



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	1 of 9

Signatures and Dates:

Author:

For signatures, please see original in the
Division of Human Subjects Protection

QA Review:

Approving
Authority:

Review/Approval for unchanged documents

Date	Author	QA Review	Approving Authority



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	2 of 9

1. **Purpose/Applicability:** This Standard Operating Procedure (SOP) documents the process used by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) regarding conflicts of interest (COI). It is the practice of the WRAIR IRB to protect the integrity of human subjects research reviewed by the IRB and to keep all research as free from potential bias as possible. The WRAIR IRB shall identify and reduce potential conflicts in the conduct of the individual or group's respective obligations.

This SOP applies to all human subjects research protocols, the Division of Human Subjects Protection (DHSP) Staff, WRAIR IRB Members, and the Institutional Official (IO).

2. **Responsibilities:** Those taking responsibility for the actions in this SOP are the IRB members, IO, the IRB administrative director, and DHSP staff.
 - a. The IRB members:
 - 1) Disclose any COI, potential or perceived,
 - 2) Not review when there is a COI and recuse from voting, and
 - 3) Review investigator COI disclosure forms and take appropriate action.
 - b. The IRB administrative director determines appropriate management of COI disclosure forms in order to present them to the IRB.
 - c. The DHSP staff:
 - 1) Ensure that appropriate documents are submitted for review by the IRB, and
 - 2) Ensure that copies of any COI disclosure documents submitted by an investigator are kept in the IRB study files.
 - d. The IO is responsible for not signing the implementation approval if he/she has a COI, potential or perceived, and if so, for forwarding to a signatory without a COI.



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	3 of 9

3. Investigator Guidance:

Principal and Associate Investigators (Key study personnel) are expected to:

- a. Disclose any conflict, potential conflict or perceived COI.
- b. Comply with IRB requirements pertaining to the management of a COI once identified.
- c. Comply with Sponsor requirements related to the disclosure of any COI.

4. Materials and Equipment: Not Applicable.

5. Procedures:

- a. The WRAIR IRB requires that all Investigators disclose any conflict, *potential* conflict or *perceived* COI, such as:
 - 1) Speaking or consulting engagements on behalf of the Sponsor;
 - 2) Board appointments for the Sponsoring Company;
 - 3) Patents, copyrights or trademarks, royalties, licenses, intellectual property or other interest related to the articles, compounds, etc. under study in the protocol or that may be affected by the outcome of the study (Note: this includes applications for patents, copyrights, trademarks, etc.);
 - 4) Financial, managerial or ownership/equity interest, stock in the Sponsoring Company or in the company producing the drug/ device/biologic under study or that has a component of the research (investigator or immediate family);
 - 5) Up-front payments to the institution, beyond those necessary for carrying out the research;
 - 6) Compensation in the form of equipment;
 - 7) Inappropriate use of institutional resources or assets in research;
 - 8) Board positions with the sponsoring or involved company;
 - 9) Recruitment bonuses;
 - 10) Finders' fees or referral fees;
 - 11) Other areas that may be of conflict, including, but not limited to, personal (i.e., ideological) differences or supervisory/work relationships (i.e., investigator and potential participant are engaged in an evaluative and supervisory relationship).

Note: Management of a COI may include, but are not limited to: disclosure publicly of the significant COI; monitoring of the research by independent



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	4 of 9

reviewers; modification of the research plan; disqualification of the investigator; divestiture of significant financial interests; severance of relationships that create actual or potential COI; or other action, as deemed appropriate.

b. Investigator/Key Study Personnel COI:

- 1) In addition to disclosing any of those conflicts identified above, for Food and Drug Administration (FDA)-regulated studies, all investigators listed on the FDA Form 1572 must submit a Financial Disclosure Form (Appendix A) in the submission packet for studies involving investigational products. For industry-sponsored trials and trials sponsored by the Office of The Surgeon General (OTSG), the Sponsor's Financial Disclosure Form is accepted for this purpose.
- 2) COI Disclosure Forms are reviewed annually and revised, if changes occur. Investigators have the responsibility to submit updated information to the Sponsor for one year following completion of the study.
- 3) The WRAIR IRB has the authority to form a sub-committee to evaluate completed Financial COI forms and any other information pertaining to potential COI in human subjects research protocols. The role of this sub-committee is both adjudicative and arbitative. However, whether or not the IRB uses a sub-committee, the IRB is ultimately responsible for determining how any conflicts might be managed or resolved. The sub-committee shall consist of at least two IRB Members who will meet prior to the IRB meeting. The sub-committee shall notify the IRB and the investigator as to whether the financial interests or other potential or actual conflicts could directly, have the appearance of, or does significantly affect the study. The sub-committee findings, along with recommendations will be recorded into the IRB minutes.
- 4) The sub-committee may recommend that the individual reduce or eliminate conflicts or potential conflicts arising from significant COI. Recommendations are taken to a vote at a fully convened IRB meeting.
- 5) The IRB Administrative Director (or Designee), in lieu of a sub-committee, may determine appropriate management of COI disclosure forms in order to present them to the IRB. Recommendations would then come from the full IRB. The sub-committee or the IRB Administrative Director can use a COI checklist (Appendix B) to assist in managing the COI Disclosure Form (Appendix A).



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	5 of 9

c. IRB Member COI:

- 1) For expedited review actions, IRB members must disclose COI and must not review those items. This COI should be documented and then the protocol item given to another member who has been delegated expedited review authority.
- 2) At the beginning of each IRB meeting, the IRB Chair or Acting Chair requests that the IRB members disclose any COI related to the day's agenda. Any conflicts are noted in the IRB minutes. No IRB member may participate in the deliberations of voting on any protocol in which the member has a conflicting interest and must recuse him/herself, except to provide information to the IRB when requested. A recused IRB member must leave the meeting room during active discussion & deliberations.

d. Institutional COI:

- 1) Should the IO or one of his/her signatory designees have a COI, he/she should document this COI on the approval routing slip, not sign the implementation approval, and forward to a signatory without a COI. Since most of the alternate approving authorities will also be in the rating chain of the IO, alternatively, if the IO has a COI, the protocol can be forwarded to the Commanding General, Medical Research and Material Command (MRMC) for approval to implement.
- 2) The Institutional COI may occur when the Institution or any of its senior management (to include Outside the continental United States (OCONUS) Commanders) has an external COI in a company or organization that itself has a financial interest in a specific research project.

- e. Copies of any COI disclosure documents submitted by an investigator will be kept in the IRB study files maintained by the DHSP.



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	6 of 9

6. Explanation of Abbreviations and Terms:

Conflict of Interest (COI)	Situation in which financial or other personal situations may compromise, or have the appearance of compromising an Investigator's or IRB Member's professional judgment in conducting, reporting or reviewing research.
DHSP	Division of Human Subjects Protection, WRAIR, is the administrative support of the WRAIR IRB
FDA	Food and Drug Administration
Human Subjects Research	Research involving humans as research subjects, or involving data, biological specimens, specimens from repositories or anatomical substances of human origin. This includes the administration of questionnaires or surveys, as well as research done in an educational setting.
IO	Institutional Official
Immediate Family	Spouse/domestic partner, children, parents, siblings.
Institutional Review Board	(IRB) An ethical review committee that reviews research involving human subjects, as per the cited regulations and policies.
MRMC	Medical Research and Material Command
PI	Principal Investigator or WRAIR Point of Contact
POC	Point of Contact
OCONUS	Outside the continental United States
OTSG	Office of the Surgeon General (US Army)
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	7 of 9

- Risk** The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study.
- Significant Financial Interest** Anything of monetary value which the IRB Member, Investigator or his/her immediate family receives from or holds in the Sponsor of a study or an entity that would reasonably appear to affect, or be affected by the studies design, conduct, reporting or review. Significant Financial Interest includes salary or other payments for services including consulting fees or honoraria, equity interests (stocks, stock options, or other ownership interests), intellectual property rights (patents, copyrights, and royalties from such rights), equipment, etc.
- WRAIR** Walter Reed Army Institute of Research
- WRAIR IRB** The ethical review committee for research involving human subjects at WRAIR, its CONUS detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (e.g., investigator). This includes protocols for which recruitment of subjects is through WRAIR.



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	8 of 9

7. References:

Reference Number or Authors	Document Title
AR-40-68	<i>Clinical Quality Management, 26 February 2004.</i>
AR-70-25	<i>Use of Volunteers as Subjects of Research, 25 January 1990</i>
AR-40-7	<i>Use of Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule 1 Controlled Substances</i>
WRAIR Policy 08-03	
WRAIR IRB Charter	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter.
MCMR-UWZ-C-613	Expedited Human Subjects Research Protocol Review
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)
ICH-GCP-E6	<i>Guideline for Good Clinical Practice.</i>
Titles 21, 32 and 45	<i>Code of Federal Regulations</i>



Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure

SOP Title	IDENTIFICATION AND MANAGEMENT OF CONFLICTS OF INTEREST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	9 of 9

8. Forms and Appendices:

Form or Appendix Number	Title
UWZ-C-609-A Appendix A	Disclosure of Significant Conflict of Interests of Investigator Form
UWZ-C-609-B Appendix B	Conflict of Interest Checklist

9. Document Revision History:

Version Number	Brief Description of Changes	Effective Date
.00	Original Document	3 Jan 07
.01	Biennial review, widening of COI definition to include non-financial COI, and procedures for documenting IRB Member COI, including relevant updates to the attachments (Appendices A and B).	14 Jan 09
.02	Biennial review of procedures for documenting COI, including relevant updates to the attachments (Appendices A and B).	APR 06 2011

Appendix A	DISCLOSURE OF SIGNIFICANT CONFLICT OF INTERESTS OF INVESTIGATOR FORM	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	1 of 3

Conflicts of interest can be financial or non-financial. "Significant financial interests" are anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria, grants for ongoing research, payments for a favorable outcome, subject recruitment bonuses, or payment for enrolling a certain number of subjects within a specific time-frame), equity interests (e.g., stocks, stock options, or other ownership interests, not including mutual funds), and intellectual property rights (e.g., patents, copyrights, licensing agreements, and royalties from such rights). The term does not include: (1) salary, royalties, or other payments from the institution conducting the research or from the U.S. Army or any organizational unit within the Army; (2) ownership interests in the institution conducting the research; (3) equity interest that does not exceed \$10,000 and does not represent more than a 5% ownership in any single entity; and (4) salary, royalties, or other payments that are not expected to exceed \$10,000 over the next twelve months. Financial interests include the financial interests of your spouse and dependent children.

Examples of non-financial conflicts include, but are not limited to the following: Speaking or consulting engagements on behalf of the sponsor, board appointments for the sponsoring company, compensation in the form of equipment, personal (i.e., ideological) differences or supervisory (i.e., investigator and potential participant are engaged in an evaluative and supervisory relationship).

1. Investigator's name, title, organization:
2. Name of research protocol:
3. Sponsor(s) of the protocol:

Appendix A	DISCLOSURE OF SIGNIFICANT CONFLICT OF INTERESTS OF INVESTIGATOR FORM	SOP No.	UWZ-C-609
		Version	.01
Effective Date	APR 06 2011	Page	2 of 3

4. Check one of the following:

Initials: _____ Date: _____ I certify that I have no significant conflict of interests with a research sponsor, or that may otherwise reasonably appear to affect or be affected by the research.

Initials: _____ Date: _____ I have "significant financial interests" or other non-financial conflicts of interest with sponsors of this research protocol, or that may otherwise reasonably appear to affect or be affected by this research. I have listed these interests in the table below. Attach additional information as necessary.

Type of Conflict of Interest (financial or non-financial)	Name of Organization in Which I Have an Interest (if applicable)	Nature of Interest (e.g., salary, equity, intellectual property rights, supervisory)	Detailed Description of Interest, Including Approximate Dollar Amount (if applicable)

Appendix A	DISCLOSURE OF SIGNIFICANT CONFLICT OF INTERESTS OF INVESTIGATOR FORM	SOP No.	UWZ-C-609
		Version	.01
Effective Date	APR 06 2011	Page	3 of 3

5. Steps taken to minimize potential harm to subject safety or research objectivity resulting from interests disclosed above (e.g., divestiture of the interest, severance of the relationship that creates the interest, modifications to the protocol and/or consent form, third-party oversight of the research or consent process, having a non-biased third party obtain consent, or disqualification from participation in a portion of the research that could be affected (for example, disqualification from design of the research, adverse event reporting, or analysis of the data)):

Date:	Investigator Signature:
	Printed Name:

Appendix B	CONFLICT OF INTEREST CHECKLIST	SOP No.	UWZ-C-609
		Version	.02
Effective Date	APR 06 2011	Page	1 of 1

WRAIR Protocol # _____ HSRRB Log Number: _____ PI: _____

Date Checklist Completed: _____

Sub-Committee Chair or WRAIR IRB Administrative Director's Signature: _____

Date Checklist Updated (if applicable): _____

Initial Questions	Is Element Addressed?			Comments
	Yes	No	N/A	
Has investigator submitted a "Disclosure of Significant Conflicts of Interests of Investigator" form?				
Did investigator list any "significant conflicts of interests," with research sponsors, or that may otherwise reasonably appear to affect or be affected by the research?				
THERE IS A CONFLICT OF INTEREST (COI) IF:				
Any of the listed conflicts of interest affect or be affected by the design or conduct of the research				
Any of the listed conflicts of interest affect or be affected by the data analysis				
Any of the listed conflicts of interest affect or be affected by the study outcome				
Any of the listed conflicts of interest interests affect or be affected by the number of subjects enrolled				
TO ELIMINATE, MANAGE, OR REDUCE COIs				
Steps being taken to minimize potential for the COIs to harm subjects or research objectivity				

Additional Comments