



**Najit Technologies, Inc.**  
**Financial Conflict of Interest Policy**  
**Effective Date: August 24, 2012**  
**Last Updated: September 25, 2014**

**1. Purpose**

The purpose of this policy is to promote objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct or reporting of research funded under Public Health Service (PHS) grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator.

**2. Overview**

This policy is modeled after the conflict of interest (COI) policy developed and implemented at Oregon Health & Science University (OHSU) and complies with NIH policies and regulations with regard to monitoring, reporting, managing or eliminating financial conflicts of interest in research. In the following pages of this policy, we describe the procedures that are in place to inform Investigators of the company's COI policy, prepare and submit COI disclosures to the NTI COI Compliance Officer, enforce appropriate management plans and provide timely reporting of these efforts to the NIH.

**3. General**

For purposes of this policy, a conflict of interest in research exists when an investigator has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research, or may otherwise require management because of the appearance of conflict of interest.

**4. Objectives**

The Company shall seek to:

- A. Safeguard the scientific integrity of NTI research and development.
- B. Ensure that the professional progress of postdoctoral researchers and other NTI personnel are assigned only research duties consistent with their status or position.
- C. Ensure any financial interest of an Investigator which could affect the design, conduct, or reporting of research or educational activities be disclosed and eliminated or managed as appropriate.
- D. Ensure that research sponsors' access to and use of Company resources is consistent with NTI's legal, policy, financial and reputational interests.

## 5. Definitions

As used in this policy, the following terms mean:

- A. Designated Official/COI Compliance Officer – Head of Accounting/Admin or individual appointed by the President of NTI.
- B. Conflict of Interest in Research (CoIR): A determination by the designated official that a significant financial interest (SFI) might affect, or reasonably appear to affect the design, conduct, or reporting of research. Such situations may require management, but may not be found to constitute a FCoI as defined below:
- C. Financial Conflict of Interest (FCoI): A determination by the designated official that a significant financial interest (SFI) could directly affect the design, conduct, or reporting of the PHS-funded research. An FCoI is a specific type of CoIR.
- D. Institutional Responsibilities: Investigator's professional responsibilities on behalf of NTI, which include, but are not limited to, activities such as research, teaching, professional practice, committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- E. **Investigator:** The principal investigator, co-investigator and other NTI employees or volunteers, or any NTI research collaborator, including visiting scientists, or consultants, responsible for the design, conduct or reporting of research or educational activities or responsible for preparing a proposal for research funding.
- E. **Significant Financial Interest (SFI)** includes the following interests of the Investigator (and those of the investigator's spouse or registered domestic partner and dependent children), or of any business controlled or directed by the individual or his or her spouse, that reasonably appears to be related to the investigator's institutional responsibilities:
  - 1) Compensation: i.e., anything of monetary value including, but not limited to, salary, gifts, consulting fees, honoraria or other payments for services that is more than five thousand US Dollars (\$5,000) in the aggregate over the last 12 months.
  - 2) Equity interests: e.g. stocks, stock options, warrants, contractual rights to acquire or receive ownership interests, or other ownership interests in a publicly-traded company that is more than five thousand US Dollars (\$5,000) in the aggregate over the last 12 months, or any amount in a non-publicly traded company.
  - 3) The aggregated value of equity interest and compensation as defined above, that exceed \$5,000 over the last twelve (12) months in a publicly-traded company.
  - 4) Intellectual property rights: e.g. patents, copyrights and royalty income or the right to receive future royalties under a patent license or copyright.
  - 5) Non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (e.g. bonus or milestone payments to the investigators in excess of reasonable costs incurred);
  - 6) Service as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service; and
  - 7) Reimbursed or sponsored travel (applies to investigators involved in Public Health Service funded research only and not their spouse, registered domestic partner, or dependent children). Disclosures shall include the purpose of the travel, the identity of the sponsor/organizer, the destination and the duration of the travel, and any other information as requested by the disclosure form or designated official. See exemptions in (6) below.
- F. **Significant financial interest does not include:**

- (1) Interests of any amount in publicly traded, diversified mutual funds, or retirement accounts so long as the investigator does not directly control the investment decisions made in these vehicles.
- (2) Payments to the institution, or via the institution to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution.
- (3) Income from occasional seminars, lectures or teaching engagements 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, a medical center, or a research institute that is affiliated with an institution of higher education.
- (4) Income from service on advisory committees or review panels for 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, a medical center, or a research institute that is affiliated with an institution of higher education.
- (5) Salary and other remuneration from NTI, including approved faculty practice plan earnings and the distribution of those earnings that may be established by departmental or other similar agreements provided that those agreements and departmental/divisional group plans are approved by the President.
- (5) Reimbursed or sponsored travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

G. **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. As used in NTI policies, the term “research” encompasses basic and applied research and product development.

H. **Retrospective Review:** A review conducted of an investigator’s activities, SFIs and PHS-funded research to determine whether any such research, or portion thereof, conducted during the period of non-compliance was biased in the design, conduct, or reporting of such research.

## 6. Investigator Service

Service by an investigator on the governing board or as an officer of any sponsor of the Investigator’s research shall require the prior approval of the Investigator’s direct supervisor as well as by the CSO of NTI.

## 7. Investigator Responsibilities

An NTI Investigator applying to conduct research:

- A. Are required to familiarize themselves with this policy and identify all SFIs as described herein during all annual or updated Conflict of Interest in Research disclosure submissions.
- B. Are required to complete required training at least every four years and as otherwise required by NTI.
- C. Must file, on at least an annual basis, a Conflict of Interest in Research Disclosure in the form approved by NTI. This disclosure is submitted to the designated official and is reviewed by the Investigator’s direct supervisor as well as the COI Compliance Officer and the COI committee as deemed necessary. If circumstances change, the Investigator must also revise and add new disclosures. This annual disclosure is in addition to the annual disclosure statement covering outside activities.

- D. Must fulfill all requests from the designated official, or the COI committee for more information relative to the investigator's annual or updated Conflict of Interest in Research Disclosure in a timely manner.
- E. Must include a conflict of interest statement in any manuscript, publication, or presentation. The following is an example statement that can be used as a template with modifications as required.
  - a. “[Employee Name] is an employee of Najit Technologies, Inc. (NTI), a vaccine development company. NTI is involved in active collaborations with Oregon Health & Science University but the author has no other relevant affiliations\* with any financially interested businesses related to the subject matter discussed in this manuscript [or presentation, etc.]. No writing assistance was utilized in the preparation of this manuscript.”

\*Employee needs to review/confirm that there are no other affiliations or financial involvements relating to the publication with their designated supervisor.

- F. For investigators conducting research funded by PHS only, investigators must:
  - a. Submit an updated Conflict of Interest in Research Disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.
  - b. Submit a Conflict of Interest in Research Disclosure as described in 6(a) no later than the time of application for PHS-funded research.

#### **8. For Research Funded by Public Health Service (PHS) Only**

- A. It is the expectation that the investigators will work with the designated official(s) in a timely manner to create a complete and correct disclosure submission of conflict of interest in research disclosures for institutional review. Unless otherwise specified by law or regulation, any review required by the institution shall not have deemed to have started until a complete and correct submission of the Conflict of Interest in Research Disclosure has been provided to a designated official.
- B. Reviewing SFIs for Financial Conflict of Interest (FCoI). Only a designated official may determine if a SFI requires additional review to determine if an FCoI exists. Prior to funds being spent on a new award, or within sixty (60) days of determining a new SFI required a review, the designated official reviewing the SFI shall determine whether a FCoI exists and implement a conflict management plan, at least on an interim basis, in accordance with Section 11 below. The FCoI determination is risk based and is made according to internal guidance developed in consultation with the Conflict of Interest in Research Committee.
- C. Determination of need for retrospective review. Only a designated official may make a determination that a retrospective review is required. When required, NTI shall complete a retrospective review. A retrospective review must occur in the following circumstances: failure by the investigator to disclose a SFI in accordance with Sections 7(E) and 7(F) that is determined by the designated official to constitute a FCoI; failure by NTI to review or manage such an FCoI; or failure by the investigator or NTI to comply with a FCoI management plan.
- D. Retrospective reviews. Retrospective reviews shall only be completed for PHS research. SBIR or STTR Phase I applications are exempt from retrospective reviews.
- E. Determining bias. Only a designated official may determine whether any PHS-funded research, or portion thereof, conducted during a period of non-compliance was biased in the design, conduct, or reporting of such research. If a designated office determines bias was found, a designated office shall promptly notify and submit a mitigation report to the PHS Awarding Component.

## **9. Research Conflict of Interest Committee**

The CSO shall appoint the Conflict of Interest in Research Committee composed of not more than five persons from the Company. A majority of members of the Committee shall constitute a quorum. Appointments shall be for a term of three years. Once a committee member completes his or her term, or resigns from the committee, a replacement will be recommended to the CSO from the retiring member. The Committee shall select its chair and establish procedures for its operation.

## **10. Approval of Conflicts of Interest in Research; Appeal**

- A. Upon receipt of a proposal to conduct research, the Supervisor in charge of the Investigator or Investigator's unit shall review the proposal to acknowledge if all investigators have certified on the Conflict of Interest Disclosure that there is or is not a potential or actual conflict, as indicated by an affirmative response on the COI Disclosure form, with any of the requirements or objectives of this policy. Where a potential conflict is disclosed, the Supervisor may suggest a preferred method of managing the conflict to the Investigator and to the designated official and/or the Committee.
- B. The Committee or designated official shall review in a timely manner proposals for which a potential conflict has been disclosed to determine whether the interest may reasonably be thought to directly and significantly affect the design, conduct, or reporting of the sponsored research or educational activities.
- C. If a conflict is found, the Committee shall determine how to manage, reduce, or eliminate the conflict and shall inform the Investigator and the Unit Leader in charge of the Investigator's unit of the decision.
- D. An Investigator who disagrees with the decision of the Committee may appeal to the Chief Scientific Officer. Such an appeal shall be in writing only and must be made within ten (10) days of the decision of the Committee. An appeal to the Chief Scientific Officer may only be made upon grounds of procedural irregularity that resulted in prejudice to the Investigator, new material information that could not have been presented to the Committee or that the decision is in conflict with applicable laws, rules or NTI policies. The Chief Scientific Officer shall make a decision within ten (10) days of the date of the investigator's appeal to the Chief Scientific Officer and the Chief Scientific Officer's decision shall be final.

## **11. Conditions to Manage Conflicts**

The COI Management Table will be generally used in determining the appropriate management of financial conflicts of interest (see **Appendix B**) and may impose conditions to manage a conflict of interest involving sponsored research including, but not limited to:

- A. Public disclosure of an investigator's financial interest in any research sponsor or the commercial success of any therapeutic strategy or product that is the subject of any research results being reported;
- B. Monitoring of any research project by independent reviewers;
- C. Modification of any research proposal or plan;
- D. Disqualification of any Investigator from participating in all or a portion of specific sponsored research;
- E. Divestiture by an Investigator of any financial interest in any research sponsor; or
- F. Severance of any relationship between an Investigator and a research sponsor which may create actual or potential conflicts of interest.

The investigator must agree to the conditions imposed by the Conflict of Interest in Research Committee or appeal such conditions as described in section 10(D) above.

## **12. Maintenance of Records; Certification and Enforcement**

- A. The COI Compliance Officer or Designated Official shall inform those sponsors that require notification of the FCoI and action. The COI Compliance Officer shall keep and maintain records, of all disclosures and all actions taken to manage any actual or potential conflicts of interests for at least three (3) years beyond the termination or completion of the award or until resolution of any action by any federal agency involving the records, whichever is longer.
- B. The NTI CSO shall certify to applicable federal agencies NTI's enforcement and management of FCoIs under this policy.
- C. The Supervisor in charge of the Investigator's unit and the CSO shall investigate and resolve any alleged violations of this policy. They shall take appropriate action to enforce this policy, including, not but limited to, imposing sanctions including termination from employment upon Investigators found to be in violation of this policy. The CSO shall promptly notify the federal sponsor of unresolved conflicts.

## **13. Policy Compliance**

### **A. Who Must Comply**

NTI policies and requirements must be honored and followed by all officers, employees, students, volunteers, contractors, units and others present on or using NTI facilities.

### **B. Applicable Requirements**

(1) Depending on their terms and context, NTI policies and requirements include:

- Completing the NIH Conflict of Interest Tutorial (**Appendix D**) to become informed about the responsibilities and requirements for the disclosure of financial conflicts of interest. This tutorial can be found at:  
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- NTI Code of Conduct
- NTI Policies
- Individual unit policies and procedures
- Applicable federal, state and local laws and regulations
- Administrative and management prerogatives
- Contractual obligations
- Judicial orders(2) Employees and students on other college and university campuses are subject to some of the host university's rules and policies where applicable, e.g. policies regarding security, public activities, and smoking on site.

### **C. Remedies for Failure to Comply**

(1) Failure to comply with NTI policies and requirements may result in loss of privileges, disciplinary actions, termination of relationships with NTI, or any other lawful administrative, judicial, contractual, managerial or other mechanism available to NTI to secure compliance.

(2) Some NTI policies and requirements may specifically address compliance and detail particular actions that may be undertaken for non-compliance. Unless the context requires otherwise, such terms shall not be construed to limit the options provided in this policy.

## **14. Institutional Reporting Requirements**

Prior to the expenditure of funds under an NIH award (with the exception of SBIR/STTR Phase I awards), the Company will FCoIs to the PHS Awarding Component in accordance with regulations (43 CFR 50.605) and assure that the interest has been managed, reduced, or eliminated. Financial disclosures will be made on an annual basis or when there

has been a change in COI. For any financial COI identified as conflicting subsequent to the initial report...

under the award, the report will be updated within 60 days of notification with a written description indicating that the new COI has been managed, reduced, or eliminated.

## **15. Implementation**

FCOI determinations, Sections 7(E, F) and 8 will apply to each grant or cooperative agreement with an issue date of the Notice of Award after August 24, 2012 or when the investigator's next annual conflict of interest in research disclosure submission is due, whichever is earlier.

## **16. References and Contact Information**

Please see: Public Health Service, Department of Health and Human Services, Code of Federal Regulations, Title 42 Part 50 Subpart F, for grants and cooperative agreements found at:  
<http://grants.nih.gov/grants/policy/coi/>

For specific questions regarding the NTI COI policy or the NTI COI committee, please contact Mark Slifka at 503-806-3254 or by e-mail at [info@najittech.com](mailto:info@najittech.com).

## **NTI Conflict of Interest Committee Charter**

### **Introduction**

NTI's COI committee reviews and develops strategies for resolving cases of potential, real, or perceived conflict of interest involving individual investigators that arise from research activities, consultation, or technology transfer agreements. Any conflicts involving the Company are reviewed and managed by the NTI COI committee. The recommendations of the COI Committee are transmitted to the investigator, their supervisor, and the CSO of NTI.

### **Membership**

The COI committee consists of no less than three members. The committee may call upon non-member (outside) consultants or experts as required to perform its duties. Members are appointed to the COI committee by the CSO of NTI. Members serve a term of three years. Terms of appointment for members will be staggered in order to provide continuity of representation. Members may be reappointed to serve additional terms upon recommendation by the CSO. The chair will be selected by the committee.

### **Function**

The COI committee meets as required to review and determine management strategies for disclosures it receives under NTI disclosure policies. Updated and revised disclosures may also be reviewed by the committee. The committee may conduct its business outside of scheduled meetings through the use of electronic communications. Approval of a management strategy requires an affirmative vote by the majority of the voting members.

The COI committee may meet with the Investigator and/or his or her direct supervisor to obtain additional information as needed.

### **Committee Constitution and Voting**

No decisions may be made without a quorum of the committee members present or polled. A quorum is a majority (one-half plus one) of committee members. For business conducted electronically, a quorum of votes must be received. A majority of a quorum is required to pass a motion. Votes of abstention or opposition will be noted in the minutes with a brief explanation for such a vote.



## **Requirements for Public Disclosure of Potential Conflicts of Interest**

This document is meant to advise Investigators on the specific requirements for public disclosure when required in the management plan approved by the NTI Conflict of Interest Committee, addressing some frequently asked questions regarding the public disclosure procedures.

Public disclosure is a management plan element that serves to protect Investigators and NTI against any accusations of malfeasance by identifying all potential dual or competing interests that the Investigator may have or appear to have in relation to their research, and including these in a statement in publications and presentations. Providing a full disclosure of these facts helps to dispel any belief that financial interests or other commercial interests in technology are being hidden from the public eye. As has been demonstrated at several other institutions, complete transparency related to competing interests is extremely beneficial to Investigators and their institutions. Management of dual interests by mechanisms such as public disclosure allows NTI investigators to continue in mutually beneficial commercial activities and industry partnerships.

### **When is public disclosure required?**

Public disclosure is required in any public presentations of data from research that is related to the Investigator's financial interests. The statement must be included as applicable for all authors on the publication or presentation.

### **Definitions**

Public presentations include conferences, lectures, and any other speaking engagements, journal articles, including review articles, letters to the editor, etc.

Research related to the Investigator's financial interests includes any research project that:

- Is fully or partially sponsored by the company in which the Investigator has a financial interest
- Involves technology licensed to or owned by the company in which the Investigator has a financial interest (including manufacturers of the investigational product used in the research)
- Any other research projects not covered above where the conduct or outcome of the research may appear to affect the company in which the Investigator has a financial interest (including financial interests in companies that are direct competitors with the sponsor of the research or the manufacturer of the investigational product).

### **How is the public disclosure statement to be incorporated in presentation materials?**

A public disclosure statement should be included in any journal article, PowerPoint or other presentation slides or documents, posters, etc. presenting research related to the potential conflict as described above.

- Investigators should follow the journal or scientific organization's policy for submission of financial disclosure information.
- If the journal or meeting host does not have a policy, the investigator should include a disclosure of their financial interests in a letter to the editor or meeting organizer and should indicate that NTI requires a statement of these financial interests in the publication or presentation. It is the investigator's responsibility to assure that the statement is included in the final publication.
- If the journal has a template statement to use for the financial disclosure, it is appropriate to use that statement instead of the specific statement provided in the management plan. This does not need to be submitted for review by the NTI COI Committee.
- If the journal does not have a financial disclosure template, the statement from the management plan should be used.
- The statement may be placed in any location in the article, slide, or poster presentation as preferred by the investigator. It only needs to be included in one location (not on every slide).

- If a statement in a consent form for a human subject's research project is required, the statement as required by the management plan should be placed at the beginning of the consent form (below the sponsor and above the purpose section).

**What if the journal or scientific meeting host's financial disclosure requirements are different from NTI's?**

So long as the public disclosure occurs, the exact wording and placement of that disclosure is negotiable. **Although the investigator must complete any financial disclosure statements required by the journal or by the meeting host, he or she must also include a public disclosure statement in the article or presentation materials as described above.** If the journal or meeting host wishes to modify the wording approved by the COI Committee that is fine. NTI understands that there are differing definitions of "significant financial interest" (SFI) among universities and journals. NTI's definition is in keeping with the preponderance of current national guidance. We recognize that it may be more stringent in some cases, but less stringent in others. Please see the resources below that include examples of some journals' CoI policies and reports from national organizations that provide an overview of SFI definitions used at other academic medical centers and at various journals.

**What happens if an investigator fails to include the public disclosure statement as required?**

Upon annual update of the Investigator's disclosure form, the designated official requests information from each investigator for evidence of the public disclosure statements s/he has made. The designated official will also conduct random and for cause audits of the investigator's published journal articles to check for the public disclosure statement in articles presenting research related to the potential conflict. Any evidence of non-compliance with the public disclosure requirements (or other management plan requirements) will be reviewed by the COI Committee. The committee may require the investigator to inform the journal of any omissions of financial relationships and to publish a correction. Additional corrective actions may also be required.

**Additional helpful resources:**

- OHSU's definition of significant financial interest: <http://www.ohsu.edu/xd/research/about/integrity/coi/glossary.cfm>
- OHSU's Conflict of Interest in Research web site: <http://www.ohsu.edu/research/rda/coir/>
- Association of American Universities (AAU) Report on Individual and Institutional Financial Conflict of Interest: <http://www.aau.edu/research/COI.01.pdf>

**Example Journal and Professional Organization CoI policies:**

- J. Clinical Oncology: <http://www.jco.org/misc/authordisclosuredeclaration.pdf>
- JAMA: <http://jama.ama-assn.org/cgi/content/full/294/1/110>
- Nature: <http://www.nature.com/nature/submit/policies/competing/index.html>
- New England Journal of Medicine: <http://authors.nejm.org/Misc/disclos.asp>
- Science: <http://www.sciencemag.org/feature/contribinfo/prep/coi.shtml>
- American Society of Clinical Oncology: <http://www.asco.org/asco/downloads/ConflictofInterest.pdf>

## **Guidelines for Disclosure of Potential Conflicts of Interest in Research**

Examples of potential conflicts of interest in research (COI) that must be disclosed on the COI disclosure form. See Management Strategies for information on possible management plans that may be applied when a real or apparent COI is found to exist.

- Receipt of NTI-supervised research support (whether in dollars or in kind) from a business with which the employee or his/her family has a significant financial interest.
- Participating in NTI research on a technology owned, licensed, or contractually obligated to a business with which the employee or his/her family has a significant financial interest
- Receipt of royalties on products undergoing research or testing under the supervision or control of the employee.
- Service on a board of directors or scientific advisory board of, or executive position with, an outside business from which the employee, employee's family, or a business associated with the employee or his/her family receives NTI-sponsored research support.
- Receiving funds, gifts, or any compensation from a business that is sponsoring an employee's research, for activities or purposes unrelated to the actual costs of performing that research.
- Assigning to fellows and/or students, tasks related to an employee's involvement with an outside business.
- Purchasing equipment, services, or supplies for NTI research or research support activities or other business from a business with which the employee, the employee's family, or a business associated with the employee or his/her family has a significant financial interest.
- Receipt of any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution).

### **Other financial interests do not need to be disclosed unless there is a potential relationship with a current or proposed research project, for example:**

- Having a significant financial interest by the employee or his/ her family in a business engaged in biomedical research or future options to purchase such equity.
- Assuming an advisory role, board position, directorship, or executive position in an outside business engaged in biomedical research.
- Ownership of or equity in a business used solely for one's consulting activities when those activities are not in potential or actual competition with NTI's interests or activities.

**If the business is not a financially interested business, no disclosure is required.**

## **COI Management Strategies**

In cases where an employee's disclosed activity is permitted but requires implementation of certain management plans, options for resolution and a mechanism for reporting back to those with oversight responsibility must be developed. Because each disclosed conflict is likely to be unique, supervisors have considerable discretion in suggesting management strategies to the Conflict of Interest Committee. Consultation with others who have experience and expertise in a particular area is encouraged (e.g., compliance officers, administrative officials, Legal counsel, etc.). Based on current national guidance, NTI's Conflict of Interest in Research Committee has developed management plan guidelines for participation in clinical trials where the investigator has a significant financial interest.

Essential goals for conflict management include:

- Compliance with federal, state, and local laws and regulations
- Protection of confidentiality
- Protection of reputation (NTI, employee, research unit)
- Protection of NTI's interests
- Least obtrusive measures
- Expedient response
- Objectivity
- Credibility
- Means for verification
- Amenable to internal and external review/audit


Possible options for managing conflicts include:

- Public disclosure of all relevant information
- Reformulation of the relationship
- Modification of the work plan
- Use of a disinterested third party in key decision-making roles
- Divestiture of relevant personal interests or relationship
- Termination or reduction of involvement in the relevant work

Questions to consider when managing an employee's disclosed conflict include:

- Has all relevant information concerning the employee's activities been acquired?
- Do the employee's relevant financial interests exceed predetermined thresholds of acceptability, as determined by NTI policy?
- Do the employee's external commitments exceed permissible levels, as determined by the executive level of the employee's supervisor (i.e., CSO)?
- Is there any indication that the employee's outside commitments have biased or otherwise interfered with the quality/quantity of his/her duties to NTI?
- Is there any indication that the employee has improperly favored any outside business or appears to have an incentive to do so?
- Has the employee inappropriately represented NTI to an outside business?
- Does the employee appear to be subject to incentives that might lead to inappropriate bias or impropriety in the conduct of research?
- Could the employee's circumstances represent violation of federal, state, or local laws or regulations?

## Guidelines for Disclosure of Potential Conflicts of Interest in Research

<b>Risk</b>	<b>Type of relationship with a company</b>	<b>Disclosable on COI form</b>	<b>Conflict</b>	<b>Review Type</b>
low 	Patent alone – no license	Not unless assigned to other business	Not a conflict	Expedited – no management
	Non-exclusive license with no other company ties (with or without patent)	Yes, if materials used in Investigator’s ongoing research	Not a conflict <sup>1</sup>	Expedited – no management <sup>1</sup>
	Exclusive license with no other ties to the company	Yes, if materials used in Investigator’s ongoing research	Potential conflict	Administrative review, may go to the committee to review (may still determine not to be managed)
	Exclusive license + sponsored research agreement <sup>2</sup> with no other ties to the company	Yes, if materials used in Investigator’s ongoing research	Potential conflict	Reviewed by committee or administratively for appropriate management
	Exclusive license + other ties to the company (consulting equity)	Yes, if materials used in Investigator’s ongoing research	Potential conflict	Reviewed by committee or administratively for appropriate management
high	Exclusive license + sponsored research agreement + other ties to the company (consulting equity)	Yes	Potential conflict	Reviewed by committee or administratively for appropriate management

<sup>1</sup> Review of individual situations may still warrant management in some circumstances

<sup>2</sup> Additional review will be provided by IRB if human subjects are involved; the IRB may require additional management.

## **Helpful Resources**

There are a number of guidance documents that the Conflict of Interest in Research Committee considers when reviewing potential conflicts. These resources should be reviewed by NTI investigators to help in their understanding of the Conflict of Interest in Research Committee review process and management decisions.

### **Association of American Medical Colleges (AAMC)**

- Report on Individual Financial Interest in Human Subjects Research
- Report on Institution's Financial Interests in Human Subjects Research

### **Association of American Universities (AAU)**

- Report on Individual and Institutional Conflict of Interest
- NIH Conflict of Interest in Research page
- Conflict of Interest in Research Requirements for NIH grantees
- NSF COI Policy FDA "Guidance: Financial Disclosure by Clinical Investigators" (March 20, 2001)

### **CoI Policy Comparison**

To compare OHSU's policies (which NTI's follows) with those of similar institutions across the nation, OHSU has surveyed several academic medical centers and research institutes and compiled a report summarizing their policies. For more information contact the OHSU CoIR Officer at:  
[http://www.ohsu.edu/xd/research/about/integrity/coi/coir-regulation-changes.cfm?WT\\_rank=2](http://www.ohsu.edu/xd/research/about/integrity/coi/coir-regulation-changes.cfm?WT_rank=2).

**Appendix A.**

**Annual Najit Technologies, Inc. (NTI) Conflict of Interest in Research Disclosure Form**

**Revision date: 8/24/12**

**If this is your first submission of a Conflict of Interest in Research Disclosure Form, please go to the following website and take the NIH tutorial at:**

- <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

**Please be sure to print the Certificate at the end of the tutorial and submit a copy of it with this disclosure form, to the Designated Official**

**To learn more about NIH’s Conflict of Interest requirements, please see the company COI Policy or:**

- <http://grants.nih.gov/grants/policy/coi/>

**Directions:**

- Review Section I; if your answers to questions 1-4 in Section I are, “NO”, then you may check the EZ box below instead of answering each question individually. For EZ disclosure, check the EZ disclosure box below and submit only the first page of the form with the Disclosure Certification completed. Only your signature is required.

EZ Disclosure	<input type="checkbox"/>
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- **If you answer YES to any question in Section I**, complete the entire section and appropriate addenda, complete Section II listing all of your current and pending grants and projects, including IRB #s where appropriate. Additionally:
  - Complete Discloser Certification below.
  - Obtain signatures from your direct supervisor and NTI’s CoIR Designated Official.
- Forward the completed form with signatures to the NTI Designated Official.

<b>Discloser Certification (complete for all disclosures)</b>			
<b>Type of Disclosure:</b>	New Disclosure: <input type="checkbox"/>	<a href="#">Revision to Previous Disclosure:</a> <input type="checkbox"/>	Annual Update: <input type="checkbox"/>
In submitting this form, I certify that the above information is true to the best of my knowledge and that I have read the NTI Conflict of Interest in Research policy. I supply this information for confidential review by NTI and understand that NTI agrees, to the extent permitted under the Oregon Public Records Act, to keep it confidential and not to disclose it to other persons.			
Full name (Please print)		Title (Please print)	
Department		Address	
E-mail		Phone/Ext.	
Signature	Date	Contact name	Contact e-mail

**Obtain supervisor signatures only for disclosures with a “yes” answer in Section I.**

Direct Supervisor Signature	Direct Supervisor Printed Name	Date
CoIR Designated Official Signature	CoIR Designated Official Printed Name	Date



**Please read the following definitions before responding to the questions on the following pages.**

**Significant Financial Interests in Research (SFI)** include the following interests of the [investigator](#) (and those of the investigator's spouse, registered domestic partner, and dependent children), or of any [business](#) controlled or directed by the individual or his or her spouse:

- Compensation: i.e., anything of monetary value including, but not limited to, salary, gifts, consulting fees, honoraria or other payments for services that is more than five thousand U.S. dollars (\$5,000) in the aggregate over the last twelve (12) months.
- Equity interests, including stocks, stock options, warrants, contractual rights to acquire or receive ownership interest, or the ownership interests in a publicly-traded company that is more than \$5,000 in aggregate over the last 12 months, or any amount in a non-publicly traded company.
- 
- Royalty income or the right to receive future royalties under a patent license, copyright, or other agreement where the research is directly related to the licensed [technology](#) or work.
- Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution). This includes any bonus or milestone payments to the [investigator](#)s in excess of reasonable costs incurred, whether such payments are received from a [financially interested business](#) or from the institution.
- Service as an officer, director, or in any other [executive position](#) for a [financially interested business](#), whether or not remuneration is received for such service.
- Reimbursed or Sponsored Travel (applies to investigators involved in Public Health Service funded research only and not their spouse, registered domestic partner or dependent children). Disclosures shall include the purpose of the travel, the identity of the sponsor/organizer, the destination and the duration of the travel, and any other information as requested by the disclosure form or designated official. See exceptions below.

**Exceptions:** Significant financial interests in research *do not include* the following:

- Interests of any amount in publicly traded, diversified mutual funds, or retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles.
- Payments to the institution, or via the institution to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution.
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
- Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institute of higher education.
- Reimbursed or sponsored travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

**Financially Interested Business** means any [business](#) with financial interests that would reasonably appear to be affected by the conduct or outcome of any of the current or proposed research projects listed in Section II (including the sponsor of the research and/or the manufacturer, owner, assignee, or licensee of an investigational product or technology used in the research). This term includes businesses that compete with the sponsor or the manufacturer/licensee of an investigational product, if the covered individual actually knows that the financial interests of such a business would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested business (e.g., a contract research organization).

**Additional Definitions used in this document:**

**Business (noun, e.g., a business):** Any corporation, but excluding NTI, partnership, sole proprietorship, limited liability company, limited liability partnership, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes, any affiliated hospital, any private medical practice, or any other entity controlled by, controlling, or under common control with NTI.

**Conflict of Interest:** A conflict of interest exists when an employee's financial interests or other obligations interfere, or appear to interfere, with the employee's obligations to act in the best interest of the company and without improper bias. The mere appearance of a conflict may be as serious and potentially damaging to the public trust as an actual conflict. Therefore, potential conflicts must be disclosed, evaluated, and managed with the same thoroughness as actual conflicts.

**Executive Position:** Any position that includes responsibilities for a material segment of the operation or management of a business. This would include a position on a Board of Directors.

**Family:** A spouse, registered domestic partner, and/or dependent child/children.

**Investigator:** The principal investigator, co-investigator and other NTI employees or volunteers, or any NTI research collaborator, including visiting scientists, responsible for the design, conduct or reporting of research or responsible for preparing a proposal for research funding.

**Outside Business:** Any [business](#) that is not affiliated with or controlled by NTI.

**Participate:** To be part of the described activity in any capacity or position that may influence an outcome.

**Project Period:** The project period should match the performance dates on the grant or contract or similar document. This may be an anticipated start and completion date.

**Revision to Previous Disclosure:** A revised CoIR form is required prior to the annual update, within 30 days of discovering or acquiring a new SFI if any response to an item in Section I has changed from "NO" to "YES". A revised CoIR form does not have to be submitted to update Section II unless the new project involves a [financially interested business](#) with which you have a [significant financial interest](#).

**Student YES Student:** Any person enrolled in an undergraduate or graduate program, postdoctoral fellows, interns, or other trainees.

**Section I – Please read the definitions on the previous page before responding to the questions below.**

**Business Relationships:** Place an **X** in the appropriate box.  
**Yes** **No**

1.	Based on the above definitions, do you or members of your <a href="#">family</a> have or expect to have in the next 12 months a <a href="#">significant financial interest</a> in a <a href="#">financially interested business</a> ?		
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*If you answered “yes” to question 1 above, please complete Addendum 1*

**Intellectual Property** **Yes** **No**

2.	Are you the inventor of a licensed or copyrighted product or technology, or a technology assigned to an outside business that you continue to utilize in any of your current or pending research projects?		
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3.	In the previous 12 months, did you create, discover, or reduce to practice an invention to which title has not been assigned to NTI?		
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*If you answered “yes” to question 2 or 3 above, please complete Addendum 2 or 3, respectively*

**Student Involvement** **Yes** **No**

4.	In the previous 12 months, did you involve any of your <a href="#">students</a> in NTI projects that are sponsored by a business in which you or a family member has a <a href="#">significant financial interest</a> ?		
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5.	In the previous 12 months, did you involve any of your <a href="#">students</a> in remunerated <a href="#">participation</a> in professional activities for an <a href="#">outside business</a> in which you or a family member has a <a href="#">significant financial interest</a> ?		
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*If you answered “yes” to question 4 or 5 above, please complete Addendum 4 or 5, respectively*

**Previous Disclosure Information** **Yes** **No**

6.	Based on your last annual disclosure, did the Conflict of Interest in Research Designated official require a management plan?		
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*If you answered “yes” to question 4 above, please complete Addendum 6*

**If you answered YES to any of the above questions (1-6), complete Section II and the appropriate addenda.**

**Section II – Complete this section if you have answered YES to any questions in Section I. Please be sure to reflect in the addendum which projects below are related to the potential conflict.**

**List all current and pending NTI-related projects, grants, or contracts.** Include research projects with government, industry, foundation, university, or any other funding source. Also include any internally funded projects and IRB or other research projects not covered above.

The list of projects/grants should include all those in which you are: principal investigator, co-investigator, collaborator or other key personnel (see definition of [investigator](#)).

***This table will expand as needed (use the tab key to move to the next cell).***

1	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
2	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
3	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
4	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
5	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
6	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
7	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
8	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:
9	Full Title of Project/Grant and number (IRB/IACUC # if applicable):		
	Funding Agency/Sponsor:	<a href="#">Project Period:</a>	Principal Investigator:

***Attach additional pages as needed.***

**ADDENDUM 1 – *Business Relationships*** If you answered “yes” to question 1 in Section I, please answer each question below:

1	I. Describe the nature of your (your family member’s) financial relationship and your relationship with the business and list the business(es). If you are a consultant or hold a position in the company, please also describe the specific services you provide to the company in that role.
	II. Indicate (by line #) which projects from Section II are sponsored by the business, involve technology owned or licensed by the business, or are otherwise associated with the business:
	III. For human subject research, describe the extent of your involvement in the research (e.g., consent patients, analyze data, etc.):
	IV. Describe any controls already in place that may mitigate any potential Col (e.g., outside data analysis, data safety monitoring, blinded trial):
	V. Do you anticipate that any of your pre-clinical research listed in Section II will be a component of an investigational New Drug or Investigational Device Exemption submission or progress to research involving human subjects in the coming 12 months?

**ADDENDUM 2 – Intellectual Property** If you answered “yes” to question 2 in Section I, please answer the questions below:

2A	List the invention(s) and the business(es) that have been assigned or licensed the technology.
2B	Indicate (by line #) which projects from Section II utilize the technology(s) and/or are sponsored by the business(es) that licensed the technology.

**ADDENDUM 3 – Intellectual Property** If you answered “yes” to question 3 in Section I, please answer the question below:

3	List the invention(s). To whom is title assigned? Was this invention prior to your employment at NTI?
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**ADDENDUM 4 – Student Involvement** If you answered “yes” to question 4 in Section I, please answer the question below:

4	List the project(s), student(s) involved, and the business(es). Describe the activities/involvement of students. Describe your (your family member’s) relationship with the business.
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**ADDENDUM 5 – Student Involvement** If you answered “yes” to question 5 in Section I, please answer the question below:

5	Describe the professional activity. List the student(s) involved and describe the remuneration. Describe your (your family member’s) relationship with the business. Have any graduate students been involved in or supported by this activity?
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**ADDENDUM 6 – Previously managed conflict** If you answered “yes” to question 4 in Section I, please answer the questions below:

6A	Have there been any publications or presentations resulting from your research related to your financial interests since your last management plan was issued? (check appropriate box)			
	Yes		No	
6B	If yes to 6A above, please provide any references or presentations where a statement of your financial interests was included. If the public disclosure statement was not included please explain why. Publications: Presentations: Explanation:			

**Appendix B**

**Najit Technologies, Inc. Travel Disclosure**

Revised: 8/24/12

PHS-funded researchers are required to disclose all\* sponsored travel related to their work at OHSU within 30 days of occurrence. You may enter travel prior to its occurrence to avoid missing the 30-day deadline. Note however, that you will be required to know the basic information (sponsor, purpose, duration and location) to submit the disclosure.

\*Public Health Service (PHS) funding includes NIH, CDC, HRSA and others. You do not need to submit travel information if you do not receive any PHS funding. Exceptions to the disclosure requirement also include travel paid by a federal, state or local government agency, an institution of higher education, or a medical center/research institute that is affiliated with an institution of higher education.

Entity sponsoring or reimbursing the trip

Purpose of the travel

Destination of the trip

Duration of the trip (number of days, including travel that is funded by sponsoring entity)

## Appendix C

### NTI Conflict of Interest Management Table

Risk	Type of Financial Interest Held in "Financially Interested Business"	Management(Mgmt) Plan Guidelines <sup>1</sup>	Typically applies for	
			All Research	Human Subjects Research
Low	Compensation < \$5,000 <sup>2</sup> in previous 12 months (none expected in future)	-None required. Note that some journals may still require public disclosure.	X	
Low	Compensation expected to be < \$5,000 <sup>2</sup> in upcoming 12 months	-None required. Investigator should closely monitor dollar amounts to assure does not rise above \$5,000. Also note that some journals may still require public disclosure.	X	
↓	Monetary compensation > \$5,000 (in either previous or future 12 month period)	<b>Mgmt will include:</b> -Conflicted investigator should not be solely involved in consenting/enrolling subjects -Conflicted investigator should not be solely responsible for reporting UPs		X
↓	Stock or stock options (>\$5,000 or any amount of non-publicly traded)	<b>Mgmt will include:</b> -Conflicted investigator should not be involved in consenting/enrolling subjects -Conflicted investigator should not be involved in reporting UPs		X
↓	Inventor of technology studied in trial (if exclusively licensed), or Multiple Interests (e.g., stock and position in company)	<b>Mgmt will include:</b> -Conflicted investigator should not be involved in consenting/enrolling subjects -Conflicted investigator should not be involved in reporting UPs		X
		<b>Mgmt may include:</b> Should not be solely responsible for data analysis	X	
		<b>Mgmt may include (for greater than minimal risk research, as determined by the IRB):</b> -Monitoring by independent monitor or DSMB		X
High	Multiple Interests, including institutional conflict for NTI (start-up company)	- Committee will also consider management for Institutional Conflict of Interest (ICoI). Management as above in orange will apply. There may be additional restrictions in order for a human subject's trial to take place at NTI.	See ICoI review & management table	

Any investigator involved in research that has a significant financial interest in a research sponsor and/or the manufacturer, owner, assignee, or licensee of an investigational product or technology used in the research (defined as a financially interested business) must disclose this potential conflict on the Conflict of Interest (COI) disclosure for review by the NTI COI administrative official. This table shows examples of conflict of interest management plans that may be applied by the COI administrative official. The "Conditions for level of management" listed below are factors that the committee considers in determining appropriate management. Because these factors are study-specific, each new human-subjects study where the investigator has a potential conflict must be reviewed.

<sup>1</sup>In all cases where management is required, public disclosure in publications and presentations and in the consent form (for human subject's research) will be required.



<sup>2</sup>Compensation or stock amounts refer to the amount received from a single entity/business. Compensation in the green rows is defined as both monetary compensation and stock or stock options in a publicly traded company.

**Considerations for level of management** (The presence or absence of any of these factors may alter the risk and result in a modified management plan)

- Single or multi-site trial and number of subjects to be recruited at NTI or OHSU (for multi-site studies)
- Design of research and existing controls (double-blind, etc.)
- Presence of DSMB or independent monitor
- Nature of research and degree of risk to potential subjects
- Degree to which financial interest is related to the research and whether financially interested business is the sponsor of the trial
- Unique qualifications of the investigator to participate in the research

## **Appendix D**

**NIH conflict of interest Tutorial used for informing and educating Investigators at NTI**

**Located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>**