FCOI Policy and trained on their responsibility to disclose foreign and domestic SFIs under this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. Training must be completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly (as described below) when any of the following occur:

- Reselute revises this policy or related procedures in a way that affects Investigator requirements.
- An Investigator is new to Reselute research under an NIH award (training must be completed before participating in the research).

- Reselute determines that an Investigator has not complied with this policy or with a management plan issued under it (training must be completed within 30 days as directed by the DOs).

To supplement the regulatory training requirements, Reselute will utilize NIH's training programs to train Investigators on the FCOI regulation. Reselute requires Investigators to complete either:

- The NIH FCOI Training module and retain the Completion Certificate for audit purposes. The certificate should be provided to the DOs; or
- Review the NIH Virtual Seminar presentation on FCOI compliance and provide the DOs with the date of completion by email for audit purposes.
- Training completion will be documented and maintained as part of Reselute's FCOI records.
- Investigators participating in research funded by other federal agencies will complete any additional training required by the applicable sponsor. Where an agency imposes training requirements that differ from or are more stringent than those described in this policy, the agency-specific requirements will govern.

13. Noncompliance and Corrective Actions

If Reselute identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the DOs will, within 60 days: review the SFI; determine whether it is related to PHS/NIH-funded research; determine whether it constitutes an FCOI; and, if so, implement an interim management plan describing actions that have been and will be taken to manage the FCOI going forward. Reselute will also submit an FCOI report to NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose an SFI that is later determined to constitute an FCOI;
- Failure by Reselute to review or manage an FCOI; or
- Failure by the Investigator to comply with an established management plan;

Reselute will, within 120 days of identifying noncompliance:

1. Complete a retrospective review of the Investigator’s activities and the PHS/NIH-funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting.
2. Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B). Based on the results of the retrospective review, if appropriate, Reselute will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

The retrospective review will be documented and include, at a minimum:

- Project number and project title;
- PD/PI;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has the FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the review, including the review process, composition of the review panel, and documents reviewed;
- Findings of the review; and
- Conclusions of the review.

If bias is found, Reselute will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) via the eRA Commons FCOI Module. The report will include the impact of the bias on the

research project and the plan of action or corrective steps taken to eliminate or mitigate the effect of the bias.

Reselute will thereafter submit FCOI reports annually to NIH as required by the regulations and the terms and conditions of the award. Depending on the circumstances, Reselute may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete.

If bias is not found following completion of the retrospective review, no further action will be taken unless new information is discovered that needs to be reported to NIH. If applicable, Reselute will update an existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report information (e.g., an increase in the value of the SFI or newly identified SFIs) following completion of the retrospective review.

If the failure of an Investigator to comply with Reselute's FCOI Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, Reselute will promptly notify the PHS/NIH Awarding Component of the corrective action taken or to be taken. The PHS/NIH Awarding Component may consider the situation and take appropriate action or refer the matter to Reselute for further action, including directions regarding how to maintain appropriate objectivity in the PHS/NIH-funded research project.

14. Clinical Research Requirements

Reselute will comply with any additional disclosure or corrective-action requirements applicable to federally funded clinical research, including requirements for public disclosure of an unmanaged or unreported FCOI when required by the sponsor.

In any case in which the U.S. Department of Health and Human Services determines that a federally funded clinical research project designed to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Reselute as required by 42 CFR Part 50, Subpart F, Reselute shall require the Investigator to (a) disclose the FCOI in each public presentation of the results of the research, and (b) request an addendum to previously published presentations.

15. Subrecipient Requirements

A subrecipient relationship exists when federal funds flow from or through Reselute to another individual or entity that will carry out a substantive portion of a federally funded research project and is accountable to Reselute for programmatic outcomes and compliance.

For PHS/NIH-funded research, subrecipients (e.g., collaborators or consortium members) are subject to Reselute's terms and conditions. Reselute will take reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations at 42 CFR Part 50 Subpart F. Reselute will include in each written agreement with a subrecipient terms specifying whether Reselute's FCOI Policy or the subrecipient's own FCOI policy will apply to subrecipient Investigators.

If the subrecipient's FCOI policy applies:

The subrecipient institution must certify in the agreement that its policy complies with federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to Reselute in time for Reselute to meet NIH reporting deadlines (i.e., before funds are spent and within 60 days of the subrecipient identifying an FCOI). Typically, this means requiring subrecipients to report FCOIs to Reselute within 50–55 days of identification. Reselute's FCOI Signing Official will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

If the subrecipient cannot certify compliance:

The agreement will specify that Reselute's FCOI Policy applies. In this case, subrecipient Investigators must disclose their SFIs to Reselute. The SFI disclosure must include SFIs that are directly related to the subrecipient's work for Reselute. The agreement will allow sufficient time for Reselute to review, manage, and report any resulting FCOIs. When an FCOI is identified, the DOs will implement a management plan,

monitor compliance by the subrecipient Investigator, and ensure that the required FCOI report is submitted to NIH via the eRA Commons FCOI Module.

16. Maintenance of Records

Reselute shall maintain records in accordance with 42 CFR 50.604(i) relating to Investigator disclosures, reviews and determinations, management plans, monitoring, retrospective reviews, mitigation reports, training, and other actions under this policy for the period required by the applicable federal sponsor, and for PHS/NIH awards for at least three (3) years from submission of the final expenditure report or such longer period as otherwise required.

Quality is responsible for administration and maintenance of FCOI records, including disclosure forms, review determinations, management plans, training documentation, retrospective reviews, mitigation documentation, and related correspondence, in accordance with the Company's document control practices in SOP-040, SOP-180 and Section 14 of this policy.

17. Enforcement Actions for Investigator Noncompliance and Remedies for Noncompliance

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Failure to comply with this policy, including failure to disclose Significant Financial Interests, failure to comply with an FCOI management plan, or failure to complete required training, may result in appropriate corrective or disciplinary actions.

Such actions may include, but are not limited to, formal notification or disciplinary measures, restrictions on participation in research activities or use of research funds, suspension or termination of employment or contractual relationship, and/or disqualification from participation in federally funded research, as appropriate.

In addition, the PHS/NIH Awarding Component and/or HHS may inquire at any time before, during, or after an award into any Investigator disclosure of financial interests and Reselute's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in Reselute's determination of an FCOI. Reselute will submit, or permit on-site review of, all records pertinent to compliance with the regulation and this policy.

On the basis of its review of records or other available information, the PHS/NIH Awarding Component may determine that additional corrective action, specific award conditions, suspension of funding, or other enforcement action is necessary until the matter is resolved.

DOCUMENT OWNER: Quality				
Revision	**Reason for Change**	**Change by**	**DCR Number**	**Issue Date**
A	Initial Release	F. Kesseli	2026-026	8/26/2026