



HRP – 055 – SOP: Research Team Conflicts of Interest

NUMBER	Effective Date	Version Number	Previous Version
HRP-055	19Jan2021	v.3	v.2

1. Purpose

The purpose of HRP-055 – SOP Research Team COI policy is to ensure that investigators and research staff conflicts of interest (COI) “do not adversely affect the protection of participants, the integrity of the research, or the credibility of the Human Research Protection Program” (AAHRPP).

2. Policy

1. It is the policy of NASA IRB that investigators and research staff abide by all existing conflict of interest policies held by their home institution. In addition, NASA IRB requires that the conflicts of interest described in this policy be reported to NASA IRB for review and management.
2. Principal Investigators and Sub-Investigators responsible for the design, conduct, or reporting of research must disclose significant financial interests in accordance with this policy annually and when interests change, or new interests occur. All financial interests will take into consideration the person disclosing and their family (spouse/partner and dependent children) and will be considered in aggregate (combined total) over the previous 12 months prior to disclosure, unless otherwise stated.
3. In the event of a conflict, NASA IRB will ensure that any management plan is incorporated into its deliberations and that any mandated disclosures to subjects are included in the approved informed consent documents, as NASA IRB deems applicable.
 - a. NASA IRB may not modify any management plan or mandated disclosure to subjects without discussion and acceptance by the Relying Institution and retains the authority to impose additional prohibitions or conflict management requirements that are more stringent or restrictive than those included in the Relying Institution’s management plan.
4. For investigators and research staff, the following significant financial interests must be disclosed when these conflicts are related to the research. A financial interest is “related to the research” when the financial interest is in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

- a. Financial arrangements entered into between the sponsor of a study and the investigator whereby the value of the compensation for conducting the study could be influenced by its outcome. 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 the sales of the product, such as royalty interest [21 CFR 54.2(a)].
- b. For publicly traded entities: the value of any remuneration received from the entity in the past 12 months and the current value of any equity interest in the entity, when aggregated, exceeds \$5,000 and this financial interest is related to the research.
 - (1) Remuneration includes salary and any other payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
 - (2) Equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value. [42 CFR 50.603(1)(i)]
- c. For non-publicly traded entities: the aggregate value of any remuneration received from the entity in the past 12 months exceeds \$5,000 *or* any equity interest is held (e.g., stock, stock option, or other ownership interest) *and* this financial interest is related to the research. [42 CFR 50.603 (1)(ii)]
- d. Any significant equity interest in a study's sponsor (i.e., any ownership interest, stock options, or other financial interest) whose value cannot be readily determined through reference to public prices. This generally applies to interests in a sponsor that is not a publicly-traded entity.
- e. Intellectual property or other proprietary rights and interest (e.g. patents, copyrights, trademarks, licensing agreements) that reasonably appear to be related to the investigator's responsibilities for a study (e.g. rights/interest in the tested product); includes receipt of income related to such rights and interests. [42 CFR 50.603(1)(iii)]
- f. Reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to the investigator's responsibilities for a study; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education. [42 CFR 50.603(2)]
- g. Receipt of significant payments of other sorts with a cumulative monetary value of \$25,000 or more made by a study's sponsor to the investigator or their institution to support activities of the investigator exclusive of the costs of conducting clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the

clinical investigator is carrying out the study and for 1 year following the completion of the study. [21 CFR 54.2(f)]

- h. Roles as an executive, director, or employee of the sponsor of a study. NASA researchers simply doing research at NASA as an employee is not a conflict that needs to be disclosed; however, if the researcher has another connection to the study that could be a real or perceived conflict of interest the researcher does need to disclose that conflict.
 - i. Any non-financial interest which may unduly influence the design, conduct and/or reporting of the research.
 - j. Any time the financial interests of the investigator's institution, or of an institutional official who has authority to act on behalf of the investigator's institution, might affect – or reasonably appear to affect – institutional processes for the design, conduct, reporting, review, or oversight of research.
5. In situations where the design, conduct, and/or reporting of research may be compromised by a conflict of interest, or by the appearance of a conflict of interest, the NASA IRB will review the conflict and will help to determine a management strategy that is compatible with the investigator's home institution policies.
6. Education
- a. Principal Investigators
 - i. To help ensure that investigators are equipped to recognize and mitigate an actual or perceived conflict of interest, NASA IRB requires completion of Conflict of Interest training by all Investigators and Research Staff. Consistent with AAHRPP accreditation standards [and 42 CFR 50.604], research staff must undergo COI training every four years. The training requirement may be fulfilled and documented by any one of the following, as elected by the investigator and/or the investigator's home institution:
 1. Submission of a CITI training report that includes documentation of the completed Conflict of Interest module.
 2. Submission of the NIH Financial Conflict of Interest completion of training certificate.
 3. Written certification by the investigator's home institution that the investigator has completed an equivalent training accepted by the home institution.
 - b. Sub-Investigators and Research Staff
 - i. It is the responsibility of the Principal Investigator to ensure proper conflict of interest education of any research staff involved in the design, conduct and/or reporting of the research.
 - ii. It is the responsibility of the Principal Investigator to ensure proper reporting to NASA IRB of any Sub-Investigators and research staff involved in the design, conduct and/or reporting of the research.
 - c. Education is required immediately when:
 - i. Financial conflict of interest policies are revised in a manner that changes researcher requirements.

- ii. A researcher is new to the research team and has not previously fulfilled the training requirements for investigators or research staff, as listed above.
- iii. A researcher is non-compliant with financial conflict of interest policies and procedures.

3. Procedures

1. Reporting of Conflicts of Interest:

- a. When applying for NASA IRB approval, investigators will submit a “Financial Disclosure for Investigators” form as part of their application. Updated forms are to be submitted to NASA IRB within 30 days when there are changes in financial circumstances, and annually thereafter.
 - i. Disclosures will be kept on file in the NASA IRB office and made accessible only to the NASA IRB and NASA IRB Office for a period of at least 3 years from the completion of research.
 - ii. Note: COI Disclosures are not study-specific and only require updating annually. However, as stated in this policy, should a new conflict arise during the year for any research the PI is involved, a new Disclosure form must be submitted.
 - iii. Failure to disclose conflicts of interest in a timely manner is considered noncompliance and the procedures and sanctions for noncompliance as outlined in the NASA IRB SOP on Reportable Events will be implemented.
- b. Sub-investigators and research staff involved in the design, conduct and/or reporting of the research are required to report conflicts of interest to their site’s Principal Investigator using procedures established by the home institution.
 - i. When a conflict is disclosed to the PI, the PI will facilitate reporting of the conflict to NASA IRB using NASA IRB’s COI reporting procedures.
- c. Both investigators and staff will follow any additional reporting policies required by their home institution.

2. Review and Management of Conflicts of Interest

- a. In situations where the design, conduct, and/or reporting of research may be compromised by a conflict of interest, or by the appearance of a conflict of interest, the NASA IRB will review the conflict and will help to determine a management strategy that is compatible with the PI’s home institution’s policies.
- b. When an actual or perceived conflict of interest is disclosed to NASA IRB:
 - i. Prior to IRB review, the NASA IRB Office screens the disclosure to verify that it meets the definition of a real or apparent conflict of interest as described above and including local institutional policy as reflected in site application documents.
 - ii. If deemed necessary, NASA IRB will prompt the investigator to complete the form, ‘Financial Disclosures and COI Management Plan’.

- iii. With consideration of the following, the NASA IRB reviews the Management Plan to determine whether the plan is adequate, or whether further management is required before approval:
 - (1) Will the conflict of interest adversely affect the protection of participants in terms of the criteria for NASA IRB approval?
 - (2) Will the conflict of interest adversely affect the integrity of the research?
 - c. The NASA IRB has the final authority to decide whether the conflict and its management, if any, allows for approval or whether Management Plan modifications are required before IRB approval of the research can occur. Additional action may include, but is not limited to:
 - i. Disclosing the conflict in the informed consent document
 - ii. Disclosing the conflict in public presentations (written and verbal) of the research
 - iii. Increased monitoring of research by independent reviewers
 - iv. Reassignment of research duties to non-conflicted team members or other personnel
 - v. Not purchasing stock or stock options during the conduct of the research
 - vi. Not selling, transferring or redeeming owned stock or stock options during the conduct of the research
 - vii. Modifications to the research plan or research end points
 - viii. Additional Conflict of Interest training (CITI) to be completed by the investigator and study staff prior to engaging in the research
 - ix. Divestiture of significant business or financial interests
 - x. Severance of relationships that give rise to conflicts
 - d. In the extraordinary circumstance that NASA IRB is unable to implement or approve a Relying Institution's prohibitions or management plans, NASA IRB will inform the Relying Institution and withdraw the Ceded Review with respect to that Relying Institution.
 - e. Approved Management Plans and disclosures of COIs will be kept on file in the NASA IRB Office for a period of at least 3 years from the completion of research.
3. Oversight of the Management Plan
- a. The site PI is responsible for ensuring compliance with the Management Plan as approved by the NASA IRB.
 - i. Failure to fully implement the Management Plan is considered noncompliance and the procedures and sanctions for noncompliance as outlined in the NASA IRB policy on Reportable Events will be implemented.
 - b. Reporting on continued compliance with the Management Plan should be provided to the NASA IRB at least annually, unless otherwise specified in the Board's approved version of the Management Plan.
4. Conflicts of Interest Officer

- a. If a consensus cannot be reached on whether 1) disclosures constitute a COI or 2) the COI management plan is sufficient, the NASA Legal representative serves as the Conflict of Interests Officer with the authority to finalize the decision.

4. Definitions

Conflict of Interest (COI): Financial or non-financial; any “set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest” (IOM).

Consultant: When necessary, the NASA IRB Chair or NASA IRB Manager/NORA Manager may solicit individuals from the organization or the research community with competence in special areas to assist in the review of issues or research plans, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the NASA IRB.

Engaged: NASA is considered engaged in research when NASA’s *employees or agents* obtain:

- (1) data about the subjects of the research through intervention or interaction with them,
or
- (2) identifiable private information about the subjects or research, or
- (3) the informed consent of human subjects for the research.

And parabolic flight studies funded by NASA and performed by NoveSpace, France

Financial interest: anything of monetary value, whether or not the value is readily ascertainable. [42 CFR 50.603]

Investigator: the individual who conducts an investigation (i.e., under whose immediate direction the research is conducted). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. [21 CFR 312.3(b)] Also synonymous with “Principal Investigator.”

NASA IRB Office: Office staff to include the NASA IRB Manager, IRB Coordinators, the NASA IRB Chair (when appropriate), and other administrative staff.

Research Staff: Members of the research team who are not investigators are research staff. This may include clinical research coordinators, study staff, data managers, medical monitors, statisticians, phlebotomists, and other personnel who are engaged in the research.

5. References

1. 42 CFR 50 Subpart F
2. 14 CFR 1230
 - a. In accordance with NPD 7100.8F, NPR 7100.1B, and NPD 7170.1
3. [OHRP’s “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection” \(5/12/2004\)](#)
4. FDA: Financial Disclosure by Clinical Investigators
5. Institute of Medicine (US) (IOM) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, editors. Conflict of Interest in Medical Research,

Education, and Practice. Washington (DC): National Academies Press (US); 2009. 2, Principles for Identifying and Assessing Conflicts of Interest. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK22937/>

6. AAHRPP Tip Sheet 10 – Financial Conflict of Interest for Researchers and Research Staff
7. AAHRPP Standards: Element 1.6.B and III.1.B
8. *NASA IRB Financial Disclosures for Investigators*
9. *NASA IRB Financial Disclosures and COI Management Plan*

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