

Orthocare Innovations, LLC
CONFLICT OF INTEREST POLICY APPLICABLE
TO ANY AWARD FROM US PUBLIC HEALTH SERVICES

The federal Public Health Service (PHS) has adopted regulations ([42 CFR Part 50 Subpart F and 45 CFR Part 94](#)) on *Promoting Objectivity in Research*. These regulations describe the actions an individual and an organization must take in order to promote objectivity in research. The regulations apply to all PHS funded grants, cooperative agreements, research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants), and subawards where the originating sponsor is PHS. The regulations require that investigators submitting applications for funding, where the prime sponsor is PHS (e.g., funding from the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control), including prior to the submission of the application to the PHS Grantee organization¹, disclose to Orthocare Innovations, LLC (Orthocare) any significant financial interests related to their institutional responsibilities at Orthocare.

Definitions

Institutional responsibilities means an Investigator's professional activities on behalf of Orthocare (e.g., teaching, administration, engineering, research or clinical care). Specifically, these include:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
- Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical Service activities such as performing services for the University's Faculty Practice Plan and affiliated hospitals;
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards, etc.; or
- Special Service activities on behalf of Orthocare including institutional community service.

Investigator means the Project Director or Principal Investigator (PD, PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an award, or proposed for such funding, which may include, for example, collaborators or consultants. Orthocare's Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

¹ For purposes of this Policy, PHS Grantee is the organization that receives an award directly from PHS. This policy may also be used for those subawards and awards under a non-PHS sponsor adopting the PHS *Promoting Objectivity in Research* regulations.

Significant Financial Interest means:

(1) A 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 on behalf of Orthocare:

- (i) **With regard to any publicly traded entity**, a *significant financial interest* 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 for the investigator, investigator's spouse and dependent children, 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;
- (ii) **With regard to any non-publicly traded entity**, a *significant financial interest* 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); or
- (iii) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- (iv) **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, engineering, research, or clinical activities) must be disclosed to Orthocare. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by Orthocare and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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.

(2) The term **significant financial interest does not** include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by Orthocare to the Investigator if the Investigator is currently employed or otherwise appointed by Orthocare, including intellectual property rights assigned to Orthocare and agreements to share in royalties related to such rights;
- (ii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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 an U.S. 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.

Disclosure

Prior to the submission of an application to the PHS Grantee for funding, the Principal Investigator and all other Investigators at Orthocare must have disclosed to Orthocare's Conflict of Interest Committee (COIC)/designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to the PHS for funding, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the COIC/designated official promptly and prior to participation in the project. Each Investigator who is participating in research under a subaward where the prime award originates from PHS must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to Orthocare, pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS-funded project directly as a PHS Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research under an award or subaward where the prime award originates from PHS must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review by Orthocare's COIC/Designated Official

The COIC/designated official will conduct reviews of disclosures. The COIC/designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research subaward funded under a PHS prime award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research subaward.

Guidelines for Determining "Relatedness" and Financial Conflict of Interest

The COIC/designated official will determine whether an Investigator's SFI is related to the research under an award supported by PHS and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research under the award when the COIC/designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research. The COIC/designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the award.

A financial conflict of interest exists when the COIC/designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's SFI is related to the research supported by a PHS prime award or subaward, and if so, whether the relationship creates an FCOI, the COIC/designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the COIC/designated official may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has SFI; or
13. Whether the project involves a subaward to an entity in which the Investigator has an SFI.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the COIC/designated official will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the COIC/designated official will be guided by the principles discussed in this Policy, the COIC/designated official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project;
- l) Annual reports on the research progress to the COIC/designated official.

If the COIC/designated official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The COIC/designated official will keep a record of the disclosure and other relevant information for at least three years. If the COIC/designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a PHS prime award or subaward will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the COIC/designated official necessary to manage the Conflict of Interest. The COIC/designated official will communicate, in writing, with the PHS Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the PHS Grantee has reported the FCOI to PHS. The PHS Grantee will notify Orthocare when it may incur expenditures.

The COIC/designated official will keep a record of Investigator disclosures of financial interests and the COIC/designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the prime award or subaward and relevant PHS Regulations.

Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS prime award or subaward, Orthocare will ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- (i) The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by Orthocare in the prime award or subaward application to the PHS Grantee, progress report or any other report submitted to the PHS Grantee;
- (ii) Orthocare has determined that the Significant Financial Interest is related to the research funded through a prime award or subaward; and
- (iii) Orthocare has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The information that Orthocare will make available via a written response to any requestor within five days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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. If Orthocare is using a publicly accessible website to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the PHS-funded research project, if it is determined by the COIC/designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

If Orthocare responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of the Orthocare's identification of a new financial conflict of interest, which should be requested subsequently by the requestor. Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for at least three years from the date that the information was most recently updated.

Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS prime award or subaward, Orthocare will provide to the PHS Grantee an FCOI report compliant with PHS regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. Orthocare cannot incur expenditures until it has received notification to do so from the PHS Grantee.

While the PHS prime award or subaward is ongoing (including any extensions with or without funds), Orthocare will provide to the PHS Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Orthocare will provide to the PHS Grantee, within forty-five (45) days, an FCOI report regarding the financial conflict of interest and ensure that Orthocare has implemented a management plan and the Investigator has agreed to the relevant management plan.

Training Requirements

Each Investigator must complete training on *Orthocare Conflict of Interest Policy Applicable to Any Award Issued Under A Public Health Services Prime Award* prior to engaging in research related to any PHS-funded prime award or subaward and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- 1) Orthocare revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
- 2) An Investigator is new to Orthocare research under an award or subaward issued under a PHS prime award (training is to be completed prior to his/her participation in the research); or
- 3) Orthocare finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within thirty (30) days in the manner specified by the COIC/designated official).

In fulfillment of the training requirement, Orthocare requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes.

Failure to Comply with Orthocare's Conflict of Interest Policy Applicable to Public Health Service Funded Awards and Subawards

When an FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because an FCOI was not timely reviewed or reported by a second tier subrecipient or by Orthocare; or because an investigator failed to comply with a management plan; then Orthocare will within ninety (90) days:

- a) Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- b) Document the retrospective review consistent with the regulation;
- c) Document Orthocare's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research; and
- d) Notify the PHS Grantee in writing if working under a PHS prime award or subaward.

If bias is found, Orthocare shall notify the PHS Grantee promptly and submit a mitigation report to the PHS Grantee that shall address the following:

- Impact of the bias on the research project, and
- Orthocare's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Orthocare shall submit FCOI reports annually to the PHS Grantee, in accordance with the regulation and terms and conditions of the prime award or subaward agreement. Depending on the nature of the Financial Conflict of Interest, Orthocare may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Orthocare's independent retrospective review.

Clinical Research

If the PHS Grantee determines that one of its funded clinical research projects 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 a Financial Conflict of Interest that was not managed by or reported to Orthocare, shall 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.

Failure to Comply with This Policy

No expenditures of funds on any award supported by PHS will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any COIC/designated official-approved FCOI management plan. Any failure by an individual to adhere to this Policy may be cause for disciplinary action.