

**JOHNSON & JOHNSON FINANCIAL CONFLICTS OF INTEREST POLICY for
U.S. GOVERNMENT-FUNDED RESEARCH & DEVELOPMENT PROJECTS
&
Financial Conflicts of Interest Standard Operating Procedures**

I. INTRODUCTION

A. Purpose

This policy implements U.S. federal requirements pertaining to “Objectivity in Research” promulgated by the Public Health System (“PHS”) of the U.S. Department of Health and Human Services (“HHS”), which includes the U.S. National Institutes of Health (“NIH”), the Biomedical Advanced Research and Development Authority (“BARDA”), the Center for Disease Control and Prevention, and the Agency for Healthcare Research and Quality (“FCOI Policy”). Financial Conflict of Interest (“FCOI”) requirements, related to PHS Organization-funded research, are published in U.S. regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

The intent of this FCOI Policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research performed under grants or contracts with PHS Organizations will be biased by any conflicting financial interest. To apply for funding with PHS Organizations, J&J Operating Companies must be able to certify, in each application for funding, that the J&J Operating Company:

- i. has in effect, an up-to-date, written and enforced administrative process to identify and manage any FCOI;
- ii. will promote and enforce Covered Individual compliance with the regulation;
- iii. will manage FCOI and provide initial and ongoing FCOI reports;
- iv. will make FCOI and significant financial interest information available to the PHS Organization, promptly, upon request; and
- v. will fully comply with the regulation’s requirements

This FCOI Policy and FCOI SOP address training requirements; disclosure, review, and monitoring requirements; reporting requirements; maintenance of records; enforcement mechanisms and remedies for noncompliance; sub-recipient requirements; and public accessibility requirements.

B. Scope

A J&J Operating Company employee or contractor who submits a grant or contract proposal or conducts research under a PHS Organization’s funding grants or contracts must adhere to the applicable requirements of the PHS Organization, including those involving the disclosure and regulation of outside activities and financial interests. Specific FCOI laws and regulations are applicable to all project directors and principal investigators, whether

employees or contractors, who are responsible for the design, conduct and reporting of research work under grants and contracts with PHS Organizations.

Many non-PHS organizations have adopted the PHS regulations. These include, but are not limited to, the American Cancer Society, the American Heart Association, and the Juvenile Diabetes Research Foundation. FCOI disclosure process could be implemented on a case by case basis for non-PHS, non-profit organizational funded grants requiring similar disclosure, but this Policy does not require it.

II. DEFINITIONS

- A. **Covered Individual (“CI”)**: any J&J Operating Company employee or contractor who is responsible for the design, conduct or reporting of a PHS-Funded Research project or proposed for such project, including any project director, principal investigator and any other key personnel designated as such in a PHS-Funded grant application or contract.
- B. **Covered Individual Responsibilities**: A Covered Individual’s professional responsibilities performed on behalf of an entity that proposes to undertake or undertakes PHS-Funded Research.
- C. **Equity Interest**: Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- D. **Financial Conflict of Interest (“FCOI”)**: A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.
- E. **Financial Interest**: Any interest of monetary value, whether or not the value is readily ascertainable.
- F. **Immediate Family**: A Covered Individual’s spouse or domestic partner and dependent children.
- G. **J&J Operating Company**: any company that is majority-owned by (i) Johnson & Johnson or (ii) an affiliate of Johnson & Johnson.
- H. **Non-Significant Financial Interests (“Non-SFI”)**: include the following types of Financial Interests:
 - (i) Remuneration paid by an entity to which a CI owes Covered Individual Responsibilities, if the CI is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or
 - (ii) Any ownership interest in an entity held by the CI or income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI does not directly control the investment decisions made in these vehicles; or

- (iii) Income from seminars, lectures, or teaching engagements sponsored by a US federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
 - (iv) Income from service on advisory committees or review panels for a US federal, state or local government agency, an institution of higher education, as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- I. **PHS:** 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, among others, the NIH. A listing of the PHS agencies and their offices may be located on the U.S. Department of Health and Human Services Organizational Chart.
 - J. **PHS-Funded Research:** any Research funded by way of a grant from, or a contract with, a PHS Organization.
 - K. **PHS Organization:** (i) an agency that is part of the PHS or (ii) an organization that has adopted the PHS Regulations, but not a non-governmental non-profit organization.
 - L. **PHS Regulations:** U.S. 42 CFR Part 50, Subpart F and 45 CFR Part 94
 - M. **Remuneration:** (i) Salary and any payment for services including consulting fees and honoraria; (ii) any Equity Interest; and (iii) travel reimbursement related to the Covered Individual Responsibilities.
 - N. **Research:** 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, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
 - O. **Significant Financial Interest (“SFI”):** A Financial Interest consisting of one or more of the following interests of a Covered Individual (and those of the Covered Individual’s Immediate Family) that reasonably appear to be related to Covered Individual Responsibilities, but specifically excludes any Non-SFI:
 - i. any Remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000;
 - ii. any Remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or

- iii. intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

III. TRAINING REQUIREMENTS

The J&J Operating Company, its employees, and contractors shall adhere to this FCOI Policy and the Standard Operating Procedure (“SOP”) attached to this FCOI Policy to inform each Covered Individual of the FCOI Policy, the Covered Individual’s Responsibilities, and the PHS Regulations. In addition, the FCOI SOP attached to this FCOI Policy requires each Covered Individual (“CI”) to complete FCOI training and the FCOI Disclosure form as follows:

A. At the Time of Application/Proposal Submittal or Earlier

The identified Covered Individuals, including Principal Investigator or Co-Principal Investigator shall:

- i. complete the FCOI Training requirements;
- ii. complete the FCOI Disclosure Form; and
- iii. submit their FCOI Disclosure Form.

B. Prior to engaging in PHS-Funded Research (i.e., billing time against the PHS-Funded Research)

Covered Individuals, including PI and Co-PI shall:

- i. at least every four years from the time of initial training and disclosure;
- ii. immediately, if the FCOI Policy;
- iii. is revised in a manner that affects the obligations and requirements of Covered Individuals;
- iv. a Covered Individual is new to the J&J Operating Company;
- v. a Covered Individual is not in compliance with the FCOI Policy; or
- vi. a Covered Individual is not in compliance with a remediation plan.¹

IV. DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

This FCOI Policy and the attached FCOI SOP establish a process to require each Covered Individual to disclose SFIs (and those of the Covered Individual’s Immediate Family) related to the Covered Individual Responsibilities that meet or exceed the definition of SFI. (See Section III.A.ii – iii). This disclosure must occur no later than at the time of application/proposal submittal for PHS-Funded Research, at least annually during the period of the award, and within 30 days of discovering or acquiring a new SFI.²

The accompanying FCOI SOP designates individual(s) to solicit and review disclosures of SFIs of the Covered Individual (and those of the Covered Individual’s Immediate Family) related to a Covered Individual Responsibilities.³ Guidelines have been created for the designated individual

¹ 42 CFR 50.604(b).

² 42 CFR 50.604(e)(1)-(3).

³ 42 CFR 50.604(d).

or committee to determine whether a Covered Individual's SFI is related to PHS-Funded Research and, if so related, whether the SFI is an FCOI.⁴

This FCOI Policy and the FCOI SOP establish a process to require the designated individual or committee, prior to the J&J Operating Company expenditure of award funds, to review all Covered Individual SFI disclosures, determine if any SFIs relate to PHS-Funded Research, determine if an FCOI exists (i.e. SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research), and develop and implement remediation plans, as needed, to manage FCOIs.⁵

This Janssen FCOI Policy and the FCOI SOP establish a process to review disclosure of SFIs, make determination of FCOIs, and implement a remediation plan:

- A. when required for a Covered Individual who is new to participating in a PHS-Funded Research project or for an existing Covered Individual, who discloses a new SF⁶;
- B. within sixty (60) days whenever the J&J Operating Company identifies an SFI that was not disclosed by a Covered Individual or not previously reviewed by the J&J Operating Company.⁷

This FCOI Policy and the FCOI SOP also establish a process to take such actions, as necessary, to manage FCOIs, including any financial conflicts of a Subcontractor, if applicable, and monitor Covered Individual compliance with remediation plans until completion of the PHS-Funded Research project.⁸

V. REPORTING REQUIREMENTS

This FCOI Policy and the FCOI SOP establish a process to send initial, annual (i.e. ongoing) and revised FCOI reports to the PHS Organization including all reporting elements required by the regulation⁹ for the J&J Operating Company and its sub-recipients, if applicable, as required by PHS Regulations

- A. Prior to expenditure of funds;
- B. Within 60 days of identification of an FCOI for a Covered Individual who is newly participating in the project;
- C. Within 30 days for new, or newly identified, FCOIs, for existing Covered Individuals;
- D. At least annually (at the same time as when the J&J Operating Company is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- E. Following a retrospective review to update a previously submitted report, if appropriate.

⁴ 42 CFR 50.604(f).

⁵ 42 CFR 50.605(a)(1).

⁶ 42 CFR 50.605(a)(2).

⁷ 42 CFR 50.605(a)(3)(i)-(iii).

⁸ 42 CFR 50.604 (g) and 42 CFR 50.605 (a)(4).

⁹ 42 CFR 50.604(h) and 42 CFR 50.605(b).

Whenever a J&J Operating Company identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the J&J Operating Company during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall escalate the matter in accordance with the J&J Escalation Policy, and within sixty (60) days: review the SFI; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a remediation plan that shall specify the actions that have been, and will be taken to manage such financial conflict of interest going forward;

(ii)

(A) In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the J&J Operating Company to constitute an FCOI; failure by the J&J Operating Company to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI remediation plan, the J&J Operating Company shall, within 120 days of the J&J Operating Company's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(B) The J&J Operating Company is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) 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.

(iii) Based on the results of the retrospective review, if appropriate, the J&J Operating Company shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the J&J Operating

Company 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 the J&J Operating Company's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the J&J Operating Company will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the FCOI, the J&J Operating Company may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the J&J Operating Company's retrospective review.¹⁰

The J&J Operating Company must establish a policy and procedure to notify the PHS Organization promptly if a Covered Individual's failure to comply with the FCOI Policy or if an FCOI remediation plan appears to have biased the design, conduct or reporting of the PHS-Funded Research, and, in such an instance, inform the PHS Organization of the corrective action taken or to be taken.¹¹

VI. MAINTENANCE OF RECORDS

The J&J Operating Company must adhere to its Records and Information Management ("RIM") Policy and at a minimum maintain all FCOI-related records¹²:

- For at least 3 years from the date the final expenditure report is submitted to the PHS Organization.
- From other dates specified in 45 CFR 74.53(b) and 92.42(b) where applicable.

VII. ENFORCEMENT MECHANISM AND REMEDIES FOR NONCOMPLIANCE

The J&J Operating Company shall utilize the "Performance and Conduct Standards Policy" or its equivalent for the country in which the employee is based to remedy any nonconformance with this FCOI Policy to ensure Covered Individual compliance.¹³

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 a Covered Individual with an FCOI that was not managed or reported by the J&J Operating Company as required, the J&J Operating Company shall require the Covered Individual to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations and publications.¹⁴

¹⁰ 42 CFR 50.605(a)(3)(i)-(iii).

¹¹ 42 CFR 50.606(a).

¹² 42 CFR §50.604(i).

¹³ 42 CFR 50.604(j).

¹⁴ 42 CFR 50.606(c).

VIII. THIRD PARTY REQUIREMENTS

The J&J Operating Company must have a process in place to assure that any contractor or collaborator who carries out PHS-Funded Research with the J&J Operating Company (“Subcontractor”) certifies, via written agreement, that it will follow this FCOI Policy or the Subcontractor’s own FCOI policy.¹⁵

If the Subcontractor certifies that it will comply with this FCOI Policy, the agreement shall specify the time periods for the Subcontractor to report all SFI to the J&J Operating Company. Such time periods shall be sufficient to enable the J&J Operating Company to comply with timely review, management and reporting obligations required by this FCOI Policy.

If the Subcontractor certifies that it will comply with its own FCOI policy, the written agreement with the Subcontractor shall include:

- (i) A certification by the Subcontractor that its policy complies with all applicable laws, regulations, and rules (including, but not limited to the PHS Regulations; and
- (ii) Time periods for the Subcontractor to report any identified FCOI to the J&J Operating Company defined to permit sufficient time to enable the J&J Operating Company to provide timely FCOI reports under this FCOI Policy, as necessary, to the PHS Organization.

IX. ACCESSIBILITY OF DISCLOSURE DOCUMENTATION

The most recent version of this FCOI Policy is accessible to the public on the Janssen.com website.¹⁶ Prior to the expenditure of funds, J&J Operating Company shall establish a process to make information concerning identified FCOI available within 5 business days to any requesting PHS organization. The information will be updated by CIs at least annually, be updated within 60 days of a newly identified FCOI, and all records should remain available for three (3) years from the date of the last payment by PHS Organization.¹⁷

¹⁵ 42 CFR 50.604(c)(1)(i)-(iii).

¹⁶ 42 CFR 50.604(a).

¹⁷ 42 CFR 50.605(a)(5)(i)-(iv).