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(A) Policy statement

Research and other scholarly activities are essential components of academic careers. The University of Toledo (UT) fully endorses faculty efforts in these activities and strives to maintain an environment supportive of scholarly activities. For activities using UT (college or hospital) resources, services, or personnel, institutional policies must be followed, regardless of the source of support. However, when activities are sponsored, i.e., funded, by an external agency or corporation via a grant or contract, additional requirements must be met because UT, and not the Principal Investigator/Program Director (PI/PD), is the grantee or contractor. As the grantee/contractor, UT has legal obligations to the grantor or contracting entity. The procedures set forth in the policies and procedures herein are intended to enable UT investigators to participate in externally sponsored programs while protecting the integrity of the University's research and educational mission and to comply with all applicable federal and state laws and regulations.

(B) Purpose of policy

The purpose of this collection of policies is to provide rules for UT investigators to seek, develop and participate in externally sponsored programs.

(C) Applicability

(1) Sponsored programs.

All grant, contract, clinical trial and other sponsored program applications (collectively, "Sponsored Programs") that have a UT faculty/staff member or student as the PI/PD and are part of that individual's UT responsibilities must name UT as the grantee/contractor, regardless of the performance site.

For the purposes of this policy, a clinical trial is defined as a study, generally involving human subjects, designed to assess the safety and/or efficacy of drugs, devices, diagnostics, treatments, or preventive measures. All UT personnel are encouraged to contact Research and Sponsored Programs (RSP) staff early in the proposal development process so that informed decisions regarding an application can be made in a timely manner before a proposal deadline. (ResearchAdmin.MC@utoledo.edu, Rm 2300 University Hall, 419-530-2844; ResearchAdmin.HSC@utoledo.edu, Rm 2102, Center for Creative Instruction, 419-383-4252)

In cases where a UT faculty/staff member or student has a role at another institution/organization (e.g., a UT staff member who is a student at another educational institution, or a part-time UT faculty member also employed by another entity), only those sponsored program applications that are relevant to the UT staff/faculty member's UT responsibilities must name UT as the grantee/contractor. When a sponsored program application is for a program that is relevant to an individual's duties on behalf of the other institution/organization, the application may be submitted through that other institution/organization. The PI/PD may request to have UT be the grantee organization on his/her behalf, even when UT is not required to be the grantee. In such cases, RSP will

decide, based on the merits of each case whether UT should comply with the request. (For example, if a UT staff member is working on an advanced degree at a neighboring institution, and it would be more convenient for the staff member to have the sponsored program account set up at UT, the staff member may request that UT act as the grantee.) To avoid future questions, individuals should disclose to UT RSP any sponsored program applications that will be submitted through other organizations. Such disclosure is required so that decisions can be made regarding the applicability of the UT regulatory compliance assurances to the activity, even though UT may not be the grantee/contractor of record.

All proposals for such extramural funds must be reviewed and approved by RSP prior to submission, and any awards made as a result of these proposals must be set up in UT restricted, sponsored program accounts monitored by UT Grants Accounting.

Additional requirements apply to all externally sponsored programs (including nonresearch programs) for which there are a written application, agreement or contract with the sponsor which binds UT to terms and conditions set forth by the sponsor, and for which any one of the following applies:

- (a) The agreement obligates the Principal Investigator/Program Director to a line of scholarly or scientific activity that follows a plan or work scope set forth in the proposal, protocol, or agreement, provides for systematic evaluation, or seeks to meet stated performance goals;
- (b) There is a requirement for UT to provide technical or programmatic reports;
- (c) There is a requirement for UT to provide financial accountability, as evidenced by the submission of financial reports to the sponsor, an audit provision, or for return of unexpended funds;
- (d) There is a requirement that something of value be provided to the sponsor or that the sponsor is promised any rights, or option thereto, to intellectual property discovered/developed during the program;
- (e) There is a requirement for an institutional commitment to maintain confidentiality of information provided by the sponsor;
- (f) There is a requirement for UT to define and/or track personnel effort devoted to the program;
- (g) There is a requirement for UT to cost-share any portion of the program costs;
- (h) There is a requirement that a portion of the program be subcontracted to another entity; or
- (i) There is a requirement for assurance of regulatory compliance (e.g., IRB or IACUC protocol approval).

(2) Gifts for research

Requests to philanthropic foundations and other entities for gifts to support faculty research will be subject to formal endorsement by appropriate UT officials, including the Office of Research Development. Such requests will be submitted through the RSP Office or the Office of Research Development and Economic Development. Any gift supporting research programs which deal with human subjects, clinical trials, vertebrate animals, radioisotopes, radiation-generating equipment, lasers, nanotechnology or hazardous materials, must have approved protocols through the appropriate review committees. The RSP office must review

and approve all such projects before proposals are submitted by the Office of Research Development and Economic Development to a private or corporate source on behalf of the UT Foundation. Normally the gift would be received by the UT Foundation, which would accept the gift on behalf of the University and subsequently transfer the funds to an account that could be used by a faculty member. This is acceptable under the following conditions:

- (a) There are no deliverables required by the entity that provided the gift. Examples of deliverables include data, data analysis, computer code and materials.
- (b) The research or activity does not entail any unmanaged risks or liabilities for individuals or the University.
- (c) The research or activity does not incur uncompensated facilities and administrative costs for the University, beyond those minimal costs associated with, for example, processing of purchase orders and minimal use of facilities.
- (d) Complex projects that require deliverables, substantial risk management and incur more extensive facilities and administrative costs must be submitted as proposals endorsed by the University and received as gifts to the University.

Examples of acceptable use of gifts for research include a gift to a faculty member for unrestricted travel for professional development or a gift to a faculty member for supplies to engage undergraduate students in research. In neither instance would there be deliverables to the companies that provided the gifts or unmanaged risks or liabilities. Only minimal facilities and administrative costs would be incurred in these situations.

(3) Institutional approval

Grants or agreements for research (including clinical trials) or other programs involving UT faculty cannot be entered into between individual faculty members and a sponsoring agency or corporation. These agreements must be made between UT and the sponsoring agency or company. Salaried university faculty members or other qualified salaried university contract employees may serve as PI/PDs on sponsored program agreements. The PI/PD must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the sponsored program. Because of the obligations UT assumes as the grantee/contractor, protocols and budgets for all applications for grants, agreements or contracts must be reviewed and approved by the RSP office and signed by one of the UT officials authorized by the Board of Trustees to commit UT to externally sponsored agreements ([Delegation of Signatory Authority for Documents that Bind the University - 3364-40-08](#)). To facilitate this review the PI/PD and other personnel named in grant or contract proposals or research agreements must disclose to RSP any and all consulting or other arrangements they may have with the potential sponsor and provide to RSP copies of all written agreements relating to these arrangements. This disclosure is necessary to ensure that terms of personal consulting and other agreements (e.g., confidentiality or intellectual property commitments) do not conflict with the terms of the grant or contract agreement between UT and the sponsor. RSP review must be completed prior to transmission of any application/request to potential extramural sponsors. This institutional approval is required by UT even if it is not a requirement of the sponsor. RSP will obtain this approval/signature after review of the proposal, budget, agreement, etc. Normally, the Senior Director for Research Administration provides UT approval and signs these documents.

- (4) Principal Investigator/Program Director eligibility, responsibility and grants management plan

UT recognizes that the Principal Investigator (PI), or Project Director (PD), is the primary individual in charge of a research grant, cooperative agreement, training or public service project, contract or other sponsored project. The UT policy [Principal investigator/project director responsibilities \(PI/PD\) on sponsored projects](#) (3364-70-22) provides guidance for researchers on the roles and responsibilities of the PI/PD. The policy also describes how Multi-PI/PD grants are to be managed.

- (5) Study personnel

Contractual obligations contained in research agreements and policies of nearly all sponsoring agencies require that all personnel working on a study be employees or students of UT. In addition, UT Liability Control requires that all individuals working on UT-related sponsored programs be one of the following:

- (a) Paid UT faculty;
- (b) Volunteer UT faculty;
- (c) UT employee;
- (d) Registered UT student; or
- (e) Registered UT volunteer

If you anticipate the need to utilize non-UT personnel, including individuals employed by University of Toledo Physicians (UTP), these individuals must be registered as UT volunteers through the UT volunteer office and cannot be paid for their sponsored program-related activities. Any study personnel who are to be paid for sponsored program-related activities must be UT employees or registered UT students. All investigators involved in UT clinical trials must have a regular or volunteer faculty appointment at UT. When UT employees, whose primary UT job is unrelated to a given sponsored program, work on that program on a part-time basis, it is the responsibility of the PI/PD of the sponsored program restricted account paying for the part-time work and the employee to guarantee that the hours being paid from the sponsored program restricted account do not overlap with the employees' primary UT job. All such arrangements must be in compliance with UT policies regarding employment issues. All co-investigators on a grant/contract proposal must commit to some level of effort on the project, but consultants do not have to commit to any level of effort.

All personnel participating in research activities involving vertebrate animal or human subjects, or biohazardous materials must be approved by the appropriate UT research regulatory committee for their activities related to a specific project/program prior to their beginning this work programs.

- (6) Institutional data

UT information for grant proposals can be found on the RSP website (<http://www.utoledo.edu/research/funding/information.html>). The site contains the names and

addresses of Authorized University Officials, Federal Facilities and Administrative Cost Rates (Indirect Costs) and Fringe Benefit Rates. Registration and accreditation numbers for federal agencies may also be found at the site.

(7) Regulatory compliance

(a) Vertebrate animals in research

Regulations governing the use of vertebrate animals in research at the University of Toledo are described in [Laboratory animal welfare, care and use](#) (3364-70-10) for both the Main Campus (Assurance number-A3264-01) and the Health Science Campus (Assurance number- 3414-01). These documents can be found at <http://www.utoledo.edu/research/RC/animal.html>.

Before spending accounts can be opened for an extramural funding award, Institutional Animal Care and Use Committee (IACUC) protocols for all work described in the proposal must be approved. Forms to initiate the IACUC review process can be obtained from the RSP offices and website (<http://www.utoledo.edu/research/forms.html>). The IACUC is responsible for ensuring that funds are not made available to researchers until all proposed work has been approved by the committee. The RSP office will confirm that work described in the proposal is also described in the attached IACUC protocols. The PI is responsible for ensuring that all required IACUC protocols are approved and have been attached to the research proposal.

Pre-award attachment of IACUC protocols to extramural research proposals will be dictated by the instructions provided by the program sponsor. Compliance with program sponsor's instructions is required for UT endorsement of the proposal. Typically, proof of IACUC approval is not required until funding is awarded, however as IACUC approval can take many months for new protocols, the applicant is strongly advised to apply for IACUC approval for the work described concurrent with application for extramural funding.

Vertebrate animal work performed at other institutions using funds awarded to UT investigators can only occur at Office of Laboratory Animal Welfare (OLAW)-assured institutions, and approved by the off-site institution's IACUC. Approval by the off-site institution's committee is tracked by assigning a UT shell-protocol in the name of the responsible UT PI. That shell protocol must be attached to the research proposal. The UT PI is responsible for requesting the shell protocol and providing proof of approval by the off-site committee along with that institution's OLAW assurance number.

Questions regarding IACUC protocols and sponsored programs may be directed to the regulatory compliance person in the appropriate RSP office, or to the IACUC administrator. The name of the funding institution, the specific funding opportunity, and either a digital copy of the instructions for the funding opportunity or an internet link to the instructions should be obtained before contacting the RSP office.

- (b) Recombinant DNA, infectious or biohazardous materials, toxins, and select agents

Work involving recombinant DNA, infectious or biohazardous materials (pathogenic bacteria, viruses, prions, body fluids, clinical isolates), toxins, and select agents must be performed under the supervision of the Institutional Biosafety Committee (IBC) as described in institution-wide policy [Use of biohazardous materials, recombinant DNA and select agents and toxin in research](#) (3364-70-06). All salient regulations can be found at: <http://www.utoledo.edu/research/RC/biosafety.html>.

BSL-1/ABSL-1/PBSL-1 work may begin concurrent with alerting the IBC. Authorization of spending accounts for awards on this type of work will be done soon after receipt of award. BSL-2/ABSL-2/PBSL-2 and BSL-3/ABSL-3/PBSL-3 work requires IBC approval before work can commence. Spending accounts for awards including this type of work will not be opened until IBC approval is complete. It is the PI's responsibility to secure IBC approval. Contact the RSP office to begin procedures to acquire IBC protocol approval.

Pre-Award attachment of IBC protocols to research proposals is not required by UT policy, however specific program sponsors may require it. Consult the instructions for the funding opportunity to find this requirement. Compliance with program sponsor's instructions is required for UT endorsement of extramural funding proposals.

Questions regarding IBC protocols and sponsored programs can be directed to the regulatory compliance person in the appropriate RSP office, or to the IBC administrator. It is recommended that the investigator have the name of the funding institution, the name of the specific funding opportunity, and either a digital copy of the instructions for the funding opportunity or a web link to the instructions available when contacting the RSP office.

- (c) Human subjects research

All research protocols involving human subjects must be approved by one of the UT Institutional Review Boards (IRB) prior to establishing a UT account for the expenditure of funds supporting the study and prior to entering any patients into the study (See [Protection of human subjects in research](#), 3364-70-05). Research conducted by UT faculty at performance sites other than UT must also be approved by the UT IRB (as well as the IRB of the non-UT performance site). If the IRB at the non-UT performance site is recognized by the UT IRB as the IRB of record, then additional UT IRB approval is not required. If the non-UT performance site (e.g., a nursing home) does not have an IRB, and that entity is not "engaged in research," written permission to perform the project at that facility must be obtained from an authorized representative of the facility, prior to review by the UT IRB. This requirement must be met even when no grant/contract funds are available for support of the research program.

Policies and Procedures of the Department of Human Research Protections can be found at: http://www.utoledo.edu/research/RC/HumanSubs_Menu.html.

The PI/PD or a co-investigator on any research grant, agreement or contract requiring IRB, IACUC, or IBC approval must be the PI/PD on the IRB, IACUC, or IBC protocol(s) supporting the work described in the research grant, agreement or contract. In the case of a Fellowship application, the faculty sponsor/mentor for the trainee applicant must be the PI on the regulatory protocol(s) supporting the work described in the application, and the trainee applicant must be among the authorized personnel on the same regulatory protocol(s).

(8) Support for graduate students

The University recognizes and affirms the importance of the research enterprise to the training of graduate students. In support of strengthening the interface between faculty research and graduate education, the Graduate School will provide instructional fees for graduate students supported by external grants. In cases where the sponsor supports a graduate student, matching support of a graduate student may be provided at the discretion of the Graduate School. In the College of Medicine tuition may be waived.

(9) Confidentiality

The existence of a sponsored program agreement is to be a matter of public record. In all cases, the existence of the agreement, the name of the sponsor, the study title, inclusive dates of the study, and the dollar amount of the sponsorship is public information and may be made public by UT. Sponsored programs allowing UT personnel access to and/or use of sponsor's confidential or proprietary information, data, or material will be accepted only if restrictions regarding access, use, and protection of such information, data, or material do not restrict the full dissemination of scholarly findings made under the grant or contract and do not put UT in a position of assuming financial liability. A sponsor's confidential information, data, or material should be labeled as such by the sponsor before release to UT project personnel. Confidential disclosure agreements ([Confidentiality Agreements](#)) should be entered into if the sponsor, the sponsor's agents or UT personnel intend to disclose confidential or proprietary information.

(10) Timely publication of research results

It is the policy of UT that research results should be published in a timely manner in order to meet our responsibility of performing research in the public interest and that UT investigators retain full and free rights to determine what they shall publish. With the exception of reasonable delays for the purposes provided below, research sponsors shall not influence the publication process. Contractual requirements for reasonable delays in publication for the following reasons are acceptable:

- (a) In order to secure intellectual property rights pertaining to research discoveries/inventions prior to public disclosure;
- (b) In order to coordinate the publication of the results of multi-center studies in which UT investigators participate; and

- (c) In order to allow for sponsor's review of manuscript(s) prior to publication for identification of any of sponsor's confidential information that may have been included unintentionally.

UT will not enter into agreements which define study results as confidential information not to be published or which convey to the sponsor the right to veto publication or to censure the content of publications.

Where applicable, pursuant to Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) the [NIH Public Access Policy](#), all UT primary investigators must ensure that the public has access to the published results of NIH funded research. Scientists are to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. This includes publications where non-UT authors submit the manuscript but NIH funds awarded to UT were used to generate the data.

(11) Responsible conduct of research and research misconduct

Integrity in research and scholarship is a fundamental value upon which the University of Toledo is founded. Without integrity, we could not justify the privilege of academic freedom intrinsic to research, other forms of scholarship, and education, nor could we provide to society the advancements of knowledge that derive from free and open inquiry. It is, therefore, a fundamental responsibility of the faculty, staff, students, and administration of the university to maintain the trust of the public in all research and scholarly activity. It is the shared responsibility of all members of our academic community to assure that misconduct in academic endeavors is dealt with in a timely and effective manner, and that the reputation of the university for high standards of scholarly integrity is preserved. University-endorsed principles for responsible conduct of research and scholarship are contained in university policy [Responsible Conduct of Scholarship and Research](#) (3364-70-02). Some lapses in integrity are more serious than others. Lesser offenses, such as carelessness or questionable research practices, including authorship disputes not involving plagiarism, should be handled through the normal administrative channels. Other situations are sufficiently serious that they require university review through a formal process. It is critical to distinguish serious misconduct, committed intentionally or knowingly or recklessly, from honest error and from the differences of interpretation that are inherent in the scientific process and are normally corrected through the peer review process and through further research and scholarship. It is also critical to distinguish misconduct from appropriation of borrowed elements in the creation of a new work of art. The university community views serious research and scholarly misconduct as potential grounds for termination of employment under appropriate university procedures.

Procedures outlined in the University policy [Integrity in Research and Scholarship](#) (3364-70-21) govern the steps to be taken in handling those serious offenses. These procedures are designed to (1) provide a statement on integrity in research; (2) describe the responsibilities of research personnel, administrators, and others in the academic community; and (3) set forth both swift and fair procedures for handling instances of alleged misconduct in research.

- (12) Funding for potentially controversial programs or from potentially controversial sources

It is UT policy that we will not accept Sponsored Program funding from tobacco companies.

- (13) Contract and subcontract negotiation and approval

All awards which involve a contract or a subcontract must be negotiated by the RSP office. Clinical Trial Agreements must be negotiated by staff in the Jacobsen Center for Clinical and Translational Research. Contracts issued to UT by a funding sponsor as a grant award, will be reviewed, negotiated and signed by the RSP office. Grant awards which require that a sub-award be issued to another institution or other organization, must be prepared and negotiated by RSP office staff.

Faculty and staff members may not sign contracts in the name of the university. Specific staff members in the RSP office are designated as authorized UT signatories.

- (D) Facilities and administrative costs

When UT facilities and/or personnel are utilized for sponsored programs, the sponsoring agency or corporation must reimburse UT for the facilities and administrative costs (FAC, also known as Indirect Costs) associated with the sponsored program. FAC includes those institutional costs which cannot be identified with a specific sponsored program (e.g., library operation, facilities and infrastructure support and administrative costs). The FAC rate is negotiated on a periodic basis with the Department of Health and Human Services. FAC rates are not negotiable on any federally funded program or project. The purpose of the UT policy on [Facilities and Administrative Costs](#) (3364-70-15) is to provide UT faculty and staff guidance on the use of FAC in proposal and budget development. Current federal FAC rates may be found on the UT Research and Sponsored Programs web site (<http://www.utoledo.edu/research/funding/information.html>)

- (E) Intellectual property

- (1) Copyright and patents

Consistent with Ohio law, it is the policy of the University to treat all individuals—faculty, staff and students—equally with respect to their rights as authors, inventors of discoveries, inventions, or patents. The UT policy on [Patent policy](#) (3364-70-04) provides guidelines for the ownership and disposition of any discoveries, inventions, or patents that results from research, investigation or work conducted on University property or by University faculty, staff or students. The UT [Copyright policy](#) (3364-70-14) indicates that a copyrightable material or work shall be owned by the employee when it is originated by the employee without significant support from the University. Such materials or works shall include employee-authored books, journal articles, research studies, musical works, syllabi, distance learning courses, workbooks, examinations, and tests.

Faculty rights and obligations regarding Intellectual Property are set forth in detail in Article 17-“Discoveries, Inventions, Patents and Copyrights” in the Collective Bargaining Agreement

between the University of Toledo Board of Trustees and the American Association of University Professors.

(2) Material transfer agreements

Material Transfer Agreements (MTAs) are agreements between a supplier and a user of research materials. MTAs govern the use of the transferred material and are necessary to protect the rights of both the provider and recipient and advance academic research.

Many MTAs include provisions that can cause the recipient to lose the rights to their creations or inventions. Additionally, these agreements may include language that can be used to prevent the recipient from publishing or even continuing his/her research. Accordingly, it is vital that you never enter into an MTA on your own behalf.

All MTAs must be processed by the Office of Research Development (http://www.utoledo.edu/research/TechTransfer/material_transfer.html). Please note that the process is the same for both incoming and outgoing MTAs.

(F) Faculty and staff participation in companies commercializing UT intellectual property

Pursuant to Ohio Revised Code §3345.14, The University of Toledo Board of Trustees has determined that UT faculty and staff should be afforded the opportunity to hold personal financial interests in companies commercializing technology developed in conjunction with their University research and development activities. Faculty and staff participation in technology licensing transactions will facilitate the University's goal of making products of its research and development available for use in the private marketplace by providing an incentive for inventors, who develop inventions with commercial applications. The procedures and guidelines set forth in the UT [Commercialization policy](#) (3364-70-15) are intended to enable the University to realize the benefits of these entrepreneurial activities while protecting the integrity of the University's research and educational mission and to comply with University policies and applicable federal and state laws and regulations.

(G) Faculty/Staff compensation from sponsored programs

UT Faculty that are members of the American Association of University Professors Collective Bargaining unit are directed to the Collective Bargaining Agreement for regulations regarding Extra Compensation for research and grants.

Any compensation for UT faculty/staff time and effort from research grants, agreements or contracts on which a salaried faculty/staff member is named as the PI/PD, a Co-Investigator or a Collaborator must be paid through the UT payroll system as part of that individual's UT salary. Clinical services provided to study subjects by the PI/PD, Co-Investigators, Collaborators and other study personnel, including any individuals listed in the approved IRB protocol supporting the grant or agreement, but not listed in the grant or agreement itself, may not be charged to the grant account. Only those research-related clinical services provided to study subjects by practitioners with an "arms length" relationship to the study may be charged to the grant budget. For example, a radiologist not associated with the study may charge the grant/contract account for reading an X-ray required by the study protocol.

The maximum salary that can be requested in a grant/contract budget is the PI's UT Institutional Base Salary, i.e., exclusive of any practice plan compensation, multiplied by the percent effort to be devoted to the Sponsored Program [NOTE: Some funding agencies have salary caps which must be considered in budget development. Consult the RSP office for current salary caps.]. Any fraction of faculty effort which exceeds the fraction of salary budgeted represents budgeted cost-sharing by UT. [NOTE: Actual UT cost-sharing is faculty effort devoted or committed to the Sponsored Program, but NOT charged to the Sponsored Program restricted account] All compensation to individuals for work done in support of a Sponsored Program, whether as a part of, or in addition to, the individual's regular UT job duties, must be approved by the UT Human Resources Department PRIOR to any commitment being made to the staff member or any work being done on the Sponsored Program by the UT staff member. All such compensation must be paid through the College payroll system. No direct compensation, either monetary or non-monetary, may be received by UT faculty or staff directly from a sponsor as a result of his or her participation in a Sponsored Program.

(H) Incentives paid by sponsors

All incentive payments, either monetary or non-monetary, in excess of budgeted Sponsored Program costs paid by sponsors in association with clinical trials or other Sponsored Programs must receive prior approval by the RSP and by the UT IRB (if human research subjects are involved). Approved incentive payments may not be paid directly to investigators, other Sponsored Program personnel, or study subjects, but must be deposited in the same UT Sponsored Program restricted account utilized for other monies received in support of that Sponsored Program. These procedures are further described in the policy on [Clinical Trial Incentive](#) (3364-81-02-008-00).

It is the policy of UT that neither it, nor its investigators or subunits will accept incentives or bonuses linked to the rate of recruitment of study subjects or to early enrollment of subjects in clinical trials, whether such incentives or bonuses are offered as a part of a research agreement or at any other time. For the purposes of this policy, the terms "incentives" and "bonuses" include anything of value. [NOTE: This does NOT preclude acceptance of clinical trials whose regular study budget is per capita based (e.g., \$2,000 per patient). It does, however, prohibit acceptance of bonuses or incentives above that amount which are linked to accelerated rates of subject accrual. Using the above study as an example, there might be a bonus or incentive offered of an additional \$1,000 for all subjects over 3 entered in each calendar month. In the case of this example, the \$2,000 per patient represents sponsor payments to cover the costs associated with conducting the research, and is acceptable, but the extra \$1,000 for the 4th and subsequent patients per month is NOT acceptable. The same would hold true for EXTRA money offered for early entry of subjects into studies (e.g., within the first 2 hours of onset of symptoms).]

(I) Clinical studies

(1) The Jacobsen Center for clinical and translational research

The [Joan and Julius Jacobson Center for Clinical & Translational Research](#) (CCTR) at The University of Toledo integrates basic and clinical science programs to generate new knowledge and improve the human condition. The strategic goals of the CCTR are to promote internal and external research collaborations, to support the training and

development of current and future clinical investigators, and to increase clinical research capacity at the University.

All clinical studies must be developed in conjunction with the staff in the CCTR. The CCTR is committed to providing support and resources for a wide array of clinical research studies. Specific services offered by the CCTR include: research development, assistance with regulatory documents, biostatistical support, study coordinator support, nurse coordinator support, educational resources and audit preparation and monitoring.

(2). Compensation for treatment of injuries to subjects

It is the policy of The University of Toledo that clinical trial agreements will contain a provision by which the sponsor agrees to the conditions of payment for protocol-induced injuries to human subjects as set forth in this policy when the clinical trial is sponsored by a for-profit company, employs a company-originated protocol, includes non-FDA approved drugs or devices, and involves more than minimal risk to study subjects. The purpose of the policy on [Compensation for treatment of injuries to subjects in covered clinical trials](#) (3364-70-09) is to set forth the conditions under which company sponsors of clinical trials must be responsible for the cost of treatment of protocol-induced injuries that result as a consequence of human subject participation in the clinical trial.

(J) Financial disclosure

All personnel responsible for the design, conduct or reporting of research in Sponsored Programs must complete a UT Financial Disclosure Form (RSP102, <http://www.utoledo.edu/research/forms.html>). This form discloses potential conflict-of-interest and must be submitted: (a) annually, (b) whenever a new transaction or activity is proposed that might involve a potential conflict of interest, (c) whenever there is a change in interests that might pose a conflict of interest or (d) whenever a sponsored or unsponsored protocol/proposal is submitted. This disclosure document must be completed and signed the investigator. "Per" signatures or stamped signatures of investigators or chairs are unacceptable on this form. The UT financial disclosure form, which must be signed by each signatory's department chair (if any financial interest is disclosed), will be reviewed by the RSP office and the UT Conflict-of-Interest Review Committee, if required under the terms of the UT [Financial conflict of interest policy for sponsored programs](#) (3354-70-01). This committee will make recommendations for reducing, managing, or eliminating any conflicts-of-interest or the appearance thereof.

(K) UT Faculty as Consultants

In general, UT faculty cannot serve as paid consultants on research grants, agreements or contracts awarded to UT. When an outside agency contracts with UT to provide research, it agrees to reimburse UT for the costs of that work, including all personnel costs, except for any approved UT cost-sharing. Appropriate reimbursement for all faculty effort devoted to that Sponsored Program should be included in the contract. Accordingly, it is not permissible for a sponsor to pay UT faculty additional compensation (e.g., as a consultant) for the performance of the same work. Nor is it permissible for the sponsor to pay a consulting fee which is, in essence, intended to compensate the faculty member for interpreting the data obtained under the contract. Data Interpretation represents an extension of the basic work and, in the event that more faculty time is required, UT should be reimbursed for it.

Members of the UTAAUP collective bargaining unit are also directed to Article 16.0-Outside Employment in the Collective Bargaining Agreement.

<p>Approved by:</p> <p><u>/s/ laj</u> Lloyd A Jacobs, M.D. President</p> <p><u>April 1, 2011</u> Date</p> <p><i>Review/Revision Completed by: Senior Vice President for Research Administration; University Research Council</i></p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none">• <i>03-001 Grants, Contracts, Clinical Trials and All Other Sponsored Programs (Former Health Science Campus Policy, revised January 5 2007)</i>• <i>III and III-1 Research and Economic Development and Responsibility (Former Main Campus Policy, adopted February 10, 1999)</i>• <i>III-2-1 Externally Sponsored Programs (Former Main Campus Policy)</i>• <i>III-2-2 Compliance with External and Internal Policies (Former Main Campus Policy)</i>• <i>III-3-1 Externally Sponsored Programs: Procedures for Grant Development (Former Main Campus Policy, adopted February 10, 1999)</i>• <i>III-3-2 Procedures for Accepting Grant or Contract Awards (Former Main Campus Policy, adopted February 10, 1999)</i>• <i>III-3-4 Compliance (Former Main Campus Policy, adopted February 10, 1999)</i> <p>Initial effective date: April 1, 2011 Review/Revision Date: Next review date: April 1, 2014</p>
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Research & Sponsored Programs
Health Science Campus 419-383-4252
Main Campus 419-530-2844

APPENDIX A

Procedures for Grant Development

Section 1. Proposal Narratives.

The Principal Investigator/Program Director (PI/PD) and Co-Investigators are responsible for compliance with the appropriate agency or organizational guidelines as stated in agency requests for proposals or application forms.

Section 2. Preparation of Proposal Budgets

a. Budget Development

University grants and contracts are governed by OMB Circular A-21 Cost Principals for Educational Institutions. To ensure compliance with federal regulations the budget of every proposal to be submitted in the name of the University should be developed in consultation with Research & Sponsored Programs to ensure appropriateness of budgeted items, precision of calculation, and the proper inclusion of allowed costs including financial and administrative costs. Budget development is accomplished with the assistance from an RSP Grant Coordinator, who assures that all budget requests appear in the appropriate format acceptable to the University as well as to the agency. A period of **five working days** shall be given to Research & Sponsored Program staff to prepare budget plans.

b. University Contributions

Many funding agencies require cost sharing by the University on sponsored research projects. Cost-sharing becomes a mandatory part of the resulting contract or award notice, and the University is held specifically responsible for reporting the exact contribution in federal time and effort reports and other cost-keeping reports. The University's contribution to the project may consist of two distinct components: **in-kind** and **cash** contributions.

- **In-kind** contributions to a research project are common and will usually consist of a percentage of **effort** determined as appropriately representing the investigator's University-supported time spent on a research or sponsored project. This representation of time and effort is calculated to include salary, the related fringe benefit costs and the appropriate facilities and administrative (indirect cost) fees associated with the salary. Facilities and administrative (indirect cost) fees are calculated on University contributions as well as on the externally funded portion of the budget. If a funding source does not support the payment of facilities and administrative cost recovery and that policy is documented, the under-recovered portion is then calculated and considered a University in-kind contribution.
- University **cash** contributions, such as stipends or instructional fees for graduate students, cost-sharing on capital equipment, travel expenses or office supplies, under certain circumstances,

may be provided to the project. Under certain conditions released-time may be contributed and investigators may be released from specific duties without remuneration for the department, from the grant or the University. This is done only with the full agreement of the department and the college. This would be considered a **cash** contribution.

At the time the proposal is submitted to Research & Sponsored Programs for internal endorsements, the specific source of funds and an account number where the funds will be drawn from for the cash contribution must be identified and clearly listed on the Proposal Submission Form under the "Sources of Cost Share" section. Approval of the proposal by the department chairperson, the college dean and all other approving authorities certifies that the funds will be made available when the proposal is funded.

c. General Categories

Individual budget items will generally consist of personnel costs, equipment, travel, publications, research supplies and facilities and administrative fees (indirect costs). These items are discussed separately below.

1. Personnel Costs

Each position involving payment of a salary should be separately identified. The availability of the necessary personnel is a consideration for both the project and the departments from which the Investigators will be released or will spend effort; therefore, the percentage of time to be devoted to a project by each investigator must be supported by the department chairperson and the dean of the college. Principal Investigators and others who work on grants/contracts may be released from teaching or professional duties to perform such work. Such time is referred to as **released-time**. Time designated as a University contribution by the department and college and *not* specifically supported by an external source is referred to as an Investigator's **effort** on the project. University policy on released-time supported by external sources is that such recovered costs may be retained by the department to provide for replacement in the classroom and to support other research endeavors. Funds remaining in the released-time recovery accounts in the departments may be carried over to subsequent years for expenditure at the discretion of the chairperson. The return of recovered released-time salaries to the department is a component of the University's support of the research environment.

Summer salaries for faculty holding nine-month teaching contracts may be requested. Summer salary is to be calculated at a rate based on the preceding academic year salary. The most common calculation of faculty summer support for a research project is at the rate of 2/9 of the academic year salary. Funding sources determine the actual amount of time of support, not excluding a full three months of support for faculty on nine-month contracts. Multiple year grants may realize escalations for anticipated salary increases. These estimates are based on criteria provided to Research & Sponsored Programs.

Administrators holding 12-month positions involved in research program activities may also request one month of salary and/or be released from duties with the approval of the appropriate dean and the Provost.

Positions created for participation on grant and contract activity must be appropriately funded. It is further understood by the individuals hired for such positions that their employment is temporary and dependent on external funding. Salary increases for multi-year programs may be restricted by the funding source. The University is not obligated to retain such grant funded persons after the expiration of the grant.

When a new position such as research associate or research technician is established, a position description questionnaire must be completed by the Investigator and returned to Human Resources for evaluation if no similar description exists. Employees hired on grants and contracts are considered as special services employees and compensation for such employees varies by grant but will fall within accepted standards of compensation set by the national professional associations. Fringe benefit costs including retirement, workman's compensation and medical insurance should be budgeted according to the current schedule of costs. This schedule is available from Research & Sponsored Programs or the Grants Accounting Office.

Where a project requires the use of consultants, the rate to be paid should be clearly stated in the budget and the work expectations explained in the proposal. The rate of pay is a flat fee for services and may be billed on a monthly or quarterly basis. The consultant must be hired in accordance with regular University procedures and according to agency restrictions if applicable. The University considers outside consultants as independent contractors. A consultant is characterized by the following:

- Work is performed at the University or consultant's location
- There is a written agreement for services
- Consultant does not receive any training or instruction from the University
- Investigator does not supervise or control the performance of the service
- Consultant provides his/her own equipment, materials, and supplies as needed
- Services are provided under the consultant's name
- Services are provided to other entities
- Consultant bears all risk of loss
- University supplies information to the extent necessary to perform the job or analysis

Consultant Personal Contracts are required in order to document the agreement as to the amount to be paid and the scope of expertise expected. These contracts are available through UT Human Resources.

University faculty employees may not be paid as consultants on grants and contracts to the University.

2. Equipment

In all cases each item of equipment to be purchased from grant funds should be specifically listed. As part of the University's commitment to support the research environment, capital equipment is defined as equipment with a unit cost greater than \$5,000. The University's ability to share in the cost of capital equipment is dependent upon the availability of funds.

The cost of equipment usage by persons outside of a specific department or college may be permitted at a rate set and approved by the department.

The cost of equipment usage for existing large-scale equipment for a specific research project may be charged to a granting organization if such use is essential to the research activity presented in the proposal.

Regular equipment usage by faculty and staff involved in on-going research at the department level may not be charged to grants and contracts.

Specific sponsor authorization and RSP approval is required for the purchase or lease of any vehicle with grant funds.

3. Travel

All travel which is undertaken on grant funds must be done so in accordance with Agency or University regulations, whichever are more restrictive. The proposal should indicate whether the travel funds requested are for travel by project staff, participants, consultants, or others.

4. Publications

Funds to cover the cost of publication of the results of the project should be included in the proposed budget. In cases where it is anticipated that the publications will not be produced prior to the termination date of the award, provision for incurring these costs should be clearly spelled out in the proposal.

5. Research Supplies

The type of supplies to be purchased with grant funds should be clearly stated and purchased according to University purchasing policies.

6. Computers

Charges on grant requests are limited to initial purchase of computer equipment and upgrades. Computer "usage" is not an allowable cost. If the grant request on which computer equipment items are to be purchased is developed to extend for a multi-year period, funding for service agreements may be requested. Generally, support for service agreements may not be requested on proposals which do not originally fund the equipment.

7. Tuition

Instructional and general fee payments and associated medical insurance costs for students working on a grant should be specifically budgeted as direct costs if they are to be charged against a project. These charges are treated as a fringe benefit to the student. The current schedule of

fees is available from Research & Sponsored Programs. When support for assistantship tuition is used as a cost-sharing element of the budget, only the instructional fee is provided by the University. General fees and medical insurance are paid either by the grant or by the student.

8. *Facilities and Administrative Fees (Indirect Costs)*

Information concerning F&A Fees may be obtained from this policy manual under the section entitled *Facilities and Administrative Costs*. The Facilities and Administrative Fee rate (indirect cost) is negotiated with the Department of Health and Human Services at regular intervals. Information concerning the current indirect cost rate can be obtained from the Grants Accounting Office or Research & Sponsored Programs. Although there are occasions when the University will support a project by assuming all or part of the project's indirect costs, these occasions are the exception rather than the rule. When an exception can be justified, the PI/PD must seek approval from Research & Sponsored Programs prior to submission of the proposal. **The Facilities and Administrative Fee rate is not negotiable on any federally funded program or project.**

Section 3. Proposal Endorsement

Once proposals are prepared, they are presented to Research & Sponsored Programs **at least five working days prior to the last possible mailing date** for review by the appropriate University offices. Most proposals for external support of academically related research involve University contributions. It is important that the PI/PD discuss the proposal and secure fiscal commitment from the departmental chair, college dean, Graduate School, Office of Research and Economic Development in advance of the submission deadline. Securing commitments at the time of submission assures that cash and time commitments to a project are met in an appropriate manner.

a. Proposal Submission Form

The Research & Sponsored Programs [Proposal Submission Form](#) must accompany every request for external grant support. All application pages requiring original signatures will be signed during the endorsement process in the order established by the Research & Sponsored Programs. Any specific guidelines creating unusual requests should be attached to the proposal during the endorsement process for clarification purposes. On the endorsement form, the Investigator (and all Co-Investigators) are required to obtain the signatures of the Chairperson, and the Dean of his/her College,

The proposal package is then brought to Research & Sponsored Programs where a final review of the proposal takes place for appropriateness and completeness. Any proposals to private foundations and some corporations are also endorsed by the Research and Economic Development. The final authorization is the responsibility of Research & Sponsored Programs and all original endorsement forms remain in the RSP office.

b. Compliance

If the proposed project involves the use of human subjects, research animals, biohazardous materials or radioactive isotopes, the protocols for conducting the research are subject to federal guidelines. In

some cases compliance with these guidelines must be demonstrated before funding can be committed by the agency. In any case, compliance with federal regulations must be completed before the project can be initiated by the Investigator whether or not the research is conducted on or off campus. The Investigator should contact Research & Sponsored Programs for clarification of policies concerning research which must comply with Federal and State guidelines.

All areas of regulatory compliance are addressed in the Research & Sponsored Programs [Proposal Submission Form](#).

A completed [Financial Conflict of Interest](#) form for disclosure of potential conflicts of interest must be completed at the time of endorsement. It is required that the endorsement form be completed before the endorsement signature process is initiated. All endorsements must include a completed disclosure form documenting any potential conflicts of interest for any proposals submitted to an external sponsor.

Once the endorsement process has been completed, the Investigator will provide a copy of the final document submitted to the sponsor to Research & Sponsored Programs. The copy is retained by Research & Sponsored Programs for permanent reference purposes and a copy of any funded proposal is provided to the Grants Accounting Office, for accounting control, audit, and report purposes.

Electronic submissions of grant proposals are accomplished through Research & Sponsored Programs.

c. Protection of Intellectual Property

As required by State of Ohio statute any invention developed by a University employee which results from research or investigation conducted in University facilities or under University auspices is the property of the University. For additional information concerning University policy with respect to inventions consult this policy manual under the section entitled Intellectual Property.

APPENDIX B

Procedures for Accepting Grant or Contract Awards

Section 1. Procedures for Acceptance

a. Official Signatures

Prior to acceptance of an award by the University, certain signatures must be obtained to indicate that the award document is acceptable. In the event that the award is determined to be identical to the proposal, only the signature of the Senior Director for Research Administration or the Vice President of Research and Economic Development is necessary. In the event that the award is not identical to the proposal, the award may require an additional endorsement process. The University reserves the right to require the approval by the University legal counsel. If for some reason, a project has not been appropriately endorsed by the University and it is awarded, the University reserves the right not to accept such an award.

b. University as Recipient

All grants and contracts will be considered to have been made to The University of Toledo, and therefore are subject to all the rules and regulations set forth in *The University of Toledo Policies and Procedures Manual* (e.g., Personnel, Purchasing, Travel, etc.). Payments made to the University by any outside agency or benefactor, which may be construed to have been made to an individual or department, are to be coordinated in the same manner as any other grant, and each is to be assigned a separate, specific University restricted fund account number.

Acceptance of each grant to the University is accomplished by the review conducted by Research & Sponsored Programs and the President's presentation of award information to the Board of Trustees. A fully executed award document is to be provided to and retained by the Grants Accounting Office as a permanent record of the University. The Grants Accounting Office will perform post-award activities.

Section 2. Procedures for Conducting the Program

The Principal Investigator/Program Director (PI/PD) will assume responsibility for the direction of all programmatic aspects of the funded program as well as the following post-award activities:

a. Forms.

- Timely preparation of Personnel Action Forms is required by the Payroll office for payment of salaries, wages and stipends. The forms must be in the Payroll office with all required approvals by noon on Thursday one week prior to the first payday.
- All Graduate Assistants who receive remuneration from grant funds must be appointed according to the regular Graduate School procedures. The PI/PD is responsible for the proper completion and distribution of the appropriate stipend and fee payment forms.

- The proper account number and subaccount codes must be assigned to each requisition, travel voucher and Personnel Action Form. The University Procurement Policy (#3364- 40-14) must be followed for all purchases.
- Certification of effort or released-time is to be reported as a University contribution to the grant. All federal and pass-through grants require verification of the actual percentage of time spent on a grant or contract by the PI/PD and all grant employees. The Grants Accounting Office is responsible for completing the Time and Effort form on a quarterly basis. The certification is made by the PI/PD or the chairperson or dean in the absence of the PI/PD. Employees are required to sign time and effort reports and the PI/PD also signs as the responsible official. Forms for reporting time and effort certification are available in the Grants Accounting Office and must be approved by that office.
- All other University contributions which are not charged against the project account must be specifically identified with the project to which they are related.

b. Adherence to Approved Budgets

While many grants provide some flexibility in determining allowable costs, in general, the following guidelines must be followed:

- Costs may not be incurred before the inception date or after the termination date of a grant unless specific written authority from the sponsoring agency is obtained and on record in the Research & Sponsored Programs or Grants Accounting Office in advance of incurring the expense.
- The Grants Accounting Office, will be responsible for determining whether each item of cost is allowed as it relates to sponsor and University purchasing regulations. Determination of whether cost items are allowable and allocable to the sponsored project is governed by OMB Circular A-21, "Cost Principals of Educational Institutions."
- Deviations from a grant or contract budget are allowable only in consultation with Research & Sponsored Programs or the Grants Accounting Office. In the case of grants made by federal agencies which provide the institution with the flexibility of internally approving budget re-allocations, such re-allocations may be initiated by the PI/PD. In cases where sponsors require pre-approval of budget re-allocations, such requests will be initiated through Research & Sponsored Programs and endorsed through the regular University endorsement process.
- Research & Sponsored Programs maintains the appropriate federally required forms and monitors the requests to assure compliance with federal and University regulations. The final approving authority for such action is the Senior Director for Research Administration or the Vice President for Research and Economic Development.
- The PI/PD retains primary responsibility for preventing unallowable deviations from the budget. Any doubts regarding allowable deviations may be resolved by consultation with the Grants Accounting Office.
- No Cost Time Extensions must be requested through Research & Sponsored Programs if continuing activities under a grant agreement are necessary and appropriate.

Section 3. Procedures for Recovery of Facilities and Administrative Fees

a. Facilities and Administrative Fees

No charges may be made directly against the indirect cost allowance provided by a grant or contract. The President's directive, approved by the Board of Trustees in February, 1989 establishes the current policy on the distribution and use of recovered indirect costs. Academic departments receive 20% of the recovered indirect costs while divisional deans receive 10%. University approved Centers and Institutes receive 30% of the recovered indirect costs. In the instance where co-investigators are named on the proposal and award document, and more than one college and department are involved, distribution of the recovered F & A fees shall be shared according to the Portion of Credit and F& A Recovery noted on the Proposal Submission Form. The remaining 70% of recovered indirect costs further sustains the University's research endeavor by supporting new research development programs as well as by expanding the existing research incentive activities, and by providing for the research administrative expenses of both pre-award and post-award activities. The distribution policy may be revised by the President to include percentage distributions to other areas either on a temporary or permanent basis.

b. Facilities and Administrative Fees – College of Medicine

The College of Medicine has a separate indirect cost recovery formula. The departmental component of the recovered indirect costs will be an amount equal to 30% of the Facilities and Administrative Costs recovered from extramural grants/contracts for which faculty members with their primary academic appointment in that department were the principal investigator during the previous calendar quarter. In the event that faculty members have multiple peer-reviewed national funded awards the department component will be increased by an additional 10% of the Facilities and Administrative Costs recovered from each additional sponsored award. Grants/contracts which are in no-cost extensions will not be considered in this “multi-award” additional incentive. The incentive for the first sponsored award will be 30%, for the second sponsored award the incentive will be 40%, and 50% for the third sponsored award. The order of grants will be determined by the order of their budget period begin dates, with the earliest date being the first grant. This component of the recovered indirect costs will be deposited in the departmental Sponsored Projects Incentive account. This account shall be under the control of the department chair to utilize for the benefit of the departmental research/academic environment and/or to provide departmental support for faculty research and/or other academic endeavors.

Section 4. Procedures for Grant and Contract Reporting

Upon completion of sponsored programs activities final technical and financial reports must be filed with the funding agency and the University.

- When submitting a required interim or final technical report, the PI/PD should send a copy of the cover letter and a copy of the report to Research & Sponsored Programs and the Grants Accounting Office. Such report will become part of the permanent grant record.

- The Grants Accounting Office assumes responsibility and authority for preparation and submission of all fiscal reports. The PI/PD will be asked where appropriate to review the fiscal report and suggest any needed changes prior to submission.
- The Grants Accounting Office assumes responsibility for preparing and transmitting government-owned property reports and government funded, purchased property reports on the schedule developed by the cognizant federal agency.
- Research & Sponsored Programs and the Technology Transfer office assumes responsibility for completing required patent, invention and new technology reports as required by federal agencies. Research & Sponsored Programs and the Technology Transfer office, assumes compliance responsibility for reporting to the appropriate sponsors including the federal government, inventions conceived and reduced to practice under specifically funded research programs.

Section 5. Procedures for Equipment Identification

- All equipment purchased under federal grants or contracts must be specifically tagged and inventoried under one of the following categories:
 - Property of the Federal Government
 - Property of the University (title is vested in the University)
 - Property of the University (title is conditionally vested in the University)
- The Property Control office of the University will request information necessary to properly tag equipment from the PI/PD at the time such equipment is received by the University. The equipment can be identified at the time of delivery by the Restricted Fund account to which the equipment was funded.
- All equipment loaned to the University on federal grants and contracts must be tracked and all upkeep performed under the conditions presented in the loan agreement. The Grants Accounting Office will retain such records and at the termination of the grant or contract, notify the appropriate sponsor property officers for disposal instructions.
- Equipment loaned by other than federal sources must be properly maintained under a loan agreement with the lending source. At the termination of the agreement such equipment will be returned to the entity holding title.