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NOTE: The first occurrence of bolded words or phrases within these procedures refers to terms listed in the ‘Definitions’ section of the Interim Policy on Investigator Conflict of Interest in Research (http://orcr.arizona.edu/coi/uapol/investigator).

1. Required Disclosures of Significant Financial Interests

a. Investigators (including the Investigators of subrecipients for whom the University has contractual responsibility for Conflict of Interest compliance) are required to submit a disclosure of significant financial interests regardless of whether the Investigator has significant financial interests to disclose. The disclosure statement may be found online at http://orcr.arizona.edu/coi/forms.

Each Investigator is required to submit an initial disclosure and then to update and recertify this disclosure:

(1) Annually; and
(2) Within 30 days of acquisition of a new significant financial interest not previously disclosed; and
(3) As may be required by the University’s Human Subjects Protection Program for new or continuing IRB review applications; and
(4) For projects that have received from PHS (including NIH) on or after August 24, 2012, a Notice of Award or noncompeting continuation with funding (except Phase I SBIR/STTR grants):
   (a) For new awards, at least 45 days prior to access to funds;
   (b) For ongoing projects, at least 105 days before the start of the new budget period; and
   (c) For Investigators newly joining an existing sponsored project, no later than 45 days in advance of their first day of participation as an Investigator in the project
2. Required Training on Conflict of Interest

   a. Course content

      The content of the University’s required “Investigator Conflict of Interest in Research” course includes discussion of Conflict of Interest (COI) in general, federal regulations regarding COI in research, and the specifics of the University’s COI policy and procedures for research.

   b. Who must complete this course and when

      Every Investigator must complete the University’s required training course on “Investigator Conflict of Interest in Research”:

      (1) Prior to engaging in any PHS-funded (including NIH) research project with an award issuance date on or after August 24, 2012 (except Phase I SBIR/STTR grants); and

      (2) Prior to January 1, 2013; and

      (3) At least every four years; and

      (4) As directed by the University when one of the following applies:

         (i) the University revises the requirements for Investigators pursuant to this policy;

         (ii) the Investigator is new to the University;

         (iii) the Investigator is found not to be in compliance with this policy or a University management plan for the Investigator’s Financial Conflict of Interest (FCOI).

   c. How to complete this course

      Instructions for completing the “Investigator Conflict of Interest in Research” training, along with a link to the course, is located online at http://orcr.arizona.edu/coi/training.

3. Related University Grants and Contracts Procedures

   a. For each of the following trigger events, the Sponsored Project Services (“SPS”) Office will notify Investigators, with a copy to the COI Program Office, of their obligation to review and update their disclosure statement:

      • Grant Proposal (no later than 45 days prior to anticipated issue date of Notice of Award);

      • Annual Renewal (no later than 105 days prior to anticipated issue date of Notice of Award continuation or no-cost extension or filing of annual report, whichever is earlier);

      • Addition of a new Investigator to a project (no later than 45 days before anticipated participation in the research).

   b. For projects that are receiving or have received PHS funding (including NIH), SPS will also provide the COI Program Office with the names of all who are listed as Senior/key personnel for the project.

   c. SPS will coordinate its funding draws and report submissions to PHS with the COI Program Office so that the COI Office is able to submit the required FCOI reports to PHS in accord with the following event timing:
(1) prior to the University’s expenditure of PHS project funding; and
(2) at the time of a submission of an extension notification for the PHS-supported project; and
(3) at the time of submission of the annual progress report for a continuing PHS-supported project.

d. For any subcontract pursuant to a PHS award to the University of funding (initial or noncompeting continuation) on or after August 24, 2012, the Office of Research and Contract Analysis (ORCA) will be responsible for ensuring that one of the two options described below for contract provisions are established in the subcontract. Subrecipients who are listed on the FDP Institutional Clearinghouse website at http://sites.nationalacademies.org/PGA/fdp/PGA_070596 will automatically be afforded the option to apply their own COI policy and procedures as described in Option 1. Subrecipients not listed on the FDP Institutional Clearinghouse website will be required to comply with the University of Arizona COI policy and procedures pursuant to Option 2 below, unless otherwise approved for Option 1 by the University of Arizona COI Program Office.

(1) Option 1

(a) For subrecipients who are listed on the FDP Institutional Clearinghouse website or those approved for Option 1 by the University of Arizona COI Program Office, ORCA will require the subrecipient to sign a certification of compliance indicating that the subrecipient is aware that the award requires compliance with PHS rules, and agrees that:

• It will apply its PHS-compliant COI policy to all of its investigators performing under the PHS-supported subcontract and that it will be responsible for its investigators’ compliance under its policy and pursuant to the subcontract; and

• It will provide its own PHS-compliant response to public requests for FCOI information on subrecipient investigators in the PHS-funded project (in addition to the University’s performance of its own obligation for responding to such requests with any relevant FCOI of subrecipient investigators); and

• Subrecipient shall provide to ORCA, using the timeframes set forth below:
  o A report listing all of the subrecipient’s Investigators performing the subaward and indicating whether the Investigators have any FCOI, together with an FCOI report in the PHS-required format for all identified FCOI prior to final execution of the subcontract and at least thirty (30) days in advance of participation in the research; and
  o A copy of documentation showing completed COI training for each subrecipient Investigator, which will include at a minimum each Investigator’s name, listing of classes completed, date completed and grade received for each individual course, to be provided prior to final execution of the subcontract or prior to payment on an existing subcontract; and
o An updated list and accompanying FCOI report(s) within thirty (30) days of addition of a new subrecipient Investigator; and

o An updated list and accompanying FCOI report(s) within thirty (30) days of a new FCOI among its Investigators; and

o An updated list and accompanying FCOI report(s) at least sixty (60) days prior to the anniversary date of the contract.

(b) ORCA retains the right to refuse signature and/or payment on any subaward if subrecipient has not completed the requirements of this Option 1

(2) Option 2

(i) For subrecipients not listed on the FDP Institutional Clearinghouse website (http://sites.nationalacademies.org/PGA/fdp/PGA_070596) and not approved for Option 1 by the University of Arizona COI Program Office, ORCA will require the subrecipient to sign a certification of compliance indicating that the subrecipient is aware that the award requires compliance with PHS rules and that subrecipient must comply with the University of Arizona’s PHS-compliant COI policy and process. The contract terms will require the subrecipient to agree that:

• All of its investigators participating in the subcontracted work will be subject to the University’s COI policy and processes, and that it will be responsible for its investigators’ compliance under the University’s policy and pursuant to the subcontract; and

• All of its investigators participating in the subcontracted work will complete the Collaborative Institutional Training Initiative (CITI) Financial Conflict of Interest modules (see http://orcr.arizona.edu/coi/training) required by the University with a grade of 85% or more; and

• It shall provide to ORCA:
  o A report listing all of the subcontractor’s Investigators performing the subcontract, together with completed University of Arizona Financial Disclosure and Certification forms executed by each of the listed Investigators prior to final execution of the subcontract and at least forty-five (45) days in advance of participation in the research; and

  o A copy of each participating Investigator’s complete CITI Grade Book clearly showing the individual Investigator’s full name, Member ID number, courses completed, date completed and grade received; and

  o An updated list and accompanying Financial Disclosure and Certification form(s) within thirty (30) days of addition of a new subcontractor Investigator; and

  o An updated list and accompanying Financial Disclosure and Certification form(s) within thirty (30) days of a new FCOI among its Investigators; and
An updated list and accompanying Financial Disclosure and Certification form(s) at least ninety (90) days prior to the anniversary date of the contract.

(ii) ORCA shall provide subrecipient with a copy of the University’s COI policy and procedures, as well as information and guidance about completing the requirements set forth in this Option 2.

(iii) ORCA retains the right to refuse signature and/or payment on any subaward if subrecipient has not completed the requirements of this Option 2.

e. When ORCA receives the above-referenced documents from the subrecipient prior to final execution of the contract, ORCA will timely forward the information to the COI Program Office, along with a summary of the subrecipient contract terms relevant to COI so that the COI Program Office can perform the University’s obligations pursuant to the PHS rules. ORCA will also timely forward to the COI Program Office all subsequent report updates and forms submitted by the subrecipient and any revisions to the subrecipient contract terms relevant to COI.

4. Related Human Subjects Protection Program Procedures

a. The University of Arizona Human Subjects Protection Program (HSPP) requires the Principal Investigator to take responsibility for ensuring prior to submission of an application for HSPP initial or continuing review that (1) all Investigators in the human subjects project have disclosed to the University’s COI Program Office all significant financial interests related to that human subjects project; (2) the COI Program Office has completed all review and evaluation of the disclosures; and (3) the Principal Investigator has provided the HSPP with all relevant COI Program Office determinations (including management plans or other directives) concerning disclosed financial interests related to the human subjects project.

b. The COI Program Office does not have responsibility for monitoring Investigators’ performance of the HSPP requirements described above; however, the COI Program Office will respond to the best of its ability to any inquiries from the HSPP about COI reviews related to any human subjects research proposal submitted to the HSPP.

c. The HSPP has a non-voting ex officio seat on the COI Program’s Institutional Review Committee (IRC) to facilitate HSPP input and acquisition of information about COI Program Office reviews relevant to human subjects research projects.

5. Review, Assessment, Management and Reporting of Financial Conflict of Interest in Research

The University is responsible for the review, assessment, management, and reporting of Financial Conflict of Interest in Research (FCOI). The Office of the Senior Vice President for Research performs this set of responsibilities for the University through its COI Program Office and the Institutional Review Committee.
a. Institutional Review Committee (“IRC”)

(1) The Institutional Review Committee (IRC) shall be a University-wide committee, consisting of at least 10 voting members who are appointed by the Senior Vice President for Research: 3 faculty from the Health Sciences; 1 faculty from the College of Engineering; 2 faculty from the College of Science; 4 faculty from other academic units. Members should be active researchers with an understanding of their respective disciplines’ research practices and activities.

(2) The committee shall also include non-voting, ex-officio members, including, as necessary: the Assistant Vice President for Research Compliance and Policy; Director of Technology Transfer; Director of Office of Research Contracts and Analysis; a representative from Sponsored Projects; the Human Subjects Protection Program; Procurement and Purchasing. Office of the General Counsel shall provide legal advice to the committee. The committee may invite other non-voting, ad hoc members to assist in discussions and decisions as needed.

(3) A quorum required to conduct the business of the IRC shall consist of half-plus-one voting members in attendance at a meeting. In the absence of a quorum, the voting members in attendance may review agenda items and recommend IRC action. Recommended actions must be subsequently ratified by a majority of the remaining IRC members prior to implementation. Ratification may take place via an electronic mail vote after IRC members are given the opportunity to review the draft meeting minutes. Member ratification of a recommended action shall constitute official IRC action on the agenda item.

(4) The Senior Vice President for Research shall appoint members to renewable 3-year terms and shall appoint the Chair to a renewable 4-year term. The IRC shall elect a Vice Chair to assume the duties of Chair in the absence of the Chair.

b. IRC Review

(1) Review and management of an FCOI related to a project currently or previously funded by PHS must be completed by the University and reported to PHS by the COI Program Office on the following timeline:

(i) prior to the University’s expenditure of PHS project funding; and

(ii) within sixty (60) days of a disclosure of a previously unreviewed significant financial interest (SFI), either because of new Investigator added to project or new SFI reported for existing Investigators; and

(iii) at the time of a submission of an extension notification for the PHS-supported project; and

(iv) at the time of submission of the annual progress report for a continuing PHS-supported project.

(2) An IRC committee member shall be recused from discussion and voting on a particular case if the committee member has a compelling personal interest in the case (such as research or academic affiliation or collaboration with the Investigator whose case is
under consideration) or if the committee member has a financial or other interest in the entity or asset involved in the case under consideration.

(3) Some disclosures of significant financial interests are eligible for expedited review, which means that they can be reviewed outside of the IRC meeting by delegation from the IRC Chair, and then the results of the expedited review will be reported to the IRC at the next committee meeting and will be open to any IRC member questions that may arise.

Disclosures of significant financial interests that meet both of the following criteria may be handled in expedited review:

- Prior disclosure and IRC review and determinations of the same financial interests related to the same or essentially the same projects; and
- No human subjects research involvement.

(4) The first tasks in the review and evaluation process are to determine whether there are significant financial interests that constitute an FCOI and if so, whether the FCOI is permissible with a management plan. These evaluations are performed by the IRC with the support of the University’s COI Program Office. This first task encompasses a variety of determinations for each disclosure:

- Does the disclosure include SFI as defined in the “University of Arizona Policy on Investigator Financial Conflict of Interest in Research”?
- If so, do any of these SFI constitute an FCOI; that is, do any of these SFI have the potential to directly and significantly affect the design, conduct or reporting of any University research that the disclosing individual may conduct. “Directly” means that the potential influence would be on actions or omissions by the Investigators in the design, conduct or reporting of the research. “Significantly” means that the consequences would be important. In its deliberations to determine the relevance of a given financial interest to research, the IRC is entitled to consult with the investigator to acquire relevant information about the research, the financial interest and the nature of any relationship between them.

- In determining both whether there is an FCOI and whether an effective management plan is feasible, the IRC assessment will include consideration of potential effects of the research on the value of the financial interest and potential effects of the financial interest on the design, conduct or reporting of the research, including:
  - What is the magnitude of the financial interest and what is the nature of its relationship to any contemplated research?
  - What are the magnitude and nature of any potential effects the research itself may have on the financial interest?
  - Through what actions or omissions could there be a direct effect on design, conduct or reporting of the research?
If any of these actions or omissions were to occur, what are consequential potential effects on the design, conduct or reporting of the research, including assessment of any potential risk to human subjects, other research colleagues and students or trainees involved in the research, data integrity, analytical bias or other factors in the research?

(5) If the IRC identifies an FCOI, what does the IRC consider an appropriate management plan to effectively mitigate against the potential for direct and significant effect(s) on the design, conduct or reporting of the research?

Management plans that the IRC may determine to be feasible and effective could include, but are not limited to, one or more of the following components:

- Disclosure using an IRC-specified disclosure statement in every presentation or publication of the research.
- Independent monitors or participants in data review at specified stages in the research.
- Independent participants in review of draft research reports.
- Disclosure in informed consent.
- A designated independent professional to conduct informed consent.
- Disclosure to all other researchers and students or trainees involved in the research using an IRC-specified disclosure statement.
- Modification of the research plan.
- Modification or elimination of the FCOI.
- Change of personnel or personnel responsibilities in the research.

(6) As part of the IRC’s review, the committee may determine that disclosed SFI do not constitute FCOI for the design, conduct or reporting of a research project but may represent potential conflicts of commitment or interest as those that are defined in other University of Arizona or Arizona Board of Regents policies (see http://orcr.arizona.edu/coi/uapol) or otherwise merit guidance to the disclosing investigator. The IRC may respond with a letter providing some standard directives or guidance to the Investigator, or it may submit more substantial recommendations to the Senior Vice president for Research, who will make the final determination regarding specific actions on a case-by-case basis.

c. Reporting IRC Review

(1) If the IRC determines that there is an FCOI, the IRC will report that determination and any IRC-specified management plan to the Investigator, the Investigator’s immediate supervisor, and the Investigator’s dean.

(2) If the Investigator certifies in writing his or her commitment to the IRC’s management plan, then the affected research will be permitted to proceed.
(3) Unless the identified FCOI is eliminated prior to any expenditure of PHS project funding, the FCOI and associated management plan related to a PHS-funded project must be reported to PHS by the COI Program Office through the electronic Research Administration (eRA) Commons FCOI Module (See NIH Guide for Grants and Contracts, Notice No. NOT-OD-09-072) on the following timeline:

(a) prior to expenditure of any PHS project funding; and
(b) within sixty (60) days of a disclosure of a previously unreviewed SFI; and
(c) at the time of an extension to the PHS-supported project; and
(d) at the time of submission of the annual progress report for a continuing PHS-supported project.

(4) The University’s report to PHS will include the following information:

- PHS Project number;
- Contact information for the Project Director or Principal Investigator;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the NIH-funded research and why the University determined that the financial interest conflicts with such research;
- A description of the key elements of the University’s management plan, including:
  o Role and principal duties of the conflicted Investigator in the research project;
  o Conditions of the management plan;
  o How the management plan is designed to safeguard objectivity in the research project;
  o Confirmation of the Investigator’s agreement to the management plan;
  o How the management plan will be monitored to ensure Investigator compliance; and
  o Other information as needed.

(5) The annual FCOI report shall address the status of the FCOI and any changes to the management plan. The annual FCOI report shall specify whether the financial conflict is still being managed or include an explanation why the FCOI no longer exists.
(6) For projects currently or previously funded by PHS, the University is required to respond within five (5) business days to requests from members of the public for information about any identified FCOI of the Project Director or Principal Investigator or Senior/key personnel in the project by providing: the Investigator’s name, title and role in the research project, the name of the entity in which the FCOI is held by the Investigator, the nature of the FCOI and its approximate dollar value.

6. Inquiries from the Public about FCOI in PHS-Funded Research Projects
   a. The Public Health Service Rules on Financial Conflict of Interest effective August 24, 2012, require that the University must provide public accessibility to certain defined information about FCOI identified and managed by the University for the Project Director or Principal Investigator or Senior/key personnel in projects for which the PHS issues on or after August 24, 2012 funding awards or continuations (funded or unfunded) [42 CFR 50.605(a)(5)(i) and 45 CFR 94.5(a)(5)(i)].
   b. The PHS rules give institutions the choice of either posting the information on a publicly available website or responding within five (5) business days to a request for the information.
   c. The information that must be available on the website or in response to a request is the following for any specified PHS-funded project in which the University has identified an FCOI for the Project Director or Principal Investigator or Senior/key personnel: the Investigator’s name, title and role in the research project, the name of entity in which the FCOI is held by the Investigator, the nature of the FCOI and its approximate dollar value, which may be reported in specified dollar ranges.
   d. The University will post on its COI Program Office website the procedure and the request template for members of the public to use to request information about identified FCOI of the Project Director or Principal Investigator or Senior/key personnel in a project that has received on or after August 24, 2012, a Notice of Award or notice of noncompeting continuation (with funding).

7. Noncompliance
   a. Non-compliance includes failure to:
      • Report financial interests accurately, fully and in a timely manner, pursuant to the “University of Arizona Policy on Investigator Conflict of Interest in Research”;
      • Provide additional information as requested by University officials responsible for reviewing reports;
      • Comply fully and promptly with recommendations and decisions made by the IRC;
      • File a disclosure of significant financial interests or update the disclosure as required by the “University of Arizona Policy on Investigator Conflict of Interest in Research”;
      • Take any other necessary action required by the “University of Arizona Policy on Investigator Conflict of Interest in Research.”
b. Any third party who has a reasonable, good faith belief that a University employee has failed to comply with the “University of Arizona Policy on Investigator Conflict of Interest in Research” may notify the Chair of the IRC or the Office of the Senior Vice President for Research. University employees may also call the Ethics and Compliance Hotline (1-866-364-1908) to report possible noncompliance.

c. In the event that the University becomes aware through its monitoring processes or otherwise that there may be a situation involving potential noncompliance with one or more requirements of the Policy, the University will make appropriate inquiries to determine the facts.

d. Annually, the COI Program Office will require Investigators with FCOI management plans to explicitly recertify their compliance with the terms and conditions of the management plan.

e. Review of Alleged Noncompliance and Appeals:

(1) Upon receipt of an allegation of non-compliance, the IRC will review the allegation and determine whether there is cause for investigation. If there is cause for an investigation, the IRC will provide information about the allegation to the Investigator and his/her Unit Supervisor or Department Head. The Investigator shall have the opportunity to present a written response and may request to meet with the IRC.

(2) If the IRC finds no violation, it shall inform the Investigator and his/her Unit Supervisor or Department Head in writing. A copy of the notice will also be sent to the Office of the Senior Vice President for Research.

(3) If the IRC finds noncompliance, it shall make a written finding and recommendation for appropriate action and send a copy of the letter to the Investigator, the Unit Supervisor or Department Head, and the Office of the Senior Vice President for Research.

(4) The Investigator may present a written response and meet in person with a representative from the Office of the Senior Vice President for Research within thirty (30) business days of the finding. The Senior Vice President for Research (or designee) shall then decide upon an appropriate action. The Investigator will receive the decision in writing (with a copy to the Unit Supervisor or Department Head). The Senior Vice President for Research (or designee) will also notify the party making the allegation of the final disposition of the matter.

(5) The Investigator may appeal by sending written notice to the Provost within 30 business days after the decision of the Senior Vice President for Research (or designee). The appeal proceedings shall be conducted in accordance with the procedures of the University Committee on Ethics and Commitment, UHAP 2.13.09. Copies must be submitted to the Provost, the Office of the Senior Vice President for Research and the University employee’s Unit Supervisor or Department Head.

(6) After receipt of these materials, the Provost may make a determination or convene an Appeals Panel consisting of representatives from the University Committee on Ethics and Commitment, the Senior Vice President for Research (or designee) and the Provost. If convened, the Panel will evaluate all materials presented and allow the Investigator to
address questions in person. The Panel may either confirm the decision under review or refer the case back to the Office of the Senior Vice President for Research for further consideration. The Provost’s or the Panel’s decision, as applicable, shall be final.

a. If the University determines that there has been a significant financial interest relevant to a University research project that has not been timely reported and reviewed and managed, or that there has been Investigator noncompliance with this policy or with an FCOI management plan, the IRC will conduct a retrospective review within sixty (60) days of that discovery to assess: (a) whether the Significant Financial Interest constitutes an FCOI and (b) if so, to implement an immediate management plan and also to submit an FCOI report to the NIH if the project is now, or has been at any point, PHS-supported. Also, for PHS-supported projects, the University must determine and report to PHS within one hundred and twenty (120) days whether the FCOI has biased the design, conduct or reporting of the research and how any identified bias may be mitigated.

b. In cases of noncompliance with this policy, the University may apply employee sanctions or administrative actions as it deems appropriate to the case and in accord with relevant Arizona Board of Regents and University policies and procedures, and applicable state and federal laws. Sanctions or disciplinary action may include but are not limited to one or more of the following:

• Removal of the Investigator from a particular project;
• Written reprimand;
• Suspension of project funding at the time of sponsored project award or upon request for backstop funding for the project. Before access is permitted to any funds, SPS will confirm that for all project Investigators, the COI Program Office has completed review of the required financial disclosures and certifications, and that the Investigators have fulfilled the COI training requirement.
• Restriction of the Investigator’s privileges;
• Suspension without pay;
• Dismissal; and/or
• Other appropriate sanctions or discipline, depending on the severity and nature of the noncompliance.

c. Research sponsors may also direct specific corrective actions. For example: In any case in which HHS determines that a PHS-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 University as required under PHS regulations, PHS regulations [42 CFR 50.606(c)] require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

8. Record Retention

a. The COI Program Office, on behalf of the Office of the Senior Vice President for Research, will act as staff to the IRC and, in keeping with Arizona State Records Retention laws, will
maintain all report forms and related files (including disclosures with no significant financial interests), a database of all reports, allegations of noncompliance, and sanctions related to research transactions. Records related to federally-sponsored research are subject to the federal records retention regulations as well. All records will be maintained for six (6) years following elimination of any disclosed significant financial interest or the completion of all related UA research, or in accord with University record retention policy, whichever is latest.