

## POLICY AND PROCEDURE MANUAL

<b>Pennington Biomedical</b>	<b>POLICY NO. 401.00</b>	<b>ORIGIN DATE:8/1/00</b>
<b>IMPACTS:</b>	<b>ALL PERSONNEL</b>	<b>LAST REVISED:01/21/15</b>
<b>SUBJECT:</b>	<b>Individual Financial Conflict of Interest Policy</b>	<b>EFFECTIVE DATE: 7/18/14</b>
<b>SOURCE:</b>	<b>Legal and Regulatory Compliance</b>	<b>VERSION NO. 9</b>

### **PURPOSE:**

The purpose of this policy is to promote objectivity in research and to comply with Federal, Louisiana and LSU System regulations regarding Significant Financial Interests held by Covered Individuals of Pennington Biomedical Research Center (PBRC).

This policy seeks to provide PBRC with the ability to identify and manage perceived, potential, and real individual financial conflicts of interest (FCOI) that may bias research or interfere with institutional duties in order to protect the integrity of the relationship between the Covered Individuals, research activities, and human subjects.

When Covered Individuals have an economic interest in an outside entity that can affect the conduct of their PBRC institutional duties, an individual financial conflict of interest may exist. While this is not always problematic, consideration must be given to determine if these outside economic interests may bias, or have the appearance of bias in the design, conduct, or reporting of research. Preserving the objectivity of research conducted at PBRC is essential for the maintenance of public trust, integrity in research, and the health and safety of those participants in the research conducted at PBRC.

This policy provides for the disclosure of Significant Financial Interests that comply with the Public Health Service (PHS) regulations disclosure requirements, but also applies broadly to activities performed at the PBRC, without regard to the funding source.

### **SCOPE:**

This policy only addresses Individual Financial Conflicts of Interest (FCOI). There are other areas in which Financial and Non-Financial Conflicts may arise and other types of conflicts, e.g. conflicts of commitment, institutional conflicts of interest or other outside activities, which may conflict with PBRC's obligations.

### **DEFINITIONS:**

Covered Personnel: include, but are not limited to:

- An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research conducted by Pennington Biomedical Research Center including a Principal Investigator, Co-investigator, or Project Director
- All employees of Pennington Biomedical Research Center and institutional community members or consultants participating or advising the IRB, IACUC and IBC

**Covered Family Member:** Parents, siblings, spouses<sup>1</sup>, dependent children (including step-children and grandchildren), spouses of children, spouses of siblings of Covered Personnel and any other person financially dependent on the Covered Personnel or any other person with whom the Covered Personnel has joint Significant Financial Interests such that an objective third party could reasonably conclude that the Covered Personnel's decisions or other exercise of professional responsibilities at PBRC could be influenced by the effect of that action on the person's Significant Financial Interest.

Covered Family Members are considered without regard to whether a legal or biological family relationship exists with the Covered Personnel. If the Covered Personnel is in doubt about if someone is a Covered Family Member, he/she should resolve the doubt in favor of disclosure.

**Covered Individuals:** includes both Covered Personnel and Covered Family Members

**Research:** means any systematic investigation, study, or experiment designed to develop or contribute to general knowledge, including behavioral and social sciences research. The term includes both basic and applied research and product development.

**Individual Financial Conflict of Interest (FCOI):** arises when there is a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Research.

**Entity:** is any for-profit organization, institution, corporation, partnership, or other legal entity (other than a 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) that conducts or seeks to conduct business with PBRC/LSU.

**Significant Financial Interest:** one or more of the following interests of the Covered Personnel and those of the Covered Family Members that reasonably appears to be related to the Covered Personnel's institutional responsibilities:

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, (which

---

<sup>1</sup> Effective April 18, 2014, all HHS grantees are expected to recognize any same-sex marriage legally entered in a U.S. jurisdiction that recognizes their marriage, including one of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country so long as the marriage would also be recognized by a U.S. jurisdiction. This applies regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. However, this does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under the law of jurisdiction of celebration as something other than marriage.

includes any stock, stock option or other ownership interest)), as determined through reference to public prices or other reasonable measures of fair market value.

A Significant Financial Interest exists if one or more of the following interests of the Covered Personnel and those of the Covered Family Members that reasonably appears to be related to the Covered Personnel's Institutional Responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if any remuneration is received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds five thousand dollars (\$5,000)
2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration is received from the entity in the past twelve (12) months preceding the disclosure, when aggregated, exceeds five thousand dollars (\$5,000) or when the Covered Personnel or the Covered Personnel's Family Members holds any equity interest (e.g. stock, stock options, or other ownership interest); or
3. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.
4. Covered Personnel must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Covered Personnel and not reimbursed to the Covered Personnel so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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.
  - a. Travel disclosures must at a minimum include but are not limited to:
    - i. Purpose of the trip
    - ii. the Identity of the Sponsor/Organization
    - iii. Destination
    - iv. Duration

The term "Significant Financial Interest" does not include the following types of financial interests:

1. salary, royalties, or other remuneration paid by the Institution to the Covered Personnel if the Covered Personnel is currently employed or otherwise appointed by the PBRC/LSU, including intellectual property rights assigned to the PBRC/LSU and agreements to share in royalties related to such rights, any ownership interest in the PBRC/LSU held by the Covered Personnel,
2. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Personnel or Covered Family Members do not directly control the investment decisions made in these vehicles,
3. income from seminars, lectures, or teaching engagements sponsored by a 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

4. income from service on advisory committees or review panels for a 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.

+++Please note that the abovementioned exclusions shall not apply if the ownerships, stock options, or compensations, transfer of equity interest, or other financial interest will be affected by the outcome of the research +++

**“Related To”:** the COIC, the Conflicts Review Committee and/or the Conflicts Committee reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the project

**PBRC/LSU:** is defined as Pennington Biomedical Research Center and/or any other campus or component of the Louisiana State University System.

**COIC:** the PBRC personnel designated the Conflict of Interest Coordinator

**Conflicts Review Committee (CRC):** A subset of the Conflicts Committee composed of a minimum of three persons to include the COIC, and a representative of Sponsored Projects.

**Conflicts Committee:** composed of a minimum of five persons to include the CRC members and additional rotating representatives from two of the following departments.

- Safety
- IRB
- IACUC
- Sponsored Projects

Department representatives shall serve for at least a one year period once selected for service on the committee, which may be extended if a particular disclosure requires ongoing oversight from the Conflicts committee. Other departments may be asked to send an ad-hoc representative based on the particular research area of the disclosing covered personnel.

In the event of committee member recusal, or when a committee member will be absent for an extended period of time, the committee member shall inform the COIC so that an appropriate replacement can be found.

**Senior/Key Personnel:** Any person of faculty or director rank or members of the research team who will be responsible for the design, conduct or reporting of the research or other activities of the proposed project.

**Institutional Responsibilities:** Any of the professional responsibilities of Covered Personnel on behalf of PBRC and other LSU System campuses, including research, research consultation, teaching, professional practice, institutional committee membership, or service on an institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

**POLICY:**

Covered Personnel shall not be permitted to begin any research activity (e.g. design, conduct or reporting of research, educational, or service activities) when there is a perceived, potential or actual FCOI until a review of the disclosure had been conducted and, if necessary, a Conflict of Interest Management Plan (“Management Plan”) has been developed and approved by the Executive Director and the IRB Chair, when the Conflict involves a Covered Personnel in clinical research and the Executive Director and the IACUC Chair, when the conflict involves a Covered Personnel in basic research . If the Executive Director is the subject of the Conflict, the Associate Executive Director of Clinical Research and the IRB Chair shall review and approve a proposed management plan.

The COIC and the Conflicts Committee are the official(s) to solicit and review disclosures of Significant Financial Interests from each Covered Personnel planning to participate or participating in research.

**DISCLOSURE REQUIREMENTS:**

It is the responsibility of all Covered Personnel to initiate the disclosure process to update any change in status regarding Non-PBRC/LSU activities or Significant Financial Interests that do not occur/exist at the time of hire or at annual renewal.

Disclosure must occur:

- At the time of hire,
- Annually thereafter, and
- Within thirty (30) days of a change in status regarding non-PBRC/LSU Significant Financial Interest, all Covered Personnel are required to complete an online or in some cases a manual disclosure of their non-PBRC/LSU Significant Financial Interests and their Covered Family Members’ Significant Financial Interests. In determining whether a Significant Financial Interest should be disclosed, the Covered Personnel should resolve any doubt in favor of disclosure.

Each Principal Investigator, Co-Principal Investigator, or Supervisor shall be responsible for ensuring that Covered Personnel under his or her supervision comply with this policy in identifying and disclosing any reportable Significant Financial Interests. PBRC/LSU is responsible for ensuring compliance with the disclosure requirements noted above.

**REVIEW OF DISCLOSURE FORMS:**

The COIC will review all of the information gathered to determine if the Significant Financial Interest is related to any proposed or ongoing project to create a perceived, potential, or actual FCOI. If the COIC determines that there is a perceived, potential or actual FCOI, the COIC will convene the CRC.

Depending on the nature of the financial information disclosed, the COIC may request additional clarifying information from the Covered Personnel and forward the all information to the CRC. Neither PBRC/LSU nor Covered Personnel may expend research funds unless the COIC, CRC and/or the Conflicts Committee have determined that:

- 1.) No conflict of interest exists for all covered individuals (or)
- 2.) If a conflict of interest exists, it is manageable in accordance with the terms of a management plan that has been adopted and implemented, along with completion of the submission of a financial conflict of interest report to the NIH/PHS awarding component.

Whenever Covered Personnel is new to participating in a research project discloses a Significant Financial Interest or an existing Covered Personnel discloses a new Significant Financial Interest to PBRC/LSU or a Significant Financial Interest that was not previously reviewed by PBRC/LSU (for whatever reason), the CRC shall within sixty (60) days:

- Review the disclosure of Significant Financial Interest;
- Determine whether it is related to the research;
- Determine whether a perceived, potential or actual Conflict of Interest exists

Depending on the nature of the Significant Financial Interest, the CRC may determine that additional interim measures are necessary and impose interim measures with regard to the Investigator's participation between the date of disclosure and before the Conflicts Committee concludes its review.

If the CRC determines that an appearance of a conflict exists, the CRC will advise the Conflicts Committee that a full review is necessary. The Conflicts Committee will consider steps to manage the conflict in such a way to reduce any perceived bias. The Conflicts Committee shall include, but is not limited to the following factors in its evaluation of the FCOI:

- Length or nature of the involvement with the Sponsor
- Type of Sponsor, how the Research Project is supported or financed
- Estimated degree of separation between the Research Project's and Investigator's activities
- The nature of the Conflict of Interest and when and where the relationship commenced
- Whether the conditions of the relationship have changed
- Whether the results of the Research Project are likely to be affected by the Conflict of Interest
- The mechanisms to ensure the integrity of the Research Project such as peer review, other independent research monitors or controls
- The availability of alternatives to avoid the Conflict of Interest
- Risks to the rights and safety of human subjects research

- Risks to the rights and obligations of students, residents, fellows, trainees, and any other individuals participating in the research
- By whom the study is designed
- Is PBRC the appropriate site for the Research
- Transparency of relationships

#### **MANAGEMENT PLAN:**

If the CRC determines that a management plan may be needed, the COI C will develop and present to the CRC a written Conflict of Interest Management Plan that details the proposed steps that will be taken to manage, reduce, or eliminate any actual, perceived or potential FCOI. If the CRC members are in agreement, the management plan is presented to the conflicted Covered Personnel. If the Covered Personnel agrees with the terms, he/she would then sign off on the plan. If the CRC does not reach a consensus or the Covered Personnel does not agree with the terms of the plan, the FCOI management would then be turned over to the full committee.

The Conflicts Committee shall consider the Management Plan proposed by the CRC and concerns of the Covered Personnel. After consideration of the proposal, the Committee may 1) accept the proposal; 2) make changes to the proposal; or 3) create a different plan.

As conditions of the created plan, the Committee(s) may consider but are not limited to imposing singularly or in combination any of the following:

- Public disclosure of Conflicts of Interest
- Disclosure to subjects through the consent process
- Review of Research protocol by independent reviewers
- Monitoring of the Research project by independent reviewers
- Reduction of equity holdings
- Clear separation of Research from paid activities
- Modification or disapproval of the Research plan
- Divestiture of Conflicts of Interest, complete or partial
- Appointment of a non-conflicted Principal Investigator or other Covered Personnel
- Severance of relationships that create actual or potential Conflicts of Interest
- Disqualification of the Covered Personnel with the Conflicts of Interest from participating in all or a portion of the Research
- As the regulations require, a retrospective review and mitigation report for PHS-funded projects

In certain circumstances, the Conflicts Committee may determine that the Covered Personnel has presented compelling circumstances to justify allowing research to proceed despite the presence of a Conflict of Interest. Whether the circumstances are deemed compelling shall depend upon the following:

- the nature of the science,
- the nature of the Conflict of Interest
- the amount of the Significant Financial Interest,
- how closely the Conflict of Interest is related to the Research,
- the degree to which the Conflict of Interest may be affected by the Research, and
- the degree to which the Conflict of Interest can be effectively managed.

No “compelling circumstances” will be approved which may violate federal regulations or result in actions detrimental to the PBRC and the goals of this policy.

If the Conflicts Committee determines that there are compelling circumstances and the Research should go forward despite the Conflict of Interest, then the Conflicts Committee may allow the research to proceed and shall include in the Management Plan:

- The compelling circumstances which support including the conflicted Covered Personnel in the project.
- The stages of the research and the specific activities for which there are compelling reasons for the Investigator’s involvement.
- The activities the Covered Personnel will be allowed to perform.
- Any restriction plan imposed to prevent the conflict from influencing or appearing to influence the outcome of the project and strategy to restrict the time of involvement to a minimum.

The Conflicts Committee will submit a final report of the review, including the management plan, to the IRB Chair or the IACUC Chair, as applicable. The IRB Chair or the IACUC Chair, as applicable, will present the management plan needs to the convened Board and will make a decision to approve or disapprove the recommendations of the Conflicts Committee and the Management Plan. The disclosing Covered Personnel and as applicable, the Principal Investigator involved in this review will be informed of all decisions in writing.

If the IRB or IACUC approve the management plan, the plan will be implemented. If the IRB or IACUC reject the management plan, the Conflicts Committee will reconvene to consider the objections or concerns to the proposed management plan and make changes accordingly, which may include not moving forward with the project. The IRB or IACUC, as applicable, has the final authority to decide whether the interest and its management, if any, allows the research to be approved.

Management Plans must be signed by the Principal and/or Co-Principal Investigator, the Covered Personnel with the Conflict of Interest and the Chairperson of the Conflicts Committee.

**MONITORING:**

Whenever a Conflict of Interest Resolution Management Plan is instituted by the Conflicts Committee, each person conducting research under a management plan shall comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring



compliance with the plan shall carefully and fully monitor that compliance. The HRPP or IACUC office in conjunction with Legal and Regulatory compliance shall monitor compliance with management plans and the provision of employee sanctions or other administrative action to ensure researcher compliance. Upon notification of a management plan from the Conflicts Committee, the HRPP office notifies the IRB of the management plan. The IRB will determine based on the management the actions appropriate to monitor compliance with the plan. This will be documented in the IRB minutes. See Sanctions for Non-Compliance.

#### **SANCTIONS FOR NON-COMPLIANCE:**

For non-compliance with management plans, the IRB may take appropriate action to protect the welfare and safety of human subjects. Employees who are noncompliant with management plans may be subject to disciplinary action up to and including potential termination of employment and/or affiliation in accordance with the applicable University policy and procedures.

#### **RETROSPECTIVE REVIEWS FOR PHS-FUNDED PROJECTS ONLY:**

In cases where a FCOI is not identified or managed in a timely manner including failure by the Covered Personnel to disclose a Significant Financial Interest that is determined by the PBRC to constitute a FCOI, failure by the PBRC to review or manage such a FCOI or failure by the Covered Personnel to comply with a management plan, the Conflicts Committee shall within one-hundred and twenty (120) days from the determination of non-compliance conduct a retrospective review of the Covered Personnel's activities and any PHS-funded research project conducted during the time period of noncompliance for bias in the design conduct or reporting of such research.

The Conflict Committee shall document the review and the documentation shall include, but is not limited to:

- Project number
- Project title
- Project Director/Principal Investigator (PD/PI) or contact PD/PI if multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest
- Name of the entity with which the Investigator has a Financial Conflict of Interest
- Reason(s) for the retrospective review
- Detailed methodology used for the retrospective review
  - Methodology of the review process, composition of the review panel, documents reviewed
- Findings of the review
- Conclusions of the review

If appropriate, based upon the results of the review, the Director of Sponsored Projects or his/her designee, shall update the previously submitted PHS FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is determined by the Conflicts Committee as a result of the review, the Director of Sponsored Projects or his/her designee shall promptly notify and submit a mitigation report to the PHS Awarding component.

The mitigation report shall include, but is not limited to:

- The key elements documented in the retrospective review noted above;
- A description of the impact of the bias on the research project ;
- Conflict Committee's plan of action taken to eliminate or mitigate the effect of the bias on the research project
- Extent of harm done, including any qualitative or quantitative data to support any actual or future harm.
- Analysis of whether the research project is salvageable.

When a PHS funded project involves 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 Personnel with a FCOI that was not managed or reported by the Institution, the Covered Personnel shall be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### **REPORTING REQUIREMENTS:**

The Principal Investigator will work with the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) at the time of each protocol initial submission application, at the time of each continuing review, as well as, within 30 days of any change to the previous reporting to ensure that all conflict of interest information required by the IRB or IACUC is up-to-date.

The IRB, IACUC, Sponsored Projects and/or the Conflicts Committee may require additional certification, disclosures and/or management measures separate from the management plan.

If a reported FCOI is related to research funded by PHS, Sponsored Projects will ensure that reporting required by federal regulations are completed and the Conflicts Committee will retain documentation of such compliance.

Prior to PBRC expenditure of any funds under a PHS-funded research project, the Director of Sponsored Projects or his/her designee shall provide to the PHS Awarding Component a FCOI report regarding any Covered Personnel's Significant Financial Interest that is found by PBRC Conflicts Committee to be conflicting for which a Management Plan has been implemented.

For any Significant Financial Interest that PBRC's Conflicts Committee identifies as conflicting subsequent to the initial FCOI report, the Director of Sponsored Projects or his/her designee shall provide to the PHS Awarding Component, within sixty (60) days, a FCOI report regarding the Financial Conflict of Interest and ensure that a Management Plan has been implemented.

Where a FCOI report involves a Significant Financial Interest that was not disclosed timely by an Covered Personnel or was not previously reviewed by PBRC's Conflicts Committee, a retrospective review shall be conducted to determine whether any PHS-funded research conducted, prior to the identification and management of the Conflict of Interest, was biased in the design, conduct or reporting. If bias is found, a mitigation report shall be submitted to the PHS Awarding Component.

A FCOI report shall include, but not be limited to:

- Project number
- Project Director/Principal Investigator (PD/PI) or Contact PD/PI if a multiple PD/PI model is used
- Name of the Covered Personnel with the Financial Conflict of Interest
- Name of the entity with which the Investigator has the Conflict of Interest
- Nature of the Significant Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- 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
- A description of how the Significant Financial Interest relates to the PHS-funded research and the basis for the determination that the interest conflicts with the research; and
- A description of the key elements of the Conflict of Interest Resolution Management Plan, including:
  - Role and principal duties of the conflicted Investigator in the research project
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the research project
  - Confirmation of the Investigator's agreement to the management plan
  - How the management plan will be monitored to ensure Investigator compliance;

#### **ANNUAL REPORT:**

The Director of Sponsored Projects or his/her designee shall provide the PHS Awarding Component an annual FCOI report that addresses the status of the Financial Conflicts of Interest, any changes to the management plan for the duration of the project, whether the Conflict of Interest is still being managed or why the interest no longer exists.

In accordance with the regulations, when PBRC's Conflicts Committee identifies a Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, the Director of Sponsored Projects or his/her designee shall not submit a FCOI report to the PHS Awarding Component.

#### **TRAINING AND EDUCATION:**

All Covered Personnel must acknowledge or receive training at least every 2 years that they are aware of and have read this policy and applicable federal regulations and are aware of their responsibilities regarding disclosure of Non-University Significant Financial Interests and outside activities. Training shall be provided by the FCOI training module, which is accessed through the PBRC PINE system.

Covered Personnel must complete training in regard to this policy and applicable policies, regulations, and laws before engaging in research at PBRC and at least once every year thereafter. Covered Personnel new to PBRC must complete the training before engaging in research at the institution. Covered Personnel must complete the training immediately if PBRC finds that the individual is not in compliance with this policy, or the individual's management plan, or PBRC revises its FCOI policy in a manner that impacts the individual's duties.

The COIC is responsible for ensuring that appropriate faculty, staff, trainees, and other persons participate in training in regard to this policy and applicable laws.

#### **RECORD RETENTION:**

The COIC will retain records with regard to FCOI and all actions taken to manage, reduce, or eliminate the conflict of interest according to the requirements and regulations that pertain to that conflict.

Records regarding the disclosure of Significant Financial Interests and the management of a conflict of interest, including financial interest disclosure statements, a reviewing official's determinations, and other records of PBRC actions, shall be retained for at least three (3) years after:

- (1) the date of termination or completion of a research award or contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or
- (2) the date of final resolution of any investigation, audit, or similar action involving the records, whichever is later.

#### **CONTRACTORS, COLLABORATORS AND SUB-AWARDEES:**

If a specific federal, state, or local law, regulation, or an LSU System sponsor or prime awardee applicable policy provides different requirements than this policy, the more stringent requirement applies.

- If a sub-awardee or collaborator has its own written FCOI policy, the sub recipient shall certify as part of their agreement with PBRC that their policy complies with PHS regulations.
- If a sub-awardee or collaborator does not have its own written FCOI policy, they must adhere to the requirements of this policy and must disclose Significant Financial Interests that are directly related to the sub recipient's work for PBRC. The agreement shall specify time periods for the sub recipient to submit disclosures of Significant Financial Interests. The time period will be sufficient to allow PBRC to comply timely with its review, management and reporting obligations.

#### **CONFIDENTIALITY:**

Appropriate steps shall be taken by PBRC to protect the confidentiality of the information provided however, PBRC shall make certain FCOI information available when required by law, mandated by sponsoring entities or determined to carry out the purpose and administration of this policy.

## **PUBLIC ACCESS—PHS FUNDED RESEARCH ONLY:**

As required by federal regulations, this policy and each update of this policy must be publicly accessible through the Internet via the PBRC website, [www.pbrc.edu](http://www.pbrc.edu). Requests for release of disclosures from Senior/Key personnel to external third parties must be made in writing.

For PHS-funded studies only, PBRC through the COIC will provide information concerning any Significant Financial Interest disclosed within five (5) days of written request if the following criteria are met:

1. The Significant Financial Interest was disclosed and is still held by the Covered Personnel
2. PBRC has determined that the Significant Financial Interest is Related To the PHS-funded research
3. PBRC determined that there is a FCOI

The information provided to the requestor shall include, at a minimum, the following:

- The Covered Personnel's name;
- The Covered Personnel'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;
- 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.

The COIC will reply to written requests within 5 business days as required by federal regulations. The entire content of the disclosure form (s), for the previous three (3) year period as they exist on the date of request, will be provided in response to written requests. The response will note that the information is subject to updates at least on an annual basis and within sixty (60) days of PBRC's identification of a new financial conflict of interest, which can be requested subsequently by the requestor.

## **EFFECTS OF NON-COMPLIANCE:**

Timely, complete, and accurate disclosure of Non-PBRC/LSU Significant Financial Interests consistent with this policy is a condition of employment at PBRC/LSU , and Covered Personnel who do not comply with this policy are subject to a review by the Scientific misconduct committee; disciplinary action up to and including termination of employment; prohibition of future state employment; fines of up to ten thousand dollars; revocation/ nullification of contracts; suspension of federal grant awards; and criminal liability (See La. R.S. 42:1141; 42:1153; 42:1166; 45 CFR Part 50 Subpart F §50.606).

For Covered Personnel, who are not employees of PBRC, compliance with this policy is a condition of participating with PBRC in the capacity that qualifies the person as Covered Personnel. PBRC/LSU may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation/collaboration.

Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require PBRC/LSU to notify the PHS of instances in which the failure of a Covered Personnel to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require PBRC/LSU to take action appropriate to maintaining objectivity in the research. PBRC/LSU must make information available to HHS or the PHS awarding component as required by federal regulation.

PBRC/LSU also has an obligation under state law (La. R.S. 42:1161) and LSU system regulations to report any matters that come to light which may constitute a violation of the Louisiana Code of Ethics (La. R.S. 42:1102 et. seq.) or LSU system regulations (PM-11 and PM-67) to the appropriate authority.

As employees of the State of Louisiana, all public servants are protected if they report any information which they reasonably believe to be a violation of any law, order, rule, or regulation related to the duties of public employment. As a matter of law, any person who reports such information is to be free from any and all discipline, reprisal, or threats of reprisal by their public employer (See La. R.S. 42:1169). All reports of a failure to disclose Non-University Significant Financial Interests may be made anonymously by alerting the COIC on the PBRC website [www.pbrc.edu](http://www.pbrc.edu), Compliance Hotline section or through the PBRC intranet, PINE, Compliance section.

#### **CONTACTS:**

- For those employees engaged in non-PBRC/LSU activities for which economic benefit is received, please consult Permanent Memoranda PM-11 – Outside Employment of University Employees. Please refer to PM-11 and contact the PBRC Director of Legal and Regulatory Compliance with questions. PBRC will report any PM-11 required disclosures to the LSU System President and the Board of Supervisors on an annual basis.
- For those faculty members who have ownership or other interest in a company wishing to or conducting business with the University that is “related to or resulting from research activity...conducted in the course of ... employment with LSU”, also see Permanent Memoranda PM-67 - Contracts between the University and Selected Employees and Selected Staff must be followed. Please refer to PM-67 and contact the PBRC Director of Legal and Regulatory Compliance with any questions.
- For contracting situations where PM-67 related exceptions and requirements do not apply, all employees must comply with the reporting requirements of the Louisiana Ethics Code, which may include required annual disclosures related to the financial interests of family members. See La. R.S. 42:1102 et seq. and the Louisiana Ethics Administration for details. For questions and/or clarifications with regard to the disclosure of financial interests contact the Conflict of Interest Coordinator at: [coic@pbrc.edu](mailto:coic@pbrc.edu)

The COIC is responsible for overseeing implementation of this policy and may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable sponsor regulations.

**This policy applies *in addition to* general institutional policies, such as policies on standards of conduct, as well as other policies governing disclosure of activities and financial interests relating to outside employment and interests (PM 11 and PM 67). Any changes made to these policies will supersede applicable parts of this policy.**



## Policy Committee Secretary's Attestation

Date of Policy Committee Meeting: 2/3/2015

Policy #: 401.00 Individual Financial Conflict of Interest

Date of Approval: 2/3/2015 (version #9)

Publication Date: 2/18/2015 (version #9)

Effective Date: 2/3/2015 (version #9)

Anne Duke  
Anne Duke, Policy Committee Secretary

2/13/15  
Date

## Approval by the Executive Director

William T. Cefalu, MD  
William T. Cefalu, MD  
Executive Director

2/16/15  
Date