

JP2MRI Financial Conflict of Interest in Research Policy

(Initiated 1/1/2020) and (Amended 1/1/2021)

1. **Policy.** John Paul II Medical Research Institute (JP2MRI) is committed to the principle that its research be carried out with integrity, open inquiry, and rigorous analysis, free from outside conflicts of interest that might compromise, or give the appearance of compromising, the sound professional judgment of its investigators. This policy sets forth that position and provides a mechanism for ensuring the integrity of JP2MRI's research when such conflicts arise.
2. **Scope of policy.** This policy applies to all persons at JP2MRI who meet the definition of investigator and applies to all JP2MRI activities meeting the definition of research where the activity is funded or, if unfunded, where the work involves human subjects. Designated provisions of this policy apply only to investigators applying for or conducting research funded by the Public Health Service (PHS) (including the National Institutes of Health). Investigators who conduct studies regulated by the Food and Drug Administration or who conduct research funded by the other federal agencies, including the National Science Foundation, are subject to agency-specific regulations relating to financial conflicts of interest in research. Affected investigators are advised to review such regulations prior to submission of a research proposal or application.
3. **Oversight of policy.** This policy is overseen by the Chief Scientific Officer (CSO), who will appoint a Conflict of Interest Officer (COIO) as the institutional official responsible for implementation of this policy and formation of a Conflict of Interest in Research Committee (CIRC) to review and recommend to the Chief Scientific Officer management plans for disclosed financial conflicts of interest. If the CSO is the principal investigator of a PHS grant, then the next highest ranking scientific officer at JP2MRI who does not have a financial conflict of interest will oversee the policy. If there is no one available at JP2MRI who can fulfill that role, then an outside scientific organization that has no financial or business relationship with JP2MRI will be used.
4. **Definitions.**
 - a. "Disclosure" means an investigator's disclosure of financial interests to JP2MRI related to their institutional responsibilities.
 - b. "Entity" means a non-JP2MRI organization, whether public or private. Examples include the following: a company, partnership, professional association, voluntary health organization, etc.
 - c. "Financial conflict of interest" means a significant financial interest that is related to proposed JP2MRI research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct, or reporting of research.
 - d. "Financial interest" means anything of monetary value, whether or not the value is readily ascertainable, in any one of the following categories: compensation; equity (stock, stock

options, or other ownership interest) in a public or private company; royalty/licensing income; a position in an entity giving rise to a fiduciary duty such as director, officer, partner, trustee, employee, or any position of management; or, for researchers with funding from the Public Health Service, any reimbursed or sponsored travel.

e. "Human subjects research" means research conducted with a living individual about whom an investigator obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.

f. "Institutional responsibilities" means an investigator's professional responsibilities on behalf of JP2MRI, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

g. "Investigator" means the principal investigator or project director and any other person, whether faculty, staff, or student and regardless of title or position, who has the authority to make independent decisions related to the design, conduct, or reporting of JP2MRI research. Also includes subgrantees, contractors, collaborators, or consultants of JP2MRI.

h. "Manage" means to act to address a financial conflict of interest, which includes reducing or eliminating the financial conflict of interest, to ensure that the design, conduct, and reporting of research are free from bias or the appearance of bias.

i. "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge and encompasses basic and applied research and product development.

j. "Senior/key personnel" means a PHS project director or principal investigator and any other individual who contributes to the scientific development or execution of a project in a substantive, measurable way, and who is included in the grant application, progress report, or any other report submitted by the institution, whether or not they receive salaries or compensation under the grant.

k. "Significant financial interest" means anything of monetary value or potential monetary value held by an investigator (and by the investigator's spouse and dependent children), and that reasonably appears to be related to the investigator's institutional responsibilities.

Definition and Examples of Financial Conflict of Interest

5. With regard to any publicly traded entity, 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 the definition of "significant financial interest," 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];

6. With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the calendar year preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest (e.g., stock, stock option, or other ownership interest);

7. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;

8. A position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any position of management;

9. For investigators applying for or conducting research funded by the PHS, any reimbursed or sponsored travel related to the investigator's institutional responsibilities (i.e., travel is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available). Disclosure of this interest will include the purpose and duration of the trip, the identity of the sponsor/organizer, and the travel destination;

10. The term "significant financial interest" does not include salary or other remuneration paid by JP2MRI to the investigator if the investigator is currently employed or otherwise appointed by JP2MRI; 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; income from seminars, lectures, teaching engagements, or travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency or institution of higher education.

Disclosures, Review and Monitoring Requirements

1. Prior to the investigator's submission of a grant application or JP2MRI's execution of a cooperative agreement or sponsored research contract, or prior to initiation of any human subjects research, whether funded or not, each investigator is required to submit a disclosure form describing any financial interest held by the investigator, the investigator's spouse, or any dependent child of the investigator that the investigator determines to be reasonably related to the investigator's institutional responsibilities. The disclosure form will be submitted to JP2MRI's Conflict of Interest Officer, who will then review any financial interest disclosed as provided in paragraph below.

2. When an investigator not covered above reasonably concludes or reasonably should conclude that their research presents or appears to present a financial conflict of interest, the investigator must disclose that fact to JP2MRI's Conflict of Interest Officer.

3. In those cases where JP2MRI has determined that a financial conflict of interest exists, no research funds may be expended and no research may begin until the investigator has agreed in writing to any management plan required by JP2MRI.

4. Annual update to disclosure. Each investigator who submits a financial interest disclosure form to JP2MRI is required to update that disclosure annually during the period of the award or, for non-sponsored research, annually during the conduct of the project.
5. Annual updates must be submitted by October 1 of each calendar year.
6. It is the responsibility of the principal investigator or project director of a research project to ensure that each investigator working on/who will work on the project submits a timely annual update to a previously submitted disclosure form.
7. The annual update will be submitted to JP2MRI's Conflict of Interest Officer, who will then review any updated financial interest disclosed as provided in the discussion below.
8. Updating FCOI: When changes occur related to a financial interest in an ongoing research project, the investigator is required to update the disclosure describing that interest. This may occur, for example, where the investigator acquires a new financial interest or has changes to a previously-disclosed financial interest. A disclosure is also required when a new investigator is added to an existing project. Such disclosures must be submitted to the Conflict of Interest Officer within 30 days of the event requiring the disclosure. The Conflict of Interest Officer will then review any such interest disclosed as provided in the discussion below.
9. Monitoring FCOI: For PHS-funded research, the investigator's management plan will be monitored on an ongoing basis until the completion of the research project.
10. Mitigation plan: If the COIO determines in the conduct of its retrospective review of PHS-funded research that the research or any part of it was biased, the COIO will recommend a mitigation plan to the Chief Scientific Officer or designee to address any such issues. JP2MRI will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.
11. When in the course of an ongoing research project an investigator new to the project discloses a significant financial interest or an existing investigator discloses a new or changed significant financial interest, and where the COIO has determined that the disclosed significant financial interest constitutes a financial conflict of interest subject to management under this policy, the COIO will review the disclosure and JP2MRI will implement a management plan for the project within 60 days of the submission of the disclosure to JP2MRI.
12. Depending on the nature of the financial conflict of interest, JP2MRI may determine that additional interim measures are necessary with regard to the investigator's participation in the research project between the date of disclosure and the implementation of JP2MRI's management plan. Consideration will be given to any additional interim measures that includes Institutional Review Board that may view as necessary for the protection of human participants in any ongoing research.
13. Implementation by the Chief Scientific Officer (CSO): The CSO or designee will review the recommendation of the COIO and determine the final management plan to be implemented for the research. This determination will be provided to the investigator, who must accept the

requirements of the management plan in writing before beginning work on the project. Copies of the signed management plan will also be provided to the investigator's departmental executive officer and in the case of research involving human participants, to the Institutional Review Board.

14. Appeal: Any investigator may appeal the decision of the CSO or designee regarding management of a financial conflict of interest in writing to the Chief Executive Officer of JP2MRI.

Training Requirements

1. Training. Prior to engaging in any research project, all investigators must complete training on the investigator obligations under this policy. This training must be repeated at least every four years and must be completed immediately if this policy is revised so as to affect the investigator obligations, if an investigator is new to JP2MRI, or if JP2MRI finds an investigator to have violated this policy or any applicable management plan. Training involves review of JP2MRI's FCOI policy and completing an online educational program (e.g. CITI Program).

Reporting Requirements to NIH

1. JP2MRI will provide initial and ongoing reports of its management of financial conflicts of interest to external sponsors of JP2MRI research as required by law and in accordance with NIH policy.

2. JP2MRI has established a process that grants funded by PHS will require that investigators with FCOI will provide a FCOI disclosure form to the COIO of their FOCI prior to expenditures of funds. The disclosure will be made within 60 days of identification for an Investigator who is new or is an established investigator participating in the project. The investigator will provide any new FOCI changes and update on any new FCOI in their management plan, if applicable, until the completion of the project. FCOI for the investigator will be automatically updated annually.

3. In the event JP2MRI identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by JP2MRI during an ongoing research project, and where the COIO has determined that the undisclosed significant financial interest constitutes a financial conflict of interest related to a PHS-funded research project, the CIRC will review the financial conflict of interest, and JP2MRI will implement a management plan for the project within 60 days of identification of that interest. In addition, the CIRC will, within 120 days of its determination of noncompliance, complete a retrospective review of the investigator's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

4. If the CIRC determines in the conduct of its retrospective review of PHS-funded research that the research or any part of it was biased, the CIRC will recommend a mitigation plan to the Chief Scientific Officer or designee to address any such issues. JP2MRI will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

5. If the CIRC determines in the conduct of its retrospective review of PHS-funded research that the investigator did not comply with the FCOI policy, the CIRC will recommend a mitigation plan to the Chief Scientific Officer or designee to address any such issues. JP2MRI will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

Maintenance of Records

1. Records relating to all investigator disclosures of significant financial interests and JP2MRI's review and management of such disclosures, will be maintained by JP2MRI in the case of externally funded research for three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements) or three years from the final payment (in the case of research contracts), or as otherwise required by law. Such records in the case of research with no external funding will be maintained for three years from the close of the study.

Enforcement Mechanisms, Remedies and Non-Compliance

1. Failure to file a complete and truthful disclosure as required by this policy or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of financial conflicts of interest constitutes a violation of JP2MRI policy and may violate state and/or federal law. In such cases, the investigator will be subject to appropriate sanctions consistent with JP2MRI policies relating to staff, or other applicable disciplinary policies. In addition, JP2MRI may suspend an ongoing research project, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy. In any case in which the investigator does not comply with any applicable conditions or restrictions imposed pursuant to this policy, JP2MRI will withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the investigator.

2. In the event JP2MRI discovers that a failure to comply with this policy has biased the design, conduct, or reporting of the research, JP2MRI will promptly notify the sponsor of the research as required by applicable law and describe the corrective action(s) taken or to be taken.

Review by Conflict of Interest Officer (COIO)

1. Determination of significant financial interest. Prior to the investigator's expenditure of any funds, or prior to the initiation of the research in the case of research with no external funding, the Conflict of Interest Officer will review the disclosed financial interest to determine whether it constitutes a significant financial interest.
2. Determination of financial conflict of interest. Upon concluding that the disclosed financial interest constitutes a significant financial interest, the COIO will review the disclosed significant financial interest to determine whether a financial conflict of interest exists and thus whether further review and management is required.
3. In this review, the COIO will notify the relevant departmental executive officer of the existence of the financial conflict of interest. This notification will alert the CSO or designee to the existence of the financial conflict of interest in the event they do not support the conduct of the research project.
4. Where the COIO has determined that a financial conflict of interest exists, the COIO will form a Conflict of Interest in Research Committee (CIRC), which will develop and recommend for implementation to the Chief Scientific Officer or designee a management plan that specifies the actions that have been and/or will be taken to manage the financial conflict of interest.
5. In so doing, the CIRC will consider the nature of the research, the nature and size of the interest, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict.
6. Management strategies or remedies may 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 participants;
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of 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 actual or potential financial conflicts;
 - h. Significant financial interests held by institutional officials. JP2MRI officials who have a significant financial interest in an externally sponsored research project may not participate in

the solicitation, negotiation of contract terms and conditions, oversight of the research (unless named as a member of the research team), or management of any financial conflict of interest held by members of the research team.

7. No member of the CIRC who holds a significant financial interest in a project may participate in the review of interest or the development of a management plan for that project.

8. CIRC meetings are closed to the public.

9. Specific provisions applicable to human subject research. As a general policy, JP2MRI will not allow an investigator with a financial conflict of interest to conduct a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. In such cases, disclosure or standard conflict management strategies may be inadequate and adequate monitoring plans may be difficult or impossible to implement. This prohibition applies not only to the principal investigator of a clinical research project, but also to any investigator involved in the design, conduct, or reporting of the research. A principal investigator would thus be prohibited not only from serving in that role, but in any investigator role on the study.

10. JP2MRI may waive the prohibitions in this section only where the investigator provides a compelling justification for its waiver. In considering an investigator's request for waiver, the CIRC at a minimum will require the investigator to address the following points:

a. The nature of the research project (including whether it is early-stage or closer to commercial application);

b. The size and nature of the investigator's financial interest;

c. The degree to which the financial interest is related to the research;

d. The extent to which the interest is or may be affected by the research;

e. The degree of risk to participants in the research;

f. The investigator's proposed role in the research, including protocol design, selection of participants, administration of informed consent, performance of protocol-mandated clinical procedures, evaluation of the effectiveness of the drug, device, or treatment, and evaluation of adverse effects is essential;

g. The existence of unique circumstances that would require the research to be performed at this institution as opposed to another (such as the unique qualifications of the investigator and/or unique resources/capabilities of JP2MRI).

11. If the committee finds a compelling justification for waiver of the prohibition in a particular case, a stringent management plan, including a plan for rigorous oversight of the study, will be implemented to ensure the safety of study participants and the integrity of the research.

12. In the event JP2MRI identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by JP2MRI during an ongoing research project, and where the COIO has determined that the undisclosed significant financial interest constitutes a financial conflict of interest related to a PHS-funded research project, the CIRC will review the financial conflict of interest, and JP2MRI will implement a management plan for the project within 60 days of identification of that interest. In addition, the CIRC will, within 120 days of its determination of noncompliance, complete a retrospective review of the investigator's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was not timely disclosed timely or previously reviewed or was biased in the design, conduct, or reporting of such research.

Subrecipient Requirements

1. If JP2MRI carries out the PHS-funded research through a subrecipient, JP2MRI will incorporate as part of a written agreement with the subrecipient terms that establish whether JP2MRI's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators.
2. If the subrecipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS Regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to JP2MRI to enable JP2MRI to provide timely reports to PHS.
3. Alternatively, if JP2MRI's policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of significant financial interests to JP2MRI. Such time periods shall be sufficient to enable JP2MRI to comply with timely review, management, and reporting obligations under the PHS regulations.

Public Accessibility Requirements

1. JP2MRI'S FOCI policy is available and posted on its website.
2. JP2MRI will make available to the public upon request information concerning any significant financial interest disclosed to JP2MRI that meets the following three criteria:
 - a. The disclosed significant financial interest is still held by the senior/key personnel of the active PHS project;
 - b. JP2MRI determines that the significant financial interest is related to the PHS-funded research; and

c. JP2MRI determines that the significant financial interest is a Financial Conflict of Interest.

3. The public information request will be directed to the Conflict of Interest in Research Officer who will respond within five business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.
4. FCOI will be updated within 60 days for any new FCOI that is made available, which will be publicly disclosed upon request.
5. FCOI will be automatically updated annually for public disclosure.