

## **1. Introduction**

The U.S. Department of Health and Human Services (HHS), which includes the Public Health Service (PHS) and its component agencies such as the National Institutes of Health (NIH), has instituted regulations in order to promote objectivity in research. These regulations establish standards designed to provide a reasonable expectation that the design, conduct, and reporting of research performed under PHS contracts will be free from bias resulting from financial conflicts of interest (FCOIs). These regulations are presented in 42 C.F.R. Part 50, Subpart F, and 45 C.F.R. Part 94, known hereafter as the “Regulations.”

Rho, Inc., including specifically its subsidiary, Rho Federal Systems Division, Inc. (“Rho”), is considered an Institution subject to the Regulations by virtue of its role as a federal contractor submitting proposals to and receiving research funding from the PHS. By extension, the Regulations also apply to individuals employed or retained by Rho who participate in such research.

## **2. Purpose**

The purpose of this policy is twofold. First, this document satisfies the requirement under 45 C.F.R. Part 94 and 42 C.F.R. Part 50, Subpart F, that Rho have in place a written, enforced policy representing its understanding of and compliance with federal FCOI standards. Second, this policy articulates the responsibilities of individual Rho employees and consultants, and defines Rho’s process for managing and reporting FCOI issues.

## **3. Scope**

The scope of this policy includes any work funded by an organizational unit of the PHS (hereafter a “PHS Awarding Component”). This funding may be awarded directly to Rho or may be passed through to Rho by another institution in receipt of PHS funding. Phase I projects under the Small Business Innovative Research (SBIR) program, including the Small Business Technology Transfer (STTR) program, are currently exempted from the regulations and, therefore, do not fall under the scope of this policy.

The Regulations use the term Investigator to specify any person affiliated with an Institution who is accountable for individual compliance. An Investigator is defined as “the project director or principal investigator and any other person, regardless of title or



position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.” The broadness of this definition makes it difficult to align it with specific roles or groups within Rho. Therefore, for the purposes of this policy, an Investigator shall mean any Rho employee or consultant/contractor who charges time directly to a project falling within the scope of this policy, as defined above.

#### **4. Responsible Corporate Official**

Rho will designate an individual as the responsible Corporate Official as referenced in this policy. This individual reports directly to Rho’s Chief Executive Officer in matters concerning FCOIs and is charged with the implementation and ongoing documentation of matters concerning this policy. The Corporate Official shall be responsible for collaborating with Rho’s CEO, or their designee(s), when matters of judgment are necessary to determine compliance with this policy.

#### **5. Types of Financial Interest**

A financial interest includes anything of monetary value, whether or not the value is readily ascertainable. Having a financial interest does not necessarily constitute a conflict. Assessing a financial interest for a possible conflict first involves establishing that the interest is significant enough in its scope to potentially bias an Investigator’s activities.

##### **5.1. Significant Financial Interest**

As provided by the Regulations, a Significant Financial Interest (SFI) consists of one or more of the following interests that reasonably appears to be related to the Investigator’s institutional responsibilities:

- **Publicly traded entities:** An SFI exists if the value of any direct remuneration (payment including salary, consulting fees, honoraria, etc.) received from an individual entity within the twelve (12) months preceding the disclosure AND the value of any equity interest (including stock, stock options, or other ownership interest) in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- **Non-publicly traded entities:** An SFI exists if the value of any direct remuneration (payment including salary, consulting fees, honoraria, etc.) received from an individual entity within the twelve (12) months preceding the disclosure exceeds



\$5,000 OR when the Investigator holds any equity interest (including stock, stock options, or other ownership interest).

- Intellectual property rights: These rights and interests (e.g., patents, copyrights) may constitute an SFI if they result in the receipt of income by the Investigator.
- Reimbursed or sponsored travel: An Investigator must disclose any reimbursed or sponsored travel (paid on behalf of Investigator) related to their Rho responsibilities. This disclosure must include (1) the purpose of the trip, (2) the identity of the party paying the expenses, (3) the destination, and (4) the duration. Please note that this requirement does not apply to travel paid by a Federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. § 1001(a), or a teaching hospital, medical center, or research institution affiliated with an Institution of higher education.

An SFI does not include any of the following:

- Salary or other direct remuneration from Rho
- Any interest in intellectual property rights and interests assigned to Rho even if there is an agreement for an individual to share in royalties
- Any ownership interest held in Rho
- Income from seminars, lectures, or teaching engagements sponsored by Federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. § 1001(a), or a teaching hospital, medical center, or research institution affiliated with an Institution of higher education
- Income from service on advisory committees or review panels for Federal, state, or local government agency, an Institution of higher education, or a teaching hospital, medical center, or research institution affiliated with an Institution of higher education
- Income from investment vehicles where the Investigator is not in control of the investment decisions, e.g., mutual funds and retirement accounts

Consistent with NIH Policy Guidance, references to Institutions of higher education or a federal, state or local government agency, refer only to a U.S. Institution of higher education or a federal, state, or local government agency within the United States.



Income from foreign Institutions of higher education are not excluded from the meaning of an SFI.

## 6. Financial Conflict of Interest

In order for a financial interest to constitute an FCOI, the interest must be an SFI as defined above AND of such a nature that the interest could create a bias or suspicion of bias in the actions of the disclosing Investigator that directly and significantly affects the design, conduct, or reporting of PHS-funded research.

## 7. Investigator Disclosure Responsibilities

In addition to complying with the training requirements outlined in the Training section below, Investigators shall be required to fully disclose all of their SFIs, including any SFIs with foreign entities, and those of the Investigator's spouse and dependent children, using FRM-CP-001 Disclosure of Financial Interest and Other Support Related to PHS-Sponsored Projects. If an Investigator identifies a potential SFI, he or she will be required to complete a FRM-CP-002 Description of Significant Financial Interest Related to PHS-Sponsored Projects for each entity in which the Investigator may have an SFI.

Investigators shall undertake disclosure of their financial interests in the following situations:

- As part of Rho's annual FCOI disclosure process;
- When the Investigator is new to participating in a PHS-funded project;
- Within thirty (30) days of any change in an Investigator's financial interests that is relevant to his or her involvement in a PHS-funded project; and
- If the Investigator is being named in a proposal for PHS-funded research in a role that could be designated as Key Personnel under a resulting award.

In disclosing their SFIs, Investigators must distinguish whether the source of a significant financial interest is from a foreign or domestic entity and provide the address of the source of the significant financial interest.

In addition to all the items identified in the definition of SFI, Investigators must report any gifts that reasonably appear to be related to the Investigator's institutional responsibilities that as of the date of disclosure, when aggregated, exceeds \$5,000. For foreign entities,



Investigators must report any gifts received, regardless of value, that could reasonably appear related to the Investigator's institutional responsibilities.

Investigators must attest to the accuracy and completeness of their self-reported significant financial interests.

If an Investigator has any questions or concerns over whether a financial interest constitutes an SFI, the Investigator will seek clarification and guidance from the Corporate Official prior to submitting their SFI disclosure and prior to their involvement in a PHS-funded project. The Corporate Official will work with Investigators to resolve any questions as to whether an Investigators' financial interest constitutes an SFI.

## **8. Assessment and Management of Investigator Significant Financial Interests**

If the forms submitted by an Investigator do not declare the existence of an SFI, these forms shall be archived for future reference. If the existence of an SFI is declared, the Corporate Official shall have sixty (60) days to complete the following steps:

1. Review the documentation to identify gaps or inconsistencies in the information disclosed by the Investigator and follow up with the Investigator for more information or clarification as needed;
2. Review the documentation to determine if an actual FCOI exists, including whether any such FCOI is with a foreign entity;
3. Meet with the involved Investigator to determine a means for managing or eliminating the conflict;
4. Create a management plan that shall specify the actions that will be taken to manage such financial conflict of interest going forward; and
5. Implement any other action determined necessary.

If complete resolution of the conflict cannot be achieved within sixty (60) days, the Corporate Official shall implement reasonable interim measures within this timeframe.

Whenever a management plan is implemented, the Corporate Official shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Documentation of and discussions surrounding a disclosed SFI shall be kept confidential and disclosed internally only as necessary to ensure proper assessment and management



of the relevant issues. No external disclosures shall be made except to the extent that disclosure is required by law.

## 9. Retrospective Reviews

In the event that an SFI is not reported by an Investigator in a timely manner or, for whatever reason, was not previously reviewed, the Corporate Official shall, within sixty (60) days, complete the Assessment and Management steps described above and if the SFI is then found to constitute a conflict, the Corporate Official will initiate a retrospective review and any additional measures required by the Regulations to assess whether any PHS-funded research undertaken by that Investigator may have been biased by the existence of the FCOI.

The Corporate Official shall document the retrospective review; such documentation will include the following key elements:

1. Project number;
2. Project title;
3. Project director or principal Investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

The Corporate Official will complete the retrospective review within 120 days of a determination of noncompliance. If complete resolution of the conflict cannot be achieved between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review, the Corporate Official may implement reasonable interim measures within this timeframe.



Based on the results of the retrospective review, if appropriate, the Corporate Official will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, the Corporate Official will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Rho's plan of action taken to eliminate or mitigate the effect of the bias. Thereafter, Rho will submit FCOI reports annually.

## **10. Sub-Recipient Compliance**

Rho shall ensure that written agreements with sub-recipients supporting PHS-funded work contain FCOI provisions if, and as applicable to, the type of work being performed. Such provisions shall be in compliance with the Regulations and the requirements of the applicable award.

## **11. PHS Reporting**

Rho will provide initial and ongoing FCOI reports to the PHS as is required by the provisions of each PHS-sponsored award. Rho will also submit timely reports to the PHS regarding any individual conflict of interest issues that may arise during the term of an award.

## **12. Retention**

Records related to Investigator disclosures and Rho's review of, and response to, such disclosures will be retained for at least three (3) years after the date when final payment is received by Rho for the applicable project or the date the final expenditure report is submitted to the PHS, whichever is later, or for such other period required by law (45 C.F.R. Subpart 4.7; 45 C.F.R. 75.361).

## **13. Training on this Policy**

Documented training on this policy is required for all new Rho employees regardless of whether or not it is anticipated that the employee will meet the definition contained herein as an Investigator. Training shall also be required for contractors/consultants within 30 days of execution of the relevant contract if that contractor or consultant is expected to engage in activities that will be billed directly to a federal contract or grant.



Any employee or consultant/contractor who has not previously been trained on this policy and is asked to perform work that will be billed directly to a PHS-funded project shall document training on this policy as soon as is practically possible. In the case of a consultant/contractor, it shall be the responsibility of that individual's Rho personnel manager to ensure that the consultant/contractor is aware of this requirement and documents training appropriately.

Training on this policy for any employee or consultant/contractor meeting the definition of Investigator shall be renewed every four (4) years. Immediate retraining shall be necessary if an Investigator is found to have failed to comply with this policy.

Training or retraining on this policy will be required for all Investigators as soon as practicable if Rho revises this policy or any associated documents in a manner that affects the responsibilities of Investigators. Determinations regarding the need for retraining shall be made by the Corporate Official.

## 14. Enforcement

If the failure of an Investigator to comply with this policy is shown to have biased the design, conduct, or reporting of PBS-sponsored research, Rho will promptly inform the PHS Awarding Component of the corrective action taken or to be taken and will implement any reasonable corrective measures specified by the awarding component.

If the Corporate Official determines that an Investigator has failed to disclose significant financial interests, the Corporate Official will follow up with investigator to request additional information or clarification and recommend administrative or disciplinary actions, as appropriate, to ensure compliance with this policy. Such action may include, but is not limited to:

- Formal counseling (such as through a Human Resources [HR] action) regarding the breach of policies;
- Requiring the Investigator to take additional training(s);
- Suspending the Investigator from participating on the research project;
- Suspending the Investigator's employment; and
- Terminating the Investigator's employment.





In any case in which HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Rho as required by Regulation, Rho will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Any Rho employee found to have deliberately concealed an SFI or to have willfully provided false information regarding an SFI is subject to disciplinary action up to and including termination of employment.

## 15. Other Support

NIH requires applicants for NIH grants and cooperative agreements to supply certain information on other active and pending support (Other Support) as part of NIH's Just-in-Time procedures to prevent scientific, budgetary, or commitment overlap.

Other Support includes all resources made available to Rho in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution Rho identifies for the current grant. This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology).

Other Support does not include training awards, prizes, or gifts. Rho will provide Other Support information for all individuals designated in an application as senior/key personnel, which are those devoting measurable effort to a project. The designation of an individual or role as "Key" is specifically written into a grant or contract. Thus for purposes of this policy, "Key" shall mean those individuals or roles that are specifically named in the award.

As part of its reporting of Other Support, Rho will:

1. List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments. This includes titled academic, professional, or



institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

2. Report all resources and Other Support for all individuals designated in an application as senior/key personnel—including for the program director/principal Investigator (PD/PI) and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information will be provided about all current support for ongoing projects, irrespective of whether such support is provided through Rho, through another domestic or foreign organization, or is provided directly to an individual that supports the senior/key personnel’s research efforts.
3. Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). Rho will report all research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign “talents” or similar-type program, or other foreign or domestic support.
4. Provide the total award amount for the entire award period covered (including facilities and administrative costs), as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior/key personnel involved.

Rho will report all pending support at the time of application submission and prior to the award using the Just-in-Time Procedures by providing all information indicated above.

Rho will promptly notify NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award, including “Other Support” changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any senior/key personnel.

Further, if Other Support, as described as above, is obtained after the initial NIH award period, from any source either through Rho or directly to senior/key personnel, Rho will disclose the Other Support in its annual research performance progress report (RPPR) as needed.



Post-award, Rho will address any substantive changes by submitting a prior approval request to NIH in accordance with the NIH Grants Policy Statement (NIHGPS) section on “Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.” NIH may also request additional Just-in-Time information on a case-by-case basis. Rho will provide additionally requested information as appropriate to comply with the Just-in-Time procedures and any appropriate request.

Rho will verify the accuracy and validity of all administrative, fiscal, and programmatic information it submits through the Just-in-Time process. In addition, Rho will monitor its compliance with this policy and inform NIH of any problems or concerns.

## **16. Investigator Responsibilities to Self-Report “Other Support”**

Investigators identified in an application as senior/key personnel must self-report to Rho the following types of information regarding their Other Support:

1. In-kind resources (e.g., office/laboratory space, equipment, supplies, employees, students, and visiting scholars);
2. Financial support through active grants;
3. Financial support through pending grants;
4. Financial support through other awards;
5. Financial support through cooperative agreements;
6. Financial support through contracts;
7. Professional affiliations (e.g., positions and scientific appointments);
8. Current or pending participation in “talents” or similar-type programs;
9. “Gifts” where items or funds are received with conditions attached or deliverables expected in return; and
10. Any other type(s) of support.

In addition, Investigators must identify whether the Other Support they receive is from a domestic or foreign entity. Investigators must attest to the accuracy and completeness of any self-reported Other Support.

If an Investigator has any questions or concerns over reporting of their Other Support, the Investigator will seek clarification and guidance from the Corporate Official. The Corporate



Official will work with Investigators to resolve any questions regarding their reporting of Other Support.

## 17. Review of Investigators' "Other Support"

The Corporate Official will review each Investigator's self-report to identify gaps or inconsistencies in the information disclosed by the Investigator and will follow up with the Investigator for more information or clarification as needed. In addition, the Corporate Official will contact entities with which an Investigator reports an agreement, contract, or grant to confirm the nature of the entity's relationship with the Investigator.

The Corporate Official will review Investigators' Other Support to identify whether it may cause scientific, budgetary, or commitment overlap to Investigators' research.

If the Corporate Official determines that an Investigator has failed to self-report Other Support, the Corporate Official will follow up with investigator to request additional information or clarification and recommend administrative or disciplinary actions, as appropriate, to ensure compliance with this policy. Such action may include, but is not limited to:

- Formal counseling (such as through an HR action) regarding the breach of policies;
- Requiring the Investigator to take training(s);
- Suspending the Investigator from participating on the research project;
- Suspending the Investigator's employment; and
- Terminating the Investigator's employment.

In addition, the Corporate Official will take the following action(s):

- Review the previously undisclosed information and identify possible scientific, budgetary, or commitment overlap in the Investigators' research;
- Determine if the integrity of the research was impacted by the nondisclosed information;
- Determine if information about the research was inappropriately shared with outside entities;
- Report incident to NIH or other Federal entity(ies) as needed.



## 18. Foreign Components

NIH requires award recipients to determine whether activities it supports include a foreign component, defined as the existence of any “significant scientific element or segment of a project” outside of the United States. This includes:

1. Performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended; and/or
2. Performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended.

If Rho determines that a portion of the project will be conducted outside of the United States, Rho will review the foreign activities to determine if they are considered significant. Rho, consistent with NIH policy, will obtain approval from NIH prior to adding a foreign component to an ongoing NIH grant.

If an activity does not meet the definition of foreign component because all research is being conducted within the United States, but there is a non-U.S. resource that supports the research of an Investigator and/or researcher, Rho will report the support as Other Support.

## 19. Public Accessibility

This policy is publicly accessible on Rho’s website, available at <https://www.rhoworld.com/wp-content/uploads/FICOI-Policy-Rho.pdf>.

Information concerning identified financial conflicts of interest held by senior/key personnel will be made publicly accessible via written response (within 5 business days of a request) prior to Rho’s expenditure of any funds under a PHS-funded research project.

Publicly accessible information concerning identified financial conflicts includes:

- the Investigator’s name;
- the Investigator’s title and role with respect to the research project;
- the name of the entity in which the significant financial interest is held;
- the nature of the significant financial interest; and
- the approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.



Information concerning identified conflicts of interest will be updated and kept current as required by Regulation and will remain publicly available for three years from the date that the information was most recently updated.

## 20. Procedural Documents Referenced

- FRM-CP-001 Disclosure of Financial Interest and Other Support Related to PHS-Sponsored Projects
- FRM-CP-002 Description of Significant Financial Interest Related to PHS-Sponsored Projects