

**American Red Cross Biomedical Services
Research and Development – Holland Laboratory**

**POLICY ON FINANCIAL CONFLICT OF INTEREST MANAGEMENT
(Revised July 19, 2012)**

Effective August 24, 2012, the following American Red Cross Biomedical Services (ARCBS) policy will apply to all ARCBS researchers who currently receive or wish to apply for research funding from the U.S. Department of Health and Human Services (HHS), including the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) (Part I), as well as other entities as described below (Parts II and III).

Part I – Government Research Support

1. As a requirement of the Federal Government (42 CFR Part 50 Subpart F), all investigators seeking or currently receiving grant or contract support must, upon implementation of this policy and annually thereafter, either state that they hold no significant financial interests (as defined below), or disclose any such interests, confidentially, to the ARCBS Institutional Official (IO) for Financial Conflict of Interest (FCOI) Management. This policy does not replace or supersede the obligations and responsibilities of Red Cross staff members to comply with the corporate guidelines regarding conflict of interest, as described in the American Red Cross Code of Conduct, the American Red Cross Compliance and Ethics Manual, and the Intellectual Property Policy.
2. For the purposes of this policy, an investigator must disclose (using the attached electronic form) any of the following significant financial interests that reasonably appear related to the investigator's institutional responsibilities:
 - (1) The investigator (or his/her spouse/partner or dependent children) has, in the twelve months preceding the date of disclosure, received remuneration (including salary and any other payment for services as defined in the CFR) in excess of \$5,000 from a publicly traded entity, or holds an equity interest in a publicly traded entity, the value of which exceeds \$5,000 as of the date of the disclosure;
 - (2) The investigator (or his/her spouse/partner or dependent children) has, in the twelve months preceding the date of disclosure, received remuneration (including salary and any other payment for services as defined in the CFR) in excess of \$5,000 from a non-publicly traded entity, or holds any equity interest (of any value) in a non-publicly traded entity;
 - (3) The investigator (or his/her spouse/partner or dependent children) has received income related to intellectual property rights and interests, such as patents or copyrights.
3. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities; exclusions are described in the CFR.
4. Such disclosures must be made by investigators named on existing PHS grants upon implementation of this policy, and by all other investigators no later than the time of application for HHS-funded research. Following initial statements and disclosures, investigators must renew their statements and disclosures at least annually throughout the lifetime of any grant or contract

related to this policy, and within 30 days of discovering or acquiring a new significant financial interest.

5. Within 60 days of submission, initial and renewal disclosure statements will be reviewed by the Vice President, Research and Development, or a designee, as the IO for Financial Conflict of Interest Management (FCOIM).
6. A disclosed significant financial interest will be deemed a FCOI related to HHS-funded research when the IO reasonably determines that the significant financial interest:
 - (i) could be affected by the HHS-funded research, or
 - (ii) is in an entity whose financial interest could be affected by the research, and therefore could directly and significantly affect the design, conduct, or reporting of the HHS-funded research. The IO may involve the investigator in determining whether a significant financial interest constitutes a FCOI.
7. When a financial interest is deemed to be a FCOI, the IO will work with the investigator to develop and implement a plan to manage the conflict, which may include:
 - (i) public disclosure of FCOI, for example when presenting or publishing the research;
 - (ii) disclosure of FCOI to any human subjects whose participation is required in carrying out the research;
 - (iii) appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research to guard against bias resulting from the FCOI;
 - (iv) modification of the research plan;
 - (v) change of personnel or personnel responsibilities or disqualification of personnel from participation in any portion of the research;
 - (vi) reduction or elimination of the financial interest; for example by sale of equity;
 - (vii) severance of relationships that create financial conflicts.

The IO's determination, subsequent management plan for mitigating conflict of interest, and the outcome of implementation of the management plan will be documented on the disclosure form and kept on file as required by the CFR.

8. Prior to the institution's expenditure of any funds under a HHS-funded research project, the ARC will ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information, as described in the CFR, concerning any significant financial interest disclosed to the IO which was determined to be a FCOI and is still held by the Investigator.
9. Prior to the institution's expenditure of any funds under a HHS-funded research project, the ARC will provide to the HHS awarding component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with the CFR.
10. In the event that a non-compliance with respect to this policy is recognized during any phase of application for or funding of a HHS grant or contract, or if disclosure or management is not carried out in a timely manner, the IO will conduct a retrospective review as described in the CFR, part

50.605. Any retrospective review will be documented and the ARC will update any previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If a retrospective review reveals bias, the ARC will notify the HHS Awarding component promptly and submit a mitigation report, as described in the CFR.

11. All disclosure documentation, FCOI findings, management plans, FCOI reports, retrospective reports, and mitigation plans will be retained by the ARC for a minimum of three years from the date that the final expenditures report is submitted to the HHS, and as described in the CFR.
12. The ARC will inform its Investigators of the FCOI policy and provide FCOI training to its Investigators upon implementation of the policy, to any newly hired investigator, and at least every four years after initial training, as well as immediately upon change in the policy, or upon any finding of noncompliance.
13. For all other aspects of FCOI management, the requirements of 42 CFR Part 50 and 45 CFR Part 94 shall obtain.

Failure to provide disclosure, incomplete or false disclosure, or other violations of this policy will require appropriate ARC action. The IO or designee will recommend remedies and/or sanctions, as appropriate, to the Chief Medical Officer, Biomedical Services for consideration and action.

Part II – Industrial Research Support

1. All investigators involved in projects funded by commercial, for profit organizations through Sponsored Research or Service Agreements must disclose any significant financial interests (defined below) in the sponsoring organization. This policy does not replace or supersede the obligations and responsibilities of Red Cross staff to comply with the corporate guidelines regarding conflict of interest found in the American Red Cross Code of Conduct or Intellectual Property Policy. This policy does not replace or supersede obligations and responsibilities of ARCBS Investigators to comply with guidelines regarding conflict of interest required by the for-profit organization that is offering the Sponsored Research or Service Agreement.
2. For the purposes of this policy, disclosure statements are required whenever, during the year prior to the date of disclosure, the Investigator (or his/her spouse/partner or dependent children) 1) has held equity interests valued at greater than \$5,000 as of the date of the disclosure; 2) has received income of more than \$5,000 a year from the sponsoring company; or 3) has received income related to intellectual property rights and interests, such as patents or copyrights. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities; exclusions are described in the CFR.
3. Disclosure statements will be reviewed by the IO who will assure that any disclosed conflict of interest is managed, reduced, or eliminated by actions similar to those described in PHS policy 42 CFR Part 50.

4. Investigators will disclose new financial conflicts of interest that develop during the term of a Sponsored Research or Service Agreement to the IO or designee. They will be reviewed and managed as described above.

Failure to provide disclosure, incomplete or false disclosure, or other violations of this policy will require appropriate ARC action. The IO or designee will recommend remedies and/or sanctions, as appropriate, to the Chief Medical Officer, Biomedical Services, for consideration and action.

Part III: Private Foundation Research Support

1. All investigators involved in projects funded by private foundations must disclose any significant financial interests (defined below) relating to their professional responsibilities. This policy does not replace or supersede the obligations and responsibilities of Red Cross staff to comply with the corporate guidelines regarding conflict of interest found in the American Red Cross Code of Conduct or Intellectual Property Policy. This policy does not replace or supersede obligations and responsibilities of ARCBS Investigators to comply with guidelines regarding conflict of interest required by the for-profit organization that is offering the Sponsored Research or Service Agreement.
2. For the purposes of this policy, disclosure statements are required whenever the Investigator (or his/her spouse/partner or dependent children) during the year prior to the disclosure: 1) has held equity interests in a publicly traded company, valued at greater than \$5,000; 2) has received income of more than \$5,000 a year from any source other than the institution by which he/she is employed; 3) has held any equity interest in a non-publicly traded company; or 4) has received income related to intellectual property rights and interests, such as patents or copyrights. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities; exclusions are described in the CFR.
3. Disclosure statements will be reviewed by the IO who will assure that any disclosed conflict of interest is managed, reduced, or eliminated by actions similar to those described in PHS policy 42 CFR Part 50.
4. Investigators will disclose new financial conflicts of interest that develop during the term of a Sponsored Research or Service Agreement to the IO or designee. They will be reviewed and managed as described above.

Failure to provide disclosure, incomplete or false disclosure, or other violations of this policy will require appropriate ARC action. The IO or designee will recommend remedies and/or sanctions, as appropriate, to the Chief Medical Officer, Biomedical Services, for consideration and action.

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