

UT Health Science Center: FI0125-H Conflict of Interests	
Version 1	Publication Date: 05/26/2022

No./Title: F125 – CONFLICT OF INTERESTS	Resp. Office: FINANCE	Effective Date: 07/01/2016
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Forms: Outside Interests Disclosure Form - UTHSC		
Related Policies: FI0125 - Conflict of Interests		

PURPOSE

To provide procedures on training, reporting, and managing issues related to conflict of interests.

BACKGROUND

University of Tennessee Fiscal Policy **FI0125 - Conflict of Interests** sets forth policies related to conflict of interests for University personnel. In recognition of sponsor, state, and federal guidelines, the Health Science Center (HSC) has implemented this procedure to establish an organizational conflict of interest policy, provide personnel and HSC reporting requirements, and set enforcement, penalties, and remedies for failure to comply with this procedure.

For the HSC, the Finance & Operations Office has responsibilities mentioned throughout this fiscal procedure as assigned to the Chief Business Officer (CBO), or his/her designee(s) by UT policy.

Personnel subject to this procedure include:

- ALL full-time faculty and staff regardless of their involvement in Sponsored Activities;
- Any and all other (e.g. part-time, affiliated, volunteer, adjuncts, etc.) faculty and staff (including post docs) who are involved (with or without compensation) in a proposed or funded Sponsored Activity; and
- Undergraduate, graduate or professional students (including residents and fellows) who are involved (with or without compensation) in any proposed or funded Sponsored Activity.

Compliance with this procedure is a condition of employment for Personnel who are HSC employees, and employees who fail to comply are subject to discipline, including termination of employment. For Investigators, compliance with this procedure is a condition of participating in a research project at the HSC, and such investigators who fail to comply may be disqualified from further participation in any research at the HSC. In addition, such Investigators who are

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University students (including residents and fellows) are subject to disciplinary action under applicable student conduct rules.

A. DISCLOSURE AND REPORTING REQUIREMENTS

PERSONNEL

All Personnel are required to complete the Outside Interests Disclosure Form to identify any conflict of interests between their University duties and responsibilities and their outside interests. In addition, all Personnel will be notified annually to disclose outside interests on the form provided by the HSC. This form requires the disclosure of specific outside interests that may or may not represent conflict of interests. Personnel may also be required periodically to complete a disclosure form whether or not they have interests or activities to disclose. Disclosure requirements are as follows:

- All Personnel must have a completed disclosure form on file whether or not they have interests or activities to disclose.
- All Faculty, even those not planning to participate in any sponsored activities, are required to file a disclosure form annually whether or not they have interests or activities to disclose.
- All Personnel will receive an annual notification to disclose outside interests and activities. When Personnel disclose any outside interests or activities, they must file a disclosure form annually as long as the interest or activity exists.
- The specific requirements for Investigators are discussed below.
- New employees (except student employees) are required to complete and file a disclosure form within 30 days of their effective employment date whether or not they have interests or activities to disclose.
- Senior administrators designated by the president or the chief financial officer (or designee) are required to file a disclosure form by July 31 each year.
- Although not necessarily prohibited, certain outside interests or activities may be conflicts and must be disclosed, such as engaging in a partnership, consulting relationship, employment relationship, or other outside venture with University employees or students. Note: [Human Resources Policy HR0122](#) prohibits University supervisory staff from hiring employees in their line of authority for personal services.

INVESTIGATORS

Disclosure and reporting requirements for Investigators are as follows:

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- All Investigators who are planning to participate in any sponsored activity are required to disclose their financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for the sponsored activity.
- All Investigators who are participating in the sponsored activity are required to submit an updated Outside Interests Disclosure Form at least annually, in accordance with the specific time period prescribed by the HSC.
- Each Investigator who is participating in a sponsored activity is required to submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
- All subrecipient Investigators must disclose all conflict of interests at the time of grant submission. It is the responsibility of UTHSC Investigators to ensure that any subrecipient Investigators have disclosed any conflicts at the time of submission.
- TRAVEL - Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their University Responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by 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 institution of higher education. Each Investigator must include, at a minimum, the following:
 - Purpose of the trip;
 - Identity of the sponsor/organizer;
 - Destination; and
 - Duration/date of the trip.

The CBO will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest with the funded sponsored projects.

B. TRAINING REQUIREMENTS

Investigators are required to complete conflict of interests training prior to engaging in activities related to any sponsored activity, and at least every four years thereafter, and immediately when any of the following circumstances apply:

- The HSC revises its conflict of interests policies or procedures in any manner that affects the requirements of Investigators;
- An Investigator is new to the HSC; or

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- The HSC finds that an Investigator is not in compliance with the HSC’s financial conflict of interests policy or management plan.

In addition, the CBO may require training of other Personnel based on their disclosures of conflict of interests. The HSC will meet the training requirements through the following methods, including, but not limited to:

- The primary source of training will be conducted through the Collaborative Institutional Training Initiative [CITI](#). The CITI Program offers a conflict of interests mini-course that provides training in regulations related to financial conflict of interests.
- Campus presentations and training sessions will be developed as needed to supplement the [CITI](#) training.

C. MONITORING REQUIREMENTS

PERSONNEL

For all Personnel, the CBO is responsible for ensuring that the HSC:

- Presents and discusses this policy with new employees during their orientation.
- Requires Personnel to have an Outside Interests Disclosure Form on file whether or not they have interests or activities to disclose.
- Notifies Personnel annually of their obligation to disclose outside interests and activities and of where to file the disclosure form.
- Requires training of Personnel as outlined in Training Requirements section.
- Provides instructions to department heads and supervisors to ensure that they understand their responsibilities in reviewing and identifying conflict of interests.
- Maintains the disclosure forms of non-Investigator personnel in their personnel files.
- Maintains in the CBO’s office the disclosure forms of all other personnel who are involved (with or without compensation) in a proposed or funded Sponsored Activity.

INVESTIGATORS

In addition to the requirements set forth above, the CBO is responsible for ensuring that the HSC:

- Determines whether an Investigator's financial interest is related to a sponsored activity and, if so related, whether the financial interest is significant and a financial conflict of interest. An Investigator's financial interest is a significant financial conflict of interest when the CBO reasonably determines that the financial interest could be affected by the sponsored activity or is in an entity whose financial interests could be affected by the sponsored activity.

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- The HSC may involve the Investigator in the CBO’s determination of whether a financial interest is related to the sponsored activity. A significant financial conflict of interest exists when the HSC reasonably determines that the financial conflict of interest could directly and significantly affect the design, conduct, or reporting of the sponsored activity.

D. MANAGEMENT OF IDENTIFIED CONFLICT OF INTERESTS

IDENTIFICATION

The HSC will take such actions as necessary to manage financial conflict of interests, including any financial conflicts of a subrecipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a Retrospective Review and Mitigation Report.

The HSC will meet the requirements set forth in this section through the following methods, including, but not limited to:

- Establish a committee(s) to review the information disclosed by Investigators to:
 - Determine whether a conflict of interests exists;
 - Propose a plan of action to mitigate any identified conflict; and
 - Work with Investigators to resolve conflicts. Resolution can include eliminating such conflicts or managing conflicts that cannot be eliminated. Conflicts can be managed through independent reviewers, reassignment of responsibilities, modifying the sponsored activity plan, or other methods to reduce or minimize the effects of a conflict.
- Recognize the conflict of interests in the following ways:
 - Report annually any conflict of interests that were disclosed or became known over the past twelve months and their resolution; and
 - Report immediately any conflict of interests that cannot be resolved to sponsoring organizations according to their requirements.
- Document the review of information disclosed by Investigators and the actions taken to resolve any conflicts.
- Provide sponsoring organizations with required certifications that, for example, the HSC's conflict of interests policy was implemented, disclosures were made, and identified conflicts are being managed satisfactorily, etc.

MANAGEMENT PLAN

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Whenever the HSC implements a management plan, the CBO must monitor Investigator compliance with the management plan on an ongoing basis until the completion of the sponsored project. Prior to the HSC's expenditure of new funds under a sponsored project, the CBO must:

- Review all Investigator disclosures of financial interests and determine whether any financial interests are significant and relate to the sponsored project; and
- Determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that must specify the actions that have been, and must be, taken to manage such financial conflict of interest.
- Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - Public disclosure of financial conflict of interest (e.g., when presenting or publishing the research);
 - For projects involving human subjects research, disclosure of financial conflict of interest directly to participants;
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the sponsored project against bias resulting from the financial conflict of interest;
 - Modification of the research/sponsored project plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the sponsored project;
 - Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing sponsored project, an Investigator who is new to participating in the sponsored project discloses a financial interest or an existing Investigator discloses a new financial interest to the HSC, the CBO must, within sixty days:

- Review the disclosure of the financial interest and determine whether it is related to the sponsored project;
- Determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that must specify the actions that have been, and will be, taken to manage such financial conflict of interest.
- Depending on the nature of the financial interest, the HSC may determine that additional interim measures are necessary with regard to the Investigator's participation in the sponsored project between the date of disclosure and the completion of the HSC's review.

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Whenever the HSC identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the HSC during an ongoing sponsored project (e.g., was not timely reviewed or reported by a subrecipient), the CBO must, within sixty days:

- Review the significant financial interest and determine whether it is related to the sponsored project; and
- Determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that must specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

RETROSPECTIVE REVIEW AND MITIGATION REPORT

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a financial interest that is determined by the HSC to constitute a financial conflict of interest; failure by the HSC to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a federal conflict of interest management plan, the HSC must, within 120 days of the HSC's determination of noncompliance, complete a Retrospective Review of the Investigator's activities and the sponsored project to determine whether any sponsored project, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such activity.

- The HSC is required to document the Retrospective Review and such documentation must include, but not necessarily be limited to, all of the following key elements:
 - Project number;
 - Project title;
 - Project director/principal investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the financial conflict of interest;
 - Name of the entity with which the Investigator has a financial conflict of interest;
 - Reason(s) for the Retrospective Review;
 - Detailed methodology used for the Retrospective Review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - Findings of the review; and
 - Conclusions of the review.
- Based on the results of the Retrospective Review, if appropriate, the HSC must update the previously submitted financial conflict of interest report, specifying the actions that will be taken to manage the financial conflict of interest going forward.
- If bias is found, the HSC is required to notify the Awarding Agency promptly and submit a Mitigation Report to the Awarding Agency.

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- The Mitigation Report must include, at a minimum, the key elements documented in the Retrospective Review above and a description of the impact of the bias on the sponsored project and the HSC's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the sponsored project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the sponsored project is salvageable).
- Thereafter, the HSC will submit financial conflict of interest reports annually to the Awarding Agency. Depending on the nature of the financial conflict of interest, the HSC may determine that additional interim measures are necessary with regard to the Investigator's participation in the sponsored project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the HSC's Retrospective Review.
- For a funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not properly managed or reported by the HSC as required by this procedure, the HSC will:
 - Require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research; and
 - Request an addendum to previously published presentations.

E. SUBRECIPIENT REQUIREMENTS

- If the HSC carries out the sponsored project through a subrecipient (e.g., subcontractors or consortium members), the HSC (awardee institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this procedure as follows:
 - All subrecipient Investigators are required to disclose all conflict of interests at the time of grant submission.
 - As part of a written agreement with the subrecipient, incorporating terms that establish whether the financial conflict of interest policy of the HSC or that of the subrecipient will apply to the subrecipient's Investigators.
 - If the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the subrecipient must certify as part of the agreement referenced above that its policy complies with Awarding Agency requirements.
 - If the subrecipient cannot provide such certification, the agreement must state that subrecipient Investigators are subject to the financial conflict of interest policy of the HSC for disclosing financial interests that are directly related to the subrecipient's work for the HSC.
 - Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the agreement must specify time period(s) for the subrecipient to report all identified financial conflict of interests to the HSC. Such time

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- period(s) must be sufficient to enable the HSC to provide timely financial conflict of interest reports, as necessary, to the Awarding Agency as required by this procedure.
- Alternatively, if the subrecipient's Investigators must comply with the HSC's financial conflict of interest policy, the agreement must specify time period(s) for the subrecipient to submit all Investigator disclosures of financial interests to the HSC. Such time period(s) must be sufficient to enable the HSC to comply timely with its review, management, and reporting obligations under this procedure.
 - The HSC must provide financial conflict of interest reports to the Awarding Agency regarding all financial conflict of interests of all subrecipient Investigators consistent with this procedure, i.e., prior to the expenditure of funds and within sixty days of any subsequently identified financial conflict of interest.
 - In order to monitor the subrecipient's compliance with this Section:
 - The HSC will review the Federal Demonstration Project Clearinghouse which shows a list of institutions who have attested their compliance with financial conflict of interest requirements.
 - The Office of Grants and Research Agreements will ensure that the subaward agreement meets the requirements set forth above;
 - The Office of Sponsored Projects Accounting will not establish an account number until these requirements are met; and
 - The CBO, or his designee, will review any conflict of interest disclosures received from subrecipients and notify the Awarding Agency as necessary in accordance with the requirements set forth in this procedure.

F. AGENCY REPORTING REQUIREMENTS

The HSC will provide initial and ongoing financial conflict of interest reports to the Awarding Agency as follows:

- Prior to the HSC's expenditure of any funds under a sponsored project, the HSC must provide to the Awarding Agency a financial conflict of interest report regarding any Investigator's financial interest found by the HSC to be conflicting and ensure that the HSC has implemented a management plan. In cases in which the HSC identifies a financial conflict of interest and eliminates it prior to the expenditure of awarded funds, the HSC must not submit a financial conflict of interest report to the Awarding Agency.
- For any financial interest that the HSC identifies as conflicting subsequent to the HSC's initial financial conflict of interest report during an ongoing funded project (e.g., upon the participation of an Investigator who is new to the sponsored project), the HSC must provide to the Awarding Agency, within sixty days, a financial conflict of interest report and ensure that the HSC has implemented a management plan.

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- Any financial conflict of interest report required must include sufficient information to enable the Awarding Agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of the HSC's management plan. Elements of the financial conflict of interest report must include, but are not necessarily limited to the following:
 - Project number;
 - Project director/principal investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the financial conflict of interest;
 - Name of the entity with which the Investigator has a financial conflict of interest;
 - Nature of the financial interest (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 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 financial interest relates to the funded project and the basis for the HSC's determination that the financial interest conflicts with such project; and
 - A description of the key elements of the HSC's management plan, including:
 - Role and principal duties of the conflicted Investigator in the project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.
- For any financial conflict of interest previously reported by the HSC with regard to an ongoing funded project, the HSC must provide to the Awarding Agency an annual financial conflict of interest report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the project. The annual financial conflict of interest report must specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The HSC must provide annual financial conflict of interest reports to the Awarding Agency for the duration of the project period (including extensions with or without funds) in the time and manner specified by the Awarding Agency.
- If the failure of an Investigator to comply with the HSC's financial conflict of interest or a management plan appears to have biased the design, conduct, or reporting of the funded project, the HSC must promptly notify the Awarding Agency of the corrective action taken or to be taken.

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G. PUBLIC ACCESSIBILITY REQUIREMENTS

The HSC will maintain an up-to-date, written, enforced policy on financial conflict of interest that complies with UT, HSC, State, and federal law, regulations, and policies, and make such policy available via a publicly accessible web site.

- Prior to the HSC’s expenditure of any funds under a sponsored project, the HSC, through the CBO, will ensure public accessibility (via written response to any requestor within five business days of a request) of information concerning any financial interest disclosed to the HSC that meets the following three criteria:
 - The financial interest was disclosed and is still held by the Investigator as defined by this procedure;
 - The HSC determines that the financial interest is related to the sponsored project; and
 - The HSC determines that the financial interest is a financial conflict of interest.
- The information that the HSC makes available via written response to any requestor within five business days of a request, will include, at a minimum, the following:
 - Investigator’s name, title and role with respect to the sponsored project;
 - Name of the entity in which the financial interest is held;
 - Nature of the financial interest; and
 - Approximate dollar 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 interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- The HSC will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of the HSC’s identification of a new financial conflict of interest. After the HSC responds to their initial request, the requestor must submit additional request(s) for any updated information.

H. MAINTENANCE OF RECORDS

The HSC will maintain records relating to all Investigator disclosures of financial interests and the HSC’s review of, and response to, such disclosures (whether or not a disclosure resulted in the HSC’s determination of a financial conflict of interest) and all actions under the HSC’s policy or Retrospective Review, if applicable. The HSC will retain these records for at least three years from the date the final expenditures report is submitted to the Awarding Agency or, where

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applicable, from other dates as specified in other regulations (state, local, federal, etc.) for different situations.

I. DEFINITIONS

Awarding Agency means the external agency/organization that funds a research and/or other sponsored project.

Conflict of Interest is a situation whereby an individual's outside interests might benefit from his or her official University Responsibilities.

Financial Conflict of Interest (FCOI) means a financial interest that could directly and significantly affect an individual's official University Responsibilities. This includes a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research and/or other sponsored projects.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable and includes the interest of the covered individual's spouse (whether or not they commingle assets), parents, and children (both dependent and nondependent and including stepchildren and foster children).

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research and/or other sponsored projects externally funded, or proposed for such funding, which may include, for example, collaborators or consultants. This term includes **Sub-Investigators, Senior/Key Personnel** and any other person identified as senior/key personnel by the HSC in the grant application, progress report, or any other report submitted as part of a sponsored project.

Manage means to take action to address a disclosed FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research and/or other sponsored projects will be free from bias.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

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For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term **SFI** *does not* include the following types of financial interests: salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the HSC, including intellectual property rights assigned to the HSC and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by 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 Institution of higher education; or 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 Institution of higher education.

Sponsored Activity/Project includes all externally funded grants and contracts whether for research, public service, instruction, etc.

University Responsibilities means an individual's responsibilities on behalf of the HSC, which may include for example: activities such as research, research consultation, teaching, administration, service, professional practice, University committee memberships, service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards, etc.