Standard Operating Procedure
Walter Reed Army Institute of Research

SOP:	IDENTIFICATION AND MANANGMENT OF CONFLICT OF INTERESTS	**SOP No.:**	UWS-HP-609
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Signatures and Dates:

Author:

QA Review:

Approving Authority:

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
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1. Purpose and 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 Human Subjects Protection Branch (HSPB) Staff, WRAIR IRB Members, and the Institutional Official (IO).

2. Roles & Responsibilities

Those taking responsibility for the actions in this SOP are the IRB members, IO, the IRB Administrative Director, and HSPB staff.

a. The IRB members are responsible for:

1) Disclosing any COI, potential or perceived.

2) Not participating in deliberations or voting on any protocol in which they have a conflicting interest and recusing themselves, except to provide information to the IRB when requested.

3) Reviewing the investigator COI disclosure forms and taking appropriate action.

b. The IRB Administrative Director determines the appropriate management of COI disclosure forms in order to present them to the IRB.

c. The HSPB staff are responsible for:

1) Ensuring that appropriate documents are submitted for review by the IRB.

2) Ensuring 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 authorization if he/she has a COI, potential or perceived, and if so, for forwarding to a signatory without a COI.

3. Materials and Equipment

Not Applicable.

4. Procedures

a. The WRAIR IRB requires that all Investigators disclose any COI, *potential* or *perceived*, 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 other company involved in the study.

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: public disclosure of the significant COI; monitoring of the research by independent 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 actions, as deemed appropriate.

b. Investigator/Key Study Personnel COI:

1) In addition to disclosing any of those conflicts identified above, for U.S. Food and Drug Administration (FDA)-regulated studies, all investigators listed on the Form FDA 1572 must submit a Financial Disclosure Form (Appendix A) in the submission packet for studies involving investigational products. For industry-sponsored clinical trials and trials sponsored by the Office of The Surgeon General (OTSG), the Sponsor's Financial Disclosure Form may be accepted for this purpose.

2) Financial 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 Disclosure Forms and any other information pertaining to potential or perceived COI in human subjects research studies. The role of the sub-committee is both adjudicative and arbitrative. However, whether or not the IRB uses a sub-committee, the IRB is ultimately

responsible for determining how any conflicts are 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 do significantly affect the study. The sub-committee findings, along with recommendations, will be recorded into the IRB meeting minutes.

4) The sub-committee may recommend that the individual reduce or eliminate conflicts or potential conflicts arising from significant COI. Recommendations are presented for 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 Financial/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 Financial/COI Disclosure Form (Appendix A).

c. IRB Member COI:

1) For expedited review actions, IRB members must disclose COIs and must not review those items. COIs should be documented and 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. COIs 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 and 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 authorization, 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, U.S. Army Medical Research and Development Command (USAMRDC) for approval authorization to implement.

2) The institutional COI may occur when the institution or any of its senior management (to include those outside the continental United States (OCONUS) Directors) 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 HSPB.

5. Explanation of Abbreviations, Acronyms, and Definition of Terms

Note: Abbreviations and acronyms have been defined in the text at the time of first use.

6. References

Reference Number or Author	Document Title
AR-40-68	Clinical Quality Management, 26 February 2004
AR-70-25	Use of Volunteers as Subjects of Research, 25 January 1990
AR-40-7	Use of Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule 1 Controlled Substances, 19 October 2009
WRAIR IRB Charter	Walter Reed Army Institute of Research (WRAIR) Institutional

	Review Board (IRB) Charter
UWS-HP-613	Expedited Human Subjects Research Protocol Review
UWS-HP-610	IRB Meetings and Voting Requirements
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)
ICH E6(R2)	Guideline for Good Clinical Practice
Titles 21, 32 and 45	Code of Federal Regulations

7. Appendices and Attachments

Appendix or Attachment Number	Title
UWS-HP-609-A Appendix A	Disclosure of Significant Conflict of Interests of Investigator Form
UWS-HP-609-B	Conflict of Interest Checklist

8. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	Original Document	3 January 2007
.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 January 2009
.02	Biennial review of procedures for documenting COI, including relevant updates to the attachments (Appendices A and B).	6 April 2011

.03	Review of procedures for documenting COI, updated formatting, including relevant updates to the attachments (Appendices A and B)	31 January 2020
.04	Administrative corrections as requested by AHRPO audit	24 August 2022
.05	Reformatted using new WRAIR SOP template and other minor administrative and editorial changes.	07 August 2024