

Subject: CONFLICT OF INTEREST		Issued By: ADMINISTRATION	
		Approved By: Kathleen R. Hurtado President & CEO	
Policy #: 310	Issue Date: April 18, 2006	Revised Date: June 25, 2008	Effective Date: June 30, 2008

Reference: Revised and adapted from LAC + USC Healthcare Network Policy #310 and original Conflict of Interest Policy dated 6-10-2005 and updated as of 4-18-2006 and further updated per the USC Conflict of Interest in Research: Policy and Procedure located here: <http://policies.usc.edu/policies/conflictresearch110107.pdf>, the USC Conflict of Interest and Ethics: Policy and Procedure located here: <http://policies.usc.edu/policies/conflictadmin110102.pdf>, and the USC Faculty Handbook Section 3, pages 13-16 located here: <http://policies.usc.edu/facultyhandbook/facultyhandbook2006.pdf>.

PURPOSE

To govern HRA Staff Member activities, which may be in conflict with and adversely affect, their job duties and responsibilities.

Note: This policy contains three sections which mirror three separate and corresponding USC policies (*press “Control” + “Left-Click” simultaneously on the blue section names below to go to the specific text of interest*):

- [**Conflict of Interest in Research**](#) – Applies to Principal Investigators (PIs), Co-PIs, Study Team Members, Volunteers and Students involved in Human Subjects’ Research;
- [**Conflict of Interest and Ethics**](#) – Applies to all HRA Staff Members (including PIs, Co-PIs and Study Team Members), Volunteers, and Students;
- [**Additional Conflict of Interest Policies for USC Faculty**](#) – Applies to all Investigators who are also USC faculty members.

OVERARCHING POLICY

Investigators are not permitted to commence any research activity when there is an actual or apparent Conflict of Interest before they receive a written determination from the Vice Provost for Research Advancement as to how to manage the conflict. The burden of responsibility is upon the Staff Member to disclose and report all potential Conflict of Interest situations, document the circumstances, and secure an approval of the conflict minimizing procedures to be followed from the appropriate Supervisor. All such procedures will be designed to protect HRA, USC, the Staff Member and the public from any harm related to any real or perceived conflict.

All Staff Members working for HRA are prohibited from:

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1. **HAVING ANY IMPAIRED JUDGMENT WITH RESPECT TO JOB DUTIES:** Engaging in any business or transaction which conflicts with – or appears to conflict with – or which impairs – their independent judgment in discharging their official duties;
2. **ACCEPTING MONEY OR FAVORS:** Accepting money, favors or other consideration for work they would be required to perform in the regular course of their duties;
3. **REFERRING PATIENTS TO PRIVATE SERVICES:** Referring Patients, Research Participants or clients for private reimbursable services to themselves or to any group in which they have a financial interest;
4. **ACCEPTING GIFTS OR GRATUITIES:** Accepting gifts, gratuities or favors of any kind from Patients, Research Participants, vendors or other persons doing business with Los Angeles County, HRA and/or USC;
5. **DISCLOSING INFORMATION FOR PERSONAL GAIN:** Disclosing confidential information made available to them in the course of their duties or using such information for speculation or personal gain.

Special Circumstances Relating to Self-Referrals

There may be situations where the prohibition of self-referral might either impact the quality of medical services or impose substantial additional costs to the Patient and/or Research Participant. In such situations, self-referral or referral to a group in which they have a financial interest is acceptable. In all such situations, the following criteria must be met:

1. **NO ALTERNATE SERVICE AVAILABLE:** Suitable alternative services are not available;
2. **IN A PERSON'S BEST INTERESTS:** The best interests of the Patient and/or Research Participant require self-referral;
3. **ADMINISTRATIVE APPROVAL REQUIRED:** HRA's President & CEO must give prior written approval for any such self-referral or transfer; and

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4. **EXPLANATION IN PERSON’S MEDICAL RECORDS:** Written documentation of the self-referral approval must be inserted into the Patient’s or the Research Participant’s health/medical record.

How to Properly Manage Conflict

HRA and USC have identified three major components, which promote an adequate management of Conflicts of Interest:

- **Identification:** The Provost’s office is equipped to assist people with identifying conflicts;
- **Disclosure:** All actual or apparent Conflicts of Interest must be reported to the appropriate Supervisor and/or authority; and
- **Action:** Address actual or apparent Conflicts of Interest either through appropriate management or through prohibition of the proposed relationship.

Review Committees: USC’s Provost’s Office has a *Conflict of Interest Review Committee (CIRC)* and a *Financial Disclosure Review Committee* either of which Investigators and their Study Teams may find useful in identifying, disclosing, managing Conflicts of Interest.

For additional information, please see Sections 5 and 6 of the USC Conflict of Interest in Research: Policy and Procedure located here: <http://policies.usc.edu/policies/conflictresearch110107.pdf>.

Definitions

The following are key Conflict of Interest terms:

- **Research:** A systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences research;
- **Investigator:** PI, Co-PI and/or any other co-investigator;
- **Research Personnel (aka. Study Team Members):** Any other HRA/USC Staff Member who contributes to a research activity, whether or not the research is funded and regardless of status (e.g., Study Team Members, key faculty, research associates, technicians, nurse coordinators, administrators, and graduate assistants);

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- **Close Relation:** A spouse, mutual financial dependent, significant other (or person with whom you are in an intimate relationship); a child, parent, sibling (including in-laws and step-relations), grandparent or grandchild, niece or nephew, aunt, uncle or cousin;
- **Conflict of Interest:** A situation in which financial and/or other personal considerations compromise, or appear to compromise, an individual's professional judgment in proposing, conducting, supervising or reporting research. Financial or non-financial Conflicts of Interest exist because non-financial interests also can be in conflict with a researcher's primary commitment to maintain scientific objectivity. Investigators should not only consider situations that are unacceptable, but also gray areas that might create the appearance of a Conflict of Interest. Conflicts of Interest related to Research Participants present unique challenges for researchers at HRA and USC. HRA and USC are committed to protecting the safety of all Patients and Research Participants under our care. All Conflicts of Interest related to Research Participants will be subject the highest level of scrutiny. For information on Research Participants' Rights, please look here: <http://www.health-research.org/files/Rights.pdf>;

I. CONFLICT OF INTEREST IN RESEARCH

PURPOSE

By promoting the highest ethical standards in situations where Conflicts of Interest in research may occur, this section of this policy is intended to help research investigators (PIs, Co-PIs, Study Team Members and Students) recognize situations with an appearance of conflict to ensure that such situations are properly reviewed and resolved. This section applies to all those proposing, conducting or reporting research regardless of funding source, as well as those in clinical trials and unfunded projects.

Because multiple types of conflict may arise in the conduct of research, please review and closely follow all of USC's Conflict of Interest policies and HRA's *Code of Ethics Policy*:

- USC's *Conflict of Interest in Research: Policy and Procedure* located here: <http://policies.usc.edu/policies/conflictresearch110107.pdf> ;
- USC's *Conflict of Interest and Ethics: Policy and Procedure* located here: <http://policies.usc.edu/policies/conflictadmin110102.pdf> ;
- USC's *Faculty Handbook* Section 3, pages 13-16 located here: <http://policies.usc.edu/facultyhandbook/facultyhandbook2006.pdf> ;

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- HRA's *Code of Ethics Policy* located here: <http://www.health-research.org/files/Ethics.pdf>;
- Researchers who are also healthcare providers must also comply with USC's *Policy Regarding Relationships with Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers* located here: <http://policies.usc.edu/policies/pharmaceutical010208.pdf>. Particular attention must be paid to sections addressing arrangement for consulting and services, receipt of gifts, and the conduct of research sponsored by pharmaceutical companies, medical device companies, healthcare suppliers and their staff or agents.

PRINCIPLES

HRA and USC encourage researchers to have meaningful professional relationships with industry, government and private partners. These partnerships are for mutually beneficial reasons and produce knowledge and intellectual property to help meet societal needs. At the same time, researchers at HRA and USC must be mindful of Conflicts of Interest that may arise from these relationships and which may affect HRA's and/or USC's commitment to:

- Discharging obligations to others in a fair and honest manner as embodied in HRA and USC's Code of Ethics policies;
- Educating Students;
- Ensuring academic freedom;
- Protecting Patient and Research Participant safety;
- Protecting the appearance, actual integrity, and objectivity of research, instruction, and public service; and
- Bringing the fruits of research to the benefit of society by transferring knowledge developed by HRA and/or USC to the public and/or private sectors.

DIFFERENT TYPES OF CONFLICTS OF INTEREST IN RESEARCH

- 1) **SIGNIFICANT CONFLICT:** A Conflict of Interest that is presumed to be unacceptable unless the Investigator or Study Team Member is able to present compelling circumstances which justify allowing the research to proceed despite the presence of the Significant Conflict. For specific examples of Significant Conflicts, please see Section 4.6 of USC's *Conflict of Interest in Research: Policy and Procedure* located here: <http://policies.usc.edu/policies/conflictresearch110107.pdf>;

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- 2) **PROHIBITED CONFLICT:** A Conflict of Interest that is never acceptable. For specific examples of Prohibited Conflicts, please see Section 4.7 of USC’s *Conflict of Interest in Research: Policy and Procedure* located here: <http://policies.usc.edu/policies/conflictresearch110107.pdf>;
- 3) **CONFLICT OF COMMITMENT:** A Conflict of Interest between outside activities and a full-time Employee’s responsibility to devote their primary professional loyalty, time and energy to teaching, research, service, administrative, and clinical duties, as applicable. For specific examples of Conflicts of Commitment, please see Section 4.8 of USC’s *Conflict of Interest in Research: Policy and Procedure* located here: <http://policies.usc.edu/policies/conflictresearch110107.pdf> as well as HRA’s *Outside Employment Policy* located here: <http://www.health-research.org/files/Outside.pdf>.

DIFFERENT EXAMPLES OF CONFLICTS OF INTEREST IN RESEARCH

Note: Although not an all-inclusive list, each of the following is a type of Conflict of Interest involving an Investigator, Research Personnel (aka Study Team), or a Close Relation of either, which must be disclosed in accordance with this policy:

- 1) **FINANCIAL INTERESTS: Note: These are all Significant Conflicts of Interest!**
- Maintaining a **private equity interest** (e.g., stocks, stock options or other ownership interests not publicly traded) in a research Sponsor or licensee, or in a company having an economic interest in the research, regardless of the value of such interest;
 - Maintaining a **publicly traded equity interest** of \$10,000 or more (except when the ownership interest is managed by a third party such as a mutual fund) or 0.5 percent of the valuation of a research Sponsor or licensee or in a company having an economic interest in the research;
- 2) **MANAGEMENT ROLES: Note: This is a Significant Conflict of Interest, which also may be a Conflict of Commitment!**
- Holding a **management role** (e.g., director, officer, scientific, or technical appointment where the Investigator or Study Team Member has significant decision-making authority) in a research Sponsor or licensee, or in a company having an economic

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interest in the research; or any other instance where the Investigator or Study Team Member have significant decision-making authority within the outside entity. For more information on HRA's *Outside Employment Policy*, look here: <http://www.health-research.org/files/Outside.pdf>;

3) STUDENTS: Note: This is a Significant Conflict of Interest!

- Using a Student to perform services for a company in which the Investigator, Study Team Member, or the Close Relation of either has an ownership or management role when:
 - a) The Student is currently enrolled in a class taught by the Investigator or any Study Team Member, or the Close Relation of either; or
 - b) The Investigator, Study Team Member, or Close Relation of either currently supervise(s) the Student in an academic capacity; or
 - c) The Investigator, Study Team Member, or Close Relation of either otherwise has the ability to influence the academic progress of the Student;

4) FUNDING AND COMPENSATION: Note: The examples below represent differing types of Conflicts of Interest. Refer to the bold green text at the end of each bullet point to determine which type of conflict is being exemplified.

- Maintaining a **financial interest or management role** in a research Sponsor of the Investigator and/or Study Team Member's laboratory; **Note: This is a Significant Conflict of Interest!**
- Maintaining a **financial interest or management role** in a company that has given, or expressed an interest in giving, a major gift to the Investigator and/or Study Team Member's department or school; **Note: This is a Significant Conflict of Interest!**
- Receiving any **incentive payments**, bonus payments or finders fees relating to the proposal, conducting or reporting of research, regardless of the amount of compensation or payments received (i.e., additional payments by research Sponsors to Investigators or Study Team Members who enroll a certain number of participants in a project within a certain period of time); **Note: This is a Prohibited Conflict of Interest!**
- Accepting **personal payments for services from any Sponsor, or any organization or individual having an economic interest in the Investigator's research that total**

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more than \$10,000 when aggregated in any 12-month period (excluding reasonable reimbursement of expenses for travel and/or provision of services). These types of payments include:

- a) Consulting arrangements;
- b) Non-managerial scientific or technical appointments;
- c) Payments for lectures and similar public appearances; **Note: These are either a Significant or a Prohibited Conflict of Interest depending on the circumstances!**
- Accepting **gifts, gratuities** or **special favors** from an actual or prospective Sponsor of an Investigator's research, other than occasional gifts of nominal or modest value (less than \$50 in value or isolated invitations to meals). **Note: This is a Prohibited Conflict of Interest!**

Note: Investigators and/or Study Team Members who are healthcare providers must comply with additional requirements for professional or consulting services on behalf of pharmaceutical suppliers and device manufacturers. Please see USC's Policy Regarding Relationships with Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers located here: <http://policies.usc.edu/policies/pharmaceutical010208.pdf>.

5) INTELLECTUAL PROPERTY:

- Maintaining a financial interest or management role in a company that is **negotiating a license** to intellectual property from HRA and/or USC; **Note: This is a Significant Conflict of Interest!**
- Receipt of **intellectual property rights** (e.g., patents, copyrights or royalties from such rights) from a research Sponsor by an Investigator, a Study Team Member or the Close Relation of either; **Note: This is a Significant Conflict of Interest if the receipt of rights is by USC and a Prohibited Conflict if the receipt of rights is by the Investigator or the Study Team Member!**
- An agreement that **restricts an Investigator or Study Team Member's public reporting** of information developed by the research contract, in combination with receiving any form of outside compensation from the Sponsor, or in combination

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withholding an officer position or private equity position with the Sponsor. **Note:**
This is a Prohibited Conflict of Interest!

II. CONFLICT OF INTEREST AND ETHICS

PURPOSE

To provide an institutional policy that protects academic freedom and encourages the full professional development of USC's faculty members and non-faculty Staff Members, while minimizing the risk of unacceptable behavior in potential conflict situations. To this end, all USC and/or HRA Staff Members working for HRA must disclose actual or perceived conflicts so that they can be managed appropriately. Disclosure will not necessarily restrict or preclude an individual's activities. In most cases, problems arise when the conflict is not disclosed or when it is not assessed or managed appropriately.

POLICY

1. **AVOID CONFLICTS OF INTEREST IN BUSINESS PRACTICES:** All HRA Staff Members and USC Staff Members working for HRA must not allow a personal or outside interest to interfere with their duties and responsibilities. Even the appearance of a Conflict of Interest should be avoided. Any arrangements or relationships that may pose an actual or apparent Conflict of Interest should be disclosed to HRA's President & CEO as soon as the conflict is known and a plan must be developed to manage the conflict;
2. **EXAMPLES OF SIGNIFICANT CONFLICTS OF INTEREST IN BUSINESS PRACTICES:** Although not an all-inclusive list, examples of actual or apparent **Significant Conflicts of Interest** in business practices that should be disclosed under this section of this policy include:
 - a) **Conducting business with** an individual or entity in which **you or your Close Relation** has a personal, managerial or substantial financial interest;
 - b) **Maintaining an external consulting relationship or other business** (including all arrangements in which you are compensated in any way) with a supplier, vendor or competitor of HRA and/or USC, which a reasonable person would expect to impair, or which might appear to impair, your independence of judgment in the performance of your duties;
 - c) **Competing with USC and/or HRA**, or competing with other external vendors for USC and/or HRA business, whether as an individual, as the Staff Member of

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another organization, or through a separate entity owned or operated by you or your Close Relation that exists outside of your professional obligations;

- d) **Accepting personal gifts or special favors** from individuals or entities that provide, or seek to provide, services or supplies to HRA and/or USC. This does not include occasional gifts of nominal or modest value (less than \$50 in value or isolated invitations to meals);
- e) **Endorsing** or authorizing the endorsement of **any product or service on behalf of HRA and/or USC**;
- f) **Making use of any USC and/or HRA assets** (including names, trademarks and/or service marks), resources or supplies (except for incidental use) outside the scope of their job duties;

3. **EXAMPLES OF PROHIBITED CONFLICTS OF INTEREST IN BUSINESS PRACTICES: Prohibited Conflicts of Interest** under this section of this policy include, but are not limited to, the following:

- a) Conditioning any actual or potential business relationship with USC and/or HRA on a **charitable gift or contribution**;
- b) Participating in any way in any **negotiation or transaction between USC and/or HRA** and a business entity in which **you or your Close Relation** has a personal, managerial or substantial financial interest;
- c) **Directly supervising or evaluating the work of a Close Relation**;
- d) Participating in any decision (such as decisions concerning initial appointment, retention, termination, promotion, salary or leave of absence) that involves either **a direct benefit or a detriment to a Close Relation**;
- e) **Soliciting personal gifts** or special favors from individuals or entities that provide, or seek to provide, services or supplies to USC and/or HRA;
- f) **Unauthorized use of confidential, privileged or proprietary information** obtained in connection with your position, or use of such information for your personal benefit or the personal benefit of another;
- g) For faculty members who conduct clinical practice, **failing to abide by your respective faculty practice plan agreements**;

4. **PERSONAL CONFLICTS OF INTEREST:** All USC and/or HRA Staff Members working for HRA shall not participate in any decision (such as decisions concerning initial appointment, retention, termination, promotion, salary or leave of absence) that involves either a direct benefit or a detriment to a Close Relation. For example, a PI shall not hire a person who is a

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Close Relation. If in doubt concerning the possibility of a personal Conflict of Interest, it is recommended that the Staff Member consult with the appropriate Supervisor, Chair or Dean. Full disclosure and consultation regarding potential Conflicts of Interest is always in the best interests of HRA/USC and the Staff Member(s) in question.

III. ADDITIONAL CONFLICT OF INTEREST ISSUES FOR USC FACULTY

1. **SERVING IN ELECTED OFFICE LIMITED TO PRIVATE TIME:** While having the same rights and responsibilities of free speech, thought and action as all U.S. citizens, USC faculty members have special obligations to exercise appropriate restraint and emphasize that they are not representatives of USC when not speaking on behalf of HRA and/or USC. Also, any private activity requiring a large portion of time may impair the faculty member's performance in discharging instructional and other regular duties. Therefore, faculty members campaigning as a political candidate for state or federal offices will do so on their own time and it is required that they obtain leave of absence for this period or work at HRA/USC on a part-time basis. Such leave of absence is not sabbatical leave and, if full-time, is without pay. Leave of absence is not required for faculty members who become candidates for, or who are elected to, offices of a temporary or part-time nature such as on a municipal charter commission, delegate to the State Constitutional Convention, school board member or holder of a municipal office;
2. **OUTSIDE CONSULTING LIMITED TO 39 DAYS IN AN ACADEMIC YEAR:** Outside consulting work must not detract from the prestige of HRA and/or USC or the professional standing of the faculty member. Since faculty member obligations to HRA and USC are complex and not easily separable from their broader activities as professionals, the degree to which faculty members meet their obligations to HRA and/or USC cannot be ascertained by time records or publication lists. Therefore, USC faculty members may not consult for more than 39 days during an academic year. During the summer months when a faculty member is supported by either USC or government contracts or grants, a prorated limit on the permissible number of consulting days applies. In the rare instance where circumstances may warrant an exception to this policy, requests must be made prior to the time consulting will take place and approval secured from the Provost. Since outside consulting is a conditional privilege granted by USC, USC is the final judge of the appropriateness of outside consulting.

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Note: If in doubt about the possibility of a Conflict of Interest, the faculty member should consult the department Chair or Dean. A department Chair or Dean having similar doubts should initiate discussion with the faculty member.

3. **CANDIDACY FOR DEGREE LIMITATIONS:** Faculty members shall not be candidates for degrees in the same school in which they have an appointment. Assistant professors on the tenure track should not simultaneously be candidates for degrees anywhere at USC. Individual exceptions only may be made with the approval of the Provost or of a special committee appointed by USC’s President;
4. **UNREPORTED CONFLICTS OF INTEREST ARE GROUNDS FOR DISMISSAL:** Unmanaged or unreported Conflicts of Interest are adequate cause for dismissal. No offense will be considered adequate cause for dismissal unless it is serious and either:
 - Relates directly and substantially to the fitness of the faculty member in their professional capacity as a teacher, researcher, or practitioner performing clinical services; or
 - Is of such nature that it would bring severe injury or discredit to USC and/or HRA;
5. **STEPS FOR DISMISSAL:** Dismissal shall not be used to restrain faculty members in their exercise of academic freedom or their other rights as U.S. citizens. Every action to dismiss a faculty member must follow carefully detailed procedures. For more information, please see Section 8-C “Dismissal Procedures”, Steps 1-3 in Section 8-C (1) “Preliminary Inquiry” and Steps 4 and 5 in Section 8-C (2) “Formal Proceedings” in the USC *Faculty Handbook* located here: <http://policies.usc.edu/facultyhandbook/facultyhandbook2006.pdf>;

RESPONSIBILITY

All Employees, Contractors & Volunteers
Human Resources

REFERENCES

Los Angeles County Code, Chapter 5.44, Section 5.44.010
DHS Policy# 741