

## RESEARCH SERVICE FINANCIAL CONFLICT OF INTEREST

1. **PURPOSE:** To define the policy regarding objectivity in VA research and procedures for identifying and addressing potential financial conflicts of interest (COI) relating to members of the Research and Development (R&D) Committee, the Institutional Review Board (IRB), and the Institutional Animal Care and Use Committee (IACUC), as well as all researchers and study staff at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC).

2. **POLICY:** To identify potential financial COI within research and to manage, mitigate or eliminate any potential conflicts that are identified.

3. **DEFINITIONS:**

a. **Conflict of Interest (COI):** COI occurs when any financial arrangement, situation or action affects, or is perceived to exert inappropriate influence on, the design, review, conduct, results or reporting of research activities or findings. It includes any situation in which financial or personal obligations may compromise, or present the appearance of compromising, an individual's or group's professional judgment in conducting or reporting research.

b. **Financial Interest:** Financial interest means anything of monetary value or anything of monetary value in components whose interests could reasonably affect, or be affected by, the research. Financial interest includes, but is not limited to, the following:

(1) Any financial arrangement whereby compensation to the investigator could influence, or be influenced by, the outcome of the study;

(2) Salary and other payments for services (e.g., consulting fees, honoraria, etc.);

(3) Payments of other sorts from the sponsor of the research (e.g., a grant to fund other ongoing or additional research, compensation in the form of equipment, retainer for on-going consultation, etc.);

(4) Equity interests (e.g., stocks, stock options, or other ownership interests);

(5) Proprietary interests or intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, royalties, etc.); and

(6) Non-cash items such as travel expenses or business gifts.

c. **Significant Financial Interest.** Significant financial interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (stocks, stock options, or other ownership interests); and intellectual property rights (patents, copyrights and royalties from such rights). This includes:

(1) Ownership interest of more than \$10,000 when aggregated for immediate family members.

(2) Ownership interest of more than 5% of one company when aggregated for immediate family members.

(3) Ownership interest whose value would be affected by the outcome of the research.

(4) Compensation whose amount would be affected by the outcome of the research.

(5) Payments that exceed \$10,000 in one year when aggregated for the IRB member and their immediate family.

(6) Proprietary interest related to the research other than copyrights and patents without royalties.

(7) Board or executive relationships.

d. **Dually-Appointed Personnel (DAP):** A DAP is an individual holding both a LSCDVAMC and an academic affiliate position.

e. **Case Western Reserve University (Case):** Case is an academic affiliate of LSCDVAMC.

f. **Case Conflict of Interest Advisory Committee (COIC):** Case's COI Committee.

#### 4. RESPONSIBILITIES:

a. **Institutional Official:** The medical center Director is the Institutional Official who is responsible for the R&D program within the medical center and as such, represents the facility in issues related to COI in research and administers the medical center's program related to financial COI in research. The medical center Director may appoint a COI Administrator and/or COI Committee to oversee the program.

b. **Associate Chief of Staff for Research and Development (ACOS/R):** The ACOS/R is responsible for ensuring that the COI process works efficiently and effectively. The ACOS/R is responsible for reviewing and monitoring possible financial

COI, as well as carrying out the recommendations from the COI Administrator and/or COI Committee. The ACOS/R will report any conflicts to the necessary authorities.

c. **Conflict of Interest Administrator:** The COI Administrator is responsible for managing the review process, including initial review of the disclosure forms prior to the R&D Committee review and determines whether a referral to the COI Committee is deemed as necessary. He/she serves as staff for the review process; and maintains records and official files for the COI process. The Research Compliance Officer (RCO) may serve as the COI Administrator. The RCO is a member of the Case COIC representing LSCDVAMC.

d. **Conflict of Interest (COI) Committee:** The COI Committee is responsible for assisting the COI Administrator in working with research personnel and/or members of the R&D Committee, IRB and/or IACUC and the ACOS/R to manage any potential COI risks. COI Committee members are appointed on an as needed basis. For DAP with a financial COI, the COI Committee may determine that a Case COIC management plan will be utilized.

e. **Research and Development (R&D) Committee:** The R&D Committee is responsible for reviewing and monitoring possible financial COI, as well as carrying out the recommendations from the COI Administrator or COI Committee.

f. **Institutional Review Board (IRB):** For research involving human subjects, the IRB is responsible for reviewing and requiring appropriate changes in protocols and informed consent forms affected by COI.

g. **Principal Investigator (PI) and Study Staff:** The PI is responsible for assuring that any potential financial COI, either for him/herself, or study staff who have the responsibility for designing, conducting or reporting the research as well as for their spouses and dependent children, is disclosed in the research project application process and that any subsequent financial COI arising after the initial application is also reported.

## 5. PROCEDURES

### a. **To Identify Conflicts of Interest for all Researchers and Study Staff:**

(1) In accordance with VA Central Office (VACO) requirements, the R&D Committee must approve all VA research before work may begin. All projects must have information on any financial COI that may exist.

(2) Each PI and study staff listed on the project must complete a COI Statement.

(3) If the PI or any study staff responds affirmatively to the existence of a potential conflict, the COI Administrator will request additional information from the PI or

study staff, as necessary. He/she will review the materials and determine whether the proposed project could reasonably appear to be directly and significantly affected by the related potential financial COI of the PI or study staff. A direct impact could occur when:

(a) The project results would be directly relevant to the development, manufacture or improvement of the products or services of an organization in which the PI or study staff has a significant financial interest;

(b) The organization in which the PI or study staff has a significant financial interest is a proposed subcontractor in the project;

(c) There is a relationship between the project sponsor and the PI or study staff outside the project that has the potential to affect performance in the project.

(4) If the COI Administrator determines there is no reasonable basis to conclude that the design, conduct or reporting of the project could be directly and significantly affected by the potential financial COI, he/she will inform the PI (and member of the study team, when applicable), the R&D Chairperson and the appropriate subcommittee Chairperson in writing that the project has been cleared of COI. A copy of the notification will be placed in the project file.

(5) If the COI Administrator determines that the design, conduct or reporting of the project could be directly and significantly affected by the potential financial COI reported by the PI or study staff, then he/she will call a meeting of the COI Committee.

(6) The COI Committee will decide whether the project should proceed and under what conditions or restrictions. These recommendations will be made in writing to the PI (and member of the study staff, when applicable), R&D Chairperson and the appropriate subcommittee Chairpersons. The COI Administrator will record the minutes from the meeting and maintain the documentation used in deliberations. This information will be strictly confidential and will be kept in a secure file maintained by the COI Administrator.

(7) If during the conduct of a project any new or related potential financial COI described above should arise, the PI must disclose this to the R&D, IRB and/or IACUC through the COI Administrator. A review will be conducted as with the original disclosure.

(8) Disclosure must be made at least annually. For human subject research and animal studies, this will be done in conjunction with the application for continuing review.

b. **To Identify Conflicts of Interest for R&D Committee, IRB or IACUC member:**

(1) Each member of the R&D Committee, IRB and IACUC will complete a COI Assessment Form (see attachments).

(2) The COI Administrator will review these forms and store them in a secure drawer within the Research Office. Confidentiality will be maintained.

(3) If at any time a member responds affirmatively to the existence of a potential financial conflict, the COI Administrator will review the material, request additional information as necessary, and determine whether the business of the R&D Committee, IRB or IACUC could reasonably appear to be directly and significantly affected by the related potential financial interest of the Committee member.

(4) If the COI Administrator determines there is no reasonable basis to conclude that the potential financial COI could directly and significantly affect R&D Committee, IRB or IACUC business, he/she will inform the member, ACOS/R, R&D Chairperson and appropriate subcommittee Chairperson in writing. The COI Administrator will place a copy of the notification in a secure file.

(5) If the COI Administrator determines that the potential financial COI could directly and significantly affect R&D Committee, IRB or IACUC business, he/she will call a meeting of the COI Committee.

(6) The COI Committee will make a decision regarding the potential financial COI and if conditions or restrictions are required. These recommendations will be made in writing to the member, ACOS/R, R&D Chairperson and appropriate subcommittee Chairpersons. The COI Administrator will record the minutes from the meeting and maintain the documentation used in deliberations. This information will be strictly confidential and will be kept in a secure file maintained by the COI Administrator.

(7) If during the conduct of R&D Committee, IRB or IACUC business any new or related potential financial COI should arise, the member must disclose this to the COI Administrator. A review will be conducted as with the original disclosure.

(8) COI disclosure will be reviewed annually for R&D Committee, IRB and IACUC members.

**c. Procedures to Remedy Identified Conflicts of Interest:**

(1) Possible remedies for managing or mitigating a potential conflict for research personnel might include:

(a) The PI or the study staff will sever relationships creating the conflict;

(b) The PI or the study staff will divest significant financial interests;

(c) The PI will disclose the relationship with the sponsor on all publications, in the consent form provided to human subjects, and in other appropriate public forum (including manuscripts, abstracts and lectures);

(d) The PI will separate the research from consulting, providing an acceptable detailed written plan for achieving this;

(e) The PI will substitute someone else to serve as project PI and is appropriately distanced from the conduct of the research.

(f) The PI will secure an independent reviewer for analysis of the data.

(g) The PI will modify the protocol or safety monitoring plan

(h) The PI will be disqualified from participating in all or a portion of the research.

(2) Possible remedies for managing or mitigating a potential conflict for a member of the R&D Committee, IRB or IACUC might include:

(a) The member will verbally disclose the conflict at the convened committee meeting at the time of review.

(b) The member will not be present during the discussion or voting of the involved research, but may answer questions pertinent to the research if requested.

(c) The R&D Committee, IRB or IACUC minutes will accurately reflect the absence of the member when he/she leaves the room during the discussion and vote as well as when he/she rejoins the meeting.

(3) For identified financial COI, the member, PI or study staff will be informed in writing of the decision, including the conditions and/or restrictions the COI Committee might impose.

(4) Appeals:

(a) The member, PI or the study staff may appeal the COI Committee's decisions through the Chief of Staff, who will determine whether the matter should go back to the COI Committee or be referred to VA general counsel for further consideration.

(b) This appeal must be made within 15 working days of the date of the COI Committee's correspondence.

c. **Failure To Comply with the COI Policy:** Failure to comply with this policy and/or committee determinations constitutes research noncompliance and will

be investigated according to medical center policy 151-016 "Noncompliance in Research."

**6. REFERENCES:** 18 U.S.C. 208; Executive Order 12674, "Standards of Ethical Conduct for Employees of the Executive Branch"; AAMC, October 2002, "Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research"; 42 CFR Parts 50 and 411.354; Federal Register: May 12, 2004 (Volume 69, Number 92); FDA Guidance "Financial Disclosure by Clinical Investigators" March 20, 2001; Medical Center Policy 151-016 "Noncompliance in Research", Appendix A, "Conflict of Interest Statement" Appendix B, "R&D Committee Member Research Conflict of Interest Assessment Form", Appendix C, "IRB Member Human Research Conflict of Interest Assessment Form", Appendix D, "IACUC Member Animal Research Conflict of Interest Assessment Form."

**7. RESCISSION:** Medical Center Policy 151-014 "Conflict of Interest Relating to all Research Personnel" dated September 1, 2004 and Medical Center Policy 151-013 dated September 1, 2004 have been rescinded. Review date for this policy is September 1, 2010.

**8. FOLLOW UP RESPONSIBILITY:** ACOS/R.

WILLIAM D. MONTAGUE  
Medical Center Director

Attachments

**LOUIS STOKES CLEVELAND DVA MEDICAL CENTER  
CONFLICT OF INTEREST STATEMENT**

This document must be completed, signed and submitted by each Principal Investigator, Responsible Investigator, Co-Principal Investigator, Co-Investigator Collaborator, Study Coordinator and other research personnel who plan to devote effort to the proposed project. The information will be used only to review the proposed research project to which it applies. This completed and signed document must accompany the proposal to which it applies or the proposal will not be considered for further review.

Name:

Title of Research Proposal:

Role (check one):

- |  |  |
|--|--|
| <input type="checkbox"/> Principal Investigator    | <input type="checkbox"/> Study Coordinator |
| <input type="checkbox"/> Responsible Investigator  | <input type="checkbox"/> Collaborator      |
| <input type="checkbox"/> Co-Investigator           | <input type="checkbox"/> Other: _____      |
| <input type="checkbox"/> Co-Principal Investigator |  |

Percent effort on research protocol:                    %

1. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a business or other source related to the research proposal that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months?     Yes     No

If Yes, explain source, value, and reason for compensation:

2. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own any patents that are related to the research project proposal?     Yes     No

If Yes, please provide additional information below.

Patent number:

Date of Patent:

Title of Patent:

Have any active or pending license agreements been issued?     Yes     No

(If yes, attach a copy of each license.)

If yes, describe the period covered by each license and the projected royalty by year.

3. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own any provisional patents that are related to the research project proposal?     Yes     No

If Yes, please provide additional information below.

Patent application number:

Date Filed:

Title of Provisional Patent:

Have any active or pending license agreements been issued?     Yes     No

(If yes, attach a copy of each license.)

If yes, describe the period covered by each license and the projected royalty by year.

4. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a non-publicly-traded company that may or may not own a patent that is related to the research project proposal?  Yes  No

If Yes, what is the value of the stock/stock options? \$

Does this value represent more than a 5% ownership of the company?  Yes  No

5. Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a publicly-traded company that may or may not own a patent that is related to the research project proposal and is valued at more than \$10,000 (or value is projected to exceed \$10,000 in the next 12 months)?  
 Yes  No

If Yes, what is the value of the stock/stock options? \$

Does this value represent more than a 5% ownership of the company?  Yes  No

6. Please describe any of your VA duties that involve management of research projects or contracts other than those on which you are a principal investigator, responsible investigator, co-principal investigator, investigator, study coordinator or other research personnel. This includes oversight, approval, advising, recommending, or initiating actions on research related projects.

I certify that, to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete and made in good faith. I understand that false or fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001). Furthermore, if my financial interest and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or up to one year following completion of this protocol, I will notify the R&D Committee promptly.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Louis Stokes Cleveland DVA Medical Center (LSCDVAMC)  
R&D Committee Member Research Conflict of Interest Assessment Form**

R&D Committee Member's Name:		Date:
Credentials:		Title (s):
Service (If not VA employee indicate relationship to R&D):		
Significant financial interest DOES NOT include the following: a) Salary or other remuneration from the LSCDVAMC. b) Income from service on advisory committees or review panels for charitable or nonprofit entities.		
Mark YES or NO if any of the financial interests or arrangements of concern (described below) apply to you, your spouse, dependent children, general partner, or an organization in which you are an officer, director, trustee or general partner. If you mark "Yes" to any of the following questions, please attach details.		
1	Yes    No	Financial arrangements whereby the value of the compensation could be influenced by the outcome of human subjects, animals or basic science research that is or may be conducted at the LSCDVAMC. This should include, for example, compensation that is explicitly greater for a favorable outcome, or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest.
2	Yes    No	Payments of other sorts from sponsors of human subjects, animal or basic science research where the company is or may become a sponsor of human subjects, animal or basic science research at the LSCDVAMC involving significant sums, excluding the costs of conducting the study or other clinical studies. This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than \$25,000 (i.e., a grant to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria).
3	Yes    No	A propriety or financial interest in any human subjects, animal or basic science test product (including intellectual property rights) such as a patent, provisional patent, trademark, copyright, royalties or licensing agreement whose value may be influenced by research conducted at the LSCDVAMC.
4	Yes    No	A significant equity interest in a sponsor of human subjects, animal or basic science research when the company is or may become a sponsor of human subjects, animal or basic science research at the LSCDVAMC. This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$50,000.
5	Yes    No	Salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a sponsor of human subjects, animal or basic science research that is or may become a sponsor of human subjects, animal or basic science research at the LSCDVAMC that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months.
<b>OR</b>		
6	Yes    No	I hereby certify that none of the financial interest or arrangements listed above exists for my spouse, my dependent children, or myself.

I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interest and arrangements, or those of my spouse and dependent children, change relative to human studies, animals or basic science

research carried out at the LSCDVAMC, I will submit a revised R&D Committee Member Research Conflict of Interest Assessment Form.

R&D Committee Member Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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**Louis Stokes Cleveland DVA Medical Center (LSCDVAMC)  
IRB Member Human Research Conflict of Interest Assessment Form**

IRB Member's Name:		Date:
Credentials:		Title (s):
Service (If not VA employee indicate relationship to IRB):		
Significant financial interest DOES NOT include the following: a) Salary or other remuneration from the LSCDVAMC. b) Income from service on advisory committees or review panels for charitable or nonprofit entities.		
Mark YES or NO if any of the financial interests or arrangements of concern (described below) apply to you, your spouse, dependent children, general partner, or an organization in which you are an officer, director, trustee or general partner. If you mark "Yes" to any of the following questions, please attach details.		
1	Yes    No	Financial arrangements whereby the value of the compensation could be influenced by the outcome of human subjects research that is or may be conducted at the LSCDVAMC. This should include, for example, compensation that is explicitly greater for a favorable outcome, or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest.
2	Yes    No	Payments of other sorts from sponsors of human subjects research where the company is or may become a sponsor of human subjects research at the LSCDVAMC involving significant sums, excluding the costs of conducting the study or other clinical studies. This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than \$25,000 (i.e., a grant to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria).
3	Yes    No	A propriety or financial interest in any human subjects test product (including intellectual property rights) such as a patent, provisional patent, trademark, copyright, royalties or licensing agreement whose value may be influenced by research conducted at the LSCDVAMC.
4	Yes    No	A significant equity interest in a sponsor of human subjects research when the company is or may become a sponsor of human subjects research at the LSCDVAMC. This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$50,000.
5	Yes    No	Salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a sponsor of human subjects research that is or may become a sponsor of human subjects research at the LSCDVAMC that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months.
<b>OR</b>		
6		I hereby certify that none of the financial interest or arrangements listed above exists for my spouse, my dependent children, or myself.

I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interest and arrangements, or those of my spouse and dependent children, change relative to human studies research carried out at the LSCDVAMC, I will submit a revised IRB Member Human Research Conflict of Interest Assessment Form.

IRB Member Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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**Louis Stokes Cleveland DVA Medical Center (LSCDVAMC)  
IACUC Member Animal Research Conflict of Interest Assessment Form**

IACUC Member's Name:		Date:
Credentials:		Title (s):
Service (If not VA employee indicate relationship to IACUC):		
Significant financial interest DOES NOT include the following: a) Salary or other remuneration from the LSCDVAMC. b) Income from service on advisory committees or review panels for charitable or nonprofit entities.		
Mark YES or NO if any of the financial interests or arrangements of concern (described below) apply to you, your spouse, dependent children, general partner, or an organization in which you are an officer, director, trustee or general partner. If you mark "Yes" to any of the following questions, please attach details.		
1	Yes    No	Financial arrangements whereby the value of the compensation could be influenced by the outcome of animal research that is or may be conducted at the LSCDVAMC. This should include, for example, compensation that is explicitly greater for a favorable outcome, or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest.
2	Yes    No	Payments of other sorts from sponsors of animal research where the company is or may become a sponsor of animal research at the LSCDVAMC involving significant sums, excluding the costs of conducting the study or other clinical studies. This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than \$25,000 (i.e., a grant to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria).
3	Yes    No	A propriety or financial interest in any animal test product (including intellectual property rights) such as a patent, provisional patent, trademark, copyright, royalties or licensing agreement whose value may be influenced by research conducted at the LSCDVAMC.
4	Yes    No	A significant equity interest in a sponsor of animal research when the company is or may become a sponsor of animal research at the LSCDVAMC. This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$50,000.
5	Yes    No	Salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a sponsor of animal research that is or may become a sponsor of animal research at the LSCDVAMC that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months.
<b>OR</b>		
6		I hereby certify that none of the financial interest or arrangements listed above exists for my spouse, my dependent children, or myself.

I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interest and arrangements, or those of my spouse and dependent children, change relative to animal studies research carried out at the LSCDVAMC, I will submit a revised IACUC Member Animal Research Conflict of Interest Assessment Form.

IACUC Member Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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