



## Conflict of Interest Policy

*Effective August, 2014 (note, replaces prior versions of COI policies)*

Given Valley Fever Solutions' affiliation with the University of Arizona, VFS has adopted formal requirements consistent with the PHS-compliant "University of Arizona Investigator Conflict of Interest in Research Policy" (effective May 21, 2014) attached and located at <http://orcr.arizona.edu/coi/uapol>. All 'investigators' (as defined in the policy) who are employees of Valley Fever Solutions shall complete the CITI Conflict of Interest Training module using a University of Arizona affiliation and submit a signed Valley Fever Solutions Financial Disclosure and Certification form. In addition, investigators who are sub-recipients/consultants to a VFS federally funded award agreement will also complete this training and attestation unless their institution is listed as compliant on the [FDP Institutional Clearinghouse website](http://sites.nationalacademies.org/PGA/fdp/PGA_070596.htm) ([http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596.htm](http://sites.nationalacademies.org/PGA/fdp/PGA_070596.htm)) in which case they may apply their institutions' COI policy and provide proof of training and disclosure.

Training and assurance filing will be completed by all investigators prior to the drawing of funds for a new federal award and (as appropriate) when competitive and non-competitive renewals are granted for on-going projects. The attestation will be renewed annually at the times of submission of the annual progress reports, or updated in real time if a new Financial Conflict of Interest develops among any project investigator. Newly joining investigators will be held to the same requirements upon joining the project. Refresher training is required no less than every four years. Training will be documented through the CITI completion form showing the individual Investigator's full name, required courses completed, date taken and grade received. This form and signed attestations will be reviewed by the Authorized Representative (Lisa Higgins, Associate Director) and maintained in VFS corporate files. Consistent with guidelines outlined in the UA's policy, Ms. Higgins will review all investigator-disclosed interests to determine if these are related to the PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. If appropriate, actions will be taken as necessary to manage the financial conflict(s) of interest which may consist of a disclosure in presentations and manuscripts, or it may include measures such as removing the conflicted individual from primary oversight of the research, or alternatively, reducing or eliminating the financial interest. When reporting FCOI to the PHS-awarding component, VFS will affirm the investigator's agreement to comply with a management plan. Newly disclosed FCOIs for PHS-funded research will be reported within sixty days of VFS becoming aware of the new interest.

The training module may be accessed through <http://orcr.arizona.edu/coi/training> by following instructions "for Individuals without a University of Arizona NetID and Password" to access the CITI website Conflicts of Interest training modules. Participants must take the module exams and receive a minimum score of 85%. Investigators will print their CITI Training Gradebook (under My Reports) and provide the printed page to VFS.



## Conflict of Interest Policy

The following will be reported to the PHS awarding component by VFS in the case of an FCOI:

- The grant/contract number
- The name of the project director, principal investigator, or contact person (when there are multiple project directors or principal investigators)
- The name of the investigator with the FCOI
- The name of the entity with which the researcher has the FCOI
- The nature of the FCOI (equity, consulting fees, travel reimbursement, honoraria, etc.)
- The value of the financial interest in specific intervals: \$0-4,999, \$5,000-9,999, \$10,000-19,999, amounts between \$20,000 and \$100,000 by increments of \$20,000, and amounts above \$100,000 by increments of \$50,000, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- A description of how the SFI relates to the PHS-funded research and the basis for the institution's determination that the SFI conflicts with the research

### Elements of a Management Plan

Valley Fever Solutions will update the funding agency on the status of the FCOI and any changes to the management plan annually. In accordance with the regulations, an institution's management plan must describe the (Promoting Objectivity in Research 2011):

- A. Role and principal duties of the conflicted Investigator in the research project;
- B. Conditions of the management plan;
- C. How the management plan is designed to safeguard objectivity in the research project;
- D. Confirmation of the Investigator's agreement to the management plan;
- E. How the management plan will be monitored to ensure Investigator compliance; and
- F. Other information as needed.

**UNIVERSITY OF ARIZONA**  
**INVESTIGATOR CONFLICT OF INTEREST IN RESEARCH POLICY**  
**(effective May 21, 2014)**

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## **INTRODUCTION**

The University of Arizona (“University”) is dedicated to maintaining high standards of objectivity, integrity, credibility and ethical conduct in the conduct of its research and research-related activities, including sponsored research services, research contracting, technology transfer, research compliance and research administration.

The University recognizes that faculty and other employees engage in many relationships with external entities, some of which could have a direct relevance to his/her University research, academic and/or administrative responsibilities. Such relationships frequently advance important public interests, by fostering public-private interactions in research and development, facilitating the transfer of University-developed knowledge into practical applications, creating new businesses and promoting general economic development for the benefit of the state of Arizona, the nation and the global community. At the same time, the intersection of an individual’s financial or other personal interests with his/her responsibilities to the University may compromise, or may reasonably appear to compromise, the individual’s objectivity, professional judgment or integrity, and/or ability to perform University research, educational or administrative responsibilities free from bias or undue outside influence.

## **POLICY PRINCIPLES**

Consistent with the University’s research, education, technology transfer and public service missions, the University encourages its faculty, staff, and students to engage in appropriate relationships with private industry and the non-profit sector. Since actual or potential conflicts of interest may frequently arise as a result of such interactions, each person who is a Covered Individual under this Policy (as defined below) has the responsibility to ensure that his/her actual or potential conflicts of interest are disclosed, reviewed and managed in accordance with this Policy.

In recognition of his/her unique access to information and his/her special obligations with respect to the University’s core missions, this Policy applies to all Investigators and Research Administrators, as defined in Section D, below.<sup>1</sup> (For purposes of this Policy, Investigators and Research Administrators are sometimes referred to collectively as “Covered Individuals”).

In general terms,<sup>2</sup> a Financial Conflict of Interest (FCOI) for purposes of this Policy means a situation in which a Covered Individual’s Significant Financial Interests (SFI) or Significant Personal Interests (SPI), or those of a Family Member (or Relative as applicable to Research Administrators) may compromise, or appear to compromise, the Covered Individual’s objectivity in the performance of his/her Institutional Responsibilities.

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<sup>1</sup> Capitalized terms used in this Policy that are not defined within the text are defined in Section D, below.

<sup>2</sup> The complete definition of “Financial Conflict of Interest” is found in Section D, below.

Members of a scientific and intellectual community such as the University recognize that in order to maintain objectivity about one's own situation and ensure credibility with outside observers, an evaluation external to oneself is required. Moreover, a determination that an actual or potential FCOI exists does not imply unethical or impermissible conduct. Such a determination does mean, however, that the relation of the conflict to the Covered Individual's Institutional Responsibilities must be carefully examined, and in some cases managed. Otherwise, even potential or perceived conflicts of interest may impair the University's ability to perform its core missions and jeopardize public trust and support.

Depending on the nature of a Covered Individual's Institutional Responsibilities, different levels of University risk exist and different types of ethical or legal requirements apply to the conflict of interest analysis.<sup>3</sup> In general terms, however, the analysis and determination of an FCOI under this Policy always involves consideration of the following three criteria:

- The existence of an Outside Interest of a Covered Individual (or his/her Family Member or Relative);
- Relatedness between the SFI or SPI and the Covered Individual's Institutional Responsibilities; and
- The appropriate management or elimination of any SFI or SPI that is determined to be Related to the Individual's Institutional Responsibilities, as set forth in this Policy and accompanying procedures.

Because federal regulatory requirements apply specifically to conflicts of interest related to the research responsibilities of Investigators, and Arizona state conflict of interest laws apply to public employees including Research Administrators, this Policy treats Investigators (Article A) separately from Research Administrators (Section B).

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<sup>3</sup> Guidance on each of these policies and procedures is available at the Conflicts of Interest Office page on the Office for the Responsible Conduct of Research website [www.orcr.arizona.edu](http://www.orcr.arizona.edu). Other University policies that require the disclosure and management of specific types of conflicts include: Policy on Managing Institutional Conflicts of Interest; Conflict of Commitment Policy; Purchasing Policy Manual; College of Medicine Policy on Interactions with Commercial Interests; Policy on Conflicts of Interest Arising from Interpersonal Relationships. Procedures for accepting gifts for the benefit of the University, including guidance about what is and what is not a gift, are detailed at: <http://policy.fso.arizona.edu/fsm/800/812>. When Research involves human subjects, the University may require additional conflict of interest review under the Institutional Conflict of Interest policy or other policies as necessary.

This Policy is supplemental to, and does not restrict the applicability of, such other policies. Members of the University community are expected to become familiar with and fulfill the requirements of each of these policies.

## A. Investigator Requirements

The Conduct of Research should be free from bias generated by FCOI on the part of any Investigator, regardless of title or position, who is responsible for the design, conduct or reporting of such Research. This includes the Principal Investigator (PI) and Co-PI, Co-Investigator, Project Director (PD) and Co-PD, as well as any students, trainees, collaborators, volunteers, Subrecipients and Consultants, if those individuals have some degree of independence in performing some aspect of design, conduct or reporting of the research. **All such individuals are included in the term “Investigator” for purposes of this Policy.**

### 1) Investigators’ Disclosure Responsibilities:

#### a) Disclosure of Outside Interests Related to the Conduct of Research.

The following SFI’s are required to be disclosed by Investigators: (1) Outside Interests of the Investigator that would reasonably appear to be related to his/her Institutional Responsibilities; and (2) Outside Interests in entities whose financial interests would reasonably appear to be affected by the Research.

#### 1. Who must disclose:

All Investigators must disclose all Outside Interests (*i.e.*, theirs and those of their Family Members) that may reasonably Relate to his/her Institutional Responsibilities (each, a “**Disclosure**”). Investigators with no Outside Interests that are reasonably Related to his/her Institutional Responsibilities must complete the Disclosure by certifying that he/she has no such Outside Interests. Investigator Disclosures are submitted using the online Disclosure system, a link to which can be found on the Conflict of Interest Program Office’s web page (<https://orcr.arizona.edu/COI/>). Investigators’ Excluded Interests, as defined in Section D below, are not subject to this Policy’s Disclosure requirements.

#### 2. When Disclosures must be submitted or updated:<sup>4</sup>

#### a) For all Investigators participating in the Conduct of Research where the activity is receiving funding from **any** federal source, including sub-

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<sup>4</sup> For more information regarding Investigator Disclosure requirements, please visit “Procedures for the Policy on Individual Conflict of Interest in Research” posted on the Website for the Office for the Responsible Conduct of Research (<http://orcr.arizona.edu/coi/procedures/investigator>) or contact the Conflict of Interest Program Office.

federal awards, an initial disclosure is required *prior* to the submission of any federal or sub-federal proposal.

- b) For all other Investigators participating in the Conduct of Research not funded by any federal or sub-federal awards, an initial Disclosure is required *prior* to participating in any Research activities at the University.
- c) After initial completion, Disclosures must be updated upon the following schedule:
  1. Annually, between June 1 and June 30 of each calendar year, all Investigators must recertify his/her disclosure.
  2. Within thirty (30) days of acquiring a new SFI, or a change in an existing SFI.
  3. For initial Disclosures where the Investigator has disclosed Outside Interests that are reasonably Related to his/her Institutional Responsibilities, subsequent Disclosure must be made upon the following schedule:
    - Prior to the expenditure of funds on any Research project where he/she is an Investigator; *and*
    - More often as circumstances require or as required by the University's Human Subjects Protection Program for research involving human subjects, or pursuant to other applicable University Conflict of Interest (COI) policies (see footnote 3).

2) Training on Conflict of Interest:

Every Investigator must successfully complete the mandatory conflict of interest Training course, provided by the Office for the Responsible Conduct of Research (see <http://orcr.arizona.edu/coi/training>), on the following schedule:

- a) Prior to proposal submission for all Investigators receiving funding from any federal source, including sub-federal awards; or
- b) Prior to participating in the Conduct of Research for all other Investigators; and
- c) Every four years thereafter or as directed by the University when either of the following applies:
  1. The University revises the training requirements; and/or

2. When the University determines that the Investigator is found to be noncompliant with this Policy or any management plan related to an identified FCOI.

3) Institutional Oversight:

- a) Review, determination, and notification.<sup>5</sup>

The Institutional Review Committee (IRC) appointed by, and advisory to, the Senior Vice President for Research (SVPR), and the COI Officer are responsible for reviewing Investigator Disclosures, making determinations of FCOIs based upon the information in the Disclosures, and notifying Investigators and relevant parties of such determinations. Several examples of determinations are as follows:

1. Identified FCOI. When an FCOI is identified, the IRC and COI Officer develop a recommended management strategy, which is presented to the Investigator by the COI Officer. The COI Officer then works with the Investigator to develop a management plan based upon the recommendations. A finalized plan is provided to IRC for review and approval and, upon approval, sent to the SVPR for final review and approval. All management plans require monitoring by the COI Officer, beginning six (6) months after the fully-approved management plan is completed, and on a recurring schedule every six (6) months until such time as it is determined by the IRC and the COI Officer that the identified FCOI no longer exists.
2. No FCOI-administrative action notice. When an Investigator's Disclosure is reviewed and no FCOI is identified, but the IRC and/or COI Officer determines that the facts of the Disclosure require advice to the Investigator to avoid a potential FCOI in the future, an administrative action notice is sent to the Investigator. Such notices are informal and sent to the individual Investigator via electronic mail from the COI Officer.
3. No FCOI-referral to separate committee or review procedure. When an Investigator's Disclosure is reviewed and no FCOI is identified, but the IRC and/or COI Officer determines that the facts of the Disclosure indicate potential issues under other University policies, the COI Officer may refer the matter to another office or review committee as appropriate (see footnote 3).

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<sup>5</sup> Information related to procedures of this policy can be found in the "Procedures for the University of Arizona Policy on Individual Conflict of Interest in Research" posted on the COI Program Office page at the website of The Office for the Responsible Conduct of Research, <http://orcr.arizona.edu/coi/procedures/investigator>.



4. No FCOI-no additional action required. When an Investigator's Disclosure is reviewed by the IRC and/or the COI Officer and no FCOI is identified and no additional action is required from the Investigator, the COI Officer will update the online Disclosure system to reflect "no FCOI" and the Investigator will receive an automated electronic message from the disclosure system stating no FCOI was found.

b) External Reporting of Investigator's FCOI

As required by the applicable Research grant, agreement or contract, the COI Officer will provide information to research sponsors or funding agencies regarding the IRC's determinations of an Investigator's FCOI and related management plans, as required by such grants, agreements, and contracts.

1. Specific reporting requirements for Research funded by the PHS/NIH: For Research funded by the PHS/NIH, (excluding Phase I SBIR/STTR grants), the University will submit reports to the funding agency regarding the IRC's determinations of an Investigator's FCOI and related management plan in accordance with the following requirements:

- Prior to the initial expenditure of PHS/NIH funds; and/or
- Within sixty (60) days of determination of a new or newly-identified FCOI; and/or
- At least annually, at the time of an extension of funding or submission of the annual progress report; and/or
- Within one hundred and twenty (120) days of completion of a retrospective review pursuant to Section C (Compliance; Sanctions for Non-Compliance), below.

2. Public access to FCOI information related to PHS/NIH-funded studies:

For Research projects funded by the PHS/NIH (excluding Phase I SBIR/STTR grants), the University is required to respond within five (5) business days of receipt of a written request from a member of the public for information regarding determination of an FCOI of Senior/Key Personnel for the funded project. Such public requests must comply with the requirements of 42 CFR § 50.605(a)(5) and 45 CFR § 94.5(a)(5) of the NIH grants policy ([http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)).<sup>6</sup>

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<sup>6</sup> The University's procedure for making such a request, along with a link to the required form, is posted online at the Conflict of Interest Program Office page on the Responsible Conduct of Research website. <http://orcr.arizona.edu/coi/public>.

c) Subrecipients and Consultants

With respect to any Subrecipient or Consultant agreement awarded pursuant to a federally funded award to the University (excluding Phase I SBIR/STTR grants), one of the options provided below shall be established:

1. Option 1 (Subrecipients and Consultants with existing PHS/NSF-compliant COI policies and processes):

A Subrecipient or Consultant under a federally funded agreement from the University may provide certification that: 1) it has implemented a PHS/NSF-compliant COI policy and process; 2) it agrees to apply the PHS/NSF-compliant COI policy to all of its Investigators (as defined herein) performing under the PHS/NSF-supported agreement; and 3) it will be responsible for its Investigators' compliance under its policy and pursuant to the agreement.

2. Option 2 (Subrecipients and Consultants lacking PHS/NSF-compliant COI policies and processes):

Any Subrecipient or Consultant that cannot certify the existence of an established a PHS/NSF-compliant COI policy and process within its organization shall agree that: 1) all of its Investigators participating in the subcontracted work or consulting project will be subject to the University's COI policy and processes, and 2) the Subrecipient organization or Consultant will be responsible for all Investigators' compliance under the University's policy and pursuant to the subcontract or consulting agreement.

For more detailed information on institutional oversight, please visit the procedures for this policy (see footnote 5, above).

## **B. Requirements for Research Administrators**

### 1) General Obligations:

In the performance of his/her Institutional Responsibilities, Research Administrators will not:

- a) Use his/her University position to derive personal or financial benefits outside the normal University compensation and benefits structure;
- b) Advise, or intentionally or knowingly influence, any University employees, contractors or students to act in a manner contrary to the interests of the University or otherwise contrary to his/her employment, academic, contractual or other responsibilities to the University;
- c) Compete with the University while pursuing his/her own Outside Interests;
- d) Show favoritism toward sponsors, licensees or other Third Party Organizations, including other University employees, to advance the Research Administrator's (or his/her Relative's) Outside Interests;
- e) Use or disclose to any Third Party Organization information, intellectual property or technology that is the property of the University or its research sponsors, without first obtaining appropriate authorization for such use or disclosure as set forth in The Arizona Board of Regents and University's Intellectual Property Policies, and applicable sponsor agreements;
- f) Participate in or influence negotiations, or make financial or business decisions related to transactions between the University and any Third Party Organization in which the Research Administrator (or his/her Relative) has an Outside Interest; or
- g) Accept gratuities, gifts or favors in exchange for the use of influence on behalf of, or the granting of special treatment to, any Third Party Organization.

Each of the foregoing actions is an FCOI under this Policy.

### 2) Disclosure Requirements: Institutional Oversight.

- a) Research Administrators are charged with the responsibility to disclose all Outside Interests (*i.e.*, theirs and those of their Family Members and Relatives) that can reasonably be deemed Related to his/her Institutional Responsibilities by submitting a Disclosure to his/her immediate supervisor, on a form to be provided by the COI Office, with a copy to the head of the Research Administrator's primary department or unit.

- b) Disclosures must be submitted by the Research Administrator promptly upon becoming aware of an Outside Interest that is Related to, or that may reasonably appear to be Related to, the individual's Institutional Responsibilities. Disclosures should be updated at least annually, or more often in the event of a change in the Research Administrator's Outside Interests.
- c) The Research Administrator's supervisor will review the Disclosure and determine whether the Outside Interest is Related, or may reasonably appear to be Related, to the Research Administrator's Institutional Responsibilities (*i.e.*, whether the Outside Interest has the potential to directly and significantly affect the individual's performance of his/her Institutional Responsibilities, including but not limited to any of the obligations listed in Section B.1, above). If the supervisor's determination is in the affirmative, an FCOI exists under this Policy.
- d) Upon the supervisor's determination that an FCOI exists, the supervisor will provide written notification of such determination to the disclosing Research Administrator, with a copy to the applicable department or unit head and the COI Officer. The Research Administrator and his/her supervisor will work with the COI Officer, to create a management plan that appropriately eliminates or manages the FCOI, and submit the plan for review and approval by the applicable department or unit head. The final, approved management plan will be signed by the Research Administrator, his/her supervisor and the applicable department or unit head. The Research Administrator's supervisor is the "**Office of Record**" and is responsible for maintaining the original documentation of the request and response as a personnel record in accord with the University policy for personnel record retention. The Office of Record also is responsible for providing a *copy* of any management plans to the COI Office and for providing relevant portions of the management plan to other University departments that are affected by the management plan.
- e) The Research Administrator's supervisor will be responsible for monitoring the Research Administrator's compliance with the obligations found in the management plan and reporting compliance status to the COI Officer on an annual basis, beginning the date the final management plan was signed.

## C. Compliance; Sanctions for Noncompliance

All Covered Individuals are required to comply with this Policy and with any management plans or administrative directives that may be issued as a result of the determination of an FCOI under this Policy. Research that is related to a disclosed Outside Interest will be permitted to proceed when the Investigator certifies in writing his/her commitment to the management plan related to the University's determination that an FCOI exists. When Research involves human subjects, the Investigator may be required to obtain additional IRB approvals pursuant to human subjects research regulations, or as required by other University review committees.

### 1) Compliance inquiries:

In the event that the University becomes aware through its active monitoring processes or otherwise that a Covered Individual may have been noncompliant with one or more requirements of this Policy, the University will make appropriate inquiries to determine the facts.

### 2) Retrospective reviews for PHS/NIH funded Research:

A retrospective review will be conducted if the University determines that an Investigator participating in any University project funded by the PHS/NIH (excluding Phase I SBIR/STTR grants) has not: a) complied with this Policy; or b) complied with a required FCOI management plan; or c) disclosed a SFI or SPI in a timely manner to allow appropriate review and management.

- a) In accord with PHS/NIH policy ([42 CFR § 50.605\(3\)](#)), the IRC will complete a review within sixty (60) days of a determination of undisclosed or un-reviewed interest to assess whether there is an FCOI related to University research, in which case the University will: (1) immediately implement an interim management plan; (2) complete a retrospective review within one hundred and twenty (120) days to determine whether any noncompliance with this Policy and/or noncompliance with an FCOI management plan has biased the design, conduct or reporting of University research; and (3) determine the means by which any identified bias may be mitigated.
- b) In the event that a retrospective review identifies an FCOI related to PHS/NIH-funded University Research, the University will timely make reports to the PHS/NIH as required under NIH grants policy pursuant to ([42 CFR § 50.605\(3\)\(B\)\(9\)\(iii\)](#)).

3) Sanctions or administrative actions:

In cases of noncompliance with this Policy, the University may apply appropriate employee sanctions or administrative actions, in accordance with relevant administrative, academic and employment policies.

Consistent with PHS/NIH grants policy ([42 CFR § 50.606\(c\)](http://www.fda.gov/oc/ohrt/42CFR50.606c.html)) ([http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)),

“in any case in which a determination is made that a PHS/NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.”

#### D. Definitions

- 1) **Conduct of Research or Research:** Any organized program of scientific inquiry that involves a systematic investigation designed to develop or contribute to generalizable knowledge that is performed at, or under the auspices of the University, whether or not such Research is sponsor-funded. “Conduct of Research,” as used in this Policy, includes the design, development, testing, evaluation, conduct, reporting, review or oversight of such program of scientific inquiry. By way of example, the Conduct of Research includes, but is not limited to, directing or serving as an Investigator, performing laboratory experiments, soliciting consent from research subjects, or making decisions related to the Research, such as eligibility of patients to participate in Research, analyzing or reporting Research data, or submitting manuscripts or abstracts related to the Research for publication. “Conduct of Research” as used in this Policy, includes, but is not limited to, basic and applied research, clinical research, research fellowships and training programs, and research-related activities in undergraduate and graduate education.
- 2) **Consultant:** An individual or firm that provides professional advice or services on a sponsored project for a fee, but is not a University employee.
- 3) **Covered Individuals:** Any Investigator (as defined in this Section D. 10) or Research Administrator (as defined in this Section D. 17).
- 4) **Equity Interest:** Any stock or other ownership interest, or an entitlement to obtain any stock or ownership interests (*e.g.*, stock options and warrants). The value of an Equity Interest is determined through reference to public prices or other reasonable measures of fair market value.

- 5) **Family Member:** An Investigator's spouse or dependent children. For purposes of this Policy, a "spouse" includes a person to whom one is married, or a person with whom one lives together in the same residence and each person shares responsibility for the other's welfare and financial obligations.
- 6) **Federally Funded:** Any sponsored research activity where the source of funds are provided, either directly or through subaward, to the University from any federal agency.
- 7) **Financial Conflict of Interest (FCOI):** A Significant Financial Interest (SFI) or Significant Personal Interest (SPI) is considered to be a Financial Conflict of Interest (FCOI) under this Policy when the SFI or SPI is Related to, or can be perceived to be Related to, the Covered Individual's Institutional Responsibilities.
- 8) **Institutional Responsibilities:** Institutional Responsibilities of Covered Individuals include research, scholarship, teaching and instruction, development and commercialization of research results, administrative service to the University, membership on institutional committees, and all other work and activities that the University considers in its review of an individual's performance in the course and scope of his/her University employment or other obligations.

An Investigator's Institutional Responsibilities include any activities: (1) performed as a University employee or a collaborator with or Consultant to the University; or (2) related to activities involving the Investigator's professional expertise, such as teaching, administrative duties, clinical activities, Research (sponsored or unsponsored), federally funded project activities, service on University committees, professional participation on panels and review boards, including data and safety monitoring boards, creation and presentation of scholarly work, etc., regardless of when and where the activities occur.

- 9) **Institutional Review Committee (IRC):** The IRC is a University-wide committee consisting of at least ten (10) voting members who are appointed by the Senior Vice President for Research:

- Three (3) faculty members from the Health Sciences;
- One (1) faculty member from the College of Engineering;
- Two (2) faculty members from the College of Science;
- Four (4) faculty members from other academic units.

Faculty members should be active researchers with an understanding of research practices and activities within his/her respective disciplines.

The committee also includes non-voting, ex-officio members from the following units as necessary: the Office for the Responsible Conduct of Research (ORCR), the Technology Transfer Arizona (TTA), the Office of Research and Contract Analysis

(ORCA), Sponsored Projects Services (SPS), the Office of the Human Subjects Protection Program (HSPP), Procurement and Contracting Services (PACS), and the Office of the General Counsel (OGC). The committee may invite other non-voting, ad hoc members to assist in discussions and decisions as needed.

**10) Investigator:** Any person who is responsible for the design, conduct or reporting of such Research. This includes, but is not limited to, the Principal Investigator (PI), Co-PI, Co-Investigator, Project Director (PD), Co- PD, Senior/Key Personnel and any other persons involved in the Conduct of Research, regardless of title or position, who are responsible for the design, conduct or reporting of Research performed by or under the auspices of the University. This may include students, trainees, collaborators, volunteers, and Consultants if those individuals have some degree of independence in performing some aspect of design, conduct or reporting of the Research. The term, “Investigator,” does not include individuals whose performance within the Research is purely ancillary or occurs solely under immediate supervision.

- a) With respect to clinical research, the term Investigator includes individuals who are directly involved in the research intervention or consenting or evaluation of human research subjects, but does not include hospital staff or office staff who only provide ancillary or intermittent care and do not make direct and significant contributions to the research data.
- b) For the purposes of compliance with this Policy, an individual’s position, title on the project, employment status (full or part-time), or percent of effort devoted to the project *do not* factor into the definition of Investigator. The term, “Investigator,” is based upon the individual’s independence in the design, conduct or reporting of the Research.
- c) For assistance in identifying Investigators, the University has developed a list of job titles that, based upon the characteristics of job duties, would automatically meet the definition of Investigator. This list can be found on the Conflict of Interest Program Office’s web page (<http://orcr.arizona.edu/COI>). This list is not intended to be all inclusive, and a determination should be made of any individuals participating in research activities whose job title is not included in the mentioned list.

**11) National Science Foundation (NSF):** The National Science Foundation (NSF) and any components of the NSF to which the authority involved may be delegated, including those federal sponsors that incorporate NSF general terms and conditions by reference into grant and contract terms and conditions for that funding agency.



**12) Outside Interests:** All Significant Personal Interests and Significant Financial Interests of a Covered Individual, or his/her Family Member (with respect to Investigators) or Relative (with respect to Research Administrators) that are not Excluded Interests, as such terms are defined in this Section D.

- a) **Significant Personal Interest (SPI):** A “Significant Personal Interest” is any managerial, professional or fiduciary position held in any Third Party Organization (*e.g.*, as an officer, director, trustee, advisory board member, board of directors or other managerial position), whether or not he or she is compensated.
- b) **Significant Financial Interest (SFI):** For purposes of this Policy, the definition of a “Significant Financial Interest” with respect to an Investigator (section D(10)(b)(1), below) differs from the definition applicable to a Research Administrator (section D(10)(b)(2), below):

1. Investigator SFIs:

A SFI exists when any of the following interests are present with respect to the Investigator or his/her Family Member:

- Intellectual Property Interests: Has received income related to intellectual property rights or interests (*e.g.*, as owner of a patent or copyright or as a licensee of such rights) except for those interests determined to be Investigator’s Excluded Interests, as outlined in this Section D(10)(c), below; *or*
- With respect to any publicly traded entity: (i) Has received Remuneration from any publicly traded entity in the twelve months prior to disclosure; *and/or* (ii) has any Equity Interest in the publicly traded entity as of the date of disclosure *and* the combined total of all such Remuneration and Equity Interests exceeds \$5,000 in value when aggregated; *or*
- With respect to any non-publicly traded entity: (i) Has received Remuneration from a non-publicly traded entity in the twelve months prior to a disclosure, and the value of all such Remuneration exceeds \$5,000 when aggregated; *or* (ii) Holds ANY Equity Interest in a non-publicly traded entity, regardless of the percentage of equity or value.

2. Research Administrator SFIs:

A Significant Financial Interest (SFI) of a Research Administrator under this Policy means ANY pecuniary or proprietary interest held by the Research Administrator or his/her Relative in a Third Party Organization, *other than* a

“remote interest.” “Remote interests” are defined in the Arizona conflict of interest law (Arizona Revised Statutes (ARS) § 38-502) and include the following types of interests, which do not need to be disclosed under this Policy (“**Research Administrators Excluded Interests**”):

- Non-salaried officer of a nonprofit corporation;
- Landlord or tenant of a contracting party;
- Attorney of a contracting party;
- Member of a nonprofit cooperative marketing association;
- Ownership of less than 3% of the shares of a for-profit corporation, provided the total annual income from stock dividend or other payments, including the value of stock dividends, from the corporation does not exceed 5% of the total annual income of such Research Administrator (or Relative) and any other payments made to him/her by the corporation do not exceed 5% per cent of his/her total annual income; and
- Reimbursement received by a public officer or employee for actual and necessary expenses incurred in performance of official duty.

c) SFIs of an Investigator do not include the following interests, which do not need to be disclosed under this Policy (**Investigators’ Excluded Interests**):

- Salary, royalties or other Remuneration paid by the University to a current University employee or appointee; and
- Payments made by the University in exchange for the transfer of intellectual property rights assigned to the University and from agreements by the University to share any royalties related to such rights; and
- Income from investment vehicles such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made by the investment managers within these funds or accounts; and
- Income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by: (i) a government agency (federal, state or local), or (ii) an institution of higher education as defined at 20 USC § 1001(a); or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education

**13) Public Health Service (PHS):** The U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**14) Related to or Relatedness:** “Relatedness” is the condition in which it may reasonably appear that decisions made by the Covered Individual in the performance of his/her Institutional Responsibilities could directly and significantly affect the value of his/her Significant Financial Interests or be in conflict with

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Significant Personal Interests. Relatedness includes situations in which a Covered Individual's Outside Interests would reasonably appear to affect, or to be affected by, the individual's Research or other Institutional Responsibilities, as well as situations in which the Outside Interest involves an entity whose financial interests would reasonably appear to affect, or be affected by, the Covered Individual's Conduct of Research or other Institutional Responsibilities. Examples in the context of Research are provided below. Relatedness is not a judgment on whether the Covered Individual would deliberately make choices in the Conduct of Research or the performance of his/her Institutional Responsibilities based on considerations related to his/her Significant Financial Interest or Significant Personal Interest. Rather, "Relatedness" refers to the condition in which it may reasonably appear that choices made in the Conduct of Research or other performance of the individual's Institutional Responsibilities could be directly and significantly influenced by the existence of Outside Interests. For detailed information on relatedness as applied in IRC reviews, please visit the procedures for this policy (see footnote 5, above).

**15) Relative:** The definition set forth in ARS § 38-502 and, for purpose of this Policy, means a Research Administrator's spouse, child, grandchild, parent, grandparent, brother or sister of the whole or half blood, and his/her spouses and the parent, brother, sister or child of a spouse. For purposes of this Policy, a "spouse" includes a person to whom one is married, or a person with whom one lives together in the same residence and each person shares responsibility for the other's welfare and financial obligations.

**16) Remuneration:** Includes the aggregate amount of all loans, salary and other payments for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria and paid authorship) received from a Third Party Organization. For purposes of this Policy, Remuneration includes the value of any loans received from a Third Party Organization, regardless of whether the lender is a for-profit or non-profit entity.

- **With respect to Investigators funded by PHS/NIH**, the Remuneration subject to this Policy includes the value in the aggregate of all sponsored or reimbursed travel costs received by the Investigator from a Third Party Organization (regardless of whether a for-profit or non-profit entity) that is related to the Investigator's Institutional Responsibilities, as set forth in PHS/NIH policy ([42 CFR § 50.606\(c\)](#)). An approximate value of travel Remuneration may be reported if the actual value is not known. *Travel costs paid from a University account for budgeted travel related to sponsored projects or other work contracted for through the University are EXCLUDED from the definition of Remuneration for purposes of this Policy.*

**17) Research Administrator:** Any individual employed by the University on a full-time or part-time basis whose responsibilities include participation in any manner in contracts or services related to research administration, research contracting, research compliance, responsible conduct of research, sponsored projects services or technology transfer (whether at the University, college, department or program level), and who are in a position to influence decisions or commit University resources in the performance of his/her Institutional Responsibilities.

This term *does not include* the following: (i) individuals whose responsibilities are purely clerical or are performed solely under immediate supervision; (ii) employees of Purchasing and Contracting Services (who are subject to Procurement and Contracting Services policy number 1.4); *nor* (iii) senior-level “University Administrators” (who are subject to the Managing Institutional Conflicts of Interest policy).<sup>7</sup>

**18) Senior/Key Personnel:** Anyone (including, but not limited to, the PI or PD) identified as senior/key personnel in the grant application, contract proposal, contract, progress report or any other report submitted to the sponsor or funding agency by the University.

**19) Subrecipient:** A party that receives a Subaward or Subcontract from the University under a University sponsored project and is accountable to the University for the use of the funds provided by the subaward.

**20) Third Party Organization:** Any group, organization or legal entity (*e.g.*, partnership, firm, trust, joint venture, corporation, etc.) that is not part of the University or The Arizona Board of Regents.

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<sup>7</sup> Conflicts of interest related to purchasing transactions are to be disclosed and managed as set forth in the Purchasing Policy Manual. Conflicts of interest involving senior-level University Administrators are subject to the University’s Policy on Managing Institutional Conflicts of Interest. Guidance on each of these policies and procedures is available at the Conflicts of Interest Office page on the Office for the Responsible Conduct of Research website, [www.orcr.arizona.edu](http://www.orcr.arizona.edu).

## E. References.

- 1) Arizona Board of Regents Conflict of Interest Policy 3-901.  
<http://azregents.asu.edu/rrc/Policy%20Manual/3-901-Conflict%20of%20Interest.pdf>
- 2) PHS/NIH 42 CFR Part 50 and 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors” (DHHS Final Rule August 25, 2011):  
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- 3) NIH FAQs on COI Rules: [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)
- 4) NSF Grant Proposal Guide Chapter II.C.1.e., Proposal Certifications:  
[http://www.nsf.gov/pubs/policydocs/pappguide/nsf14001/gpg\\_2.jsp](http://www.nsf.gov/pubs/policydocs/pappguide/nsf14001/gpg_2.jsp)
- 5) NSF Award and Administration Guide Chapter IV.A., Conflict of Interest Policies:  
[http://www.nsf.gov/pubs/policydocs/pappguide/nsf14001/aag\\_4.jsp](http://www.nsf.gov/pubs/policydocs/pappguide/nsf14001/aag_4.jsp)
- 6) U.S. Food and Drug Administration CFR Part 54, “Financial Disclosure by Clinical Investigators:”  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
- 7) FDA: <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm>
- 8) NSF: [http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp) and  
<http://www.iecjournal.org/iec/2011/10/nsf-conflict-of-interest-issues.html>
- 9) AAMC: <https://www.aamc.org/initiatives/coi/>
- 10) Arizona Revised Statutes (ARS) §§ 38-501, 502 and 503:
  - a. § 38-501:  
<http://www.azleg.state.az.us/FormatDocument.asp?inDoc=/ars/38/00501.htm&Title=38&DocType=ARS>
  - b. § 38-502:  
<http://www.azleg.state.az.us/FormatDocument.asp?inDoc=/ars/38/00502.htm&Title=38&DocType=ARS>
  - c. § 38-503:  
<http://www.azleg.state.az.us/FormatDocument.asp?inDoc=/ars/38/00503.htm&Title=38&DocType=ARS>